Study for the strategy for a non-toxic environment of the 7th Environment Action Programme

Final Report

Written by Milieu Ltd, Ökopol, Risk & Policy Analysts (RPA) and RIVM
August 2017

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Unit B.2 — Sustainable Chemicals

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Directorate-General for Environment
Sustainable Chemicals

August 2017

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ABSTRACT

The 7th Environment Action Programme (7th EAP), adopted in 2013 by the European Parliament and the Council, mandates the European Commission, inter alia, to develop by 2018 "*a Union strategy for a non-toxic environment that is conducive to innovation and the development of sustainable substitutes including non-chemical solutions*". This study supports the Commission with its development of the strategy by providing a comprehensive overview of the state of play and by identifying gaps and deficits in the current EU chemicals policy and legislative framework in relation to the following aspects:

- Substitution, including grouping of chemicals & measures to support substitution;
- Chemicals in products (articles) and non-toxic material cycles;
- The improved protection of children and vulnerable groups from harmful exposure to chemicals;
- Very persistent chemicals;
- Policy means, innovation and competitiveness;
- Programme on the development on new, non/less toxic substances;
- Early warning systems for examining chemical threats to human health and the environment.

Each of the above-mentioned topics is the subject of a sub-study under the overall study which identifies improvement opportunities in relation to all seven sub-study areas with the ultimate goal of creating and maintaining a non-toxic environment that is free of exposures to minimise and eliminate all exposures to hazardous substances.

EXECUTIVE SUMMARY

The 7th Environment Action Programme (7th EAP), adopted in 2013 by the European Parliament and the Council, mandates the European Commission, inter alia, to develop by 2018 *"a Union strategy for a non-toxic environment that is conducive to innovation and the development of sustainable substitutes including non-chemical solutions"*.

The chemicals-related objectives of the 7th EAP are not isolated but are embedded in global policy initiatives, first and foremost the goal to achieve the safe management of chemicals throughout their life-cycle, as agreed during the 2002 World Summit on Sustainable Development in Johannesburg (WSSD) and as further elaborated through the Strategic Approach to International Chemicals Management (SAICM) process. In order to achieve these international chemicals-related commitments, the European Union needs to set out a clear, longer term strategy – one that complements, guides and frames its current laws and policies in relation to chemicals.

The EU's current legislative framework is anchored by the 2006 REACH Regulation and CLP, a major milestone in the effort to establish a regulatory framework able to keep abreast of the challenges of ensuring a high level of protection of human health and the environment, whilst promoting the free circulation of substances on the internal market and enhancing innovation and competitiveness. Under the European Commission's better regulation programme (REFIT), all EU chemicals legislation except REACH is undergoing a comprehensive fitness check, expected to be finalised in 2017, and a REFIT evaluation of REACH is nearly completed. The preliminary results of this stocktaking of EU chemicals legislation to date indicate that the current instruments are basically still fit for purpose. However, some gaps have been identified, e.g., a lack of controls over substances in articles, including imported articles. Separate Commission processes are also considering other problem areas, namely combination effects, nanomaterials and endocrine disruptors.

The gaps and problem areas mentioned above are strongly interconnected and closely linked with the current chemicals *acquis.* In particular, some type of process or mechanism that acts horizontally across the various pieces of EU legislation that deal with chemical risks and pollution appears to be needed, in order to ensure a coherent approach to achieving the EU's longer-term objectives and goals as well as to meet its international commitments with regard to the protection of human health and the environment.

This study complements all of the Commission processes mentioned above. It provides support for the development of the non-toxic environment strategy by examining the possible building blocks of the strategy. It focusses on the following topic areas selected by the Commission:

- Substitution, including grouping of chemicals & measures to support substitution (sub-study a);
- Chemicals in products (articles) and non-toxic material cycles (sub-study b);
- The improved protection of children and vulnerable groups from harmful exposure to chemicals (sub-study c);
- Very persistent chemicals (sub-study d);
- Policy means, innovation and competitiveness (sub-study e);
- Programme on the development on new, non/less toxic substances (sub-study f);
- Early warning systems for examining chemical threats to human health and the environment (sub-study g).

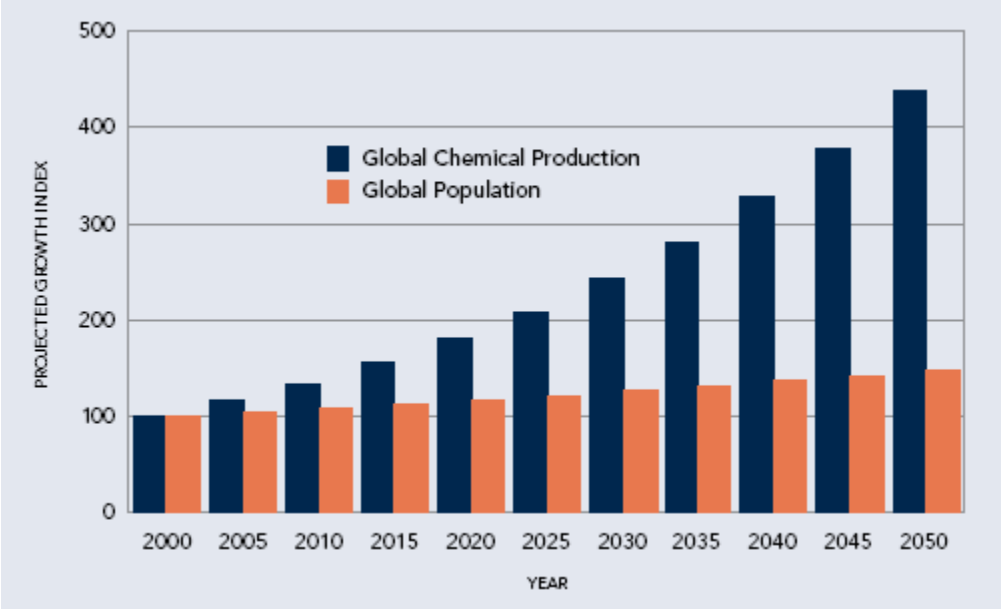
Sub-studies b, c and d present assessments of the information available concerning the scale of the problem, as well as analyses of gaps, deficits and improvement opportunities in their respective areas. Sub-studies a, e, f and g explore possible ways forward. This final report summarises key findings.

The role of chemicals in modern society and the regulatory challenge

The chemical industry shapes a range of other economic activities, from agriculture, construction and textiles to high tech industries such as aerospace, automotive, health care and electronics, more than any other manufacturing sector. Due to its role in the value chain, i.e. transforming raw materials and feedstock into tailor made solutions for downstream industries, it serves all sectors of the economy and contributes to our well-being.

The use and production of chemicals within the EU and around the globe is ever increasing. Global chemicals sales more than doubled between 2004 and 2014 (from €1,458 billion to €3,232 billion) and the total value of EU sales increased by 80% in the same period. Growth is expected to continue by 4% every year by 2020. The figure below shows how the rate of growth of the global chemicals production has already outpaced, and is expected to keep outpacing, global population growth rates over the next decades.

Figure 1: Projected growth in chemicals production in comparison to growth in global population



Source: Green Chemistry: Cornerstone to a Sustainable California (2008).

These increases in chemical production translate into more chemicals used in products and more exposures of humans, animals and environmental media such as air and water. Exposure to a chemical with an intrinsic hazard, such as the CMRs (carcinogens, mutagens, reproductive toxins), can lead to harm. But of the over 100,000 chemicals present on the EU market today, only a small fraction has been thoroughly evaluated by authorities regarding their health and environmental properties and impacts, and even fewer are actually regulated, e.g. REACH partially restricts or bans some 60 individual chemicals and some groups of chemicals with similar properties, such as carcinogens, mutagens and repro-toxic substances (CMRs).

Chemicals regulation depends on a hazard identification and a risk assessment procedure to estimate the extent of the exposure and on that basis the probability of harm as well as its possible severity. On the basis of such assessments, measures can be set in place to manage the known risks so that they are at levels considered acceptable (safe) to humans and the environment. But controlling the risk of harm is a moving target, given that quantities of chemicals and subsequent exposures are likely to increase dramatically. Moreover, risk assessments, usually carried out by a chemical's proponents (e.g., the producer), often underestimate the risk of harm. Additional scientific research into the possible hazards posed by chemicals almost always leads to increased (and seldom to lessened) concern over risks to human health and the environment.

Chemicals in products (articles) and non-toxic material cycles (sub-study b)

An estimated 35,000 chemicals are on the EU market in volumes above 1 tonne per year, and over 60% (by tonnage) of these are hazardous to human health and/or the environment. These are not just 'chemical products' (paint, glue, detergents, solvents, pharmaceuticals); they are virtually all materials (metals, plastics, paper, glass). The millions of articles used every day consist of chemicals, are manufactured using chemicals and are treated with chemicals (e.g., coatings, preservatives).

Hazardous chemicals are known to be used in a vast array of consumer articles, from clothing/textiles, furniture, buildings and infrastructure, electronics and vehicles to tinned food linings, medical devices and toys. Without labelling or laboratory analysis, it is not possible to know which products contain which chemicals -- a challenge made more difficult by the volumes of products produced in other countries and imported into the EU. The difficulty of figuring out how and when people are exposed to which hazardous chemicals risks is compounded because of the complexity of possible exposure situations, the combination (or so-called 'cocktail') effects of exposure to multiple chemicals, and the impacts of cumulative exposures from multiple sources over time.

Some of the costs of chemicals-related damages known to date

- Health care costs and lost earnings linked to exposure to endocrine disrupting chemicals comes to an estimated €157 billion each year. Impacts on the unborn child, young children and women of fertile age are of particular concern.
- Chemical-related damage to the environment can also be costly. Use of tributyltin as anti-fouling marine coatings caused population declines in shellfish, with an associated economic loss estimated in €22 million per year to the UK shellfish industry alone.
- Decontamination of buildings, infrastructure, land and water is very expensive, e.g, cleaning up contamination just from PCBs is estimated to have cost the EU more than €15 billion between 1971 and 2018.

A recent Swedish market survey illustrates by analogy the variety, number and complexity of products containing hazardous substances. It searched for articles treated with biocides, a group of substances by definition more or less toxic. The survey found a wide range of treated articles marketed with a claim such as "antibacterial", including sanitary products, electronic products, kitchen utensils, textiles, leisure equipment, home products, baby products, pet accessories etc. Much more difficult to identify were articles which made no biocidal claim but yet contained a biocide such as a preservative in order to protect the content, e.g., leather, from microbial and algal development. The survey found many more biocide-treated products than were identified as such and concluded that the numbers of treated goods on the consumer market is huge.

Scientific evidence is mounting that the exposures from everyday products, including articles, are exposing modern society to multiple hazardous chemicals, and that these chemicals, even at low dose levels, can give rise to subtle but long-term health effects such as reduced fertility, lower birth weights and neurodevelopmental diseases. Pathways of exposure to chemicals in products involve indoor air as well as household dust. And, since many of the chemicals involved are persistent and long-lived, once they are out into the environment and into our food chains they can continue to cause problems for many decades or even centuries.

The presence of hazardous substances in articles and subsequent material cycles could also undermine the EU's goal of a circular economy. Chemical contamination will make recycling more difficult and present new, unexpected exposure situations, e.g. if contaminated recycled materials get used in products not originally foreseen. Brominated flame retardants used in plastics being recycled have already been found in thermos cups and plastic tableware. Other well-known examples of problematic substances found in material flows include PCBs, lead, cadmium, and some highly fluorinated substances.

Current EU legislation does not adequately regulate the chemicals in articles and material cycles. The

REACH requirements for providing information on the content of SVHCs in articles (REACH Article 7 and 33) are insufficient, poorly complied with and rarely enforced. Gaps exist in other critical EU policy areas – products, waste -- and the interfaces between them. The very few restrictions relating to the use of chemicals in articles are scattered in different legislation, lack a systematic basis and do not take the overall and combined exposures to chemicals in articles sufficiently into account. Furthermore, the authorisation process under REACH does not cover SVHCs in articles from non-EU manufacturers and imported into the EU. Even if hazardous substances are restricted and phased out, they will continue to appear in waste streams and hence also in recycled materials, in particular from articles like buildings and infrastructure with a long lifespan of decades or more.

The scale of the problem with respect to chemicals in articles

- As global production of chemicals increases, so does the production and international trade of articles made from these chemicals. The yearly import of manufactured goods to the European Union has almost tripled between 2000 and 2015, including from countries with insufficient regulatory controls over chemicals. In 2016, 3.4 tonnes of products (2.1 raw, 0.4 semi-finished and 0.9 finished products) per capita were imported in the EU. About 20% of these were imported from China (value of €344.7 billion).
- According to Eurostat data, in 2015, products worth more than 3 trillion EUR have been produced and sold within the EU market while during that same period products worth more than 1,7 trillion EUR have been imported into the EU-28 from third countries. A high share of these products are articles in terms of REACH.
- When Member States find articles on the market that are dangerous and not in compliance with EU legislation, they circulate notifications through the EU rapid alert and information exchange system (RAPEX) so that other Member States can withdraw those products from the market also. Of 2044 notifications in 2016, 23% were related to chemicals, including in consumer products and toys. Because RAPEX notifications are mainly limited to acutely toxic chemicals, they are considered just the tip of an iceberg.
- Human biomonitoring studies in the EU point to a growing number of different hazardous chemicals in human blood and body tissue including pesticides, biocides, pharmaceuticals, heavy metals, plasticisers, flame retardants, etc.

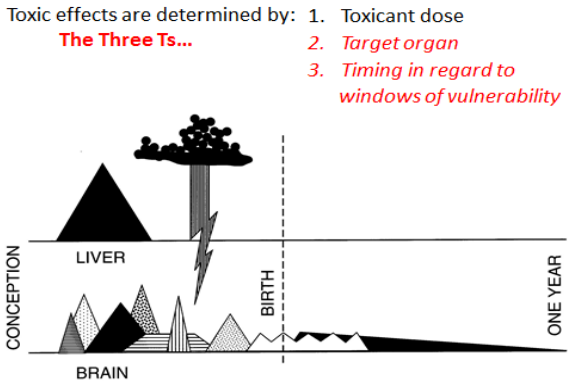
The lack of quantitative and qualitative knowledge regarding the actual content of hazardous chemicals in articles and resulting exposures provides little incentive for substitution and development of less toxic products. This knowledge base needs to be strengthened. Further, access to this information needs to be improved throughout the supply chain, including at waste and recycling stages, where this could prevent contamination of waste streams or initiate a targeted decontamination. The need for further policy development runs across chemicals, product and waste policy, and is particularly important in the light of the objectives of a circular economy.

The sub-study concludes that three approaches are necessary with regards to achieving non-toxic articles and material cycles. First, the transparency about the occurrence of toxic substances in articles needs to be increased in the supply chains and for the authorities (market overview). Secondly, strategies and implementation instruments that prevent toxic substances from entering articles and materials cycles will avoid risks to human health and to the environment throughout the substances' lifecycles. Third, strategies and implementation instruments that motivate and enable the waste treatment sector to decontaminate waste streams from toxic substances are needed, as long as toxic substances continue to enter the waste stage from articles. Complementary activities are needed to ensure that all of the actors understand, implement, and benefit from the use of less toxic substances in articles and materials.

The improved protection of children and other vulnerable groups from harmful exposure to chemicals (sub-study c)

The full impact on modern society due to continuous exposure to a range of chemicals is not yet known. But alarms are being raised, particularly with respect to certain groups of the population – such as children, pregnant women, the elderly, some categories of workers and groups of low

socioeconomic status. These groups are known to be especially vulnerable to the risks stemming from chemical exposure, and, as such, have a higher probability of developing adverse health effects throughout their life. This increased vulnerability depends on a variety of reasons, spanning from increased sensitivity to chemicals, specific biophysical characteristics, health status, constant exposure to highly hazardous chemicals, specific behaviours, reduced ability to protect oneself from exposure, and social factors, e.g. where a person lives or works or spends the majority of his/her time. In light of their higher vulnerability, these groups need special protection from chemical exposure.



Source: Grandjean, 2017

The developing human brain is particularly vulnerable to chemical exposures, with major windows of developmental vulnerability occurring in utero, during infancy and early childhood. During these sensitive life stages, exposure to neurotoxins such as lead, arsenic, mercury, PCBs, pesticides, and solvents – of which more than 200 have been identified, with many more suspected to exist - can cause functional deficits and life-long adverse health effects at low levels of exposure that would have little or no adverse effect in an adult. Early-life epigenetic changes are also known to affect subsequent gene expression in the brain. The figure above illustrates how the timing of an exposure to a toxic chemical helps to determine the effect of that dose during critical windows of vulnerability during development of a foetus and then infant.

The scale of the problem with respect to vulnerable groups

- Over 200 synthetic chemicals have been detected in umbilical cord blood, including pesticides, ingredients in consumer products, food packaging, and chemical by-products from burning coal and flame retardants.
- A 2010 study of British children aged 0-6 years showed that children, on average, consumed 1.6-3 times more food packaged in plastic than adults, implying a proportionally higher exposure to substances leaching from plastic food contact materials for children than adults.
- Certain hazardous substances can contribute to neuropsychiatric disorders in children, with disorders of neurobehavioral development affecting 10–15% of all births, and prevalence rates of autism spectrum disorder and ADHD appeared to have spread worldwide.
- The cost to the EU of female reproductive disorders and diseases as a result of exposure to endocrine-disrupting chemicals is estimated at close to €1.5 billion annually. Europe-wide epidemiological evidence indicates that diphenyldichloroethene (DDE)-attributable fibroids and phthalate-attributable endometriosis affects some 56,700 and 145,000 women, respectively. This costs the EU €163 million (for attributable fibroids) and €1.25 billion (for endometriosis) per year.
- The percentage of U.S. women having difficulty in achieving and maintaining pregnancy increased between 1982 to 2002. The sharpest increase in reported infertility between 1982 and 2002 was among younger women.

Though many policy and legislative measures are now in place at EU level, the protection of vulnerable groups from harmful exposure to chemicals remains sporadic. For instance, although the EU Toys Directive provides standards to protect children as a vulnerable group, other products aimed at children such as clothing and bedding are not covered. Other EU legislation aimed at protecting

citizens from ingesting contaminants, such as the 1998 Drinking Water Directive, need to be updated to reflect the most recent scientific evidence and lack specific measures which could strengthen the protection of vulnerable groups. Parameters for 12 of the 17 types of food contact materials listed in the 2004 Food Contact Materials Regulation are still not regulated at EU level, though some may contain substances that could migrate into food, resulting in exposures associated with adverse health effects on children.
EU risk assessments have traditionally focused on single substances and not taken into account combined or cumulative exposures to toxic chemicals. But recent studies indicate that combined exposure to several substances, including substances in articles, can have greater impacts than exposure to a single substance. Combined prenatal exposure to several chemicals led to reduced foetal growth and lower birth rates for children, just as low doses (below no observed adverse effect levels, or NOAELs) of several pesticides in combination resulted in decreased birth weights in rats. This indicates the need for a greater safety margin for exposures, in particular for foetuses and neonates.

Moreover, the scientific community has tended to study the same substances, e.g. copper, lead, zinc, cadmium, iron, nickel, chromium, etc. Additional substances and new areas, such as the health impacts of nanomaterials and chemical mixtures on certain categories of the population, need to be studied. Chemical risk assessment needs to consider any particular impacts for vulnerable groups, whose consumption patterns and exposure levels may differ significantly according to age group, geographical location, and lifestyle factors. Finally, with respect to certain industrial chemicals known to have neurotoxic properties, it may be necessary to apply precautionary measures in order to provide vulnerable groups such as foetuses and children with sufficient protection.

Very persistent chemicals (sub-study d)
The use and dispersal in the environment of very persistent (vP) chemicals represents another significant threat to health, the environment and natural resources. Due to technical/functionality reasons, such chemicals are widely used in a broad range of applications. However, concentrations of chemicals with a high degree of persistence will tend to build up and eventually reach levels where harmful effects to human health and natural resources may occur.

With the current high levels of production and widespread use of vP substances, cases of such damages are highly likely to appear or may even be unavoidable. Moreover, certain toxic effects (e.g. chronic or occurring at low concentrations) may take many years to identify and may not become evident until long after exposure, even for chemicals where laboratory tests did not indicate any considerable toxicity. By the time evidence is gathered about a chemical's propensity for harm, accumulations may have already occurred. As already experienced in the case of persistent ozone-depleting chemicals, the disruptive effects may not be discovered until they are at a global scale and affecting a vital earth system process.

The scale of the problem with respect to very persistent chemicals

- Only 220 chemicals out of a set of 95,000 industrial chemicals have been evaluated fully in relation to their biodegradation half-lives; data on bio-concentration is available for just 1,000 (UNEP).
- The Stockholm Convention covers 26 substances and groups of substances and another three are under consideration for future inclusion. Yet as many as 1,200 of the 100,000 substances on the market today could be potential POPs, i.e., meeting all criteria for persistence, bioaccumulability, toxicity and long-range transport.
- The number of substances meeting only the POPs criteria for persistence alone is certainly much higher. More than 3,000 different PFAS (a group of highly fluorinated and extremely persistent chemicals) are known to be on the market today. They are found in cosmetics, food contact materials, inks, medical devices, mobile phones, and textiles, and are used in pesticide formulations, oil production and mining.
- A 2017 study carried out by consumer groups in Belgium, Italy, Denmark, Spain and Portugal found that a third of the 65 samples of fast food packaging tested contained high levels of PFAS.
- Some 3.5 million sites around Europe are already contaminated by hazardous substances,

including vPs. Contamination of natural resources has severe economic consequences, ranging from the extremely high costs of remediation to loss of natural resources such as drinking water, land, soils and fish stocks from productive use.

Exposure to the well-studied persistent organic pollutants (POPs) has been linked to a number of serious health effects including certain cancers, birth defects, dysfunctional immune and reproductive systems, greater susceptibility to disease and damages to the central and peripheral nervous system. Further, presence of POPs in the environment is associated with severe effects such as impaired reproduction in birds and mammals.

Concern is especially mounting with regard to the highly fluorinated chemicals known as PFAS (per- and polyfluorinated alkyl substances). PFAS are extremely persistent and will remain in the environment for hundreds of years. They are highly mobile and have been found in groundwater used for drinking water across Europe as well as in remote areas such as the polar region and the deep sea. The thousands of new short-chain PFAS marketed by producers as "safer" than the long-chain PFOS and PFOA are also extremely persistent, and evidence of their toxicity and presence in the environment is increasing.

The use of PFAS-based fire-fighting foams in training exercises at major airports and other industrial uses has led to widespread contamination of water resources throughout the USA. When the USEPA established lifetime health advisory limits for PFOS and PFOA in 2016 and compared them to levels of PFAS found in drinking water, over six million US residents learned they were being supplied with water exceeding those limits. PFAS has also been found in drinking water in Sweden, Germany, the UK, the Netherlands and Italy, but because no EU-wide monitoring for PFAS contamination has been carried out to date, how many EU citizens also drink water contaminated by PFAS is not known.

Current EU policies and legislation do not provide an adequate way to control substances on the basis of their persistent properties. The lack of a common framework for screening substances for persistence combined with inadequate requirements for persistence testing have contributed to major knowledge gaps. As a consequence, the fate of a substance released during a product's use or at the end of product life is seldom fully evaluated. Moreover, in those EU acts that consider persistence as a property of concern, persistence is regulated only if bioaccumulability is also present. Failure to take persistence into account risks build-ups of vP substances, which could lead to increases in exposure similar to those occurring due to bioaccumulation including in recycled material waste streams. Strict controls over releases of any vP substances during manufacturing, product use or end of product life may be needed to prevent build-ups in the technosphere as well as the environment.

From the standpoint of public health, environmental protection and economic growth, it appears desirable to take a more precautionary and proactive approach and to prevent and/or minimise releases of vP chemicals in the future. One possibility could be to make it a principle to avoid the production and use of very persistent chemicals where persistence is not required, e.g. for use in cosmetics or consumer textiles. If persistence is needed for a specific use, manufacturers and down-stream users could be required to justify this. Other important measures identified include development of better methods for screening and testing chemicals for persistence, along with systems for recovery and destruction of persistent chemicals in production wastes and during end-of-product life recycling and disposal.

Substitution, including grouping of chemicals & measures to support substitution (sub-study a)

The traditional approach in chemicals legislation has been substance by substance regulation, which is time-consuming and not adequate to handle the range of chemicals known to be problematic. For example, several hundred individual substances meet the criteria for being considered substances of very high concern (SVHC). The criteria for carcinogenicity, mutagenicity or toxic for reproduction (CMR) alone apply to about 600 different substances, and as many as 1,200 of the 100,000 substances

on the market today could be potential POPs. In the meantime, the use of large quantities of hazardous substances in products, including consumer products, is exposing humans and the environment during manufacturing, product life, waste management and recycling as well as their likely presence in recycled materials.

To address this problem, REACH and other EU legislation have provisions to require/encourage substitution, i.e., the replacement of a hazardous substance with a less toxic substance. Indeed, studies have shown that reducing exposure to hazardous substances is cost-effective. For instance, benefits to women's and men's reproductive capability due to reduced exposure to phthalates between 1996 and 2008 is estimated at €7 billion and €6.7 billion. Further, the application of binding and indicative occupational exposure limits resulted in an avoidance of 1.4 million premature deaths across Europe. However, substitution towards less toxic/safer substances is proceeding very slowly. Moreover, resources for assessment and control being limited, manufacturers tend to focus on chemical-by-chemical substitution. In many cases they have used a structurally similar substance with similar properties, and posing similar hazards to human health and the environment, but less well-studied and regulated. This has been termed 'regrettable substitution'.

As some groups of structurally related substances and often sharing similar harmful properties are quite large, the likelihood of regrettable substitution could continue for a long time. Of particular concern are the several hundred Substances of Very High Concern (SVHC), including some 600 chemicals classified as CMR. Some of these count hundreds of congeners within each group. On the other hand, strategies grouping chemicals of similar properties or use ('grouping strategies') could help accelerating beneficial substitution and increasing the efficiency and effectiveness of the legislation.

So what is stalling progress with substitution? Some shortcomings in current EU chemicals policy include:

- Low quality, insufficient and not updated information on substances in e.g. REACH registration dossiers, including on their properties and uses,
- Lack of information on chemicals used in articles, and of their risks during such uses, including during their service life and waste stages,
- Insufficient incentives for substitution, e.g., inadequate resources for enforcement of chemical policy, lack of regulatory signals encouraging investments in innovation,
- Lack of information on alternatives, including non-chemical solutions, along with insufficiently developed tools for assessment of alternatives.

To counter the issue of regrettable substitution and to increase regulatory efficiency and effectiveness, the use of grouping strategies for assessing chemicals with structural similarities needs to be scaled up. Other measures to consider include: streamlining legislation to provide more incentives for substitution; active support and training on substitution; promotion of functional substitution; more research on grouping strategies for regulatory purposes, focusing on the systematic analysis of the structural similarities of substances and trends in (Q)SAR predictions. Measures for a transition to a non-toxic environment could also rely on economic instruments, better enforcement of current legislation and the enhancement of monitoring programmes.

Policy means, innovation and competitiveness (sub-study e)

A stable and predictable regulatory environment is a key requirement for the competitiveness of the European industry and for its ability to innovate. Regulation has the potential for both negative and positive impacts on these two aspects: negative impacts can occur when the cumulative costs of the environmental legislation on the industry add to other adverse global trends; positive impacts can be achieved by regulation through the promotion of green innovation and by ensuring a level playing field for all the actors involved.

While on the one hand the EU environmental legislation, and in particular the legislation of the chemical industry, is one of the most ambitious in the world and may constitute an additional burden to EU industry against extra-EU chemical companies, the legislation does ensure the internalisation of the externalities of the industry, enforcing the "polluter pays" principle and delivering benefits to the whole society in terms of human health and the environment on the other. An assessment by the UK DEFRA shows that for every €1 of cost incurred by industry and government authorities in implementing EU chemical legislation, €19 of health and environmental benefits accrue to society as a whole. Stricter environmental requirements can also stimulate innovation towards sustainability, providing first move competitive advantages to the more pro-active companies.

Conversely, the lack of environmental requirements can also have negative consequences on the innovation capacities of SMEs. For example, the lack of information on the uses and presence of hazardous chemicals in articles prevents informed choices and affects the efficiency of any prioritisation strategy for the purposes of substitution by downstream users. Gaps in information may also result in imperfect synergies between the different chemical legislative acts. Chemicals regulated by REACH may leak from products during their life cycle or during the waste stage, contaminating water resources regulated by the Water Framework Directive. The lack of upstream measures, such as a restriction, may lead to a need for downstream remediation, the costs of which will be covered by the water and wastewater sectors and ultimately by taxpayers/society, reducing the incentives for the producers and users of the chemicals upstream to pursue less toxic innovations.

In addition to these regulatory considerations, the potential for innovation is limited by lack of funding for supporting transformative technologies with strong innovative potential and added value. EU support is scattered over a large range of calls for proposals and topics research, and the funding available does not meet the ambition of industrial scale projects. More support or encouragement for co-operation within and/or between sectors could be helpful, as well as measures to attract foreign investment to enable innovation.

Programme on the development of new, non/less toxic substances (sub-study f)

A non-toxic environment implies that hazardous substances are replaced with safer alternatives including non-chemical solutions. The use of hazardous substances can however only be phased-out if suitable alternatives are available. With some 60% by tonnage of the chemicals on the market considered hazardous for health and the environment, a potential demand for non-toxic or at least less toxic substances of a large scale is expected, if a non-toxic environment should be achieved. Barriers to the development of new, non/less-toxic substances currently result from various challenges in the supply chain. These include:

- an overall hesitation to using new (non/less-toxic) substances because of fears about (hidden) costs and a lock-in in the current production situation (the possible need to change the overall choice of material or design of a chemical product or an article as well as processing equipment);
- the potential need to break existing supplier-customer relationships in combination with the need to identify new suppliers with whom they take the risks of developing a new substance;
- a lack of communication and collaboration opportunities and capacities, which are necessary for substitution, particularly where the alternatives do not exist yet;
- an overall lack of awareness of the benefits of using new, non/less-toxic substances;
- overall economic uncertainties as to the future performance of products, the development of markets, potential profits and stability of supply, if new, non/less-toxic substances are used

No national programmes that focus on the use of new, non/less-toxic substances were identified. However, a number of activities on green chemistry are under way in the USA, interconnected via an overall mission of the US EPA. Moreover, some Member States conduct activities related to the development and use of green or sustainable chemicals, including support for tools for substance design, hazard prediction, risks and alternatives assessment, stakeholder platforms, stakeholder dialogues and awareness raising about the needs and opportunities presented by substitution.

Several provisions exist in the EU regulatory framework and scientific programmes to support the development and use of new (non/less-toxic) substances. However, overall guidance and market signals, e.g. from the authorisation decisions under REACH, are mixed. Whilst stricter legislation may better promote the development of new, non/less-toxic substances, overall awareness on the benefits of using such substances is low and sufficient emphasis on the issue across all relevant policies is still missing.

At EU level, the Research and Innovation Programmes cover a wide range of different scientific, economic and societal challenges. Whilst no specific theme addresses the development of new, non-toxic substances, some themes -- notably LEIT-NMPB (Leadership in Enabling and Industrial Technologies, Nanotechnologies, advanced Materials, advanced manufacturing and Processing and Biotechnology) – could fund activities relevant to a non-toxic environment. One example of action is the Horizon 2020's €3 million prize for clean air, for which challengers must develop innovative, design-driven material solutions that will reduce the concentration of particulate matter in the air.
However, the overall perception is that the EU funding instruments direct their resources towards other societal challenges than the toxicity of substances, such as to climate change, resource efficiency or health sciences. Therefore, an EU programme specifically supporting research and development of new, non/less-toxic substances could be an integral part of the strategy for a non-toxic environment and could support the provision of alternatives to toxic substances as well as enhancing the design of new, benign materials at a smaller scale, thereby complementing the existing funding programmes. A programme to enhance the development of new, non/less-toxic substances should also include activities aimed at improving the overall business environment and readiness to innovate, e.g. by providing guidance at the policy level, raising awareness, improving education and supporting networking of the relevant actors.

Early warning systems for examining chemical threats to human health and the environment (sub-study g)
The EU chemicals regulatory framework provides for predicting hazardous properties and taking risk management measures that limit human and environment exposure. Despite this legislation, numerous cases have been documented of extensive damages to health and environment caused by the production and use of chemicals. It can take societal institutions a long time before warning signals are picked up and even longer for them to react, which jeopardizes any prospect of preventing or minimising damages.

For example, 10 of the 15 *Late Lessons from Early Warnings* identified by the European Environment Agency are directly linked to chemicals with hazardous properties (i.e. benzene, asbestos, PCBs, halocarbons, DES, antimicrobials, MTBE, PFAS, TBT, EDCs). Half of those cases highlighted issues caused by the persistent nature of chemicals (i.e. PCBs, halocarbons, MTBE, PFAS and TBT), several emphasized the additional risks induced by the cumulative effect of hazardous substances (i.e. PCBs, halocarbons, MTBE, TBT, EDCs), and two underlined the impacts of late lessons on vulnerable groups (i.e. PCBs, EDCs). This report highlighted instances in which years or decades spanned before regulatory intervention.

Early identification of new and/or emerging risks (NERCs) to human health and to the environment is of great importance in taking timely measures to reduce or eliminate the risk of hazardous compounds. Rather than an alternative instrument replacing current legislation, the development of such fast identification and response system is critical and must be considered as a complementary action.

At the moment, several approaches are used to pick up signals, such as online media monitoring and expert consultation, or registration systems for the collection, evaluation and systematic monitoring of spontaneous reports of undesirable events. Current systems depend heavily on observed and documented signals relating to occurrence of effects and potential exposure, the so-called 'effect-based' or 'disease first' systems. By contrast, other systems contain elements that can be used to

proactively identify possible NERCs, based on a proper risk assessment, the so-called 'exposure first' method.

Screening and filtering signals are essential for early identification. However, it is labour intensive and requires input from experts at the national level, which is currently not organised or coordinated at the EU or an international level. A related issue is the limitations of epidemiology, meaning that a harmful effect must often be rather drastic and widespread before it is detected. There is often a lack of information, due to the absence of relevant hazard data and the absence of details on exposure and use.

These issues highlight a general need for more cooperation and exchange of information on NERCs at EU level, including a supra-national platform for coordination. At the national and international levels, various existing initiatives in the area of early identification and management of chemical threats could provide the basic opportunities for more comprehensive and coordinated work. However, an overall approach covering the different steps needed for the identification and management of risks at the EU level is necessary. An essential step would be to generate an overview of existing data sources, their availability, accessibility, and their usefulness, and to make this data accessible through a central database. Investigation of appropriate risk management options, communication of the risks identified, and identification of measures to propose would be important to managing the risks observed.

Overall findings

After identifying the most significant gaps and deficits in the current situation, each sub-study concluded with lists of identified responses to those gaps and deficits. Some of the major knowledge gaps and deficits in policies and legislation identified across the different focus areas include:

- Remaining gaps in knowledge on health and environment hazardous properties of chemical substances;
- Slow progress in identification of Substances of Very High Concern, and in substitution of hazardous chemicals in industrial processes and products
- Lack of information concerning chemicals in articles, including imported articles, and the resulting exposure
- Insufficient attention to hazardous chemicals in material flows important for a Circular Economy
- Deficits in the framework for protection of children and other vulnerable groups, e.g. from chemicals in products such as e.g. textiles, electronics and other consumer products
- The still insufficient management of a number of aspects related to exposure and toxicity (sometimes termed 'emerging issues'), such as combination effects, cumulative, low dose and long-term exposure, endocrine disruptors, neurotoxicity, protection of children and vulnerable groups, and chemicals in articles including in waste, materials recycling and the circular economy.
- Insufficient knowledge of the occurrence of chemical substances in the environment and technosphere, as well as the societal costs of the resulting exposure.
- Insufficient means to address risks posed by chemicals on the basis of persistence alone
- Lack of monitoring of environmental compartments concerning possible build-ups of chemical contamination and health and environmental risks thereof, in particular with respect to sources of water intended for human consumption
- Need for better incentives for development of new, non-toxic substances as well as non-chemical solutions
- Need for more comprehensive compilation of monitoring data at EU level and establishment of an early warning system.

The gaps and deficits indicated the need for an additional, overarching framework for protection of human health and the environment from harm due to hazardous chemicals, i.e., a framework additional to REACH that has the overall objective of minimising human and environmental exposures to

hazardous chemicals. A broad outline of the types of measures that could be considered as relevant for a strategy for a non-toxic environment has been emerging in the course of the project. In particular, it could include the following building blocks:

Improve knowledge on chemicals

- Commit long-term to develop chemical knowledge bases (hazardous properties, uses, presence of chemicals in articles, monitoring data);
- Develop and implement an early warning system for identifying new chemical threats;
- Move from the current chemical-by-chemical to groupings of chemicals approaches in risk assessment and risk management.

Promote innovation, development of non/less-toxic chemicals and non-chemical solutions, and substitution

- Promote innovation in material and product design aimed at non-chemical and non/less-toxic chemical solutions;
- Promote circularity: promote chemical re-use solutions and facilitate non/less-toxic material cycles by, e.g. enabling dismantling and separation;
- Support substitution: increase access to knowledge crucial for those who can substitute and support substitution activities.

Reduce chemical exposures and promote circular economy

- Address very persistent chemicals;
- Establish a system of tracking chemicals in products (articles) and promotion of the development and use of non-toxic materials and articles;
- Improve protection of children and other vulnerable groups.

A strategy for a non-toxic environment could be translated into the overall principle that hazardous substances of particular concern (e.g substances corresponding with the criteria of SVHC in REACH and equivalent) should as far as possible be phased out in uses which are not sufficiently well contained/controlled during their life cycle. Further, there should be a constant striving towards minimising the exposure to all hazardous substances, including those of lower concern. This would include a range of different activities such as avoiding uses that are not essential, development of non or low toxic chemicals and non-chemical solutions, product and material design, reducing volumes used, avoiding uses involving large exposure, improving information and different protective measures. Choice of substances, design of products etc. should also meet the needs of reuse and recycling and aim to as far as possible achieve non-toxic material cycles.

In connection to this a type of **hierarchy in chemicals policy and management**, similar to that which guides EU waste management policy, is envisioned. Such a hierarchy could start with the principle of avoiding the production and use of chemicals of particular concern (i.e. SVHCs and equivalent including very persistent chemicals) as far as possible and limiting any uses to situations where exposure does not occur. The next step would be minimisation of exposure by different means and applying also to hazardous chemicals of lower concern. In addition, emphasis would be placed on the design of non/less-toxic chemicals and of products that would allow for toxic-free reuse and/or recycling. Finally, it would include workable approaches to address legacy chemicals, including systems for decontamination of recycled materials as well as recovery and destruction of hazardous substances in production wastes and at end-of-life product disposal.

ABBREVIATIONS USED

BPR	Regulation (EU) 528/2012 concerning the placing on the market and use of biocidal products
CEL	Critical Exposure Levels
CEPA	Canadian Environmental Protection Act
CLP	Classification, labelling and packaging or Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures
CMR	Carcinogenic, mutagenic and toxic for reproduction
CO2	Carbon Dioxide
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DNELs	Derived No-Effect Levels
EAP	Environment Action Programme
ECHA	European Chemicals Agency
EDC	Endocrine Disrupting Chemical/s
EEA	European Economic Area countries
EFSA	European Food Safety Authority
EMAS	Eco-Management and Audit Scheme
EU	European Union
EWS	Early Warning System
FAO	Food and Agriculture Organisation
GHG	Greenhouse gas
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HFC	Highly Fluorinated Chemical
ICCM	International Conference on Chemicals Management
JPOI	Johannesburg Plan of Implementation
KEMI	Swedish Chemicals Agency
KET	Key Enabling Technology
MS	Member State
MSCA	Member State Competent Authority
NERCs	New and/or Emerging Risks
NGO	Non-Governmental Organisation
NTE	Non-toxic environment
OECD	Organisation for Economic Co-operation and Development
OELs	Occupational exposure limit values
OSH	Occupational Health and Safety
PBT	Persistent, Bioaccumulative and Toxic
PCBs	Polychlorinated biphenyls
PFAS	Polyfluorinated Alkyl Substances
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctanesulfonic Acid
PIC	Prior Informed Consent
PM	Particulate matter
POPs	Persistent Organic Pollutants
PPPR	Regulation (EC) No 1107/2009 concerning the placing on the market of plant protection products on the market
PXDD	brominated-chlorinated dioxins
PXDF	brominated-chlorinated furans
RAPEX	European Rapid Alert System
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
REFIT	Regulatory Fitness and Performance Programme of the European Commission
RMM	Risk management measure

R&D	Research and Development
SAICM	Strategic Approach to International Chemicals Management
SCENHIR	Scientific Committee on Emerging and Newly- Identified Health Risks
SDG	UN Sustainable Development Goals
SiA	Substances in articles
SMEs	Small and Medium Enterprises
SVHC	Substances of very high concern
TSCA	US Toxic Substances Control Act
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
VOC	Volatile Organic Compounds
vP	Very persistent
vPvB	Very persistent, very bio-accumulative
WHO	World Health Organisation
WSSD	World Summit of Sustainable Development in Johannesburg

1 INTRODUCTION

Chemicals and their uses are essential elements of modern society. They are used as processing aids or as integral parts in the production of the articles and mixtures that people use in their daily lives and which help to ensure a high level of quality for these products. Moreover, the chemical manufacturing industry is the third largest EU industry. It is a significant contributor to the EU economy and its growth over the next ten years is projected to be robust.

However, of the over 100,000 chemicals estimated to be on the EU market today over 60% by tonnage are considered hazardous to human health and/or to the environment. The risks may be present at various points throughout a substance's life cycle: during production, when they are transported and when the mixtures and articles in which the substances are contained are used and then discarded. Given the importance of chemicals to the EU strategy for jobs and growth, it is crucial to manage these substances sustainably.

The European Union has adopted comprehensive chemicals legislation to protect both human health and the environment from these risks. The main pillars of this legislation are the REACH[1] and CLP[2] Regulations, complemented by legislation that addresses chemicals with specific functions, such as biocides, plant protection products, fertilisers and detergents. In addition, chemicals are addressed in some specific product-related legislation, such as the Toys Directive or the Medical Devices Directive, in order to prevent harm from product service lives where human exposure is of particular concern. Occupational health and safety legislation (OSH) forms another important element of the overall framework.

The knowledge and access to information on health and environment properties of chemicals has improved considerably as a result of REACH and CLP. However, chemicals legislation including the testing, assessment and risk management of chemicals is still dominated by substance-by-substance approaches and is mostly not designed to assess exposure to mixtures of chemicals, exposures from multiple sources and over long periods of time or the risks associated with this. Moreover, it is difficult for regulators to keep abreast of new developments, such as the increasing use of nanomaterials.

Many of the emerging issues related to the growing presence of chemicals in everyday life are recognised in the 7th Environment Action Programme (7th EAP), adopted in 2013 by the European Parliament and the Council. As a response, the 7th EAP commits to the development of a Non-Toxic Environment strategy in paragraph 54 under Priority objective 3: "*To safeguard the Union's citizens from environment-related pressures and risks to health and well-being by 2020*". The 7th EAP notes that to meet this objective the Commission will, inter alia, develop by 2018:

> *"a Union strategy for a non-toxic environment that is conducive to innovation and the development of sustainable substitutes including non-chemical solutions".*

In parallel, the European Commission presented an EU action plan for the Circular Economy in December 2015. The action plan refers to the transition to a more circular economy, where the value of products, materials and resources is maintained in the economy for as long as possible and in which the generation of waste is minimised. In the action plan set out in the Circular Economy package, the Commission commits to analysing and proposing options about the interface between chemicals,

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals.
[2] Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures.

products and waste legislation, and this work is destined to feed into the future non-toxic environment strategy too.

Moreover, some aspects of the EU legislative framework concerning chemicals are evaluated as part of the ongoing 'Fitness check of chemicals legislation except REACH' and the 'REACH review'. The development of the future non-toxic environment strategy should complement these processes.

To support the European Commission in examining the possibilities of such a strategy, Milieu Ltd (Milieu), together with Risk & Policy Analysts (RPA), Ökopol, and the Institute for Public Health and the Environment of the Netherlands (RIVM), was awarded a study contract by DG Environment for '[Study for] The strategy for a non-toxic environment of the 7th Environment Action Programme (EAP)' (ENV.A.3/ETU/2015/0027). The contract entered into force on 1 December 2015.

This Report summarises the results obtained from the research carried out during the course of the project. It is based on the seven sub-studies required as per the Technical Specifications:

a. Substitution, including grouping of chemicals & measures to support substitution (RPA);
b. Chemicals in products (articles) and non-toxic material cycles (Ökopol);
c. The improved protection of children and vulnerable groups from harmful exposure to chemicals (Milieu);
d. Very persistent chemicals (Milieu);
e. Policy means, innovation and competitiveness (RPA);
f. Programme on new, non-/less toxic substances(Ökopol);
g. Early warning systems for examining chemical threats to human health and the environment (RIVM).

The draft final reports for each of the seven sub-studies are included as annexes to this report. Additional input includes the results from a general literature review, from a workshop held in June 2016 and based on comments received about the interim reports. Further details are provided in Section 2 on the study's objectives and methodology.

2 STUDY OBJECTIVES AND METHODOLOGY

2.1 OBJECTIVES

This study focuses on some of the chemicals policy gaps identified in the 7th Environment Action Programme. Many of these, such as combination effects, endocrine disruptors, and chemicals in articles, cut across a range of policy areas and are already well known and long established. Seven sub-studies, on topics stipulated in the Technical Specifications from the Commission, were carried out as part of this project to strengthen the evidence base where information was lacking. The seven sub-studies (and the responsible project partner) are:

Sub-study	Subject	Author
A	Substitution, including grouping of chemicals & measures to support substitution	RPA
B	Chemicals in products (articles) and non-toxic material cycles	Ökopol
C	The improved protection of children and vulnerable groups from harmful exposure to chemicals	Milieu
D	Very persistent chemicals	Milieu
E	Policy means, innovation and competitiveness	RPA
F	Programme on new, non-/less toxic substances	Ökopol
G	Early warning systems for examining chemical threats to human health and the environment	RIVM

On the basis of the Tender Specifications, and instructions provided by the Commission throughout the course of the project, the overall objectives of the study can be summarised as follows:

- Present a comprehensive assessment of available information, i.e., the state of play, to be used as a base of evidence for the development of a non-toxic environment strategy;
- Provide an overall analysis of the current approaches for reducing health and environmental burdens in connection with the focus areas selected for analysis, including gaps and deficits and improvement possibilities presented in connection to these;
- Present an overview of the improvement opportunities and related policy instruments across the sub-study areas and identify synergies[3].

These objectives took into consideration the broader body of work that the Commission is currently undertaking in this area, including the comprehensive fitness check of all chemicals legislation being carried out by the Commission under its better regulation programme (REFIT) (see Section 4.1 on the EU regulatory framework). Several of these other studies are also likely to provide significant input to the Commission's planning on the strategy for a non-toxic environment, as they are among other things assessing the performance of current legislation and policy, including policy gaps. Hence, it was important to continuously consider the work carried out in these studies (to the extent the Commission made the (interim) results available to the contractor), and as far as possible to avoid overlaps and follow their progress.

A key difference between the fitness check/REACH review and the strategy for a non-toxic environment should be noted. Whereas the REFIT process is intended to consider how current legislation addresses the present situation, the strategy for a non-toxic environment process is more forward-looking and aims to consider chemicals policy in the long term. The study in support of the

[3] The tender specifications set out the following (p.18): "*Present a simplified impact assessment or analysis of costs and benefits for the policy options presented. This will most likely be qualitative, but possibly some elements can be quantified or illustrated through monetised examples*." This task was changed upon request of the Steering Committee after submission of the Inception Report.

strategy for a non-toxic environment was carried out from this wider perspective, in parallel to the REFIT studies and related policy processes.
The fact-gathering and inventory of improvement possibilities are meant to serve as a solid basis for the development of the non-toxic environment strategy, to enable the Commission to meet the 2018 deadline, as laid down in the 7th Environment Action Programme. The results of the work, thus, do not provide the actual 'strategy for a non-toxic environment', but instead represent a gathering of existing information that can feed into the development of the strategy, along with the results of the other studies mentioned above.

2.2 METHODOLOGY

The initial desk research, including a literature review and stakeholder consultation, focused on the respective sub-study themes. This research was supported by a general literature review, which has provided an evidence base for an analysis of the policy gaps and deficits per sub-study area. It has also informed the identification of improvement opportunities to address these gaps and deficits.

The desk research was complemented by a workshop entitled "Strategy for a Non-toxic Environment of the 7th Environment Action Programme (EAP)", organised by the Commission with the support of Milieu and held on 8-9 June 2016 in Brussels. The workshop had two central objectives: (i) to inform stakeholders from a wide range of organisations and institutions about the ongoing study and its different sub-studies and (ii) to obtain feedback from these stakeholders about the gaps and barriers identified during the course of the study and preliminary recommendations on how to address them. In total, 118 participants (excluding speakers and study team) registered and were confirmed as participants of the workshop. They represented public authorities, industry, NGOs, academia, trade unions and consultancies.

In order to foster fruitful discussions during the workshop, participants received in advance summaries ('workshop materials') of the different sub-studies' findings to date, including gaps/deficits identified and related improvement opportunities. This material was kept short, with a view to allowing participants to read the materials provided under all of the sub-studies. Tailored feedback forms were used to facilitate valuable feedback from participants beyond the discussions held at the workshop, which was then gathered by the study-team and fed into the draft sub-studies at the interim report stage; this was submitted at the end of August 2016.

This Report incorporates the additional work carried out in response to comments received from the Commission on the interim report, including the seven draft sub-studies. The seven sub-studies are annexed to this report.

Each sub-study contains a section containing the literature review (some in a separate appendix), a section on gaps and deficits and one on improvement opportunities which are relevant for the sub-study area. The improvement opportunities include short-, mid- and long-term options and cover a range of measures from soft measures, such as awareness-raising programmes, to legally binding measures. Each improvement measure identified is described qualitatively in a table at the end of each sub-study.

Section 7 of this Report comprises a horizontal overview of the gaps and deficits identified for each of the focal areas and the suggested improvement opportunities. Section 7.2 below presents the categorisation of the gaps and deficits identified in the sub-studies by type of gaps. It then draws parallels between the past and present experiences with policy instruments in the chemicals area (Section 7.3) and the identified responses, describing qualitatively the pros and cons of implementing a certain type of policy instrument to address a specific gap/deficit and comparing these with softer or harder approaches.

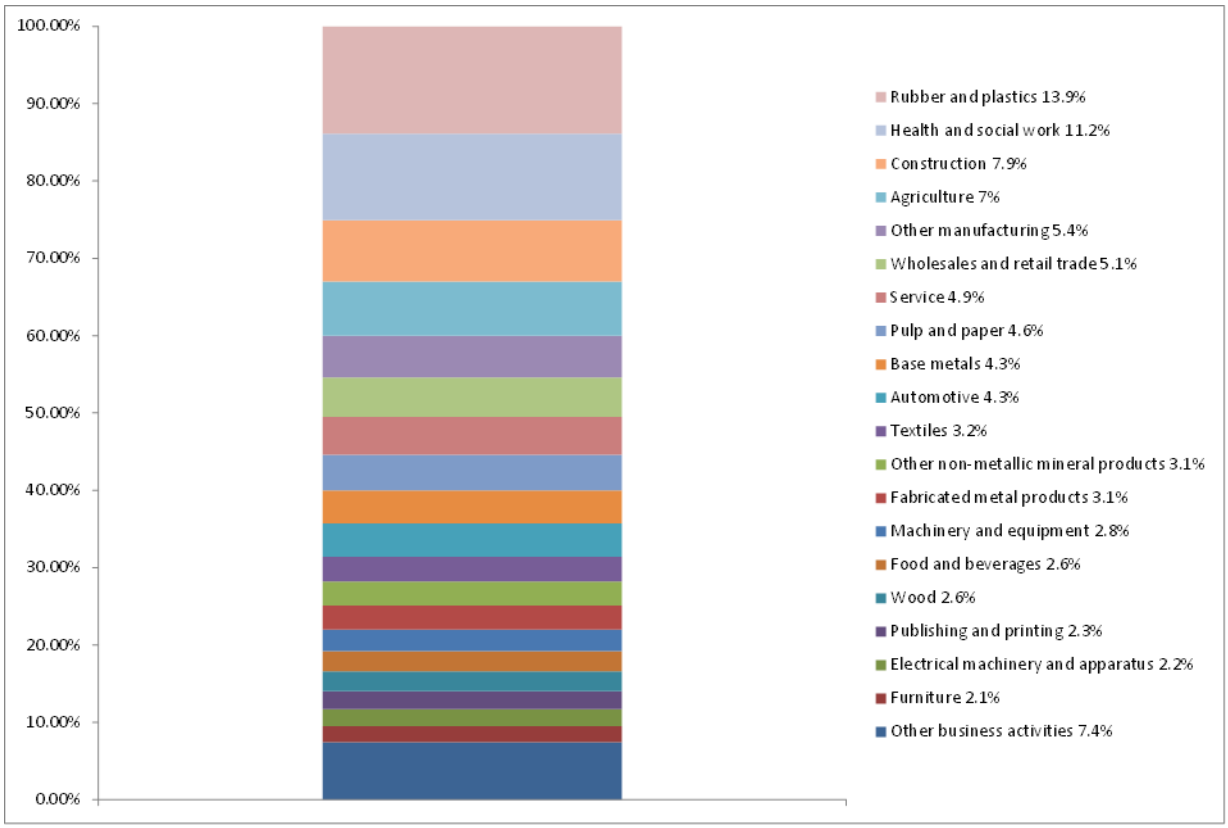
3 THE ROLE OF CHEMICALS IN MODERN SOCIETY AND INDUSTRY

This section has been drawn from the draft final report for sub-study e on *Policy means, innovation and competitiveness* drafted by RPA. More details are included in the sub-study.

The chemical industry shapes other economic activities, from agriculture, construction and textiles to high tech industries such as aerospace, automotive, health care and electronics, more than any other manufacturing sector. Due to its role in the value chain, i.e. transforming raw materials and feedstock into tailor made solutions for downstream industries, it serves all sectors of the economy (see the figure below) and contributes to our well-being.

Chemicals are not just 'chemical products' (paint, glue, detergents, solvents, pharmaceuticals); they are virtually all materials (metals, plastics, paper, glass). The millions of articles used every day (electronics, toys, clothing, vehicles, buildings) are manufactured using chemicals or consist of chemicals, treated with chemicals (e.g., coatings, preservatives) and/or manufactured using chemicals. In the EU, the biggest downstream users of chemicals are the plastics and rubber industry, construction, the pulp and paper industry and automotive manufacturing. In total, two thirds of EU chemicals sales go to the manufacturing sector and one third to agriculture, services and other industries.

Figure 2: Percentage of output consumed by customer sector



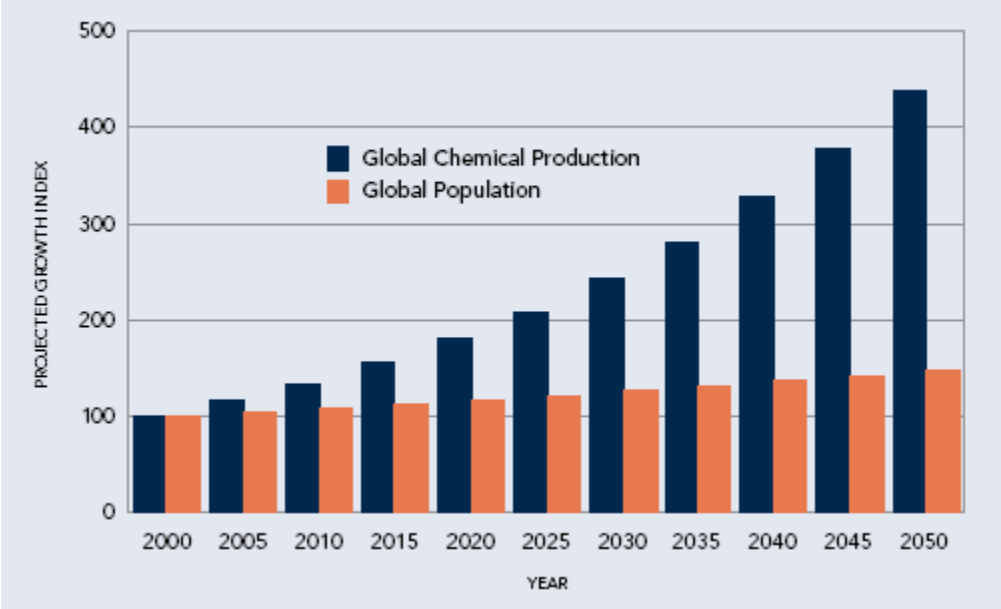
Source: Cefic, 2014

The chemical manufacturing industry is the third largest in the EU, accounting for 7% of the EU's industrial production. It directly employs around 1.2 million people and generates nearly 3.6 million indirect jobs. In terms of chemicals sales, the EU chemical industry represents 17% of the global

market, behind China (34%) but before NAFTA countries[4] (16%) (Cefic, 2014).

The use of chemicals is ever increasing. From 1950 until 2000, chemicals production expanded 60-fold by tonnage. Global chemicals sales more than doubled between 2004 and 2014 (from €1,458 billion to €3,232 billion) and the total value of EU sales increased by 80% in the same period. Growth is expected to continue by 4% every year by 2020, and by 2035 global revenues are expected to have doubled compared to 2015 (Roland Berger, 2015). The figure below shows how the rate of growth of the global chemicals production has already outpaced, and is expected to keep outpacing, global population growth rates over the next decades.

Figure 3: Projected growth in chemicals production in comparison to growth in global population[5]



Source: Green Chemistry: Cornerstone to a Sustainable California (2008).

Over 100,000 chemicals are present on the EU market today, with some 35,000 chemicals marketed in volumes above 1 tonne per year. Moreover, the number of known chemicals continues to grow. The CAS Registry, which already lists over 129 million unique organic and inorganic chemical substances, is reportedly updated with another 15,000 substances every day[6].

The chemical industry produces thousands of different products that are utilized for a broad range of end-use applications. It underpins many different sectors within the economy, which results in a strong correlation between economic growth in the region and the growth of the chemical industry. However, the expansion of global chemicals sales is primarily driven by emerging economies such as China, India, Korea and Brazil, where over 80% of new production capacities are being developed. Growth in these countries is expected to benefit European producers via increased exports and local investments, but it is vital for the European industry to retain its manufacturing and innovation capacity, not only of high added-value chemicals (e.g. specialty chemicals) but also of basic chemicals, which provides the raw materials for the high added-value sectors. This is because the proximity and close interconnection of the chemical industry with its client industries is one of the major strengths and innovation motors of the EU manufacturing industry as a whole (High Level Group on the Competitiveness of the European Chemicals Industry, 2009).

[4] Canada, Mexico and the US.
[5] http://coeh.berkeley.edu/docs/news/green_chem_brief.pdf (accessed 20.07.2017).
[6] https://www.cas.org/content/chemical-substances#how (accessed 30.03.2017).

EU chemicals sales cover three broad areas: base chemicals (petrochemical, polymers and basic inorganics), specialty chemicals and consumer chemicals. In 2014, base chemicals represented around 60% of total EU chemical sales, specialty chemicals (which include paints, dyes, inks and pigments) accounted for around 30% and consumer chemicals (e.g. soaps, detergents, perfumes, cosmetics, etc.) made up around 10%.

The competitiveness of the manufacture of basic chemicals is mainly driven by price and availability of energy and feedstock. The EU has a strong disadvantage on these factors against the US and the Middle East countries. The European Union has also high labour and capital costs compared to China. Despite an increase in fuel and power consumption efficiency (Cefic, 2016), unlike other regions, the EU chemicals industry is unable to base its growth on inexpensive resources and labour. Moreover, future opportunities of further decreasing fuel consumption in the sector appear limited unless major shifts toward recycling and bio-based chemicals will occur.

The main competitive advantage of the EU chemical industry is the high level of technological development, skilled workforce and strong research base. The chemicals industry is one of the most R&D intensive manufacturing sectors within advanced economies (behind US and China only).

One of the challenges faced by European chemicals companies is to find new ways to meet customer demands and increase market share, e.g. by continually improving products, technologies and processes.

Another challenge concerns the many chemicals that can cause harm to health and the environment. Over 60% by tonnage of the chemicals on the EU market are hazardous to human health or the environment. Diseases linked to exposure to hazardous substances include cancers, neurological disorders, allergies and other acute and chronic health effects, resulting in socioeconomic costs for the EU. As an illustrative example, exposure to endocrine disrupting chemicals has been estimated to cause €157 billion in annual health care costs and lost earnings (Trasande et al, 2015). There is a particular concern for the unborn child, young children and women in the fertile age.

Damage to biodiversity and ecosystems is also a concern. The use of tributyltin as anti-fouling marine coatings caused the decline of the population of shellfish, with an associated economic loss estimated in €22 million per year to the UK shellfish industry alone (Giacomello et al, 2006).

Environmental contamination reduces the value of fish stocks used as food or feed, contaminates drinking water and soils, and can reduce crop production by adversely affecting pollinators. Substantial costs arise from decontamination and remediation of buildings, infrastructure, land and water, e.g. the estimated EU environmental (remediation) costs just for cleaning up PCBs are estimated to be more than €15 billion between 1971 and 2018 (Von Bahr, 2004).

Only a small fraction of the many chemicals currently on the market have been thoroughly evaluated regarding their health and environmental properties and impacts, and even fewer are actually regulated, e.g. REACH partially restricts or bans some 60 individual chemicals and some groups of chemicals with similar properties, such as carcinogens, mutagens and repro-toxic substances (CMRs).

Scientific research into the possible hazards posed by chemicals almost always leads to increased (and seldom to lessened) concern over risks to human health and the environment. This implies that initial scientific assessments of a substance often underestimate the risk of harm (Grandjean, 2017). Section 7.2 of this Final Report summarises a number of the knowledge gaps relating to chemical substances and their uses, including:

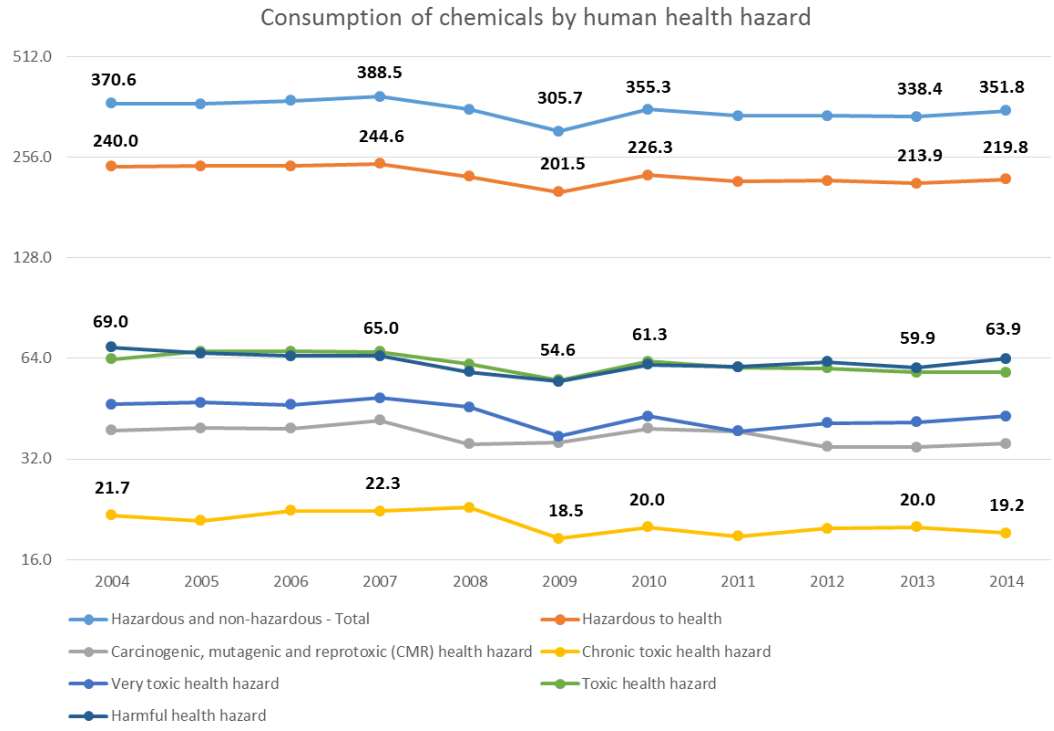
- Remaining gaps in knowledge on health and environment properties of chemical substances;
- Lack of information on the use of chemicals in articles and the resulting exposure;
- Continued usage of some substances of very high concern (SVHCs) in ways not well

controlled/contained and hence involving exposure;

- The still insufficient management of a number of aspects related to exposure (sometimes termed 'emerging issues'), such as combination effects, cumulative, low dose and long term exposure, endocrine disruptors, neurotoxicity, protection of children and vulnerable groups, and chemicals in articles including in waste, materials recycling and the circular economy.
- Insufficient knowledge of the occurrence of chemical substances in the environment and technosphere, as well as the societal costs of the resulting exposure.

There is some evidence that the EU chemical industry may be tending towards the development of safer chemicals: between 2013 and 2014, while total chemical production increased, the production of CMR substances went down. Figure 4 on the following page indicate that while the consumption of hazardous substances has increased, the increase is proportionally less than the total consumption of chemicals. It should be noted that the indicators on production and consumption of hazardous substances maintained by Eurostat are only an imperfect proxy for exposure, as this depends upon a number of other factors[7], such as how a substance is used, any safety measures in place to control emissions and exposures during the substance's life cycle, and any imports of substances, including articles containing them.

Figure 4: **Consumption of chemicals by human health hazard**



As an input provider for other industries, the chemical industry is considered to be at the forefront of innovation and a solution provider for many societal and environmental challenges, with chemical technological breakthroughs spilling over its downstream sectors. Patterns of innovation towards more sustainable solutions therefore not only have a profound effect on the industry itself but also on the wider economy. The question is whether the direction of this innovation is toward more sustainable and more benign chemicals in terms of protection of human health and the environment, and whether the rate of innovation needs to be speeded up to meet societal goals and needs.

[7] http://www.eea.europa.eu/airs/2016/environment-and-health/production-of-hazardous-chemicals.

A close co-operation between the chemical industry and the downstream sectors is therefore fundamental for the competitiveness and innovative capacity of the EU economy as a whole, but also for achieving the 2020 goal of sound chemicals management globally, set by the World Summit of Sustainable Development (WSSD) 2020 chemicals goal and the United Nations' Strategic Approach to International Chemicals Management (SAICM). The Overall Orientation and Guidance document adopted during the fourth International Conference on Chemicals Management held in Geneva in 2015 recognises the "need for stronger engagement and increased assumption of responsibility by downstream entities, in particular industries, to address the distribution and use of chemicals in the manufacture of products and throughout their lifecycle, and for a more extensive approach to stewardship"[8].

Moreover, companies in downstream sectors are closer to consumer demands for safer and greener products and have different perspectives on how to develop and implement safer chemical and non-chemical alternatives. Hence the challenge for Europe today is how to ensure steady progress towards sustainability with respect to the production, use, materials reuse, and safe recycling and disposal of synthetic chemical substances in combination with retained competitiveness.

[8] http://www.saicm.org/Portals/12/Documents/OOG%20document%20English.pdf (accessed 30.03.2017), p. 5.

4 CHEMICAL REGULATION IN THE EU AND GLOBALLY

4.1 THE EU REGULATORY FRAMEWORK FOR CHEMICALS

The European Union has put together a comprehensive regulatory framework, aiming to ensure a high level of protection of human health and the environment whilst preventing barriers to trade. EU chemicals legislation applies to all industry sectors dealing with chemicals and along the entire supply chain, making companies responsible for the safety of chemicals that they place on the market. The legislation put in place consists of rules governing the marketing and use of chemical products, major accidents and exports of dangerous substances, as well as restrictions on the placing on the market of specific hazardous substances (European Parliament, 2016). This legislation can be considered to be the most advanced and comprehensive legal framework regulating chemicals in the world.

Substantial progress in the management of chemical substances has been achieved in Europe since 2006, when the EU adopted its flagship regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[9]. As more than 100,000 substances were on the EU market but knowledge on their potentially hazardous properties was insufficient, the EU legislator decided that this knowledge would have to be generated and that the burden should be shifted from governments to the industry. To comply with the Regulation, companies must identify and manage the risks linked to the substances that they manufacture and market in the EU. They must demonstrate how the substance can be used safely and they must communicate the risk management measures to downstream users.

If the risks cannot be managed effectively, then authorities can restrict the use of substances in different ways. In the long run, the most hazardous substances should be substituted with less dangerous ones (ECHA, na). As of 12 January 2017, 173 substances have been identified as substances of very high concern (SVHC) (ECHA, 2017) and are, hence, potentially subject to the authorisation requirement and eventual phase-out or to restriction. One of the challenges in implementing REACH is how to speed up the process of identifying all substances meeting the Article 57 criteria for SVHCs as well as other substances of equivalent concern that may meet endpoints not yet adequately addressed, e.g., endocrine disrupters, neurotoxins, immunotoxins, and developmental toxins.

REACH also aims to enhance the communication on chemicals up and down the supply chain. Downstream users must communicate uses to suppliers and must know and disclose (in case of consumers, on request) if their product contains an SVHC to recipients. In reality, however, the number of notifications of SVHCs in articles is very small, raising concerns that this provision is poorly implemented and not functioning as intended by the legislation.

The complementary Regulation on the classification, labelling and packaging of substances and mixtures (CLP Regulation[10]) aims to ensure that the hazards presented by chemicals are clearly identified and communicated to workers and consumers in the European Union through the classification and labelling of hazardous chemicals. In addition to the overarching rules of REACH and CLP, specific pieces of legislation address particular groups of chemicals, such as biocides, pesticides, fertilisers, detergents, pharmaceuticals or cosmetics.

Most pieces of chemicals legislation have been subject to an impact assessment, prior to their adoption, and some of them have undergone further reporting and review during the course of their implementation. Under the European Commission's better regulation programme (REFIT), all EU

[9] REACH Regulation (EC) No. 1907/2006.
[10] CLP Regulation (EC) No. 1272/2008.

chemicals legislation except REACH has undergone a comprehensive fitness check, and a REFIT evaluation of REACH is nearly completed.

The goal of the fitness check is to assess the relevance, coherence, effectiveness, efficiency and added value of the legislative framework for the risk management of chemicals; it also aims to identify excessive administrative burdens, overlaps, gaps, inconsistencies and/or obsolete measures (European Commission, 2017). The Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs and the Directorate-General for the Environment share the responsibility for this fitness check (European Commission, 2017).

The Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation, was launched in 2015 to identify and to evaluate issues arising out of the implementation of CLP, as well as the interplay between different pieces of chemical legislation (excluding REACH) and provisions relating to chemicals management in other pieces of legislation (European Commission, 2017). Issues negatively impacting upon effectiveness include, according to the study, the lack of assessment for combination effects and multiple routes of exposure, delays in determining appropriate criteria for endocrine disrupting chemicals under some legislation and the variations in willingness of Member States to support harmonised classification dossiers under the Biocidal Products Regulation and the Plant Protection Products Regulation. The study also highlights a need for the increased use of more innovative tools to supplement current labelling requirements to increase the quality of the information being communicated. It acknowledges that the reliance on CLP, as the basis for classification across almost all other legislation, has increased the efficiency of the legislative framework. However, the study also points to some coherence issues, including the identification of allergens under different pieces of legislation and the prohibition of animal testing under the Cosmetic Products Regulation[11]. The study finds that, generally, the objectives of the chemicals legislative framework continue to be relevant and provide added value at the EU level.

Among other supporting studies, the ones particularly relevant for the development of the Strategy for the Development of a Non-toxic Environment include the following:

- Study to develop EU enforcement indicators for REACH and CLP (published in April 2015) (European Commission, 2015);
- Study on the impact of REACH on innovation, competitiveness and SMEs (published December 2015) (European Commission, 2015);
- Study on impacts of REACH and corresponding legislation in 3rd countries on the international competitiveness of the EU chemicals industry and selected downstream user (draft final report published in February 2016) (ECSIP Consortium, draft);
- Calculation of the indicators of benefits of chemical legislation on human health and the environment (published in 2016) (European Commission, 2016);
- Study on the cumulative health and environmental benefits of chemical legislation, highlighting the benefits of existing legislation and areas where there is still significant damage (for completion by early 2017) (European Commission, 2017);
- Evaluation of the Practical Implementation of the EU Occupational Safety and Health (OSH) Directives in EU Member States (not yet published);
- Supporting studies for the Fitness check for the construction sector (published in October 2016) (European Commission, 2017).

The stocktaking of chemicals legislation is expected to provide a comprehensive assessment of current chemicals legislation, preparing the ground to identify any possible additional actions needed in the

[11] Ingredients that are used in cosmetic products may still require data from animal testing derunder REACH, the BPR, the PPPR or other legislation.

area of chemicals. Thereby, they will also contribute to the factual basis for the non-toxic environment strategy.

In parallel, as part of the Circular Economy Package, the Commission has committed, by 2017, to identify ways to reduce the presence and improve the tracking of chemicals of concern in products[12].

In December 2015, the European Commission presented an EU action plan for the Circular Economy. The action plan refers to the transition to a more circular economy, where the value of products, materials and resources are maintained in the economy for as long as possible and in which the generation of waste is minimised. The plan refers to several aspects related to chemicals policy. These include the facilitation of substitution of chemicals of concern and supporting SME access to innovative technologies (p.5), the promotion of non-toxic material cycles and better tracking of chemicals of concern in products (p.12-13, Annex p.3). Furthermore, the Commission commits to analysing and proposing options on the interface between chemicals, products and waste legislation, and this work is destined to feed into the future non-toxic environment strategy.

The development of the non-toxic environment strategy should complement these processes. Horizontal Commission processes already exist for certain aspects of some problem areas; namely, combination effects, nanomaterials and endocrine disruptors. To date, in the area of substances in articles, no focused horizontal work has been carried out by the Commission. It is useful to consider them from a general level through a comprehensive strategy, given that these issues are strongly interconnected and closely linked with the current chemicals *acquis*.

4.2 OVERALL GLOBAL POLICY INITIATIVES

The production of chemicals is expected to continue growing in the near future and there are geographical shifts in production from Europe and North America to Asia and developing countries elsewhere. This causes new challenges in tackling the issue of exposure to toxics. For example, the phasing out of emissions of long-chain polyfluorinated alkyl substances (PFASs) by US and European manufacturers has been offset by a geographical shift of their manufacture and use to countries in Asia. This means that when developing a strategy for a non-toxic environment in Europe, it is important to consider the international aspects of chemicals both relating to the impact of chemicals on the environment and health and the global policy processes that attempt to govern them.

The magnitude of chemicals-related health problems around the world is difficult to estimate. On the basis of data available for 2004, the World Health Organization (WHO) found that 4.9 million deaths (8.3% of the total that year) and 86 million disability-adjusted life years (DALYs) (5.7% of total) were attributable to exposure to selected chemicals[13]. Critical chemicals not able to be included in the analysis due to lack of data included mercury, dioxins, organic chlorinated solvents, PCBs, and chronic pesticide exposures as well as health impacts from exposure to local toxic waste sites, which are estimated to affect more than 56 million people worldwide.

Of special note was the finding that children under age 15 years were especially vulnerable and bore 54% of the global burden, including 80% of that imposed by lead and 19% of acute accidental poisonings. The WHO noted the limitations in the data available, and stressed that these were underestimates of the real global burden attributable to chemicals.

[12] European Commission, Closing the loop – An EU action plan for the Circular Economy, COM(2015) 614 final, available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52015DC0614.
[13] http://www.unep.org/chemicalsandwaste/sites/unep.org.chemicalsandwaste/files/publications/GCO_web.pdf. DALYs, or disability- adjusted life years, reflect a blend of death and disease impacts.

In light of this global dimension, the EU has made the commitment to help achieve the United Nations' **2030 Agenda for Sustainable Development** including the Sustainable Development Goals (SDG) (UN, 2015). Goal 12.4 requires to:

> "[*by*]*2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment*".

The participants at the **World Summit of Sustainable Development in Johannesburg (WSSD)**, including the European Union (EU) (European Parliament and Council, 2002) and its Member States, made a commitment to the sound management of chemicals throughout their life cycle in 2002, the 'WSSD 2020 goal'. It was expanded upon in paragraph 23 of the Johannesburg Plan of Implementation (JPOI) (UN, 2002). In 2006, governments and stakeholders agreed on the Strategic Approach to International Chemicals Management (SAICM) (UNEP, 2006), a global policy framework to promote safe chemicals management with the explicit aim of implementing the WSSD 2020 Goal on chemicals.

The box below lists the international processes under way aimed at better global chemicals management. A second box provides a brief overview of the international conventions relevant to chemicals regulation.

International processes aimed at better global chemicals management

- The activities on substances in articles in the framework of the Strategic Approach to Global Chemicals Management (**SAICM**), managed by the United Nations Environment Program (UNEP) - a global policy framework to promote safe chemicals management with the explicit aim of implementing the World Summit on Sustainable Development 2020 Goal on chemicals. SAICM aims to provide a policy framework to foster the sound management of chemicals; however, it is important to note that it is a voluntary instrument and is not a legally binding agreement;
- The international activities on **endocrine disrupting chemicals (EDC)** related to several processes and organisations, e.g. SAICM, studies and reporting by UNEP and the World Health Organisation (WHO), as well as the work of the Organisation for Economic Co-operation and Development (OECD);
- The **OECD's work on combination effects of chemicals/mixture toxicity**, mainly on test methods and guidance for risk assessment;
- Work on the **safety of nanomaterials in the framework of SAICM and by the OECD**, including e.g. a programme aiming at pooling technical knowledge on testing, hazards, risk and the risk management of nanomaterials across the OECD countries and making it systematically available.

Overview of international conventions relevant for chemicals regulation

The **Rotterdam Convention's** objective is to promote shared responsibility and cooperative efforts among parties in international trade of certain hazardous chemicals in order to protect human health and the environment from harm. The Convention creates legally binding obligations for the implementation of the Prior Informed Consent (PIC) procedure, building on voluntary PIC procedure, initiated by UNEP and FAO.

The overarching objective of the **Basel Convention** is to protect human health and the environment against the adverse effects of hazardous wastes. Its scope of application covers a wide range of wastes defined as "hazardous wastes" based on their origin and/or composition and their characteristics, as well as two types of wastes defined as "other wastes" - household waste and incinerator ash.

The **Stockholm Convention** is a global treaty to protect human health and the environment from chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in the fatty tissue of humans and wildlife and have adverse effects to human health or to the environment. Parties are required to take measures to eliminate or reduce the release of POPs into the environment.

Overview of international conventions relevant for chemicals regulation

The **Minamata Convention** is the first global policy aimed at limiting anthropogenic releases of an inorganic substance –mercury and its compounds. The Convention seeks to reduce emissions to the atmosphere, soil and water from a number of sources. Under the treaty, new mercury mines are banned and existing mines are to be phased out, the use of mercury in a number of products and processes is to be reduced and/or eliminated, and measures set in place to control emissions to air as well as releases to land and water. The European Union is current working on a ratification package for the Minamata Convention for implementation.

The **Globally Harmonized System of Classification and Labelling of Chemicals** (GHS) addresses the classification of chemicals by types of hazard and proposes harmonised hazard communication elements, including labels and safety data sheets, ensuring that information on physical hazards and toxicity from chemicals be available during the handling, transport and use of these chemicals. The GHS also provides a basis for the harmonisation of rules and regulations on chemicals at national, regional and worldwide levels, another important factor for trade facilitation.

The **OSPAR Convention** (Convention for the Protection of the Marine Environment of the North-East Atlantic). It combines and up-dates the 1972 Oslo Convention on dumping waste at sea and the 1974 Paris Convention on land-based sources of marine pollution. It adopted a 'Strategy with regard to Hazardous Substances' which aims at the cessation of discharges, emissions and losses of hazardous substances by 2020 in order to achieve 'close to zero' concentrations in the marine environment.

These international agreements form the backbone of international policy relating to the sound management of chemicals. The EU has historically played a central role in developing and implementing these agreements. While developing a strategy for a non-toxic environment, it is relevant to consider both the EU's role in the development current and future international agreements, as well as links between this strategy and international chemical management policy. See also Section 7.1.

4.3 NATIONAL INITIATIVES OUTSIDE OF THE EU – EXAMPLES FROM THE USA AND CANADA

In June 2016, the **USA** adopted a new chemicals act—the Frank R. Lautenberg Chemical Safety for the 21st Century Act—which updates the 1976 US Toxic Substances Control Act (TSCA) (US EPA, 2016). The 1976 act had been widely acknowledged as an insufficient instrument for management of risks of the many chemicals in US commerce. The US Environmental Protection Agency (USEPA) had struggled to gather information about the hazard characteristics of the chemicals in commerce. As of 2015, it had tested only 250 of the more than 84,000 'existing' chemicals on the US market (Center for Effective Government, 2015). Because of the vacuum left by an ineffective TSCA, many states set in place their own more stringent state-level laws, resulting in a patch-work of requirements that created difficulties for the chemical industry to achieve compliance across the nation.

The 2016 amendment includes several much-needed improvements on the previous regime, such as increased public transparency for chemical data and a mandatory requirement for USEPA to evaluate existing chemicals, as well as a consistent source of funding so that it can carry out those responsibilities. However, in comparison to REACH, it is not very ambitious. Though the USEPA now has more authority to request data on high priority chemicals, US industry is not required to provide a minimum data set concerning any hazards inherent in the chemicals that they produce. In fact, the 2016 act explicitly prohibits USEPA from requiring minimum data sets with a common set of endpoints.

The work programme set forth for evaluating high priority substances has a long time frame, compared to the timelines of REACH. USEPA plans to carry out safety assessments for 20 substances over the next 3+ years, most of which have already been regulated under REACH.

Moreover, in contrast to REACH, where the burden is on industry to prove that any risks involved with use of the chemical can be sufficiently controlled, the USEPA still has the burden of proof of showing that certain substances pose 'unreasonable risks'. Additionally, the new act does not support downstream users and consumers with information concerning whether a product contains high priority substances. Note that actual implementation of the new act and its policies depends on the USEPA, which is currently experiencing rollbacks in funding under the Trump administration. Thus, the future of this work programme is uncertain.

For these and other reasons, those who are familiar with the history of chemicals regulation in Europe are comparing the amended TSCA as equivalent to the EU's 1993 Regulation on Existing Substances (793/93), which 15 years later was replaced by REACH.

Another national effort is **Canada**'s effort to introduce a systematic, outcome-oriented approach to chemicals management, with substances prioritized for assessment on the basis of risk. A 1999 revision of the *Canadian Environmental Protection Act* (CEPA) established a deadline of 2006 to complete a systematic sorting of the 23,000 substances on their list of 'existing' substances to determine which ones were either inherently toxic to humans or non-human organisms, and either persistent or bioaccumulative, or had the greatest potential for subjecting people in Canada to exposure to the substances. Canada's Chemicals Management Plan (CMP) was launched to implement the 1999 CEPA's sections on toxic substances, followed by a second phase in 2011. A major focus of the Plan was to launch calls for any data held by the chemicals industry and other actors on specific priority substances so that the substances could be evaluated, using powers provided under the 1999 CEPA.

A third phase of the Plan was launched in 2016 (running from 2016 to 2021), aimed at addressing the remaining 1550 priority substances out of a total of 4300 chemicals that have been identified as requiring health and ecological assessment. Under Canada's approach, the burden of data gathering has shifted from falling solely on government to a shared responsibility with industry. However, substance assessment still rests with Environment Canada and Health Canada, which means that Canada's authorities still shoulder a considerable burden of assessment and monitoring.

5 THE STATE OF PLAY, INCLUDING NEW AND EMERGING HEALTH AND ENVIRONMENTAL CONCERNS

5.1 IMPLEMENTATION OF THE CURRENT POLICY

5.1.1 Evaluation of substances

The REACH Regulation requires the registration of substances manufactured or imported in quantities of more than 1 tonne per year (per manufacturer or importer), by the provision of information on the physicochemical and (eco)toxicological properties of the substances put on the EU market. As of January 2017, around 48,000 dossiers, referring to over 10,000 unique substances, have been submitted.

Although the Regulation has brought a significant improvement of the information on chemical substances and their uses, additional efforts are necessary to ensure the protection of human health and the environment. ECHA and the Member States evaluate the information submitted by companies to examine the quality of the registration dossiers and the testing proposals and to clarify if a given substance constitutes a risk to human health or the environment. The compliance check of the dossiers submitted by the registrants has found that the information provided is of poorer quality than originally expected. As a result, substances are being used by EU citizens based on non-compliant data and the identification of needs for regulatory risk management by authorities is being hampered.

The possibility of recurring to category and read across approaches to fulfil the test data requirements for the registration process has been widely misused, with registrants not providing proper justification and grouping substances erroneously.

Registrants are also required to update their dossiers with any relevant new information (Article 22) but, despite the fact that many suppliers have certainly encountered one or more changes in the circumstances listed by the Article, two thirds of the dossiers have never been updated.

Moreover, substances which are manufactured or imported in low quantities have no or limited information requirements and the scope of the Regulation does not adequately cover nanomaterials. These substances may prove to be a good pool of potential alternatives and the lack of information considerably limits the possibility of carrying out robust comparative risk analyses.

5.1.2 Progress in substitution

This section presents some of the key findings from the sub-study a final report on "Substitution, including the grouping of chemicals & measures to support substitution" prepared by RPA.

The problem

A large number of hazardous chemicals, including substances of very high concern, are used in industrial processes as well as industrial and consumer products. These are sometimes associated with human and environmental exposure, and their presence in products may also cause problems in relation to waste management and recycling once the products become waste, e.g. by contaminating recycled materials.

Through the REACH registration process, information on the (eco)toxicological properties of the substances available on the market is being generated. However, the information provided in the registration dossiers already submitted appears to be inadequate to perform a comprehensive hazard and risk assessment for many of the registered substances. Moreover, substances manufactured or imported in low quantities (1-10 tonne per year per producer or importer) have no, or reduced, information requirements.

The lack of this information on the uses and presence of hazardous substances in articles prevents informed choices and affects the efficiency of any prioritisation strategy for the purpose of substitution by downstream users. Although REACH is enhancing the communication of information throughout the supply chain, and although there are several initiatives aiming to provide information about the content of hazardous chemicals in articles to the public, these initiatives are patchy and may benefit from some form of harmonisation.

Very few resources are currently dedicated to substitution initiatives among Member States, ECHA and the Commission. This may be linked to the budgetary limitation at both national and EU level and has already been identified as an issue, for example, with regard to the effective fulfilling of European Agencies' mandates. At Member State level, the engagement in substitution initiatives is not homogeneous, with some Member States very active and others, even those with a sizeable chemical industry, focusing mainly on traditional risk management activities and dedicating scarce resources to substitution initiatives or to supporting green chemistry solutions.

Key findings on substitution

The problem

- The prevailing use of hazardous substances including substances of very high concern and equivalent in industrial processes and industrial and consumer products may lead to human and environmental exposure.
- The presence of hazardous substances in products may cause problems through exposure of humans and the environment during the service life as well as in relation to waste management and recycling once the products become waste.

Gaps and inconsistencies in current policy

- Information on the (eco)toxicological, bioaccumulation and environmental degradation properties of the substances provided in the registration dossiers already submitted appears to be inadequate and is not kept up-to-date in 69 % of the dossers the were subject to compliance check in 2014.
- Substances manufactured or imported in low quantities have no or reduced information requirements.
- There is a lack of information on the uses and presence of hazardous substances in articles, in particular in imported articles.
- Risk assessment methodologies for the article service life and waste stage are not sufficiently developed to assist all actors.
- The available tools for the assessment of alternatives typically combine hazard and risk assessment with economic and technical feasibility, focusing on chemical-by-chemical substitution.
- There is scarcity of information on alternatives.
- The REACH authorisation does not cover imported articles and NGOs and some Member States complain about the lack of speed and ambition of the authorisation process.
- Companies complain about the regulatory uncertainty on available alternatives, the insufficient time to identify and develop suitable alternatives, the excessive lengthening of the time to market for products containing alternatives and, more in general, of the high administrative burden, in particular for SMEs.
- Synergies between chemical policies are still unsatisfactory.
- There are insufficient regulatory signals to investments in innovation.
- Resources dedicated to the enforcement of chemical policy are inadequate.
- There is a lack of resources dedicated to substitution initiatives among Member States, ECHA and the Commission.

For about half of the 31 substances currently in Annex XIV of REACH (the authorisation list), no applications for authorisation have been received, and around half of the applications are so-called "bridging authorisations", meaning that the applicants are working on phasing out the substance from their processes/products but need more time to fully develop an alternative. In addition, the inclusion of substances in the Public Activities Coordination Tool (PACT), in the Community Rolling Action Plan (CoRAP) , in the candidate list and ultimately in Annex XIV, has led to significant levels of activity as regards substitution, withdrawal and replacement. The regulatory banning of substances,

and even the anticipation f regulation itself, are strong drivers for the substitution of hazardous substances. Once initiated, regulatory processes send signals to the market and act as an incentive for innovation and substitution throughout the supply chain.
Member States' competent authorities consider that the costs of preparing proposals for restrictions under REACH have risen considerably, due to the information required from ECHA's Risk Assessment Committee (RAC) and Socio-Economic Assessment Committee (SEAC) in order to form an opinion. This has resulted in fewer restriction proposals being submitted, thus slowing down the substitution of hazardous chemicals. There is also concern that the authorisation process can become cumbersome and labour intensive, subsequently increasing ECHA's workload.

In addition, some NGOs have criticised the slow pace of including substances on the candidate list.

Beyond REACH, a number of legislative acts aim to promote substitution, directly or indirectly. A non-comprehensive list of examples from environmental, product safety and health and safety legislation is presented below:

- Directive 2011/65/EU (RoHS 2) on the *restriction of the use* of certain hazardous substances in electrical and electronic equipment (EEE) restricts the use of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) in EEE when substitution is possible from the scientific and technical point of view. Moreover, it requires the list of restricted substances to be updated as soon as new scientific evidence is available on more environmentally friendly alternatives;
- Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) is built around the "*producer responsibility*" principle and, indirectly, promotes the substitution of hazardous chemicals in EEE by making producers responsible for the collection and management of waste and hazardous waste;
- Both Directive 2000/60/EC establishing a framework for Community action in the field of water policy (WFD) and Directive 2010/75/EU on industrial emissions (IED) recall the *polluter pays principle* (Article 191 of the Treaty on European Union) and indirectly promote substitution by promoting the internalisation of the externalities due to the use and release into the environment of hazardous chemicals;
- Regulation (EC) No 1223/2009 on cosmetic products (CPR) *prohibits and restricts the use* of some hazardous chemicals, in particular carcinogens, mutagens and substances toxic for reproduction (CMR) and these are listed on annex II of the Regulation;
- Both Regulation (EU) No 528/2012 (concerning the making available on the market and use of biocidal products) and Regulation (EC) No 1107/2009 (concerning the placing of plant protection products on the market) require active substances meeting certain criteria for hazardousness to be considered as candidates for *substitution*;
- Directive 2009/48/EC on the safety of toys *restricts the use* of substances with certain hazardous properties and encourages the *replacement* of dangerous substances and materials used in toys with less dangerous substances or technologies, where suitable economically and technically feasible alternatives are available;
- Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (CMD) requires employers to *replace*, where technically possible, carcinogens and mutagens at the place of work with substances, preparations or processes which pose a lower level of risk. Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (CAD) requires that *substitution* should be undertaken, preferably with chemical agent or process, which under its condition of use is not hazardous (or less hazardous) to workers' safety and health.

Along with regulatory measures, other initiatives such as economic and information-based instruments are deployed to support companies in pursuing the substitution of hazardous chemicals form their processes and products. Scandinavian countries have successfully used taxes to reduce the consumption of pesticides and to steer farmers towards the application of fertilisers with a lower

cadmium content. Chemical action plans at local level are being used to include the objective of reducing the use of hazardous substances in public procurement strategies. Moreover, public authorities grant environmental subsidies in the form of funds for research and development, in particular to SMEs. At European level, funds for research and development into chemical substitution are awarded mainly through:

- **Horizon 2020** is the main EU funding programme for research and innovation, running from 2014 to 2020 with an €80 billion budget. The instrument provides full-cycle business innovation support from business idea conception and planning to execution, demonstration and commercialisation.
- **The environment and climate action programme (LIFE)** is the EU financial instrument for the environment and climate action. For the period 2014-2020, LIFE has a budget of €3.4 billion to co-finance projects aiming to contribute to the Europe 2020 Strategy, 7th EAP and other relevant EU environment and climate strategies and plans.
- **The new cohesion policy**, with a budget of up to €351.8 billion to invest in Europe in order to achieve the goals of smart, sustainable and inclusive economic growth by 2020.

Pressure towards the substitution of hazardous substances does not come only from public authorities, but also from NGOs and downstream users. Large enterprises and global players have developed standards to ensure quality in the supply chain. These standards are perceived as quasi-legislative and can be stricter and more detailed. They are enforced by the power of the market and so can be even more demanding than conventional enforcement of legal requirements. NGOs developed a non-regulatory list of substances to be considered priorities for substitution in order to influence the public and big product manufacturers and retailers.

Conclusions

Identified responses span from actions to streamline the existing legislation and strengthen its enforcement (e.g. increase information requirements for low production volume substances; co-ordinate substitution initiatives across member states around prioritised chemicals of concern; extend the use of grouping strategies to avoid regrettable substitution; dedicate more resources to enforcement) to the use of economic instruments (e.g. tax the use of hazardous substances; enhance government green procurement programmes, considering the functional substitution of hazardous chemicals) and to initiatives that support companies in their substitution efforts (e.g. develop tools to track hazardous chemicals in articles; fund further research into alternative assessment methodologies; scale-up research on grouping strategies based on similarity of chemical structures and trends in (Q)SAR predictions).

Other important measures that could contribute to promote substitution are chemical monitoring programmes. These can be periodic surveys of concentrations of certain substances in human, animal and plant samples (biomonitoring) or monitoring programmes of emissions of chemicals in environmental media, but also initiatives such as chemical footprint, aiming at measuring and benchmarking the progress of companies to safer chemicals.

5.1.3 Grouping approaches

This section presents some of the key findings from the sub-study a final report on "Substitution, including grouping of chemicals & measures to support substitution" prepared by RPA.

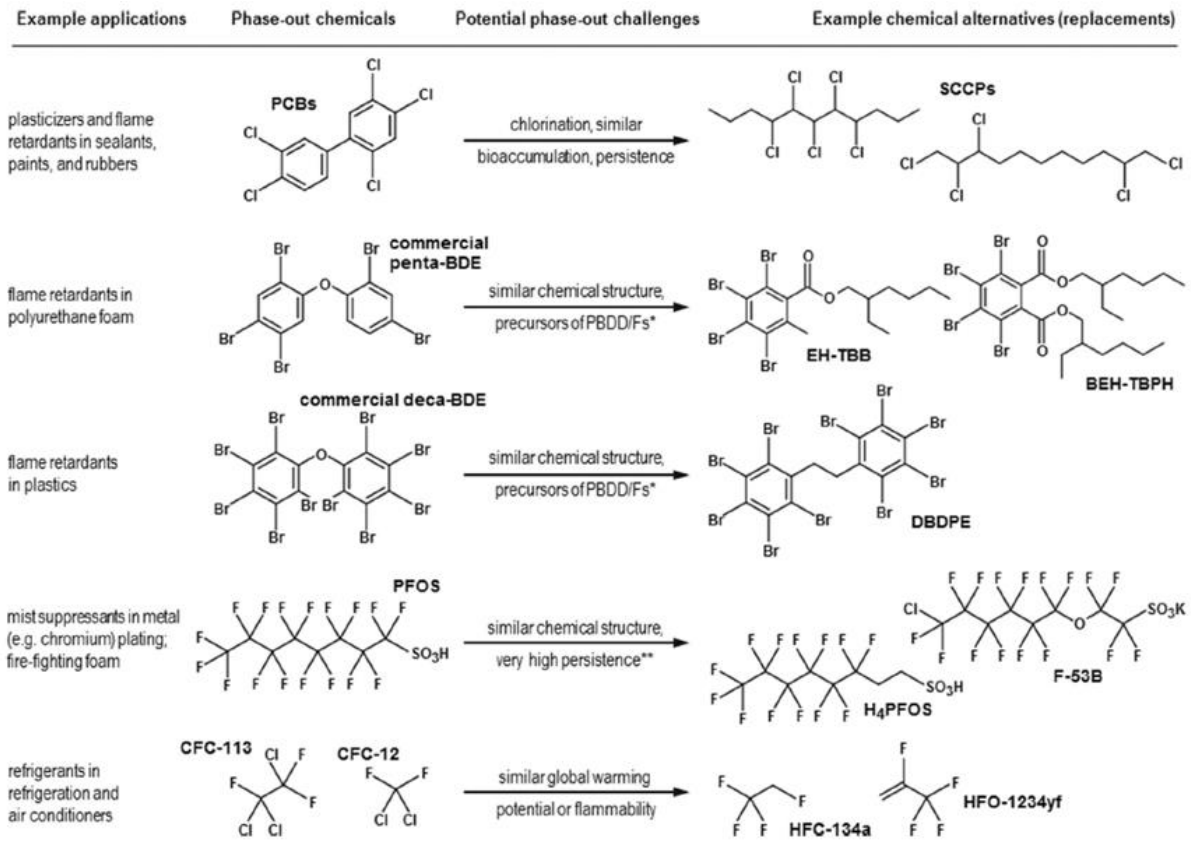
The problem

There are groups of chemical substances that have raised particular concerns and that count hundreds of congeners within each group (for example, phthalates, bisphenols, brominated flame retardants and highly fluorinated substances). Resources for assessment and control are limited. Moreover, different pieces of legislation create incentives to substitute hazardous chemicals in processes and products by restricting the use of certain substances in certain applications, resulting in companies applying

alternative assessment methodologies to find less hazardous alternatives. The available tools typically combine hazard and risk assessment with economic and technical feasibility, focusing on chemical-by-chemical substitution. This often leads to cases of regrettable substitution, i.e. the replacement of hazardous substances with structurally similar substances which exhibit similar hazardous properties. In some cases, the substitution occurs with substances for which the information on (eco)toxicological properties is limited.

While intended to promote sustainability and reduce negative impacts on human health and the environment, the application of the substitution principle in policymaking may lead to this type of unintended consequences. There are numerous examples of situations in which the restriction of certain hazardous substances did not result in their substitution with safer alternatives. Figure 5 presents some well-studied examples.

Figure 5: Archetypal cases of incremental substitution for selected phase-out chemicals used in large applications in consumer products



Source: Fantke et al, 2015

Applying the substitution principle without the appropriate comparative risk analysis may result in the premature replacement of existing chemicals with those that may be just as hazardous, or may be less toxic but carry a greater potential for release and exposure. Robust comparative risk analyses need a high level of information and can be resource and time intensive. However, research is ongoing on user-friendly approaches to develop, evaluate and interpret multiple chemical-product-application scenarios for human exposure that would enable to quantitatively assess exposure in a more rapid and efficient way.

Examples abound of regrettable substitutions within groups of chemicals with similar structures and similar hazard properties. Fantke et al described in 2015 these as cases of incremental rather than fundamental change in the structure of hazardous substances that hampers their successful phase-out and propose the use of the term "lock-in" problem. The authors suggest that several challenges and

obstacles are present in the phasing out process of hazardous chemicals: phase-out agreements are often voluntary and do not cover all relevant manufacturers or have a wide range of exemptions. It is also problematic to find a suitable alternative achieving the same performances in the applications, without altering other functions, properties or processes. There are also methodological challenges, related to the different assessment criteria applied by the different alternatives' assessment tools available and that may result in inconsistency in the results. Most tools also neglect life-cycle aspects, which are essential for identifying trade-offs and avoid burden shifting. When life-cycle impacts are considered, the available information may not be sufficient for a proper assessment.

Key findings on grouping approaches – Sub-study a

The problem

- Some groups of chemical substances (e.g. phthalates, bisphenols, brominated flame retardants, highly fluorinated substances) count hundreds of congeners, with more or less similar chemical as well as health and environmental properties, constituting major regulatory challenges as resources for assessment and controls are limited.
- The practice of adopting structurally-similar alternatives (incremental rather than fundamental substitution) often leads to cases of regrettable substitution.

Gaps and inconsistencies in current policy

- The available tools for the assessment of alternatives typically combine hazard and risk assessment with economic and technical feasibility, focusing on chemical-by-chemical substitution which is not effective or even feasible for some groups of chemicals.
- Additional efforts are required in the research of grouping strategies for regulatory purposes, focusing on the systematic analysis of the structural similarities of substances and trends in e.g. (Q)SAR predictions and other methods supporting such approaches.

The grouping of chemicals may be an effective way to enhance the efficiency and effectiveness of the regulatory initiative in promoting substitution to less-hazardous chemicals. Grouping strategies have been proposed by different stakeholders (SIEFs and registration consortia, regulators, NGOs, retailers, etc.) and carried out by different criteria (chemical structure, functional group, mode of action, particle size, etc.) for different purposes (to minimise animal testing, to manage the risks associated with chemicals with the same health and environmental effects, etc.). Various pieces of legislation make use of grouping approaches to different extents. However, further research is needed on the association between chemical structures and trends in (Q)SAR predictions, so to scale up their adoption and move from the current incremental substitution practice to a more effective substitution of hazardous substances.

In REACH, grouping of chemicals is actively promoted in the registration process and registrants are invited to use QSARs or read across methods, when possible and suitable.

With regard to the authorisation and restriction mechanisms, while in the authorisation list there are currently two groups of chemicals only, around half of the entries in the restriction list refer to groups of chemicals. It should be noted that the authorisation list includes different entries referring to chemicals that could be grouped, as chromates and dichromates, although not all chromates and dichromates have been listed. The same applies to low molecular weight phthalates DEHP, BBP, DBP and DIBP, although these have been restricted in toys and childcare products with some high molecular weight phthalates (DINP, DIDP and DNOP).

The same degree of flexibility in using grouping strategies is present in the CoRAP list and PACT table of substances. In order to maximise efficiency of substance evaluation, some substances for which there is an indication of structural similarity (e.g. o-xylene, p-xylene and m-xylene) may be jointly evaluated; other substances that could be grouped by functional group (e.g. diisocyanates) are evaluated by different Member States and in different years.

Hazard classification and use categories have also been applied to group chemicals. For example, Directive 2004/37/EC regulates the protection of workers from the risks related to exposure to carcinogens or mutagens at work. Use categories are used to regulate broad groups of substances, such as pesticides, biocides or cosmetics. Within these groups, more categories can be identified in combination with other criteria (e.g. in pesticides: fungicides, herbicides, insecticides, etc. grouped by target; these can be further categorised by chemical type, e.g. for insecticides: chlorinated hydrocarbons, organophosphorus, nicotinoids, etc.; in biocides, disinfectants, preservatives, pest control, other biocidal products; these can be further categorised by product-type: human hygiene, veterinary hygiene, food and feed area, etc.; in cosmetics, cosmetic ingredients can be grouped by function: preservatives, UV-filters, colorants, etc.).

Another criterion currently used to group chemicals for optimal risk management measures is particle size. All particles of insoluble materials, even if these materials are not classifiable as dangerous to health, are hazardous, and in many Member States there are general limit values for dust based on respirable or inhalable size criteria. Particle size is also the determinant of a new branch of technology, nanotechnology, which makes deliberate use of materials with dimensions in the order of nanometres. Nanomaterials may show novel physicochemical properties compared to the bulk form of their parent substances, and can be used to enhance the performance of materials across several different fields and in a wide range of applications. The same special properties that occur at the nanoscale, and can enhance the performance of materials, could, however, result in "hazard profiles" that may also be different from that of the bulk form. The nature and extent of these hazards are difficult to predict, and therefore need to be assessed on a case-by-case basis. This, however, would require a considerable amount of resources and, therefore, many stakeholders are working on grouping strategies of nanomaterials, using criteria such as biopersistence and high-aspect ratio.

Conclusions

In order to increase the efficiency and effectiveness of the legislation, the extent to which grouping strategies are adopted may need to be scaled up. ECHA is currently studying the possibility of a systematic analysis of the structural similarities of substances in connection with the prioritisation of such substances prior to the substance evaluation stage. Further research on grouping strategies is ongoing at national level too. The Danish EPA explored the possibility to group brominated flame-retardants that were found in a survey of consumer products in 2014. Sixty-seven brominated flame-retardants were grouped according to their chemical structures and trends in (Q)SAR predictions for a number of environmental and health effects, resulting in 15 preliminary structural groups and 7 single substances exhibiting peculiar chemical structures and (Q)SAR trends so that they could not be grouped.

In addition, Fantke et al (2015) propose to have binding phase-out agreements on groups of substances, which would push all stakeholders to design more sustainable substances or find non-chemical solutions. The design process, however, should be aligned to the principles of Green Chemistry and should consider life-cycle aspects in a wider context of the chemicals' applications in consumer products. Moreover, the focus in the alternatives assessment should be on the functions delivered by the substance (functional substitution). This should ensure that entirely new chemical structures, and even non-chemical solutions such as new materials or processes, are considered in the assessment. When alternatives can only be found in the same structurally similar chemical group, two options are suggested: the first option is that, in the absence of comprehensive information on (eco)toxicological properties and environmental fate of the alternatives, it should be assumed that they exhibit the same hazardous properties of the substance(s) to be substituted, based on the similarity in chemical structure. The second option is that the manufacturers of the alternatives generate the information required. The latter is already mandate by the REACH Regulation but, as already noted, the information provided in the registration dossiers appears to be inadequate to perform a comprehensive hazard and risk assessment for many substances registered.

5.1.4 Innovation challenges

This section presents some of the key findings from the sub-study e on *Policy means, innovation and competitiveness* prepared by RPA.

The problem
A stable and predictable regulatory environment is a key requirement for the competitiveness of the European industry and for its ability to innovate.
Regulation has the potential for both negative and positive impacts on these two aspects: negative impacts can occur when the cumulative costs of the environmental legislation on the industry add to other adverse global trends; positive impacts can be achieved by regulation through the promotion of green innovation and by ensuring an even playing field for all of the actors involved.

While on the one hand the EU environmental legislation, and in particular the legislation of the chemical industry, is one of the most ambitious in the world and may constitute an additional burden to EU industry against extra-EU chemical companies (Cefic, 2015 and Cefic, 2016, p.27), the legislation does ensure the internalisation of the externalities of the industry, enforcing the "polluter pays" principle and delivering benefits to the whole society in terms of human health and the environment on the other. Moreover, stricter environmental legislative requirements can stimulate innovation towards sustainability (Porter and van der Linde 1995, WWF, 2003, CIEL 2013, OECD, 2014) and may provide first mover competitive advantages to the EU industry, where the environment is recognised as a megatrend for the short, medium and long terms.

Key findings on innovation – Sub-study e

The problem

- The chemical policy may constitute an administrative burden that, in a context of adverse global trends, may have negative effects on the competitiveness and innovation capacity of European companies, in particular SMEs, against extra-EU companies.
- However, stricter environmental requirements can also stimulate innovation towards sustainability, providing first move competitive advantages to the more pro-active companies.

Gaps and inconsistencies in current policy

- The use of EU funding in supporting transformative technologies with strong innovative potential and added value for manufactured products and services is inadequate.
- The funding available for innovation projects does not meet the ambition of industrial scale projects, mainly due to scattering of support over calls and topics across a large range.
- There is a lack of support or encouragement for co-operation within and/or between sectors (e.g. between large businesses and SMEs; between industry and academia).
- There is an insufficient capacity to attract foreign investment to enable innovation.
- Regulatory signals to investments in innovation are lacking.

If, from one side, environmental legislation poses an administrative burden that, in particular for SMEs, may have as unintended consequences the diversion of resources from research and development activities, the lack of environmental requirements can also have negative consequences on the innovation capacities of SMEs.

For example, the lack of information on the uses and presence of hazardous chemicals in articles prevents informed choices and affects the efficiency of any prioritisation strategy for the purposes of substitution by downstream users.

Gaps in information may also result in imperfect synergies between the different chemical legislative acts, with the ultimate effect of a limited or inefficient internalisation of human health and environmental costs by the chemical or product manufacturers. For example, the emissions into water basins of substances designated as Priority and Priority Hazardous Substances by the Water

Framework Directive need to be brought under very strict Environmental Quality Standards that often can be comply with by investing heavily in tertiary treatments. Sometimes, tertiary treatments are not even sufficient. The costs of these investments are sustained by water companies and, ultimately, by companies and consumers rather than the substances manufacturers and users. Their emissions could be brought under control more effectively by implementing restrictions (through REACH) on certain uses and applications.

The lack of a legislative framework that clearly rewards the substitution of hazardous chemicals, and that at the same time penalise the continued use of hazardous substances may undermine the confidence of industry stakeholders to invest in green innovation. During the workshop, some stakeholders indicated that the granting of authorisation for the uses of substances in applications, for which safer alternatives were available, is a regulatory signal that may stifle, rather than reward, innovation. Others pointed to the inability of regulation in dealing with cases of regrettable substitution, where substances are substituted with other substances with similar hazardous properties or of equal concern.

The European framework to support innovation may benefit from enhanced co-operation between geographical areas and sectors. Many downstream users would like to manufacture and put safer products, which do not contain hazardous substances, on the market, but they face two major problems:

- Lack of communication with their chemical providers; and
- Lack of adequate expertise and the inability to find alternative providers of sustainable alternatives.

Moreover, SMEs willing to engage in green innovation may lack the adequate market power to require safer substances to their chemical providers or may lack the resources to find and switch to an alternative provider.

Trade agreements are essential for maintaining the competitiveness of the European industry. However, human health and environmental protection principles should not be seen as part of the negotiable elements for getting a good deal.

Conclusions

Responses to the identified gaps and deficits suggested in the literature and by the consulted stakeholders mainly focus on reducing the administrative burden on companies, when possible, while supporting innovation through economic instruments (e.g. VAT reduction on products with safer alternatives, promoting taxation of hazardous substances among Member States, enhancing government green procurement programmes) and support and capacity building (e.g. funding further research into chemical product life cycle risk assessment; raising awareness on the benefits of – and stimulating market demand for - safer alternatives; enhancing supply chain collaboration and engagement through shared performance testing and the creation of demonstration sites; facilitating public-private investment partnerships to support research).

5.1.5 A programme on new, non-/less toxic substances

This section presents key findings from the sub-study f final report on a *programme on new, non-/less toxic substances* prepared by Ökopol.

The problem

The use of toxic substances can only be phased-out if suitable alternatives are available. Alternatives could be selected from among existing substances or from non-chemical solutions. In addition, new, non-toxic substances could be developed that fulfil the technical needs of a particular use, have a low or no (eco-)toxicity and do not cause negative impacts on waste treatment and recycled materials. New

substances may be developed because (i) existing alternatives are not available at all, (ii) are of an insufficient (technical) quality or (iii) if even higher performance levels, additional (innovative) functions or a significantly decreased (eco-)toxicity are expected from the new substances. Finally, new substance development may occur in a larger innovation context, i.e. to develop new materials with new or significantly enhanced functionalities.

This section discusses how the development of new, non-toxic substances[14] could be enhanced through different activities and approaches at the EU level.

Key findings on new, non-toxic substances development

The problem

- A non-toxic environment implies that toxic substances are replaced with safer alternatives. Existing substances and non-chemical solutions are not always suitable alternatives and new solutions may be required;
- Barriers to the development of new, non-toxic substances include fears of costs, a lock-in in the current production situation, the potential need to establish new relationships with suppliers/customers, a lack of experience in cooperating on issues of substitution and substance development and uncertainty about the outcome of the development process and the future market opportunities for the new, non-toxic substances;
- Contextual factors that hamper the development of new, non-toxic substances include a lack of clear development goals at policy level (i.e. definition of non-toxic substances), missing inter and transdisciplinary cooperation in science and at the corporate level, a generally hesitant business environment regarding "green chemistry" and a lack of awareness and education;
- Research and innovation programmes exist which integrate the development of new, non-toxic substances as an option to achieve larger solutions to societal problems at the Member State and EU level. However, specific programmes addressing small scale innovation, without a large impact on society, are largely unavailable.

Gaps and inconsistencies in current policy

- The need to develop new, non-toxic substances is not integrated as horizontal issue in all EU policies and research programmes;
- Although substitution of hazardous substances is discussed since a long time, little emphasis has been placed on supporting the related development of new, non-toxic substances and creating a favourable business environment, e.g. with view to replace restricted substances;
- A strategy, implementation instruments and networks to raise awareness about the benefits of using non-toxic substances and building related capacities in companies, academia and the general education system should be considered; Such measures are still lacking at EU level (including providing support to Member States).

The Current Policy Framework and Research Context

Two contexts for the development of new, non-toxic substances can be distinguished in the following manner:

- The development of new or significantly improved functionalities of substances or materials; these activities are frequently embedded in larger material and product development processes aiming to create qualitatively new solutions to technical or societal problems. The development of nanomaterials and nano-enabled materials is one of the relevant research areas in this regard;
- The development of new alternatives, for use as substitutes for toxic substances, to achieve an existing functionality at least at the same level of performance, but with a significantly reduced toxicity level. One example is the phthalate DINCH (EC-431-890-2), which was developed as an alternative to hazardous phthalates.

[14] While the concept of sustainability is increasingly guiding company decision-making, and is defining requirements for solutions to societal challenges, an emphasis is being placed on the aspect of (eco-)toxicity of substances in the context of the non-toxic environment.

It is not possible to quantify the present demand for new, non-toxic substances for either of the two cases, *a fortiori* neither is it possible to quantify the demand that will arise in the future. This is due to a lack of knowledge about the extent of the requirement for substitution and the availability of already existing and suitable solutions. The following main factors determine the demand for new, non-toxic substances:

- The guidance from the policy level on substance properties to be avoided, and to strive for, as well as overall priorities for related innovations at the large and smaller scales;
- The regulatory and market pressure to phase-out toxic substances, regulatory burdens of and incentives for the development of new (non-toxic) substances;
- the need, and innovative potential in the scientific and business communities, to develop fundamentally new solutions to existing problems;
- the availability of alternatives from the existing substance portfolio or other types of substitutes;
- the openness of supply chains to accept and take the risk of developing and using new, non-toxic substances; opportunities of chemicals suppliers and users to make contacts and overall awareness of the opportunities "green chemistry" as such;
- the costs and expected prices, as well as profit margins and overall economic opportunities, for a new, non-toxic substance;
- the research funding and the availability of substance design and hazard prediction tools.

The consulted stakeholders emphasised the need to define the term "non-toxic" and give overall guidance on the envisaged phase-out and replacement process at a high level. This would include disambiguation at policy level and the integration of the "toxic issue" across policies and Commission Directorates as well as in research and innovation programmes.

The implementation of REACH - the restriction and authorization process as well as the listing of substances of very high concern in particular - increases the regulatory pressure for substitution and give overall guidance as to which substances should be avoided and eventually phased-out. However, the number of restrictions are low and they cover only specific applications, thus not promising large markets and, therefore, incentivising the development of new substances only to a lesser extent. According to some stakeholders, the regulatory clarity and substitution incentives from the authorisation process are weakened by the, partly inconsistent, authorisation decisions.

Little specific information is available about the extent to which requirements to register new substances and to provide information on their toxic properties actually hinder the development of new, non-toxic substances. Literature analyses and stakeholder comments give the overall impression that these burdens are comparatively low and are outweighed, by far, by the fact that the registration under REACH created a level playing field for new and existing substances (Engler, 2016) (Fennelly, 2015) (Green Chemistry & Commerce Council, 2015).

While options to provide regulatory incentives, such as requiring less registration information or lowering (registration) fees for non-toxic substances, do exist, the impetus they might have on new, non-toxic substances cannot be deduced from the information available. The main incentive from regulation is the pressure to substitute toxic substances as such.

The existing potential alternatives to toxic substances is difficult to assess, due to a lack of information on the current uses of (toxic) substances, their functions and functionalities in materials and articles and the other options for their substitution. This lack of information is also a barrier to new substance development, given that economic actors cannot easily estimate the market potential for an alternative and the actual needs of the market are not transparent.

The potentially largest barriers to the development and use of new, non-toxic substances result from

the challenges in the supply chain. These are, among others:

- an overall hesitation to using new (non-toxic) substances because of fears about (hidden) costs and a lock-in in the current production situation (the possible need to change the overall choice of material or design of a chemical product or an article as well as processing equipment);
- the potential need to break existing supplier-customer relationships in combination with the need to identify new suppliers with whom they take the risks of developing a new substance;
- a lack of communication and collaboration opportunities and capacities, which are necessary for substitution, particularly where the alternatives do not exist yet;
- an overall lack of awareness of the benefits of using new, non-toxic substances;
- overall economic uncertainties as to the future performance of products, the development of markets, potential profits and stability of supply, if new, non-toxic substances are used

All these challenges also exist for substitution with existing solutions, but the risks are (perceived as) higher, given that the development phase of a substance involves more uncertainty and resources for identifying an alternative than searching for one in the existing substance portfolio.
In the field of new materials innovations, these barriers have less weight, as the process is normally integrated into larger networks of actors dedicated to reach a common goal and to cooperate. Nevertheless, the challenges mentioned also apply in this area.

The availability of substance design and hazard prediction tools impact on the resources needed to develop a new substance and, therefore, modify other factors. Similarly, the availability of research funding either for developing new, benign materials in the context of larger innovation activities or for targeted research on specific alternatives might decrease the resource input needed from stakeholders into the R&D activities, which might lower the related barriers.

Gaps identified and inconsistencies in current policy/legislation
The current regulatory framework creates a level playing field for "new" and "existing" substances, with regards to the registration and assessment of hazardous properties. Several provisions exist in the EU regulatory framework and scientific programmes to support the development and use of new (non-toxic) substances, such as exemptions for process and product oriented research and development as well as lower data and authorisation requirements for low risk substances under biocides legislation.

Overall guidance and market signals, e.g. from the authorisation decisions under REACH are, however, mixed. According to literature and stakeholder comments, stricter legislation may better promote the development of new, non-toxic substances, while overall (policy) guidance is stated to be insufficient, despite the availability of the SVHC criteria of REACH Article 57. Furthermore, the overall awareness on (the benefits of using) non-toxic substances is low and an integration of, and sufficient emphasis on, the issue across all relevant policies is still missing.

No national programmes that focus on the use of new, non-toxic substances could be identified during the project research. However, a number of activities on green chemistry, which are interrelated and connected via an overall mission of the Environmental Protection Agency, do exist in the United States. Furthermore, some Member States conduct activities related to the development and use of green or sustainable chemicals. These include research and innovation funding and the development of tools for substance design, hazard prediction, risks and alternatives assessment. Furthermore, they support stakeholder platforms, stakeholder dialogues and awareness raising about the needs and opportunities presented by substitution.

At EU level, the Research and Innovation Programmes cover a wide range of domains addressing different scientific, economic and societal challenges. There is no specific theme on the development of new, non-toxic substances, but this issue is covered by projects funded under different themes; notably LEIT-NMPB (Leadership in Enabling and Industrial Technologies, Nanotechnologies, advanced Materials, advanced manufacturing and Processing and Biotechnology). Activities address

the whole innovation chain with technology readiness levels spanning the crucial range from medium levels to high levels preceding mass production. They are based on research and innovation agendas defined by industry and business, together with the research community, and have a strong focus on leveraging private sector investment. One example of action is the Horizon 2020's €3 million prize for clean air, for which challengers must develop innovative, design-driven material solutions that will reduce the concentration of particulate matter in the air.

Conclusions

Most aspects identified as barriers or potential incentives along the supply chain are out of direct reach of the EU Commission but can be (better) addressed by the Member States, the market actors themselves or by other stakeholders, such as NGOs or trade associations. These concern, among others, the integration of concepts and methods from green chemistry into the education and training systems, general awareness and creating a positive attitude to the use of non-toxic substances and the related benefits and providing opportunities for information and experience exchange as well as general networking of business and scientific actors.

Nevertheless, activities at EU level may have an important impact on these actions. These could involve the development and implementation of legislation (market demand for new, non-toxic substances), awareness raising campaigns (acceptance of new solutions, communicating good practice and benefits of substitution) and support activities e.g. on the networking of actors (facilitating contacts and experience exchange) or education and training of researchers. Here the EU Commission, and its agencies, could provide financing and infrastructure as well as capacities and competences from their staff.

While research and development funding is available, and in principle allows for and invites substance and material innovations, opportunities for smaller scale and less innovative applications to new, non-toxic substances appear to be lacking.

The extent to which current and past EU research projects foster the development of new substances, and if these constitute improvements with respect to their (low) toxicity and eco-toxicity, cannot be determined from the available evaluation reports on those projects. However, it is an overall perception observed from the consulted stakeholders that the funding instruments direct their resources towards other societal challenges than the toxicity of substances, such as to climate change, resource efficiency or health sciences. Therefore, an EU programme specifically supporting research and development of new, non-toxic substances could be an integral part of the strategy for a non-toxic environment and could support the provision of alternatives to toxic substances as well as enhancing the design of new, benign materials at a smaller scale, thereby complementing the existing funding programmes, such as Horizon 2020.

An overall programme that enhances the development of new, non-toxic substances should not stop at research funding but should include additional activities, such as of improving the overall business environment and readiness to innovate, e.g. by providing guidance at the policy level, raising awareness, improving education and supporting the related networking of the relevant actors.

5.1.6 Early warning systems[15]

Through predicting hazardous properties of substances and by requiring risk management measures that limit human and environmental exposure, the EU chemicals regulatory framework aims for the safe use of chemicals as well as protecting the population and the environment. Despite the various

[15] This section has been drawn from the draft final report for sub-study g on *Early warning systems for examining chemical threats to human health and the environment* drafted by RIVM. More details are included in the sub-study.

kinds of legislation, numerous well-documented cases exist of extensive damages to health and environment caused by the production and use of chemicals. Furthermore, it often takes a long time before these warning signals are picked up by societal institutions and even longer for these to react. Therefore, the early identification of chemical threats to human health and to the environment is of great importance in taking timely measures to reduce or eliminate the risk of hazardous compounds. Developing a fast response system for detecting and tackling approaching chemical threats to health and environment should be considered as a complementary action, and not as an alternative instrument to replace current legislation.

A variety of tools, methods and activities have been drawn up, developed or initiated for the early identification of new or upcoming chemical threats. These tools and methods are commonly known as early warning systems (EWS). The aim of early warning systems is to identify the chemicals that might potentially be hazardous and cause adverse effects as early as possible, as well as identifying situations in which exposures to substances could lead to harm coming to humans or to the environment. Early identification allows for the appropriate actions to protect man and the environment to be undertaken earlier and can provide great value in achieving a high level of public safety and environmental protection. Early identification allows more time for further investigation or taking the right measures to control issues of concern. In this way, an EWS could facilitate progress towards a non-toxic environment. A systematic approach for the early identification of chemical threats could also contribute to identifying gaps in existing legislation, as well as in data and knowledge, and could also support enforcement authorities.

Apart from early detection, early warning systems should also aim to provide insight in the appropriate risk management options for the chemical risks identified and communicating this information to the authorities concerned. This includes providing additional evidence, examining appropriate risk management measures, and providing options to communicate the information to the stakeholder concerned.

Early warning systems considered

Important aspects to consider when establishing an early warning system includes the definition of new and/or emerging risks (NERCs) and the system's specific aim. This pre-defines what the system will be able to do and sets the boundaries to the kind of information to use and which output to generate.

A variety of terms and definitions have been used, such as new risk, emerging risk, emerging issue, emerging pollutant, emerging substance, and contaminant of emerging concern. These can be grouped into three main categories: (i) newly created risk; (ii) newly identified risk; or (iii) increasing risk becoming widely known or established. Combined and cumulative exposure to chemicals and low dose and long term effects caused by chemicals, which are considered to represent major additional challenges, could be qualified as newly identified or, to some extent, as increasing risk becoming widely known or established.

A review of currently available methodologies and systems identified various components that will be required in order to develop an operational warning system for the EU aimed at proactively identifying new and emerging risks of chemicals. In general, the phases presented in **Error! Reference source ot found.** have been identified. An EU early-warning system should first be able to filter signals from media, scientific literature, and experts and to evaluate those signals. This could also include the screening of data. The second step should be to check if the signal has been identified previously, and if actions or regulatory measures have already been implemented. A third step, based on target-specific criteria, would involve the gathering of additional exposure, hazard, and policy data regarding these risks, for discussion by experts. Subsequently, the data could be translated into a risk score, thereby prioritizing newly identified risks from chemicals and, finally, defining the risk management options (RMO) required and/or the identification of the most suitable actor to address the risk.

Figure 6: Components and Steps involved in an EWS

In-depth analysis of existing systems

In general, two basic methods to analyse existing systems can be distinguished. The proactive "exposure first" method would aim to identify possible new and emerging chemical risks (NERCs) based on physical, chemical, and toxicological properties of a substance and/or the (altered) exposure resulting from the use of a substance, taking technological and societal developments into account. The second method is the 'disease first method' (or 'effect first method'). This method is a reactive method that tries to identify the environmental and health effects of NERCs as soon as possible. The 'disease first' method is complementary to the 'exposure first method'.

Environment

Only two operational systems have been identified that aim both at the identification and management of new or emerging risks of chemicals (NERCS) for the environment – the NORMAN network (2016) and the NERC system operated by the RIVM. Both non-institutionalised systems are currently operational in the EU and are discussed in greater detail below. In addition, a more general approach on the identification and prioritisation of emerging issues is presented.

NORMAN is a network of reference laboratories, research centres, and related organisations responsible for the monitoring of emerging substances. It systematically collects monitoring data and information about the effects and the hazardous properties of substances. The substances are assigned to priority action categories based on this information. A set of criteria is used for the allocation of emerging substances to these clearly pre-defined categories and their subsequent prioritisation. The ultimate result could be that substances are selected to be put on the Watch list of the Water Framework Directive 2000/60/EC. The list of substances to be considered for prioritisation is established through expert consultation and through chemical analytical methods such as non-target screening; a method aiming at a broad detection and identification of chemicals that is not directed to a specific set of chemicals. Action is taken when clear evidence on actual environmental effects emerges. The method could, therefore, be characterised as 'effects first'.

The system operated by the RIVM uses online media monitoring, expert consultation, and non-target screening for the identification of new or emerging risks. A hazard- and exposure-based approach is used to provide further evidence about the possible risk and to derive a risk score in order to prioritise them. A variety of information sources are used to provide information about the possible exposure and hazardous properties of the identified potential, new or emerging chemicals.

Highly prioritised chemicals can then be proposed for a risk management option analysis under REACH. Based on this analysis, the most suitable risk management measure within REACH or other legislation are determined. This method allows for substances to be identified and to undertake action before an effect occurs, based on the hazardous properties identified for instance, as well as to identify substances with clear environmental effects, based on the effects observed or in the exceeding of quality standards, resulting from the evaluation of monitoring data. This system uses the 'disease first' method, which is complementary to the 'exposure first method'.

The work done by the Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR) is largely based on expert consultation. Two parallel and complementary approaches may be used to identify emerging issues: (i) a proactive approach that requires 'brain storming' sessions to identify the emerging issues of principal concern, followed by the introduction of procedures to detect and characterise their development; (ii) and a more reactive approach based on the identification of indicators of change, and the monitoring thereof, to detect emerging issues.

SCENHIR proposes a decision tree approach (algorithm) for the identification and prioritisation of NERCS, based on qualitative criteria such as uniqueness, soundness, and scale of severity.

Workers

In relation to chemicals at the workplace, proactive 'exposure first' methods aim to identify possible NERCs, based on a proper risk assessment. However, the necessary information to use deductive reasoning is lacking for most substances. This holds especially true for toxicological information regarding the routes of exposure that are important for workers, i.e. inhalation and dermal exposure (the most available toxicological information is for oral exposure). Therefore, an inductive way of reasoning is needed to identify and handle those substances that have a negative impact on worker's health; i.e. 'the disease first' method. This inductive way of reasoning works from observations (cases of diseased workers) and moves toward generalisations and theories. The 'disease first' method is used in pharmacovigilance, for instance. Drugs are tested thoroughly prior to their introduction onto the market, but the identification and evaluation of negative health effects reported after their introduction onto the market remains necessary.

Considering the disease first method, there are systems based on expert forecasts. One review consists of an overview of more than 40 (potential) NERCs for workers reported over the last few decades using several data sources. A method for the prioritisation of these NERCs is presented in Palmen and Verbist (2015). As part of the current sub-study, a survey was carried out among European countries to get an overview of existing early warning systems for workers. This revealed three different methods within the 'disease first method' category:

- '*clinical watch system*' for the collection of spontaneous cases reported throughout Europe;
- *databases* that may be used for epidemiological research on possible relationships between occupation and/or exposure to substances and health effects (e.g. occupational cancer);
- *biomarkers* for exposure and/or *biomarkers* for biological effects that can be used to detect NERCs.

One limitation of such a system can be the long response time between exposure and observed effects. This can be addressed partly by detecting the more sensitive effects or end-points by using biomarkers, for instance.

No typical system using the 'exposure first' method has been identified for workers.

Consumers

Several systems or organizations dealing with new and emerging risks of chemicals in food or consumer products (toys, cosmetics and household cleaning products) were found to be of potential use for the possible layout of a future EU-wide, sector-specific early warning system for consumer protection.

The systems that exist at present highly depend on observed and documented signals relating to occurrence of effects and potential exposure. Cosmetovigilance systems such as the European Cosmetovigilance and the Dutch Consumer Exposure Skin Effects and Surveillance, and the national poison centres all provide valuable information about the epidemiology of adverse effects, intoxications, and poisoning incidents that can be used to pick up on a signal and to take measures.

The EU-wide Rapid Alert System for dangerous non-food products (RAPEX) enables the rapid exchange of information about the dangerous products found. The reports in RAPEX deal mainly with failure of compliance with regulations and, therefore, with regulated products and chemicals primarily. This system is pro-active, in a sense, given that it aims to prevent harmful effects resulting from product failure or non-compliant products.

The European Food Safety Authority (EFSA) seems, so far, to possess the most advanced early warning system regarding food related consumer exposure. This EWS aims to proactively identify a given (re)emerging hazard and to, consequently, prevent the presence of this hazard from giving rise to a risk by taking preventive measures. The key characteristic of this system is that it is anticipatory rather than responsive. It is different from rapid alert systems, such as the Rapid Alert System for Food and Feed (RASFF) where notifications are triggered by controls or by consumer complaints.

Conclusions

Several approaches have been used to pick up signals, such as online media monitoring and expert consultation or registration systems for the collection, evaluation, and systematic monitoring of spontaneous reports of undesirable events. The systems that exist at present depend highly upon effects observed, the so-called 'effect based' or 'disease first' systems. Some systems contain elements that can be used to proactively identify possible NERCs, based on a proper risk assessment, the so-called 'exposure first' methods.

Many data sources that can be used to provide further evidence for the selection or prioritisation of potential new or emerging risks related to chemical substances are already available. The selection of suitable approaches for picking up signals and prioritisation should be based on effectiveness and efficiency. Generating an overview on existing data sources, their availability, accessibility, and their usefulness would be essential in establishing an EWS. Subsequently, the data would have to be made accessible through a central database. A quantitative risk based procedure, based on hazard assessment and exposure assessment, is common in the field of risk assessment of chemicals for human health and the environment. An alternative way to identify or prioritise new or emerging risks, such as the manner proposed by SCENIHR, is based on identifying possible NERCs, based on qualitative criteria.

Investigating appropriate risk management options, the communication of the risks identified, and the identification of the measures to be proposed are essential to managing the risks observed. It appears that the component that covers risk-communication is not always well covered in existing systems, meaning that there is limited or no information on a communication plan directed at decision-makers and enforcement authorities or to defining the actions about how to communicate the results obtained. The need to develop a communication plan (where and how to do so) should, therefore, be addressed in the development of an early warning system in particular. Building an overview of the current environmental legislation and the risk management options they provide, including the competent authorities, is a first step in formulating a communication plan.

Due to the many differences that exist between the fields of environmental, consumer, and worker protection and between and within Member States about how signals on new and emerging risks are collected, processed, and interpreted, it may not be feasible at this point in time to create a single system that covers these three fields. The overall advice given, therefore, would be to utilise existing systems as much as possible and to try to make interconnections and facilitate communication at the Member State and European levels. The basic building blocks and steps from **Error! Reference ource not found.** can be used as a starting point to establish a European early warning system for identifying chemical threats to human health and to the environment.

There are several reasons why existing approaches are insufficient and greater effort at the European Union level is needed, based on the analysis of existing national and European tools and methods developed and in operation for the early identification of new or upcoming chemical threats, developed or initiated.

The continuous effort of screening and filtering signals is essential for early identification, but a labour-intensive process needs input from experts at the national level that is organised and coordinated at an international level.

Furthermore, it will always be hard to establish a causal link between exposure to chemicals and, for example, diseases. One issue relating to this is the limitations of epidemiology, meaning that a harmful effect must often be rather drastic and widespread before it is detectable. There is often a lack of information, due to the absence of relevant hazard data and the absence of exposure and use information. Therefore, it is important to identify all of the useful sources of information and databases that are available, to centralise this information, as much as possible, and to come to an effective and efficient procedure for the evaluation of the signals collected that allow the identification of new or emerging risks from exposure to a certain chemical.

An international platform, working on the identification of chemical threats, is lacking. There is a general need for greater cooperation and exchange of information at the EU level about NERCs. At the national and international levels, there are various initiatives in the area of the early identification of chemical threats that could possibly be linked to each other. An overall approach that covers the different steps needed for the identification and management at the EU level seems to be lacking to some degree.

5.1.7 Enforcement

The 7th Environment Action Programme highlights the importance of law enforcement in maximising the benefits of Union environment legislation[16].

The issue of the enforcement of chemicals legislation within the EU was also highlighted by numerous stakeholders consulted during the desk research and at the workshop held in Brussels on 8 and 9 June 2016 ('the workshop'). It has been referred to in relation to all seven sub-study topics and, hence, merits close attention, even though the Commission has limited means to impact enforcement activities of the Member States.

The focus in this context is on substances in articles (SiA), imported articles in particular, and on the non-compliance with the relevant provisions under REACH; namely, Article 33 and Annex XVII. The concern that there is a compliance issue, in relation to the obligations for companies to identify, report and to communicate on the presence and safe use conditions of the SVHCs contained or imported in articles, is also reflected in the ECHA Report on the Operation of REACH and CLP 2016. The report stresses the importance of these obligations "*for ensuring the safe use of chemicals, to facilitate*

[16] Paragraph 65 of the 7th EAP.

substitution and to support the realisation of a circular economy" (ECHA, 2016), and hence, the obligations highly relevant for this study. It states that 359 notifications of the presence of Candidate List substances in articles for a total of 38 Candidate List substances had been submitted to ECHA by the end of 2015; it also holds that the low figure is "*likely to illustrate a low level of compliance*" (ECHA, 2016).

The report also refers to a press release by the Commission according to which the European Rapid Alert System (RAPEX) reported 'chemical risk' as the most frequently notified risk in 2015 with toys (27%) and clothing, textiles and fashion items (17%) being the two main product categories for which corrective action had to be taken (ECHA, 2016).

The ECHA report reproaches that the "*activities of Member States Competent Authorities (MSCAs) […] to enforce the SiA-related objectives and legal obligations of REACH have been modest*" and that *"[t]his was confirmed by a survey launched by ECHA among MSCAs in 2013 on their plans and willingness to cooperate with ECHA in this field*" (ECHA, 2016).

The report found a lack of enforcement, which undercuts impetus for substitution, in relation to the substitution of hazardous chemicals by less or non-hazardous substances. The Commission has highlighted that enforcement of the substitution of substances classified as C1, C2, M1 or M2 under the Carcinogens and Mutagens Directive was a particularly poorly enforced area and, as a result, substitution is infrequent (European Commission, 2012).

Another Commission study highlights the importance of harmonisation in the implementation of REACH at Member State level, in terms of market surveillance and enforcement, as a critical success factor in the operation of a harmonised single market (European Commission, 2015). According to the study, "*MS authorities identified the following as the key areas to address to increase harmonisation:*

- *Issues surrounding languages (e.g. translations of SDS/ Exposure Scenarios);*
- *Lack of resources for staff, staff training and retention;*
- *Collaboration between different government bodies;*
- *The supply of test laboratories (costs and time to get a response);*
- *The lack of knowledge as regards REACH among firms*." (European Commission, 2015)

Companies interviewed as part of the above-mentioned study indicated that mainly the following factors cause problems regarding surveillance and enforcement (European Commission, 2015):

- "*Different penalties for non-compliance in different Member States;*
- *Different OSH (Occupational Safety and Health) legislation in Member States, also different Binding Occupational Exposure Limit Values (BOELV);*
- *Lack of enforcement as regards imported articles;*
- *Lack of valid test methods for SVHC contents in articles;*
- *Products entering from non-EU/ EEA countries (polymers, cosmetics, biocides and chemical articles); […]*
- *Re-imports of chemicals into the EU;*
- *Nanomaterials (amendments to REACH Annexes are not implemented yet);*
- *Varying inspection requirements between and within Member States;*
- *Knowledge levels of inspectors as regards complex technical matters*."

The Commission published a study on enforcement indicators for REACH and CLP in April 2015 (European Commission, 2015). The study proposed a set of 50 enforcement indicators at the MS level, EU level and in relation to the Forum for Exchange of Information on Enforcement ('Forum') with the aim to measure enforcement at these different levels. The idea is to help to enhance the knowledge of the state-of-play of the implementation and enforcement of REACH and CLP and to try to streamline enforcement activities in the EU.

In relation to the work carried out by the Forum, ECHA recommends that all Member States should take part in all REACH-EN-FORCE (REF) projects (ECHA, 2016). These are carried out by inspectors based in the national authorities in the participating Member States and focus on different subjects related to the compliance of registrants with REACH, CLP and the PIC regulations.

Several examples of best practices in relation to enforcement activities were identified during the desk research carried out for this study and by stakeholders who also came up with additional ideas to tackle the issue.

The **Swedish Government** passed a bill establishing a non-toxic environment as one of its overall goals (KEMI, 2015). The national Chemicals Inspectorate (**KEMI**) implements the strategy via action plans. The action plan from 2015 to 2020 includes, amongst other things, the enhanced enforcement of banned or restricted substances in articles. In 2016, KEMI adopted a strategy for the enforcement of chemicals in articles (KEMI, 2016). The strategy focusses on toys and childcare articles, clothing, shoes and accessories, electrical products, building material and furnishing and hobby and sports equipment. It includes inspections of those companies that put relevant products on the Swedish market, including via e-commerce. KEMI carries out chemical analyses of those products and cooperates with other authorities in Sweden and throughout the EU. In addition, the strategy foresees the development of a work model that combines enforcement with other activities, such as "*education for companies, information to the general public and further development of legislation*".

KEMI has also dedicated a specific enforcement action on (soft) plastic articles used by consumers (KEMI, 2015). The substances targeted in the analyses were phthalates (plasticisers), short chain chlorinated paraffins (plasticisers and flame retardant), lead, cadmium and dimethylformamide/methylacetamide. Almost 10% of the articles sampled contained restricted substances in levels that exceeded the limit values, with short chain chlorinated paraffins being the most frequently found substance. KEMI prohibited sales in instances in which companies did not stop selling the products. KEMI reported 20 companies to the environmental prosecutor and reported articles that contained high levels of short chained chlorinated paraffins and cadmium to RAPEX.

In 2013, the **Danish government** agreed with all parliamentary parties to launch a new chemicals initiative between 2014 to 2017 to protect humans and the environment from chemical risks (Ministry of Environment and Food of Denmark, 2016). A budget of DKK 184.8 mill. (around €25M) has been allocated for this period. Around €10M will be spent on the programme on 'Non-toxic products', which includes an inspection and enforcement initiative to ensure compliance of consumer products for the children and young people. Specifically, the Central Customs and Tax Administration (SKAT) and the Danish Safety Technology Authority are involved.

Participants in the June 2016 workshop, organised in the context of the Non-Toxic Environment study, referred to the US approach concerning toys. Under the **US Consumer Product Safety Improvement Act** (CPSIA), all toys intended for use by children 12 years of age and under, must be third party tested and certified in a Children's Product Certificate as compliant to the federal toy safety standard, and to other applicable requirements as well[17].

In 2013, ECHA proposed the launching of a common action plan for SiA-related activities, which was not supported by the MSCAs (ECHA, 2016). However, the **Forum for Exchange of Information on Enforcement** will run a pilot project on this topic in 2017.

The ECHA report notes that the possibility for consumers to require information about the presence of SVHCs in articles under Article 33(2) of REACH "is not generally known and therefore only sparsely

[17] Section 15 CPSA.

used" (ECHA, 2016). In this context, initiatives in Denmark and Germany should be mentioned, that encourage consumers to use their right to request the information by using online tools[18]. The German online tool is provided by the NGO BUND. The idea that NGOs could help to strengthen the implementation of legal requirements, even though they do not have a "formal role", was presented by participants at the workshop. Participants reported that models that support civil society groups in the screening of products on sale for the presence of SVHC were very effective in the US.

5.2 CHEMICALS IN ARTICLES AND THE CIRCULAR ECONOMY

This section presents key findings from the sub-study b final report on *non-toxic articles and material cycles*, prepared by Ökopol.

The overall aim of achievingnon-toxic articles and material cycles is to prevent their related risks for human health, for the environment, and to improve resource efficiency through the recycling of article wastes. Combining the goal of a non-toxic environment and a circular economy requires:

- improving article design and as far as possible preventing the inclusion of toxic substances in articles with the aim of reducing the exposure throughout the life cycle, increasing recyclability of the articles or the materials of which they are composed, and;
- collecting and separating wastes that contain toxic substances with the aim of decontaminating material streams and ensuring high quality recycled materials generated from article wastes.

The issue of non-toxic articles and material cycles is complex because three different but interconnected regulatory areas are relevant i.e. chemicals legislation, article-related legislation, and waste legislation. Furthermore, a large number of different types of actors are involved in article production and in waste treatment. Finally, numerous types of articles and waste streams, which have complex compositions, need to be considered.

Key findings on chemicals and articles and the circular economy

The problem

- Toxic substances are included in articles and may be released at any lifecycle stage, resulting in exposures and potential risks for humans and for the environment. This is true for new/currently produced articles, as well as for articles already present in society.
- The scale of the problem is significant. The following examples involves two substances from problematic substance groups widely used in articles. The annual amount of DEHP (a phthalate used as plasticiser in PVC, now listed in REACH Annex XIV as a SVHC substance subject to authorisation) included in articles on the EU market (produced in the EU or imported), which is estimated to 210,000 t/y (KEMI, 2015). Further, 7 t/y of BDE (a flame retardant listed as a POP) included in plastics waste from WEEE in the Netherlands, and 22% of this is estimated to be recycled and used in new products (RIVM).
- Linking the incidence of the health and environmental damage observed to exposures to single articles or article categories is challenging due to the complex exposure situation and a lack of basic exposure data. Furthermore, the extent of risks varies with the type of substance, type of article, and its actual use situation. However, there is evidence that many substances, including such with known toxic effects, are released from articlesand are present in the human body and the natural environment.
- Toxic substances contained in end-of-life articles eventually reach the waste stage and may contaminate recycled material streams, enter into a second service life, and potentially occur in unsafe uses, as has been demonstrated e.g. for brominated flame retardants from recycled plastics

[18] Tjek Kemien website (initiated by Danish EPA and Danish Consumer Council), available at: https://www.docdroid.net/ER4DMta/tjek-kemien-information-to-companies-2016-eng-version.pdf.html (last accessed on 18 July 2016); BUND website, available at: http://www.bund.net/themen_und_projekte/chemie/stell_die_giftfrage/anfrage_generator/ (last accessed on 18 July 2016).

Key findings on chemicals and articles and the circular economy

used in thermos cups (Samsoneka, 2013).

- Information about the content of toxic substances in articles is largely missing, both for specific articles and at a general level. This lack of data renders it extremely difficult for:
  - Regulators to carry out overall risks assessment, determine the scale of risks, and to choose regulatory risk management measures;
  - Economic operatorsand consumers to make informed choices about how to avoid toxic substances in articles;
  - Waste treatment operators to separate and treat end-of-life articles in a manner that prevents contamination of recycled materials.

Gaps and inconsistencies in current policy

- The methodology of current regulatory risk assessment under REACH and other chemicals legislation does not ensure that risks relevant for articles can be identified, because:
  - Information on relevant substance properties is partly not available or considered on a routine basis (e.g. PBT/vPvB if registered in low volumes, endocrine disruption or neurotoxicity as not sufficiently covered by information requirements under REACH, nanomaterials as testing regimes is not adapted to them);
  - Long-term and low-dose effects, cumulative and combined exposures as well as combination effects are not sufficiently well addressed;
  - The exposure assessment is generic and requires information on substance uses and releases from articles, which are frequently not available.
- Legislation preventing the presence of toxic substances in articles (where possible) is scattered, neither systematic nor consistent and applies only to very few substances, articles and uses, often with many exemptions.
- Legal information requirements on toxic substances in articles are vague and cover only a few substances (of very high concern) under certain conditions, hence rarely resulting in useful information. If information on toxic substances does exist it is frequently insufficient to support:
  - Article producers in gaining full knowledge about the presence of toxic substances in the complex objects they assemble and place on the market. Consequently, they can hardly ensure material compliance, improve product design regarding the reduction of toxic substances or provide information to their customers;
  - Waste treatment operators in separating waste streams or components thereof that include toxic substances from other waste streams that are not contaminated.
- Legislation and current practices in the waste sector were generally designed to safely treat and dispose wastes containing toxic substances rather than decontaminate waste streams in a manner intended to generate recycled materials free from toxic substances.

5.2.1 Challenges for non-toxic articles

The substance related composition of articles is complex

Most articles consist of a number of different materials which themselves include a large number of chemicals that constitute their matrices, such as polymers or metals. Chemicals may also be included as additives to provide a particular functionality to a material, such as flame retardance or general stability. They may also be present as contaminations from the production process. The possible combinations of chemicals in articles and complex objects are infinite.

It is not possible to easily deduce the substance contents of articles from their material composition or their functionalities, because frequently, the latter could be achieved using different combinations of chemicals or applying different production methods.

The possibilities to deduce a level of risk from "substance in articles" are even more limited, because even if information on the content were available, the release potential of a substance from the product matrix and the article itself would have to be estimated, including with a view to the particular use situation and the user behaviour.

Finally, situations mayoccur where the chemicals present in an article at the waste stage are not the

same as those added to the article during production. Reasons for changes could be for example chemical reactions with other substances (intended or unintended), weathering or aging (contact with oxygen or sunlight) or modifications during the use-phase (e.g. renovation or repainting of buildings).

The volume of (toxic) substances included in articles is large and increasing

The production volume of chemicals, of which a large share has toxic properties (Eurostat, 2015), and of articles are increasing in the EU and at global level (European Commission, 1992) (European Commission, 2001). However, information on the actual amounts of toxic substances used in articles ismissing due to a lack of respective statistics[19]. Therefore, some examples of information from recent studies limited to a few substances and materials is provided in the following.

Kemi has estimated the amount of hazardous substances placed on the market in specific construction products (flooring, carpets, and panel materials) (KEMI, 2016). They have concluded that, among others, 36,000 t/y of DINP are placed on the Swedish market in flooring and 22,000 tonnes of phenols in wooden panels. In addition, via flooring materials, e.g. styrene (2,6000 t/y) and bisphenol A (2,000 t/y) are placed on the Swedish market.

Kemi has also estimated the supply of phthalates in a number of article categories for the Swedish and the EU markets (KEMI, 2015). In summary, they conclude that the falling EU production volumes of DEHP indicates a use reduction following the introduction of more extensive regulation. They estimate that approximately 120,000 t/y of DEHP are used in the production of articles in the EU and 210,000 t/y are included in articles on the EU market (including imports).

The RIVM Institute for Environmental Studies analysed pentaBDE and octaBDE (POP-BDE) flows in waste plastics from WEEE and ELV wastes as well as recycled plastics in the Netherlands (Leslie, 2013). Their mass flow analysis shows that approx. 7 t/a of POP-BDE reach the waste stage in plastics from WEEE and approximately 0.2 t/a from ELV. The IVM estimated that 22% of the POP-BDE from WEEE end up in recycled plastics whereas 14% from the ELV end up in recycled plastics. The POP-BDE detected in new products, made of recycled plastics originated, in non-EU countries primarily.

The majority of supply chains are complex and dynamic

The supply chains of articles are complex and frequently include economic actors from all parts of the world. Furthermore, supply chains are not static over time, but change dynamically depending on prices and product availability. The management of, and communication about, the content of toxic substances in articles along those supply chains are hindered by a lack of harmonised communication tools and language barriers. Additionally, communication is addressed differently (or not at all) by legal requirements across the globe.

Different requirements for EU- and non-EU articles

A large share of articles on the EU-market are imported from non-EU countries. Imported articles may include substances that require authorisation in the EU and may no longer be allowed for use, if no authorisations were granted. This creates an uneven playing field for EU enterprises and generates a need for differentiation between imported and EU-produced articles by economic actors and enforcement authorities in compliance checking and material compliance management.

Imported articles may also include substances unknown to EU regulators if these are not registered under REACH or notified to the CLP inventory.

Risks from hazardous substances in articles do occur

There is evidence from several sources that exposure to hazardous substances in articles does occur and may cause risks to human health or the environment. In current and past restriction processes

[19] Production and trade statistics mostly relate to trade values rather than volumes; furthermore, information on the composition of articles, which could be linked to volume information, is not available.

under REACH, acute and long-term risks from the use of toxic substances in articles were, and have been, identified, e.g. for PBT/vPvBs or sensitisers (Annex XVII, e.g. nickel in jewellery, current proposal on PFOA, and precursors in several article categories). According to the RAPEX database, approximately 25% of all product warnings made by the enforcement authorities are due to the content of toxic substances. Most, but not all of these relate to articles (European Commission, 2016).
Articles contribute to a continuous, long-term, and low-level exposure to a mixture of different hazardous chemicals, which cause or enhance the adverse effects on human health and the environment. For example, several studies have analysed the content of toxic substances in household dust and identified, among others, considerable amounts of phthalates and brominated flame retardants, which give rise to various concerns (Mitro, 2016). These substances are likely to have emitted from articles, because they are not allowed for use in consumer mixtures and are not likely to have accumulated from other sources. The occurrence of a mixtures of various substances in the environment can be deduced from monitoring data and is demonstrated in studies on mixture toxicity in the environment.

Chemical analyses are costly
Due to the large number, and sheer variety, of chemicals that could be present in various articles, identifying the content of toxic substances via chemical testing is cumbersome and costly. Therefore, companies and enforcement authorities can use chemical analyses only to verify a suspicion, but not as a standard routine to assure the quality of the input material.

Supply chain communication is hampered by confidentiality
The (innovative) use of substances in materials and articles may form part of the specific know-how of article producers and their suppliers. Therefore, they communicate only the minimum amount of information needed to comply with restrictions and communication requirements to their customers. This information may not be sufficient for chemicals users and article producers to assess workers' risks, to check notification obligations under Art. 7(2), and to identify options to improve their product design and assess substitution options.

Overview data on the content of toxic substances in articles is missing
General information on the use (amounts) of toxic substances in articles is missing, due to the limited scope of legal provisions regarding information about hazardous substances included in various articles. Therefore, the overall assessment of the scale of risks from toxic substances is not possible nor is targeted decision making on potential risk management measures.

5.2.2 Challenges for waste management and non-toxic materials

Articles with varying composition enter the waste stage
Articles entering the waste stage are diverse, with regards to their composition and content of toxic substances. This is obvious for different article types, but the content of toxic substances may differ significantly even for the same types of articles made from similar base materials (polymers, metals, etc.). The sheer variety of articles causes challenges for sorting and separate treatment.

There are two mains reasons for the variations in the composition of articles:

- Article producers implement different design and production principles for their articles, thereby choosing different materials and technical solutions for their products. These choices also include where materials are sourced from, which may have implications on the product composition;
- Dynamic regulation and increasing numbers of restrictions, as well as pressure to substitute, as exerted e.g. by the REACH candidate list, push article producers to change their product design and to substitute restricted substances. The overall substance-related composition may change to a greater extent, given that this is normally not a 1:1 replacement.

Few waste-driven limitations exist for toxic substances atthe waste stage

A systematic regime preventing (certain) toxic substances, which may cause technical or (eco)toxic problems, from entering waste streams does not exist. From the waste treatment perspective, only very few requirements have been defined for specific (listed) substances in specific articles; e.g. some heavy metals, flame retardants, and phthalates are regulated in vehicles and electrical and electronic equipment as well as in batteries. Overall, the legislation of articles also does not provide for such systematic restrictions, as has been examined above.

Toxic substances in articles may contaminate material streams

Post-consumer wastes are heterogeneous, unlike production wastes, despite increasing trends for separation that exist already in households and in public waste collection schemes. Waste treatment that aims to close material cycles either involves the recovery and reuse of entire articles (complex articles) or their components[20] or, much more often, the separation of materials, their homogenisation, and the potential further processing thereof to obtain secondary raw materials. In the recycling processes, articles (and the materials they consist of) that contain toxic substances contaminate the respective waste streams and are diluted in materials that do not contain toxic substances. These substances will continue circulating for as long as toxic substances in articles are included in waste streams that enter recycling processes. According to modelling studies, it may take centuries to decontaminate a recycled waste stream, even if preventive measures are implemented, such as restrictions that would end the input of those substances to articles placed on the market after the restriction enters into force (Pivnenko, 2016).

Information on toxic substances in end-of-life articles and material streams is missing

There are only a few legal and practical mechanisms in place to create an information flow about the substance content of end-of-life products from article producers to the waste sector. The respective requirements are specified as part of the "extended producer responsibility" only in the case of electrical and electronic devices and vehicles. The knowledge gap on the toxic substances content in end-of-life articles is carried over to the recycled materials, in the case of packaging wastes for example.

Information on certain hazardous substances, such as PBT/vPvB and POPs, are systematically not communicated in the waste chain

Within the waste sector, actors communicate about the hazardousness of wastes via the waste codes, which are defined in the EU List of Waste. The List of Waste categorises wastes according to their origin. A waste's hazardousness is identified via the HP criteria, setting out different hazard properties of wastes. The substance categories PBT/vPvB and POPs, which may be particularly relevant for risks from articles and article wastes as well as "persistence in material cycles", are not specifically considered.

Toxic substances in recycled materials may contaminate articles

The quality of virgin and secondary materials used for the production of articles should be the same, but related legal requirements do not exist. Therefore, it appears that the content of toxic substances in recycled materials is only controlled systematically if it is used in products with critical exposures, e.g. for toys or food contact materials. Consequently, toxic substances in recycled materials are currently included in newly produced articles and may cause risks during production and article service life. When these articles become waste, the toxic substances continue circulating in the material streams. This leads to a continuous dilution of toxic substances in articles and materials over time. A widespread presence of SVHC's and substances corresponding with the criteria for identification of SVHC's but not yet listed on the REACH candidate list or substances of equivalent concern is problematic because it disables efficient risk management, while potentially being acceptable for substances with a low toxicity.

[20] The reuse of articles may be prohibited if toxic substances in the reused article have been restricted. It is, however, possible that there are exemptions from the restriction for reused articles. The issue of reuse is not further discussed in this sub-study report.

Waste management practices are not designed to systematically decontaminate waste streams
The EU regulatory framework for waste management was not developed with a view to implementing a circular economy and targeted decontaminating waste streams. Although the Waste Framework Directive generally requires the "depollution of waste streams", this is concretised only for end-of-life vehicles, electrical and electronic wastes and batteries by additional legislation (sometimes referred to as the "waste stream directives"). What depollution means and how it should be implemented remains vague and unclear for all other waste streams.
The precondition for generating non-toxic recycling material streams is the implementation of the following:

- article waste streams, and the components therein, that contain toxic substances can be distinguished from those that do not contain toxic substances;
- article waste streams, and the components therein, can be sorted according to their recycling potential/substance content and directed towards specific treatment options;
- waste managers have criteria and information to select the optimal treatment option for a particular article waste stream with a view to maximising recycling and minimising the presence of toxic substances;
- contaminated waste materials can be decontaminated from toxic substances during a recycling process;
- the waste treatment company has sufficient information to inform their customers about the secondary raw materials' quality and the content of toxic substances.

The existing legislation and infrastructure is not sufficiently well developed to support these tasks to the extent necessary. Separate collection and treatment, as well as decontamination technologies which can be operated at reasonable costs, currently do not exist.

Costs for producing recycled materials that do not contain any toxic substances, where contaminated wastes are thoroughly sorted and only the purest fractions are recycled, tend to be higher than the benefits that can be achieved on the market. It is more likely that the production costs of lower quality recycled materials can be commercially justified. In addition, due to the high level of uncertainty about the content of toxic substances in secondary raw materials, many article producers hesitate using recycled materials.

5.2.3 The Current Policy and Legislative Framework

The issue of non-toxic articles and material cycles relates to, and is influenced by, three regulatory areas; namely, chemicals legislation, articles related legislation, and waste legislation. All of these legal areas consist of overarching legislation, i.e. REACH and the CLP regulation (chemicals), the General Product Safety Directive (articles), and the Waste Framework Directive (waste) and specific legislation such as the Biocides Regulation (chemicals), the Toy Safety Directive or the RoHS Directive (articles) or the End-of-Life Vehicles Directive (waste).

Each legislative area contributes to a framework that, among others, aims at the production of non-toxic articles and for the generation of material cycles as free from toxic substances as is possible. The following description depicts the general approaches of legislation, but does not include the individual requirements. The main gaps and deficits, i.e. where legislation does not (sufficiently) fulfil the needed function to ensure production of non-toxic articles and maintaining waste streams clean, are outlined in the following section.

Chemicals legislation ensures that:

- the **hazardous** properties of substances potentially contained in articles **are identified and that this information is available** to all market actors (registration/active substances approval, substance evaluation, SVHC identification and candidate listing, notification of classification, and

labelling);

- **unsafe uses** of toxic substances in articles **are identified** via generic risk assessments **and prevented** via the limitations of their use[21] (chemical safety assessment and discouraged uses, biocide product approval for use in articles, communication of binding conditions of use through safety data sheet or article labels, restrictions and authorization procedure);
- substances and mixtures recovered from waste are the same as the substances registered as part of the virgin materials or alternatively are the recovered materials registered and safety assessed according to the same requirements as a new mixture;
- **information** about the content of **SVHC and biocides in articles is available** to all actors handling, using, and regulating articles (REACH Article 33 and Article 7 as well as labelling of treated articles under biocides legislation). The information should be sufficient to enable:
  - economic actors to comply with legal requirements, protect their workers from potential risks during processing, and to consider chemicals related risks in their product design processes;
  - consumers to make informed choices and to potentially avoid articles containing SVHC
  - regulators to assess and identify risks from SVHC in articles at an aggregated level and to implement risk management measures, if necessary.

Articles related legislation ensures that:

- **all articles** placed **on the market are safe for human health** during normal and in reasonably foreseeable use (General Product Safety Directive);
- **the content of substances** that are **of particular concern** in articles with sensitive exposure potentials or with regards to the treatment of waste **are restricted** (specific restrictions, e.g. Toy Safety Directive, RoHS or positive lists (food contact materials));
- information on the **content of certain substances** (e.g. sensitisers in toys and heavy metals in batteries) and on **how to dispose an article** properly to ensure that it enters the correct waste treatment stream (e.g. electronic devices) **is communicated** to the consumers.

This also ensures a level playing field, with regards to the content of the restricted toxic substances, given that articles legislation applies to imported and EU-produced articles alike.

Waste legislation ensures that:

- incentives are set to **prevent hazardous wastes** (waste treatment hierarchy, extended producer responsibility, ELV, and WEEE) and to increase recycling of materials (collection and recycling targets);
- **infrastructure and management routines exist to** collect, sort, and **treat large volumes of wastes** in an efficient way, including recycled materials as much as technically and economically feasible (Waste Framework Directive);
- **hazardous wastes** are identified and related information is used to decide on the treatment technology and that stricter management and documentation requirements apply (waste classification and related requirements) for hazardous wastes;
- **toxic substances** are separated from the waste streams and are either finally disposed of by incineration or landfilling or are extracted from a material stream through specific decontamination and treatment technologies, where such are available and feasible.

Use restrictions, to prevent toxic substances from entering articles, could originate from chemicals, articles, and waste legislation. Chemicals legislation generally takes a top-down perspective that integrates workers, consumer, and environmental concerns in generic risk assessment and management approaches that cover the entire lifecycle. In contrast, articles legislation focuses on

[21] There may be options to limit exposure by article-integrated risk management measures, but it is unlikely that a registrant will identify this as a risk management measure and will communicate it along the supply chain.

consumer health issues and the use phase of articles. Existing restrictions of sertain toxic substances in waste stream directives such as the ELV and WEEE Directives, consider problems encountered during waste treatment and recycling that may relate to environmental and health risks or problems in waste material management and contamination.

Specific requirements to decontaminate waste streams exist only in the ELV and the WEEE Directives. In addition, the end-of-waste criteria indirectly imply these provisions because the quality of the input and output materials are defined for recycled materials that become a product. However, these criteria exist only for very few materials. Chemicals legislation may require decontamination during recycling, given that substance bans and use restrictions (e.g. REACH authorisation, POPs regulation) apply to secondary materials as well.

5.2.4 Gaps and deficits in policies and legislation

The assessment of risks from toxic substances in articles, respective risk management measures, as well as communication on the content of toxic substances in articles are partly addressed by different pieces of the EU legal framework. However, a number of significant gaps and weaknesses have been identified with a view to producing non-toxic articles and maintaining non-toxic material cycles.

Identification of risks from toxic substances in articles
Several pieces of legislation, REACH in particular, include safety/risk assessment procedures, which may result in uses advised against/restrictions or (binding) recommendations for risk management measures. These assessment approaches do not sufficiently cover some important aspects on hazards and exposures, for instance:

- Some hazardous properties are not identified systematically or are not sufficiently well characterized for safety assessment, such as endocrine disruption, neurotoxicants or very high persistence;
- Nanomaterials are partly not identified specifically, characterized with regards to their (eco)toxic properties and potentially existing specific effects (including e.g. carrier effects and ability to cross biological membranes);
- Accumulated exposures to one chemical from multiple sources (including articles) have not been sufficiently considered;
- Rules to include combined effects from exposures to several different chemicals (including from articles) remain missing;
- Long-term and low-dose exposures are not particularly addressed.

The risk assessment practice defines an unacceptable risk as an exposure level exceeding the concentration above which adverse effects are expected (i.e. a risk characterization ratio (RCR) > 1). For articles, demonstration of an RCR > 1 is hardly possible, where the factors listed above are not taken into account in the assessment. As this is currently not sufficiently implemented, specific restrictions of toxic substances in individual article types are not very frequent.

Use restrictions and information on substances in articles

- Current chemicals and articles-related legislation, including use restrictions, are generally not precautionary but require the demonstration of a specific risk before it is possible to take action. This may lead to unnecessary damage, due to the lag time between risk assessment and measures triggered by regulatory risk management, if legal action is taken at all;
- Restrictions have been developed on case-by-case basis. They, therefore, concern only a few

substances in a few specific articles and are partly inconsistent across legislation[22].

- Aggregated information about the content of toxic substances in articles is largely missing. Therefore, neither the actual scale of exposures or risks from toxic substances in articles can be derived, nor can targeted risk management be implemented.
- The General Product Safety Directive does not consider environmental safety and human exposure via the environment, while generally applied only in simple and obvious cases of non-compliance and direct acute risks.
- The REACH authorisation scheme does not cover imported articles. This creates an uneven playing field for EU article producers and, given that these substances are SVHC, may cause risks for human health and the environment as well as prolong the lifetime of these substances in material cycles.
- There are only a few obligations that require toxic substances in articles to be communicated, in addition to REACH Article 33. This lack of specific information requirements on toxic substances in articles (except on SVHC) is a problem, because:
  - Actors in the article supply chain lack information for product design and potential phase out of toxic substances, other than SVHC; they lack information about SVHC below 0.1%
  - Article producers, who want to conduct a thorough safety assessment for their articles, lack data on the chemical composition and potential release of hazardous substances
  - Consumers wanting to avoid toxic substances in their products lack information for their purchasing decisions and have no rights to request it
  - The lack of information reduces the potential for market forces to enhance phase-out and substitution, given that this cannot be a purchasing criterion.

Prevention measures and decontamination of material streams

Similarly to the regulation of articles, waste legislation does not systematically define requirements on the content of toxic substances in (end-of-life) articles. Collection and recycling targets focus on increasing the amounts of recycled materials, not on their quality regarding the absence of toxic substances. No quality standards for recycled materials (as well as virgin materials) exist, except for the end-of-waste criteria, which exist only for a few material streams. Hence, legislation does not incentivise activities to decontaminate waste/recycled materials. The existing waste treatment infrastructure (collection, decontamination, and treatment, including recycling) appear to technically and economically limit the potential for high quality recycling.

Information about the content of toxic substances in end-of-life articles is the essential basis for the implementation of a material management system in the waste sector that includes processes that separate toxic substances from material cycles and/or destroy them. Key issues in this regard that need to be addressed are:

- Structured information about the content of toxic substances in article wastes is not generally available to the waste sector. Legal communication requirements are missing for the majority of article wastes;
- The waste sectors' efforts, necessary to accessing information on toxic substances in end-of-life articles, are generally too high in relation to the comparatively small profit margins. Time-consuming research, e.g. in safety data sheets or databases or in the separation of individual end-of-life products rarely pay-off;
- Waste management operations are often mass volume operations, i.e. the entirety of large containers with various articles having different compositions is treated, rather than individual end-of-life products. The identification of articles that contain toxic substances in theses waste

[22] An overarching, consistent, and horizontal approach could consist of restricting substances with certain hazard categories in article groups with particular exposure patterns. This would also ensure that future substance uses are covered and that resources for the development of restriction proposals are preserved. It would also enable regulatory action for substances to be predicted in a better manner.

streams is time- and resource-intensive.

- There are no legal consequences triggered by information about the content of toxic substances in wastes. For example, if the waste treatment operator knows of the presence of beryllium in electrical products' contact points, they would not separate them from the other waste materials, because they are not legally required to do so, and it is not considered economically profitable.

5.2.5 Conclusions

The goals of a non-toxic environment, and of the circular economy, are in conflict as long as toxic substances are used for the creation of technical materials and contained in articles and recycling material streams. The goals converge if toxic substances are either phased out from articles or if a gapless tracing of toxic substances is implemented, followed by waste separation based on the toxic substances content and a respective recycling or reuse (if possible and desirable) of the material or articles.

At present, the opinions on how to manage the problem of toxic substances in articles and wastes differ. Some actors prefer an increase in recycling volumes and deprioritise the need to decontaminate recycling material streams. Other actors prefer implementing a non-toxic environment and would at least temporarily reduce recycling rates in favour of finally disposing of toxic substances, thereby removing them from material cycles. A political decision on the hierarchy of goals and an analysis of the best combination of measures to achieve them is both urgent and necessary.

Two approaches are necessary with regards to non-toxic articles and material cycles. First, strategies and implementation instruments that prevent toxic substances from entering articles and materials cycles will avoid risks to human health and to the environment throughout the substances' lifecycles. Second, strategies and implementation instruments that motivate and enable the waste treatment sector to decontaminate waste streams from toxic substances are needed, as long as toxic substances continue to enter the waste stage from (long-lived and imported) articles. These strategies will also help with the extraction of those substances from waste streams in the future which, at present, are not yet known to cause problems.

A systematic and fundamental approach to restrict substances is useful in order to manage the complexity of articles, article supply chains, functionalised technical materials, and substance combinations used to produce articles. The restriction approach should complement the top-down risk management approach under REACH and consider all of the relevant hazards, should integrate long-term, low-level multiple exposures as well as related combination effects. Furthermore, it should integrate the needs from waste treatment practices. In addition, modern article design principles should be amended to include the goals of a non-toxic environment and of the circular economy. Requirements and mechanisms to communicate information on toxic substances in functionalised technical materials and articles along the supply chain, which are sufficient for informed decision making on article design and substitution, would increase incentives for the (voluntary) phase-out of toxic substances.

Legal requirements regarding the decontamination of material streams appear to be indispensable for the waste sector, given that the related economic incentives are low. Furthermore, instruments like extended producer responsibility could be amended to also cover the waste stage until the final secondary materials. This could enable the triggering of preventive approaches in article design that consider the needs of the waste sector. Requirements and tools that ensure that the necessary information to separate contaminated from non-contaminated wastes, as a fundamental step to keeping material streams clean, are urgently needed.

The prioritisation of substances, articles, and material streams, with regards to preventive measures, as well as decontamination requires more elaborated risk assessment approaches than are currently in place. Article-specific emission characteristics and exposure situations (long-term, low-level, multiple

exposures, and combined effects) need to be assessed and taken into account, as well as a thorough approach for the evaluation of risks from the waste stage, including for recycled materials is needed.

To enable the closure of material cycles, the legal interfaces between chemicals and waste legislation should be better interlinked, so that the status of a material is clear (waste or product). In addition, a situation in which the (information) basis for compliance under either legislation is not structurally available or is insufficient, it should be avoided.

Apart from improving the legal framework in relation to the content of, and information about, toxic substances in articles, complementary activities are necessary to ensure that all of the actors understand, implement, and benefit from the use of less toxic substances in articles and materials. This includes economic incentives, information campaigns, and training as well as funding and supporting research on technological developments and substitution options.

5.3 PERSISTENCE

This section presents key findings from the sub-study d final report on *very persistent chemicals*, prepared by Milieu. The full sub-study is annexed to this Final Report.

The problem

The use and dispersal in the environment of very persistent (vP) chemicals represents a (potential) threat to health, the environment and natural resources. Due to technical/functionality reasons, such chemicals are widely used in a broad range of applications. Chemicals with a high degree of persistence will remain in the environment for a long time, and lead to exposure of humans and the environment, including a.o. vulnerable population groups, wildlife and environmental media. This may involve previously overlooked or unpredictable negative effects even for chemicals where laboratory tests did not indicate any considerable toxicity, e.g. if the effects are chronic or appear at low concentration levels.

Key findings on very persistent substances

The problem

- A range of very persistent substances, including several groups of halogenated organic compounds, are widely used in different applications, often due to the functionality of the substance.
- Very persistent (vP) substances may accumulate in the environment and man-made materials to levels harmful to human health and natural resources.
- Certain toxic effects (e.g. chronic or occurring at low concentrations) may take many years to identify, by which time rising concentrations/levels could have already occurred and prove irreversible.
- Highly fluorinated chemicals such as PFAS are extremely persistent and will remain in the environment for hundreds of years. They are highly mobile and have been found in groundwater used for drinking water across Europe as well as in remote areas such as the polar region and the deep sea.
- The thousands of new short-chain PFAS marketed by producers as "safer" than the long-chain PFOS and PFOA are also extremely persistent. Evidence of their toxicity and of their presence in the environment is mounting. Known technologies are not able to remove short-chain PFAS from drinking water.
- An estimated 3.5 million sites around Europe are contaminated by hazardous including vP substances. Contamination of natural resources has severe economic consequences, ranging from the extremely high costs of remediation to removal of natural resources such as drinking water, land, soils and fish stocks from productive use.

Gaps and inconsistencies in current policy

- Current EU legislation does not provide an adequate way to systematically control substances on the basis of their persistent properties.
- Major gaps in knowledge concerning vP substances are due to lack of a common framework for screening substances for persistence and inadequate requirements for persistence testing and for

further testing of health and environment properties if a substance is found to be persistent.

- Evaluation of risks from exposure to vP chemicals during the use phase of products is insufficient, and almost entirely missing in the case of imported products, with a few exceptions covering a limited number of substances in certain product groups such as toys. Product regulations also seldom take account of a substance's fate at end of product life, which risks build-ups of vP substances in recycled material waste streams. Strict controls over releases of any vP substances during manufacturing, product use or end of product life may be needed to prevent build-ups in the technosphere as well as the environment.
- Criteria for maximum allowable levels of vP substances in food, drinking waterand groundwater are needed to ensure that accumulations of vP pollutants in water and soil resources are given sufficient attention.

Concentrations of a vP chemical will tend to build up and eventually reach levels where harmful effects to health and natural resources may occur. Damage from exposure to vP chemicals is poorly reversible or even irreversible and may entail considerable cost to society. With the current high levels of production and widespread use of vP substances, cases of such damages are highly likely to appear or may even be unavoidable. Moreover, some health effects may not become evident until long after exposure.

Some scientists argue that persistence is in fact the most important single factor affecting chemical exposure and risk from the environment, because build-ups of a vP chemical could lead to the same type of continuous exposure as occurs with bioaccumulation (Stephenson, 1977) (Cousins G. B., 2016). Because of uncertainty about chemical properties, a situation could arise where accumulations have already occurred by the time evidence is gathered about a chemical's propensity for harm. As already experienced in the case of persistent ozone-depleting chemicals, the disruptive effects may not be discovered until they occur on a global scale and are affecting a vital earth system process.

Exposure to the well-studied persistent organic pollutants (POPs) has been linked to a number of serious health effects including certain cancers, birth defects, dysfunctional immune and reproductive systems, greater susceptibility to disease and damages to the central and peripheral nervous system. Further, presence of POPs in the environment is associated with severe effects such as impaired reproduction in birds and mammals.

Once a vP substance is released into the environment, its breakdown or transformation products may raise new concerns. In the case of PCBs, for example, it took considerable time for scientists to discover that the process of bioaccumulation resulted in concentrations of the more toxic congeners than were found in the commercial products. DDT is another example in that the compound itself is considered to have low toxicity for humans, but when released into the environment its transformation products include the more toxic DDE (U.S. Department of Health and Human Services, 2002).

The problems related to vP chemicals are particularly challenging in view of a **circular economy** that strives to close the loops by e.g. increasing reuse and recycling of material. If the material is recycled and used again, vP substances may accumulate in recycled materials, leading to increasing concentrations of contaminants in recycled materials, along with increased long term dispersal and presence of vP chemicals in the technosphere as well as the natural environment.

Testing and identification of persistence in substances. A common misconception is that environmental persistence is an inherent property of the substance that can be readily measured. However, assessing the persistence of chemical substances in the environment is not straightforward. It entails an assortment of supporting information and the need to address gaps and uncertainties (Boethling, 2009).

Moreover, current requirements for testing and test methods to screen and test chemicals for persistence are insufficient (Scheringer, 2012). According to UNEP, only 220 chemicals out of a set of

95,000 industrial chemicals have been evaluated fully in relation to their biodegradation half-lives and only 1,000 have data on bio-concentration (UNEP & WHO, 2013).

A major challenge is that testing for multimedia half-lives is time consuming and costly. While chemicals might be screened for persistence potential based on chemical structures and characteristics, no common framework for doing this has been adopted or accepted. As a result, knowledge and/or information available about the persistence of chemicals produced and used as well as about actual quantities and uses of many vP substances is poor.

To be included in the Stockholm Convention on persistent organic pollutants (POPs), a substance must meet the POPs screening criteria for persistence, bioaccumulation, long-range transport potential and toxicity. At this point only 26 substances and groups of substances are covered under the POPs Convention, with another three under consideration for future inclusion. Yet as many as 1,200 of the 90,000+ substances on the market today could be potential POPs (Scheringer, 2012). The number of substances meeting the POPs criteria for persistence alone is surely much higher.

In the regulatory context, persistence is defined by single-media half-life criteria. REACH provides, for example, that a chemical is persistent (P) if its half-life in soil exceeds 120 days or its half-life in water is more than 60 days. It is considered very persistent (vP) when the half-life in water is higher than 60 days, or when the half-life in soil or in water sediment is higher than 180 days.

The highly-fluorinated chemicals – especially the per- and polyfluorinated alkyl substances known collectively as PFASs – are very stable and durable, which makes them useful for a broad range of applications. However, scientific tests to determine their degradation half-lives have found almost no degradation during the testing period, meaning they will persist in the environment for hundreds or even thousands of years (Russell, 2008) (Washington, 2009).

In the 1950s, when highly fluorinated compounds were first commercialised, the focus was on long-chain PFASs -- the so-called C-8 substances used in the manufacture of Teflon-coated cookware, water- and stain-resistant textiles, and fire-fighting foams. In the 1980s and 1990s, evidence emerged of the toxicity and bioaccumulability of the long-chain PFAS, such as PFOS and PFOA. Human epidemiological studies have found positive associations between exposure to PFASs and hepatocellular damage affecting liver function in adults, obesogenic effects in females, liver and kidney cancer, and, low birthweight and reduced length of gestation. Exposures to low levels of highly fluorinated chemicals have also been linked to reduced immune response to routine childhood immunizations (Grandjean, P., et al., 2015).

Regulatory pressure has led to phase-out of the manufacture and use of long-chain PFAS in Europe and the USA. As a result, many manufacturers have replaced the C-8s with short-chain homologues -- the C-6s and C-4s. PFAS producers argue that the short-chain PFAS are "safer" in that they are not as bioaccumulative as the long-chain PFAS. However, they are just as persistent, and evidence is emerging that the short-chain alternatives are also problematic in terms of risks to health (Lerner, 2016).

Today, more than 3,000 different types of PFAS are estimated to be on the market. They are found in cosmetics, food contact materials, inks, medical devices, mobile phones, pharmaceuticals and textiles, and they are used in pesticide formulations, oil production and mining. They are capable of long-range transport and are found even in remote locations. A major source has been the use or spillage of PFAS-containing aqueous film firefighting foam (AFFF); in the EU, PFAS-contaminated waters have so far been documented in the Netherlands, UK, Germany, and Sweden. However, the problem is likely to affect most Member States. Discharges from industrial production processes, wastewater treatment and landfill leachate are also important sources.

Other groupings of highly persistent substances. **Highly chlorinated substances** form another

grouping of chemical compounds that tend to be very persistent and therefore problematic. Many of them are known to be toxic for health and environment. For example, the manufacture and use of polychlorinated biphenyls (PCBs) was banned by the EU and most other industrialised countries some 30 years ago, because of concerns about their extreme environmental persistence, ability to bioaccumulate and their association with adverse human health and environmental effects. While concentrations in air, soil, sediment and biota declined rapidly during the first decade of the ban, since then they have remained stubbornly at the same levels and are now ubiquitous in food from terrestrial and aquatic sources. Types of highly chlorinated substances also of concern include chlorinated paraffins, and unintentionally formed POPs such as dioxins and furans. Other groups of highly persistent substances discussed in the study include **highly brominated substances**, **siloxanes** (D4 & D5), and **organometallics**, e.g., organotin compounds, methyl mercury and tetraethyl lead.

Contamination from vP substances has already had a significant impact on Europe's natural resource base. The use of hazardous substances in industrial production processes over the years has led to some 3.5 million potentially contaminated sites across Europe, with 0.5 million of these considered highly contaminated and needing remediation. Though it is not possible to estimate how many of these sites are contaminated by vP substances, overviews showing contamination of media by specific vPs, including PCDD/Fs (Weber, 2008), HCHs (Vijgen, 2006) and PFASs (Rumsby, 2009) (Cousins I. V., 2016) do indicate a widespread problem.

In addition to local sources, contamination from vP substances has also been documented in soils away from point sources, e.g. highly fluorinated chemicals (HFCs) have been found at high altitudes due to tendency for long-range transport. Recently, contamination of waters by highly fluorinated chemicals (HFCs) has drawn attention in the USA, where drinking water supplies for 6 million residents were found to exceed national lifetime health advisory limits (70 ng/L) for PFOS and PFOA. While activated charcoal can remove the long-chain HFCs from drinking water, currently available technologies cannot remove the short-chain HFCs. The same type of activities that contaminated groundwater in the USA have also been carried out in the EU, e.g., releases from industrial sites and use of aqueous film firefighting foams at major airports and military bases. But because no EU-wide monitoring for HFCs in water has occurred, it is not known how many similarly contaminated drinking water supplies are to be found around the EU.

The presence of vPs in recycled products will be a particular challenge for the EU's action plan on a Circular Economy aimed at maximizing the use of, and minimizing the waste of, material resources in the economy. These substances by their nature can persist and therefore accumulate in recycling streams for long periods, including through now-restricted products made before regulations were applied. The potential for contamination of the 'technosphere' is a serious concern because of the long-term implications for human and ecosystem health.

The Current Policy and Legislative Framework

A number of EU acts consider persistence as a property of concern. However, in almost all cases, persistence is regulated only if bioaccumulability is also present. For example, the **REACH Regulation** sets criteria for identifying if a substance is PBT or vPvB. A PBT or vPvB substance may then be identified as a Substance of Very High Concern (SVHC) under Article 57 and added to the Candidate List for eventual inclusion in Annex XIV as subject to authorisation. Alternately, the substance may be restricted under Annex XVII.

In theory, REACH Article 57(f) might be invoked if evidence can be presented that a vP substance gives rise to an equivalent level of concern as a substance meeting the criteria for PBT/vPvB. In addition, REACH Annex I mentions the possibility of assessing particular effects such as ozone depletion, strong odour or tainting, which could in theory also include the particular effect of persistence. However, to date, neither of these provisions has been applied to a substance solely on the basis of persistence.

In addition to being persistent, the substances controlled under the 1996 **PCBs Directive**, the 2004 **POPs Regulation** implementing the Stockholm Convention, and the 2008 **Mercury Regulation** are also bioaccumulative and toxic. Similarly, the cut-off criteria for active substances set forth in the 2009 **Plant Protection Products Regulation** (PPPR) and the 2012 **Biocidal Products Regulation** (BPR) also require findings of BT and vB in addition to P or vP.

The **Detergents Regulation** is an exception in that it requires surfactants used in detergents to meet biodegradability standards.

The 2011 (recast) **RoHS Directive** is one of the few pieces of legislation dedicated to controlling the use of hazardous substances in articles in order to reduce downstream impacts of the substance at the end of the product's life. By banning the use of the hazardous substance, the RoHS Directive prevents it from entering the material waste stream, i.e., the technosphere. The Directive targets four metals and two toxic and persistent flame retardants. However, the other persistent flame retardants now used extensively in plastic casings of electronic goods are not covered. These other substances are an instance of "regrettable substitution") in that plastics with added flame retardants may not be recyclable and in any case the flame retardants should be kept out of recycled material flows. The substance-specific provisions in the other "waste stream directives", e.g. end-of-life vehicles, batteries and packaging materials, play similar (albeit incomplete) roles in keeping problematic substances out of the technosphere.

The 2010 **Industrial Emissions Directive** (IED) is aimed at achieving best overall reduction of polluting emissions. This does not take into account the intrinsic quality of persistence which may require measures to prevent any releases of vP substances in order to avoid build-ups in the environment, e.g., the emission limit values (concentration levels) set in integrated permits would not prevent such releases. A vP substance not meeting the additional criteria for BT and vB would not be included in the controls over the industrial facility's emissions.

Systematic environmental monitoring and surveillance of vP substances is also needed in order to track their presence in the environment, including any build-ups, e.g., as part of an early warning system. The so-called WATCH List under the 2000 **Water Framework Directive** is an example of an instrument that could be adapted for such a purpose, though additional analytical methods may be needed to detect the range of vP substances of concern.

An additional gap in the EU regulatory regime is the lack of standards in the **Drinking Water Directive** for PFAS and the other vP substances now showing up in Europe's waters. PFAS have already been found in water resources used for drinking water in Germany, the Netherlands, and Sweden. Without limit values for PFAS in drinking water and EU-wide monitoring for the presence of PFAS in water, the number of other EU residents with drinking water supplies contaminated by PFAS and other chemical substances cannot be known. EU legislation for food contact materials and for contaminants in food stuffs is also in need of revision to include health-based limit values for e.g. PFAS and brominated flame retardants.

Identified gaps and inconsistencies in current policy/legislation

The current EU regulatory framework is insufficient for protecting human health, environment and natural resources from risks of exposure due to accumulations of very persistent substances. Four types of gaps were identified:

1. **Gaps in identifying and regulating vP substances.** Testing of chemicals to determine their half-lives is time consuming and costly, and no common framework for comprehensive screening of substances for persistence has been agreed on EU level. REACH does not require data on persistence for low volume substances. Moreover, the role of vP substances in combination effects and cumulative exposures is not adequately considered.

2. **Gaps in regimes to protect the ecosphere from releases of vPs.** Controls over releases of pollutants during manufacturing or production are usually in the form of emission limit values (concentration levels). In the case of vP pollutants, strict controls over any releases may be needed to prevent substances from building up in the environment. Related to this is the lack of controls over vP substances used in certain products, such as in cosmetics or textiles, which will end up being released into the natural environment via wastewater discharges.
3. **Deficits in controlling vP substances in the technosphere.** In general, product regulations often do not evaluate the risk of a vP during a product's entire life cycle – just the risk associated with the exposure to the chemical during the use phase. Failure to take account of the substance's fate at end of product life risks build-ups of vP substances in waste materials recycled as part of the circular economy and which could form reservoirs for future exposure.
4. **Deficits in protecting human health and in addressing vP build-ups in the ecosphere**. Systematic monitoring is not carried out to spot the presence and/or build-up of vP chemicals in environmental media and biota, including humans. For example, the Groundwater and Drinking Water Directives do not set criteria for maximum allowable levels of vP substances, so build-ups of vP pollutants in water resources are not given sufficient attention. EU food safety legislation also lacks monitoring requirements and limit values for a number of vP substances.

Conclusions

The traditional approach in chemicals legislation has been substance by substance regulation, which is too time-consuming and not adequate to handle the range of chemicals known to be very persistent. The risk is that by the time action covering all of the problematic chemicals is taken, concentration levels in the environment will have reached levels where health or environmental impacts occur, and reversibility of contamination would take a very long time (depending on the nature of the chemicals involved) and be very costly to society, or may no longer be possible.

Very persistent chemicals released into the environment can render resources such as soil and water unusable far into the future as well as damaging ecosystem services. In the context of an increasingly resource-constrained world, preserving the usefulness of these essential resources appears important. Related to this, limiting the presence of persistent chemicals in products is an important consideration of the circular economy package, in order to avoid its goals being undermined by the accumulation of persistent chemicals in material recycling streams.

For these reasons, from the standpoint of public health, environmental protection and economic growth, it appears desirable to take a more precautionary and proactive approach and to prevent and/or minimize releases of vP chemicals in the future.

One possibility could be to make it a principle to avoid the production and use of very persistent chemicals where persistence is not required and where release into the environment is likely to take place, e.g. for use in cosmetics or consumer textiles. If persistence is needed for a specific use, manufacturers and down-stream users could be required to justify this. There may also be a need for some type of very strict authorisation requirement –something that would allow only so-called essential uses where persistence was required, and where manufacture and use was carried out in closed systems. Systems for recovery and destruction of the persistent chemical would also need to be in place, for production wastes and to ensure end-of-product life disposal.

5.4 THE PROTECTION OF VULNERABLE GROUPS

This section presents key findings from the sub-study c final report on *protection of children and vulnerable groups from harmful exposure to chemicals*, prepared by Milieu.

The problem

Certain groups of the population – such as children, pregnant women, the elderly, and certain categories of workers – are particularly vulnerable to the risks stemming from chemical exposure, and, as such, have a higher probability of developing adverse health effects throughout their life. This increased vulnerability depends on a variety of reasons, spanning from specific behaviours, increased sensitivity to chemicals, specific biophysical characteristics, health status, constant exposure to highly hazardous chemicals, lower ability ability to protect themselves from exposure, and social factors (e.g. where a person lives or works or spends the majority of his/her time). In light of their higher vulnerability, these categories of the population need special protection from potential adverse health effects.

Key Findings

The problem

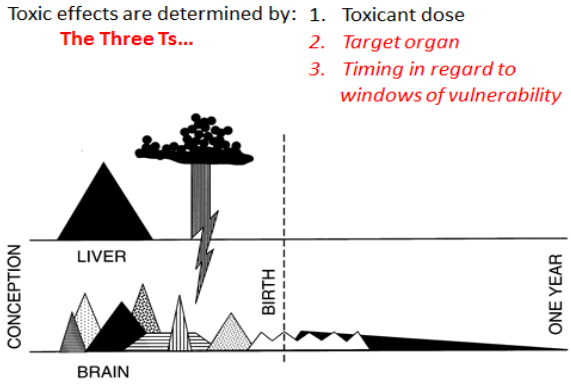
- Children, pregnant women, workers, and the elderly are particularly vulnerable to risks arising from chemical exposure, and have higher probabilities of adverse health symptoms or diseases throughout their lives.
- The developing human brain is particularly vulnerable to chemical exposures, with major windows of developmental vulnerability occurring in utero, during infancy and early childhood. During these sensitive life stages, exposure to EDCs and neurotoxins such as lead, arsenic, mercury, PCBs, pesticides, and solvents can cause lifelong neurological damage.
- Chemicals can enter the body through ingestion, inhalation, skin contact, and injection. Everyday sources of exposure include consumer products, household dust and drinking water. Toddlers, who often play or crawl on floors and carpets, are especially vulnerable because of hand to mouth behaviour.
- Lack of attention to the vulnerabilities of specific populations has led to only sporadic protective measures in the relevant pieces of legislation.

Gaps and inconsistencies

- Lack of provisions in EU legislation defining which vulnerable groups should be ensured special protection, especially for those pieces of legislation that are of particular relevance to the protection of certain groups in society from chemical exposure.
- Although the EU Toys Directive provides standards to protect children as a vulnerable group, other consumer products aimed at children such as clothing and bedding are not covered.
- Chemicals having developmental neurotoxic (DNT) properties should be further regulated in order to ensure an adequate level of protection for the foetus and children.
- Certain EU legislation, e.g. the Drinking Water Directive and Food Contact Materials Framework Regulation, are not updated with the most relevant scientific evidence and lack specific measures which could strengthen the protection of vulnerable groups.
- EU risk assessments focus on single substances and do not protect children and other vulnerable groups from combined or cumulative exposures to toxic chemicals.
- Knowledge is lacking on the toxic effects that certain categories of chemicals (e.g. Non-intentionally added substances [NIASs] and nanomaterials) can have on vulnerable groups. More research is also needed on how chemicals interfere with brain development.

Vulnerable groups

The **foetus** is particularly vulnerable to chemical exposure due to developmental mechanisms which increase both exposure and risks. These include: cellular differentiation and specialisation, rapid cell reproduction rates, the sensitive periods of development for different organ systems, the immature liver and kidney enzyme systems to metabolise, conjugate and eliminate toxicants, as well as the undeveloped blood brain barrier which does not shield the developing brain from transport of toxic chemicals. Over 200 synthetic chemicals have been detected in umbilical cord blood, including pesticides, ingredients in consumer products, food packaging, and chemical by-products from burning coal and flame retardants (EWG, 2005).



Children also have increased susceptibility to chemicals in the environment. Firstly, children have greater exposures to toxic chemicals in proportion to their bodyweight. They are constantly growing and they breathe more air, consume more food, and drink more water relative to adults. A 2011 study of British children aged 0-6 years showed that children, on average, consumed 1.6-3 times more food packaged in plastic than adults, implying a proportionally higher exposure to substances leaching from plastic food contact materials for children than adults (Muncke J, 2011). Secondly, children's ability to metabolise toxic chemicals is weaker than adults, making more difficult for them to process and eliminate residual toxic substances. Thirdly, children's early developmental processes are sensitive and vulnerable to chemicals. At certain early stages of postnatal development, exposure to environmental toxicants can lead to irreversible damage. Fourthly, children exposed to chemicals related hazards will have more time than adults to develop chronic diseases during their lifetime. Fifthly, children's behavioural patterns can exposure them to increased levels of toxic substances compared to adults, (e.g. playing closer to the ground may lead them to be exposed to toxic chemicals in household dust). Certain hazardous substances can contribute to neuropsychiatric disorders in children, with disorders of neurobehavioral development affecting 10–15% of all births, and prevalence rates of autism spectrum disorder and ADHD appeared to have spread worldwide (Landrigan PJ, et al., 2012.)

Pregnant women are vulnerable to due to the numerous physiological changes occurring during pregnancy, such as weight gain and increases in blood and plasma volume, both of which can affect concentrations of chemicals and thus lead to a greater absorption of toxins. Pregnant women, and the developing foetus, also potentially suffer major exposure to chemicals contained in personal care products, such as sunscreens, fragrances, shower gels and hairsprays, as well as to some medicine which may lead to adverse health outcomes. The cost to the EU of female reproductive disorders and diseases as a result of exposure to endocrine-disrupting chemicals is estimated at close to €1.5 billion annually. Europe-wide epidemiological evidence indicates that diphenyldichloroethene (DDE)-attributable fibroids and phthalate-attributable endometriosis affects some 56,700 and 145,000 women, respectively. This costs the EU €163 million (for attributable fibroids) and €1.25 billion (for endometriosis) per year (Hunt PA, et al., 2016).

The elderly are also vulnerable due to the ageing process, which imposes both physiological and metabolic limitations. Declines in the structure and function of the nervous system limit their ability to respond to, or compensate for, toxic effects. Furthermore, decreased liver and kidney function increases the likelihood of not being able to metabolise or excreate toxic substances. Concentrations of certain toxic chemicals – lead, palladium, cadmium and mercury - appear to increase with age ((Croes, 2014); (Alimonti, 2011); (Lee, 2011)). Further, elderly also tend to suffer from certain medical conditions where chemicals exposure might aggravate the symptoms. An example of this is cadmium exposure aggravating osteoporosis. In addition, the elderly often spend the majority of their time indoors, so that their main source of exposure to pollutants comes from household products. Inadequate ventilation in elderly care centres further increases the risk of absorption of toxic substances.

Certain categories of **workers** might be more vulnerable to chemical exposure than the general population due to: constant exposure to hazardous chemicals in certain occupations, language barriers which may hamper access to safety and health information, poor working conditions which increase the likelihood to be exposed to toxic chemicals, lack of training on safety standards, lack of access to preventative services, as well as working at client premises with changing or unregulated conditions. Migrant workers, young workers, pregnant workers and those with certain medical conditions are particularly vulnerable. Other workers may also be vulnerable at certain times, e.g. when conducting high risk, non-routine work activity such as maintenance work involving chemicals.

Lower socio-economic groups (e.g., low income, minority andcertain indigenous groups) bear multiple sources of chemical exposure and disease burdens associated with where they live, work, or play which can increase their risk of adverse health outcomes. For instance, some studies have found that low-income, or indigenous populations often live in areas where the concentration of pollution is higher (e.g., high-traffic roadways, industrial sites, hazardous waste sites or in housing with higher exposure to hazardous chemicals) than the average population, which increases their risk of chemicals exposure. It is also worth noting that people with low incomes may not have the same level of education, language competence or access to health care as those in higher socioeconomic groups, which in turn might contribute to higher exposure as well as the adverse outcomes of this.

People with **medical conditions** or with a **disability** may also have particular susceptibilities to chemical exposure. For instance, atopic people are more likely to develop respiratory symptoms as a result of inhaling irritant or sensitising materials. People suffering from cardiovascular diseases are more vulnerable to particles and persons suffering from asthma and other respiratory diseases are more susceptible to several air pollutants. Likewise, decreased liver metabolism or kidney function, as may occur in the elderly, may also be prevalent in younger people with medical conditions that impair their metabolic or excretion capacities.

Routes of exposure

Exposure is defined as the contact of an individual with a chemical substance for specific durations of time. It can be described in terms of intensity, frequency, and duration (WHO, Summary of Principles for Evaluationg Health Risks in Children Assocaited with Exposure to Chemicals, 2011). A chemical can make contact with or enter the body and constitute a risk to a person's health through four major routes: ingestion, inhalation (breathing), skin contact and injection. Exposures also occur through the placenta and breast milk. The route of exposure is important to consider as it often predicts which organ system or part of the body will be affected directly or later in life.

Ingestion can involve swallowing contaminated mucus expelled from the lungs, or eating and drinking contaminated food. Food and drink are frequently contaminated by contact with unwashed hands, gloves or clothing, or by being left exposed in the workplace. Children and the elderly are more susceptible to the ingestion of chemicals products because of their behaviour and differences in some physiological parameters.

Inhalation of contaminated air is one of the most common ways of chemicals entering the body. Chemical vapours, gases and mists, which reach the alveoli in the lungs, pass into the blood stream and are distributed around the body where they may cause a wide range of adverse effects on human health. Inhalation exposure can involve indoor as well as outdoor pollutants.

I**ndoor air pollution** is responsible for 2 million deaths per year globally (WHO, Air Pollution, n.d.) where the major sources are combustion for heating and cooking purposes as well as sources in the outdoor environment. Groups particularly susceptible to indoor air pollution include children, pregnant women, the elderly, and people suffering from respiratory and cardiovascular diseases. Genetic traits, nutritional status and lifestyle factors may also contribute in making certain population groups more

vulnerable. A particular area of concern is **indoor dust**, which can harbour a cocktail of toxic chemicals linked to increased risk of a range of adverse health hazards, including endocrine disruption, cognitive and behavioural impairment, cancer, asthma, and immune dysfunction.

Outdoor air pollution is a significant and increasing consequence of the inefficient combustion of fuels for transport, power generation and other human activities like home heating and cooking. According to the World Health Organisation (WHO), urban air pollution causes significant health problems throughout Europe, reducing the life expectancy of residents of more polluted areas by over one year. The six main outdoor pollutants of concern are: ozone (O3), particulate matter (PM10 and PM2.5), lead, sulphur dioxide (SO2), carbon monoxide (CO) and nitrogen oxide (NO2). The most vulnerable people to the effects of outdoor pollution are children and elderly.

Chemicals can also enter the body through **skin contact**. Organic and caustic (alkaline) chemicals can soften the keratin cells in the skin and pass through this layer to the dermis, where they are able to enter the veins and hence the blood stream. Areas of the body such as the forearms, which may be particularly hairy, are more easily penetrated by chemicals since they can enter the small duct containing the hair shaft. Chemicals can also enter through cuts, punctures or scrapes of the skin since these are breaks in the protective layer. In some instances, chemicals may enter by accidental injection through the skin. Once in the blood stream, the chemicals can be transported to any site or organ of the body where they may exert their effects. Female adolescents, pregnant women, children and workers are particularly vulnerable to chemical absorption through the skin.

Particular routes of exposure

The **placenta** is a key organ for the growth and development of the embryo and foetus during pregnancy. While originally the placenta was thought to shield the cord blood and the developing foetus from most chemicals and pollutants in the environment, this has now proved to be untrue. Any toxic substances that the mother is exposed to might be transported to the foetus. In particular, the placental transport can in fact be either a passive diffusion for smaller molecules that are lipid soluble or an active transport for substances that are larger and/or electrically charged. Moreover, since the foetus has an immature metabolism and it is thus unable to detoxify substances efficiently, the role played by the placenta is crucial insofar it determines the substance exchanged between the mother and the foetus. Lead, ethanol (alcohol), and compounds in cigarette smoke are all examples of substances that are likely to be transferred through the placenta.

Breast milk provides a range of benefits for the growth, immunity, and development of the infant. It contains powerful immune factors that help infants fight infections, as well as growth factors that appear to influence brain development and increase resistance to chronic diseases such as asthma, allergies, and diabetes. However, breast milk can be also a source of chemical exposure. Since the 1950s, scientists are aware of the widespread contamination of human breast milk, as a consequence of decades of inadequately controlled pollution of the environment by toxic chemicals. Polychlorinated biphenyls, perfluorinated compounds, dioxins, dibenzofurans, polybrominated diphenyl ethers, and bisphenol A (BPA) are among the toxic chemicals most often found in breast milk. The level of risk to infants and children of exposure to chemical residues in human milk depends on the food consumption patterns of the mother, the nature and levels of chemical residues in her milk, and the toxicological potency of those chemicals.

The EU policy and legislative framework

The **7th Environmental Action Programme** (7th EAP) stresses the need to "*develop a comprehensive approach to minimising exposure to hazardous substances, in particular for vulnerable groups, including children and pregnant women*". The EU is equipped with a comprehensive regulatory framework to protect human health and the environment from the risks associated with chemical exposure, including **REACH** and **CLP Regulations** and specific pieces of legislation regulating particular groups of chemicals, such as biocides, pesticides, pharmaceuticals or cosmetics.

However, the EU chemicals regulatory framework is fragmented as far as the protection of vulnerable groups from chemical hazards is concerned. A range of provisions, spread across different legal acts, refer to the importance of protecting vulnerable people from chemical exposure. Most of these provisions stress the need to protect vulnerable groups in a general way, such as recital 12 of the REACH Regulation, or recital 8 of the Plant Protection Products Regulation. Other provisions are more specific, and require concrete actions to be taken, such as Article 33 of the CLP Regulation which establishes that '*packaging containing a hazardous substance or a mixture supplied to the general public shall not have either a shape or design likely to attract or arouse the active curiosity of children*'[23], or article 6 of Council Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding, which prevents pregnant and breastfeeding workers to be obliged to perform duties for which the assessment has revealed a risk of exposure of toxic chemicals.

The EU legislation does not have a comprehensive definition of the groups in society that require specific attention and/or protection from the risks stemming from chemical exposure. The only two EU Regulations which define vulnerable groups are the Plant Protection Products Regulation (Art. 3) and the Biocidal Products Regulation (Art. 3). Yet, while these definitions offer a strong basis for describing population groups that are particularly vulnerable to chemical exposure, they do not cover all groups identified in the study and they only apply as far as pesticides and biocides are concerned.

The EU legal framework also features legislation that, despite dealing with chemicals and having the protection of human health as a general objective, nonetheless does not contain any direct references to vulnerable groups. Among these are the Drinking Water Directive, and the Food Contact Materials Regulation. The **Drinking Water Directive**'s Annex I, part B (chemical parameters) only contains 25 chemicals of concern for both general and vulnerable populations - such as arsenic, cadmium, chromium, lead and mercury. But other chemicals of concern, such as the highly fluorinated substances, are not included in the list.
The **Food Contact Materials Regulation** also has gaps with specific EU rules set for only 5 of the 17 types of food contact materials. Such rules usually involve more specific requirements for safety assessment and limits for the maximum migration of chemicals into the food, important for the protection of vulnerable groups.

EU risk assessment
Chemicals regulation depends on a hazard identification and a risk assessment procedure to estimate the extent of the exposure and on that basis the probability of harm as well as its possible severity. On the basis of such assessments, measures can be set in place to manage the known risks so that they are at levels considered acceptable (safe) to humans and the environment. But controlling the risk of harm is a moving target, given that quantities of chemicals and subsequent exposures are likely to increase dramatically. Moreover, risk assessments, usually carried out by a chemical's proponents (e.g., the producer), often underestimate the risk of harm. Additional scientific research into the possible hazards posed by chemicals almost always leads to increased (and seldom to lessened) concern over risks to human health and the environment.

Moreover, recent studies have pinpointed the detrimental effects caused by combined exposure to certain chemicals on the foetus which can ultimately lead to persistent pathological diseases later in life (Govarts E., *et al*., 2016). As such, these studies stressed that risk assessment based on single substances alone is not to sufficient to interpret the effects that combined exposure may cause on human health, and thus urged policymakers to develop a cumulative risk assessment which could take into account all chemicals, spanning from pesticides, to industrial chemicals, and environmental contaminants (e.g. food, cosmetics, dust, and other sources) (Hass U., *et al*, 2017).

[23] CLP Regulation (EC) N0 1272/2008.

Identified gaps and inconsistencies

Despite the policy and legislative measures and other activities put in place, the protection of vulnerable groups is insufficient. The following major gaps were identified:

1. Lack of provisions in EU legislation defining which vulnerable groups should be ensured special protection, especially for those pieces of legislation that are of particular relevance to the protection of certain groups in society from chemical exposure.
2. Although the EU Toys Directive provides standards to protect children as a vulnerable group, other consumer products aimed at children such as clothing and bedding are not covered.
3. Certain EU legislation, e.g. the Drinking Water Directive and Food Contact Materials Framework Regulation, are not updated with the most relevant scientific evidence and lack specific measures which can strengthen the protection of vulnerable groups.
4. EU risk assessments typically focus on single substances and do not consider the risks to children and other vulnerable groups from combined exposure to toxic chemicals. Therefore, a regulatory approach for cumulative risk assessment needs to be developed.
5. Chemicals having developmental neurotoxic (DNT) properties should be further regulated in order to ensure an adequate level of protection for the foetus and children.
6. Knowledge is lacking on the toxic effects that certain categories of chemicals (e.g. non-intentionally added substances(NIASs) and nanomaterials) can have on vulnerable groups. More research is also needed on how chemicals interfere with brain development.

Conclusions

Despite the many policy and legislative measures now in place at EU level, the protection of vulnerable groups from harmful exposure to chemicals remains sporadic and a wider approach is required. For instance, the EU legislation covering food contact materials has gaps; it does not regulate 12 of the 17 types of food contact materials listed in the Regulation, some with substances that may migrate into food and result in exposures associated with adverse health effects on children. Challenges also exist with respect to chemical risk assessment for vulnerable groups, whose consumption patterns and exposure levels may differ significantly according to age group, geographical location, and lifestyle factors, and who may be exposed to multiple chemicals over time.
The review of scientific and grey literature revealed a wealth of information and data collected in recent decades on these topics. However, the scientific community has tended to focus on the same substances (e.g. copper, lead, zinc, cadmium, iron, nickel, chromium, etc.). There is a need to study additional substances and new areas, such as the health impacts of nanomaterials and chemical mixtures on certain categories of the population. With respect to certain industrial chemicals known to have neurotoxic properties, it may be necessary to apply the precautionary principle in order to sufficiently protect vulnerable groups such as foetuses and children.

Finally, the general public, producers and politicians need to become more aware of the importance of protecting certain groups in society from harmful chemical exposure. This is particularly important in respect of people's daily chemical exposure in their everyday environment, including schools, playgrounds, offices, hospitals and care facilities. Improving labelling and packaging of consumer products would also help to raise awareness of the potential harmful effects of exposure to certain ingredients or compounds. For instance, there is room for the EU to develop innovative measures and advice to further reduce exposures to neurotoxic chemicals (e.g. arsenic), in particular in pregnant women and small children.

5.5 OTHER EXISTING AND EMERGING HEALTH CONCERNS

The sections below describe other specific existing and emerging health concerns related to particular classes of chemicals, their unique properties or their specific effects.

5.5.1 Combination toxicity

Scientific evidence is mounting that the exposures from everyday products, including articles, are exposing modern society to multiple hazardous chemicals, and that these chemicals, even at low dose levels, can give rise to subtle but long-term health effects such as reduced fertility, lower birth weights and neurodevelopmental diseases. Chemicals with common modes of action may act jointly to produce toxic combination effects that are larger than the effects of each of the mixture components applied separately.

However, EU current risk assessments (RA) of chemicals focus on exposure to individual chemicals and do not provide a comprehensive and integrated assessment of cumulative effects of different chemicals, taking into account different sources and routes of exposure. The 2012 Commission Communication on Combination effects of Chemicals (Chemical mixtures) acknowledged the current limitations of assessing compounds individually and proposed a path forward to ensure that risks associated with chemical mixtures are properly understood and assessed. The new Commission approach draws heavily on the 2012 opinion on "Toxicity and Assessment of Chemical Mixtures", issued by the scientific committees SCHER, SCENIHR and SCCS. The report notes that the number of potential combinations of the toxic substances currently in commerce is astronomical and suggests that risk assessors focus on those situations where the potential for negative impacts is highest. This would require an initial filter to allow a focus on mixtures of potential concern. Though extensive gaps regarding knowledge and data (mainly related to the mode of action and exposure data) limit the extent to which mixtures can be properly assessed, the information being collected in the context of the REACH Regulation will contribute to reducing current uncertainties.

Other frameworks for the assessment of chemical mixtures have been developed by international bodies in recent years. For instance, a WHO/IPCS workshop resulted in a widely-accepted approach or framework for risk assessment of combined exposure to multiple chemicals that could be adapted to the needs of specific users. However, its use is often hampered by large data gaps on exposure as well as hazard information.

Although methodologies for assessing the combination effects of chemicals are being developed and applied by scientists and regulators in specific circumstances (Meek, 2011); (Price, 2012)), a systematic, comprehensive and integrated approach across different pieces of legislation is still not in place. While frameworks such as the ones described above may provide high-level guidance as well as tiered approaches for screening-level assessments and further refinements, their application for performing higher tier assessments are limited due to lack of data (Kienzler, 2016)

5.5.2 Endocrine-disrupting chemicals

Endocrine-disrupting chemicals (EDCs) represent a unique kind of toxicity. They are referred to by WHO as "…*exogenous substances or mixtures that alter function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub) populations*" (WHO-IPCS, 2002). The chemical disrupts hormone action, and can do so in three different ways:

- Mimic or partly mimic naturally occurring hormones in the body like oestrogens, androgens, and thyroid hormones, potentially producing overstimulation.
- Bind to a receptor within a cell and block the endogenous hormone from binding. The normal signal then fails to occur and the body fails to respond properly.
- Interfere or block the way natural hormones or their receptors are made or controlled, for example, by altering their metabolism in the liver or by acting directly on the proteins that control the delivery of a hormone to its normal target cell or tissue.

Most of the research conducted studying the impacts of endocrine disruptors have so far focused predominantly on the interaction of EDCs with the reproduction and thyroid hormone systems. A

growing number of studies, however, indicate that endocrine disruptors can also affect other systems, such as neural and reproductive systems. Associations with weight gain, insulin sensitivity and glucose tolerance indicate a potentially important role for endocrine disruptors in immune, digestive, and cardiovascular systems, and a possible role in the development of obesity, type 2 Diabetes and metabolic syndromes, all conditions associated with major public health impacts and socioeconomic costs.

Examples of EDCs are industrial lubricants and solvents and their by-products: polychlorinated biphenyls (PCB), polybrominated diphenyl ethers (PBDE) and dioxins such as 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD); plastics components: bisphenol A (BPA) and bisphenol S (BPS); plasticisers: phthalates; pesticides: atrazine, cypermethrin, dichlorodiphenyltrichloroethane, dieldrin, methoxychlor (MXC) and vinclozolin (VCZ); and drugs: diethylstilbestrol (DES) and ethinyl oestradiol (EE), as well as non-steroidal anti-inflammatory drugs (NSAID) and acetaminophen. Natural chemicals such as genistein, a phytoestrogen and heavy metals can also have endocrine-disruptive effects (Marques-Pinto & Carvalho, 2013). EDCs have diverse applications and thus come from a variety of sources, such as flame retardants, plasticizers, pesticides, preservatives, pharmaceuticals, clothing, and food contact materials, cosmetics and personal care products (shampoos and other hair products, toothpaste, soaps, lotions). Importantly, humans are not only exposed to EDCs through direct usages or consumptions. Such chemicals might also be dispersed during production, use and disposal and hence lead to human exposure via the environment.

The Commission adopted its first Strategy on Endocrine Disruptors in 1999. While EU legislation does take account of endocrine disruptors via the authorisation of chemical substances used in plant protection products, biocidal products, Annex XIV of REACH, and cosmetics, formal criteria for identifying substances with endocrine-disrupting properties have not yet been established, internationally or at EU level. For this reason, on 15 June 2016, the EC issued two draft legal acts – one under the Biocidal Products legislation, the other under the Plant Protection Products legislation – which set out the criteria to identify endocrine disruptors. The two draft legal acts are currently being reviewed by the Parliament and the Council under the relevant procedures for the adoption.

5.5.3 Nanomaterials

Nanomaterials are chemical substances or materials at a very small scale (some 10,000 times smaller than the diameter of a human hair). Some manufactured nanomaterials are developed to exhibit novel characteristics (such as increased strength, chemical reactivity or conductivity) compared to the same material without nanoscale features. The special properties of nanomaterials have led to their use in many applications, including medical and technical ones. However, while nanomaterials have the potential to improve the quality of life and to boost industrial competitiveness, they may also pose risks to the human health and the environment.

At EU-level today, nanomaterials are regulated only through specific measures spread in different pieces of legislation (e.g. Novel Food Regulation, Food Contact Materials Regulation, Cosmetic Regulation, etc.). Other than the European Commission Recommendation on the definition of a nanomaterial, no overarching nanotechnology-specific legislation is in place.

Due to their special properties, nanoparticles are able to enter the human body through several routes, and, consequently, they can damage human health in a range of different ways ((Niwa, 2007); (Oberdorster, 2005);. However, there is scientific uncertainty about the exact health risks associated with exposure to nanomaterials. There is also debate about whether standard procedures of risk assessment need to be modified in light of the special features of nanomaterials. Some argue that, given their special properties, together with the fact nanomaterials share no common characteristics besides the nano-scale size, the safety assessment of nanomaterials should be carried out on a case-by-case basis (Rock, 2008). There is also a lack of analytical methods for the detection of nanomaterials

in products as well as in biota and the environment.

While the literature search carried out for this project did not find studies looking at the effects of nanomaterials on specific vulnerable groups, nonetheless, certain groups have been identified as being particularly vulnerable to the effects of nanomaterials, in particular when inhaled as fine dusts. Among these groups are:

- People with pre-existing diseases (such as asthma, diabetes, among others), who may be more prone to toxic effects of nanoparticles;
- Children, as nanomaterials may interact with them in ways that differ from adults;
- Workers, especially those working in nanotechnology related industries as well as in waste management and recycling, who may be exposed at (much) higher levels than the general public and on a more consistent basis.

It is not known how many nanomaterials are being assessed for risk. REACH in fact does not explicitly require registrants to provide separate dossiers for a bulk substance and its nanoform(s) and it also does not set specific information requirements for the nanoforms of bulk substances in registration dossiers. In practice, very few registration dossiers include references to the nanoform of bulk substances, and the only supporting information from testing and risk assessment are those applying to the bulk substance, despite the potentially different characteristics of the nanoform. The current revision of the REACH Annexes is attempting to address the issue of inadequate identification and/or characterisation of nanomaterials. However, even if nanomaterials do become required to be registered under REACH, registrants will experience difficulties in providing adequate information. While many of the REACH testing strategies and standard test guidelines are in principle applicable to nanomaterials, the current natural science understanding of the environmental fate of nanomaterials is limited. Without further guidance on nanomaterials specific testing issues, assessment of their environmental and health risks will have gaps (Ricardo, 2016).

It is important to keep in mind that assumptions about how chemical substances behave once they have been used in the final product do not necessarily apply to nanomaterials. For example, even fundamental properties, such as magnetism in nanoparticles made of materials that are non-magnetic in bulk form, are still being discovered. Therefore, despite the availability of a wide range of scientific studies, more research is needed before we can fully understand the health risks that nanomaterials – nowadays used in hundreds of products world-wide - may pose to human health. As a recent study concluded: "*until we understand what realistic environmental concentrations [of nanomaterials] are likely to be, we don't really know what the impacts are*" (Garner, 2015).

5.6 EMERGING ENVIRONMENTAL CONCERNS

5.6.1 The concept of planetary boundaries

The concept of planetary boundaries developed by the Stockholm Resilience Centre stresses the need for humanity to live within the boundaries of our planet[24]. The initial work defined nine (9) areas as planetary boundaries to avoid "unacceptable global change" and to secure "a safe operating space for humanity". Five of the nine planetary boundaries identified involve chemical agents: ozone depletion (halocarbons), climate change (CO_2, CH_4 and other agents with global warming potential), the nitrogen and phosphorus cycles, ocean acidification (CO_2) and chemical pollution. The other planetary boundaries are atmospheric aerosol loading, freshwater use, land use change and biodiversity loss.

The 2009 study that introduced the concept proposed thresholds for seven of the parameters beyond

[24] Rockström J., *et al.* 2009.

which non-linear, abrupt environmental change could occur on a planetary scale. Several of these boundaries have been far exceeded, e.g., climate change, biodiversity and phosphorus cycles. The study was not able to determine boundary levels for chemical pollution. In an updating of the planetary boundary concept, the term '**chemical pollution'** has been renamed as '**introduction of novel entities'**, to include other potential human-driven global risks such as the release of radioactive materials, nanomaterials and plastics. The Stockholm Resilience Centre website notes (Steffen, 2015):

> "*These compounds can have potentially irreversible effects on living organisms and on the physical environment (by affecting atmospheric processes and climate). Even when the uptake and bioaccumulation of chemical pollution is at sub-lethal levels for organisms, the effects of reduced fertility and the potential of permanent genetic damage can have severe effects on ecosystems far removed from the source of the pollution. For example, persistent organic compounds have caused dramatic reductions in bird populations and impaired reproduction and development in marine mammals.*"

The problem of ignorance is an important factor, in that the disruptive effects are not discovered until they already occur on a global scale and are affecting a vital earth system process. The depletion of the stratospheric ozone layer because of the production and release of halocarbons is cited as a clear example of a global-scale environmental impact that no one foresaw at first. This argues for a regulatory approach based on hazard rather than risk, including the PBT and vPvB classifications, and the Stockholm Convention's definition of a POP (PBT and subject to long-range transport), with a focus on persistence (Persson, 2013).

The work to quantify chemical pollution boundaries, or thresholds, has been difficult to progress, given the vast number of commercial chemicals and the complex linkages between emissions, environmental concentrations, exposures and adverse effects to species and ecosystems. The critical point is that the assimilative capacity of the earth in terms of being able to degrade or immobilise human-released chemicals is limited at the global level, even for biodegradable chemicals. Based on this, studies have emphasised the need for a preventative approach (Diamond, 2015; MacLeod, 2013).

5.6.2 The contribution of chemical pollution to a loss of biodiversity, contamination of natural resources, and resilience of ecosystems

The 2005 Millennium Ecosystem Assessment provided a framework that acknowledges biodiversity as one key factor for ensuring the continuous supply of ecosystem services and facilitating ecosystem stability, such as formation and retention of agricultural soils for food cultivation and purification and detoxification of water resources. Biodiversity and ecosystem services that may be adversely affected by chemical pollutants include the pollination of crops and natural pest control carried out by insects and other animals. For example, pesticides and their use in intensive farming systems have long been linked to biodiversity loss, mainly due to loss in regional diversity of invertebrates. Analysis shows that pesticides currently used in Europe and Australia may cause the decline of up to 42% of stream invertebrate species (Beketov, M.A. et al., 2013). Other studies have suggested a link between POPs and immune system deficiencies of Arctic mammals and reproductive effects of TBT (AMAP, 2004). The top predators that help to maintain balance and biological diversity in ecosystems, as well as provide value for recreation and ecotourism, are particularly vulnerable to chemical pollution due to their position in the food chain (European Commission, 2017).

Trace metals and heavy metals such as cadmium, mercury and lead can harm aquatic organisms through lethal and sub-lethal effects, and can reduce or eliminate species in ecosystems through increased susceptibility to disease and mortality, and decreased fecundity. Lead in ammunition is a useful example of how a specific use of lead can result in significant annual deposits in the environment, where it contaminates soils and waterways, and may be bio-accumulated by soil-based organisms, putting vegetation, invertebrates and other organisms at risk.

Organic contaminants such as pharmaceuticals, insecticides, surfactants, and endocrine disruptors (including hormones) in wastewater being released in surface water – even if present only at trace levels – can cause widespread contamination of freshwater supplies. The case of increasing concentrations of highly fluorinated chemicals in groundwater illustrates the inability of a natural resource to recover when the contamination is in the form of very persistent chemicals.

The resilience of an ecosystem is its capacity to respond to a perturbation, disruption or disturbance by resisting damage and recovering quickly. This is a particularly important concept for examining the potentially disruptive role chemicals can play and whether ecosystems can resist damage or recover and in what time frame. Note that the ability of an ecosystem to recover depends on how persistent the chemical is in the environment or ecosystem.

An important example of the complexity in the provision of ecosystem services is the case of pollinating insects or birds nesting within the vegetation of agrarian habitats which provide important pest control in agricultural fields. Herbicides drifting to off-target areas may affect sensitive non-target plants and thereby the vital ecosystem services of various species, and eventually affect the entire food web through complex mechanisms and interlinking systems. Along these same lines, systemic insecticides, thought to have less toxic properties to humans, affect decomposition, nutrient cycles, soil respiration and invertebrate populations valued by humans. Invertebrates, particularly earthworms that are important for soil processes, wild and domestic insect pollinators, and several freshwater taxa which are involved in aquatic nutrient cycles, were all found to be highly susceptible to lethal and sub-lethal effects of neonicotinoids and/or fipronil at environmentally relevant concentrations (Chagnon, 2015) .

The ecosystem services concept is increasingly being used in policy development processes, for example, the EU Biodiversity Strategy, "Our life insurance, our natural capital", with its headline target of halting biodiversity loss and the degradation of ecosystem services. However, much of the research conducted so far has focused on a nature conservation perspective. Development of effective approaches for assessing and managing chemical risks to ecosystems services will require more systems thinking and an ability to recognise and address the complex interrelationships among single and multiple stressors across different spatial scales (global, regional and local).

5.6.3 Chemical pollution and climate change

The Intergovernmental Panel on Climate Change (IPCC) has noted a number of impacts related to chemical pollutants and climate change. Positive impacts related to synergies with measures to mitigate greenhouse gas pollution include improved energy efficiency and cleaner energy sources, leading to reduced emissions of heath damaging, climate-altering air pollutants (IPCC, 2014). However, climate change is expected to reduce the quality of freshwater resources, due to increased pollutant loadings from heavy rainfall and increased concentrations of pollutants during droughts. This will pose risks to drinking water quality even with conventional treatment (*medium evidence*, *high agreement*), including increases in sediment, nutrient and pollutant loadings due to heavy rainfall, reduced dilution of pollutants during droughts, and disruption of treatment facilities during floods. Among other deleterious effects, terrestrial, fresh water and marine ecosystems are predicted to face increased extinction risks, especially as climate change interacts with other stressors such as inter alia over-exploitation and e.g. chemicals pollution.

A 2009 workshop organized by the Society of Environmental Toxicology and Chemistry (SETAC) concluded that the fate, transport and sources of chemical substances of concern are expected to change considerably (Balbus et al., 2013), albeit by different magnitudes, affecting the contamination of air, water supplies and food resources. An overall increase in exposure to chemicals is predicted, which will have important repercussions on human health and the environment.

POPs. The fate and behaviour of persistent organic pollutants (POPs) are highly impacted by climate change (Macdonald et al., 2003). A UNEP report stresses that efforts to reduce the release of POPs into the environment can be undermined by climate change, e.g. higher temperatures will affect the transport, fate and behaviour of POPs (UNEP, 2011). The degradation of POPs will increase, but this will probably go hand in hand with the formation of new transformation products. The long-range availability of POPs will increase as a result of various atmospheric processes and changes in climate will also alter exposure of humans and wildlife to POPs. Concentrations in aquatic environments might decrease, resulting in higher concentrations in the atmosphere. In addition, higher temperatures will result in melting of permafrost and ice caps, in turn triggering release of previously contained POPs in these natural reservoirs (Noyes et al., 2009). In sum, the risk assessments done originally may no longer hold up to scrutiny.

Pesticides. Agriculture contributes to climate change and climate change will directly affect agricultural practice. Increased volatility and faster degradation could reduce pesticide concentrations in soil and aquatic environments, which might result in higher dosages and/or more frequent use of pesticides (Delcour et al., 2015). Additionally, extreme weather events like flooding and storms might increase contamination of water and soil due to increased pesticide run off. Climate change will also impact pest populations as well as location and types of crops, which might necessitate a wider geographical application of pesticides, exposing areas that have been previously unaffected by pollutants.

Air Pollution. Several studies suggest that toxicity of ground-level ozone and particulate matter will increase due to climate change and potentially endanger human health, especially for vulnerable populations like elderly and children. For example, higher levels of ozone were recorded during the 2003 heatwaves in Europe. Extreme weather events resulting from climate change are similarly expected to increase pollution levels in urban areas. For example, wild fires resulting from increased temperatures and dry periods will also affect air quality. Indoor air quality will also be affected, since increases in outdoor concentrations of ozone and other pollutants is likely to result in higher concentrations indoors.

Heavy Metals. Climate change is also expected to affect the long-range transport potential of heavy metals. For one, the deposition of mercury to the Arctic is predicted to decrease with a warmer climate (Hansen et al., 2015). In parallel, effective measures aiming to mitigate climate change will further reduce mercury in the atmosphere, resulting in lower depositions. However, interactions of climate change with other factors might also influence these processes, such as release of mercury from melting glaciers which could potentially increase concentrations of this toxic chemical in the environment. In addition, temperature variability may increase sensitivity to toxicants such as cadmium (Kimberly, 2014).

Indirect Impacts. Climate change is expected to have more subtle, secondary impacts on how pollutants interact with environment in general and human populations. It should be considered not only as a trigger but also an intensifier of risks from stressors and pollutants. In some cases, changes in climate might alter the tolerance levels of an organism for toxic pollutants (climate induced toxicant sensitivity), while in other cases exposure to toxic chemicals might alter the tolerance of an organism for stressors related to climate change (toxicity induced climate sensitivity). Since exposure to toxic chemicals can suppress immune system functions, this could reduce resilience in the face of climate induced changes to stressors like vector borne diseases. In addition, higher temperatures are likely to increase vulnerability for cardiovascular respiratory disease linked to air pollutants.

Extreme weather events related to climate change, such as heavy precipitation and flooding, may also result in increased exposure to chemical pollution. Several studies mention risks related to damage to infrastructure from extreme events, which could trigger release of pollutants from landfills,

contaminated sites, sewage systems and water recycling facilities.

A Swedish Chemicals Agency report calls the complex relationship between climate and pollutants both conflicting and synergistic (KEMI, 2010). Initiatives aiming at reducing GHG emissions will have additional positive effects on reducing concentrations of toxic pollutants, e.g. increased energy efficiency and alternative energy systems will decrease the release of mercury into the environment from fossil fuel combustion. At the same time, biofuels -- seen as an alternative to fossil fuels in the efforts to contain climate change – could lead to increased use of pesticides due to intensive cultivation of such fuels. Also, though energy efficiency is crucial, the production of the rare-earth materials incorporated into efficient energy systems such as photovoltaic cells, batteries and light bulbs is associated with toxic pollutants like mercury and cadmium.

The 2015 Lancet Commission on Health and Climate formed in 2015 to provide an overview of the impacts of climate change and the policy responses necessary to tackle these impacts stressed the many co-benefits to be obtained from the efforts to fight climate change. It predicted that ground level ozone and particulate air pollutants are the elements that will be greatly affected by climate change, especially due to higher temperatures and it noted that regional variations will be significant.

The EU's current risk assessment processes for hazardous chemicals do not yet pay sufficient attention to the complex relations between the changing climate and the impact of such changes on risks posed by chemical substances. For example, higher indoor and outdoor temperatures may result in higher concentration levels of some substances and hence higher degrees of exposure, including new combined and cumulative exposure scenarios. Higher temperatures may also increase biological sensitivity to certain substances. The unpredictable nature of extreme weather events will also require a rethinking of basic notions of risk assessment and public health protection. Climate change and chemical exposure might also interact to increase the overall stress on ecosystems and biodiversity.

Attempts to mitigate and adapt to climate change will present a number of chemicals-related challenges, such as how to include risks from chemicals in assessments of new technologies, in order to avoid creating new problems. The potentially conflicting relations mentioned above will require a critical lifecycle assessment of new technologies, if policies targeting climate change mitigation and adaptation, are to be beneficial overall and not compromised by unintended negative side effects.

6 WORKSHOP PARTICIPANTS' VIEWS ON STATUS QUO AND IMPROVEMENT OPPORTUNITIES

This section intends to summarize the points of views of stakeholders in the fields covered by the different sub-studies. Their perspectives were collected during the workshop held in June 2016 and from their subsequent written feedbacks.

6.1 SUBSTITUTION, INCLUDING GROUPING OF CHEMICALS AND MEASURES TO SUPPORT SUBSTITUTION (SUB-STUDY A)

Criteria for defining sustainable substitution **-** The workshop participants felt that the definition of "sustainable substitution" and "safer substitutes" is mainly a political decision on how to weigh hazard, risk and socioeconomic arguments. The definition of what is meant with "non-toxic" environment would be already a considerable step towards the development of the strategy. The different perspectives of businesses and society may lead to different criteria. The question is therefore: how to reconcile these different perspectives to ensure the protection of the human health and the environment without hindering innovation and competitiveness of the EU industry. In the weighing process, groups vulnerable to chemicals' exposure should be carefully considered. It was also deemed that the clear definition of the function of the chemicals used in the processes/products would be a good starting point of a step by step process. Indeed, a recurrent discussion theme has been that the first important question is whether the chemical substance is needed to achieve the desired functionality. Once this has been established, the assessment could take into account not only hazards and risks during the production of the chemicals and their use in the processes/products but also life cycle impacts and other aspects, such as impact on energy consumption. These types of assessments, however, are resource and time intensive and require good quality data that, despite the implementation of the REACH Regulation, are not yet available for most of the chemicals of concern. It is however emphasised that introducing additional layers of data demands in a situation where health and environment data is still insufficient for assessments in chemicals policy might not be realistic. Transparency in the assumptions used to overcome these information gaps but also in the weighing process is of vital importance while more efforts are put on the development of the assessment methodologies and in filling the data gaps.

Assessment and data **-** Workshop participants agreed that there is a trade-off between the quality and the quantity of data needed for the assessment of chemicals and their potential substitutes. While some participants believed that life cycle impacts should be considered not only in the assessment but also in the designing of the chemicals, others considered that methodologies should be kept as simple as possible, possibly trying to enhance the available tools and not to develop new ones. Some participants expressed the opinion that a better and more inclusive stakeholders' consultation in the gathering of data and in the decision-making process of the Scientific Committees would be beneficial too, but others pointed out that in the formation of scientific evidence, stakeholders' consultation should be avoided. All data gaps should be made transparent and highlighted so that downstream users can avoid untested materials and put pressure on suppliers to fill in data gaps.

Co-ordination **-** There was a wide consensus that enhancing the co-ordination of the different initiatives on substitution and the sharing of information among scientists, industry and regulators would be very beneficial for the promotion of the substitution of hazardous chemicals and the development of safer alternatives. In this regard, participants agreed that co-ordination at EU level would be beneficial to avoid the multiplication of efforts and initiatives at national and local level, often sharing the same objectives but not the resources to achieve them. Harmonisation of the guidance documents referring to different pieces of legislation may also help in identify remaining gaps and increase awareness. The creation of a platform at European level may also be an option to

achieve this enhancement, possibly in combination with databases searchable for functionalities, hazardous properties, upcoming/current regulations of the substances, and assessment of safer alternatives. In that respect, the databases maintained by ECHA are a good starting point but are still not sufficient for substitution purposes. Collaboration across the supply chain was also seen as very important, in terms of traceability of hazardous substances along the supply chain (and in imported articles) but also for the development of safer alternatives targeted to the needs of the articles manufacturers and users. The development of best practices on the basis of successful collaborations across the supply chain (e.g. Italian glass sector, IKEA)[25] is another important tool.

Incentives **-** As highlighted in the discussion on co-ordination, information support instruments play a vital role to promote substitution. Moreover, a "shared knowledge" between chemists and toxicologists should be facilitated through the formation of university courses on green chemistry and sustainable substitution. Factual information on the hazardousness and impacts of the chemicals contained in articles should be provided to the public, avoiding the "greenwashing" phenomena and the multiplication of ecolabels. Additionally, green public procurement, but also green private procurement by large corporations with sustainability strategies, has an important role to play in rewarding innovators and thus incentivise the development of safer chemicals, shaping market demand and raising public awareness. Engaging the directors' boards of large enterprises, to change their mind sets and to commit them on green chemistry may be an important part of the strategy. Technological support should be offered to SMEs, but also incubators (see DexLeChem's experience in Berlin[26]) and easier entry to markets to innovative start-ups dedicated to green chemistry. Taxation on the production or use of hazardous chemicals also gives a clear signal to stakeholders and incentivises substitution (see Scandinavian experiences on taxation of pesticides and solvents).

Grouping strategies **-** Workshop participants recognised the importance that grouping strategies may play in avoiding regrettable substitution. Some participants suggested that, before considering grouping strategies, it should be ensured whether the use of a chemical product is necessary and its functionality not delivered by non-chemical means. As a first step, the definition of the groups is challenging and enough flexibility should be left for dealing with different situations as, in some cases, it may not be possible to obtain the same functionality from a substance not pertaining the use of chemicals from the same structural group as the substance to be substituted. Different strategies was proposed by the participants, e.g. grouping of substances of concern for certain vulnerable groups (pregnant women, children), by intrinsic properties (persistence), by effect type or mode of action (also referring to combined exposure) or by functionality/application. Some participants suggested following a tiered approach, others suggested leaving the possibility to prove that a substance from the same group is safer or requiring more information on toxicity and exposure if the substitute is from the same problematic group as the substance to be substituted. An example of a different approach is the German evaluation procedure for volatile organic compounds (VOC) from building products. All emissions must be identified and assessed according to a list of 180 chemicals with threshold values. Sometimes the industry substitutes chemicals on the list with other compounds for which no threshold values are derived. To avoid surprises (not knowing the toxicological potential of these new compounds) the authorities set a criterion to limit the emissions of unknown chemicals or chemicals without threshold values. However, industry can apply for the derogation from threshold values for this new compound. They then have to provide the German authorities with the toxicological data.

In any case, the transparency of the criteria used to define the groups as well as the objectives of the grouping strategy was deemed very important. The promotion of a public debate on which groups of

[25] The glassmakers of Murano (a Venetian island in Italy), in collaboration with the research institute of the local chamber of commerce and thanks to the funding of the Italian government, found two suitable alternatives to arsenic trioxide, a carcinogenic substance used in glassmaking that was included in the Authorisation list.
IKEA strives to ensure that its products do not contain substances included in the REACH Candidate list. In order to achieve this objective, it needs to maintain close collaboration with all its suppliers.
[26] http://www.dexlechem.com/home_en.html

chemicals should be considered for regulatory purposes may ensure more transparency in the decision-making process. At the same time, some participants suggested that downstream leading companies are already applying grouping strategies to avoid classes of hazardous substances, hinting that legislative measures are not the only way to proceed but that information based instruments and raising public awareness may be as important.

Suggestions – Based on the discussions, a range of ideas were extracted from the views of a majority of the workshop participants to be (potentially) further explored:

- Clear signals should be provided to the market. These can be in the form of economic instruments such as taxation on the use of hazardous chemicals or through the creation of a market demand for safer alternatives, using green public procurement and raising awareness along the supply chain of chemical products, starting with the directors' boards of large companies;
- A flexible approach should be followed in developing grouping strategies for regulatory purposes and research and legislative action should be prioritised on those chemical groups that raise the highest concern, because of their presence in consumer products or because of the exposure of vulnerable population groups;
- More and better co-ordination is needed at European level to increase the efficiency and effectiveness of the multiple initiatives on substitution currently ongoing at international, national and local level, across different sectors and under different legislative frameworks;
- The networking of SMEs should be promoted and market access of innovative SMEs in green chemistry should be facilitated through the provision of funds and administrative burden ease;
- Most of the workshop participants felt that the current legislative framework provides sufficient incentives to substitute hazardous substances and argued that there is no need for new legislation but there is a strong need for a better enforcement, in particular on imported articles. Some suggested that lessons can be learned from the enforcement of legislation regulating the electronics sector.

6.2 CHEMICALS IN PRODUCTS AND NON-TOXIC MATERIAL CYCLES (SUB-STUDY B)

Information flow & gaps - In general, all stakeholders agreed on the fact that the information flow on toxic substances in articles is crucial for implementing any related risk management activities and directing waste streams in a circular economy. One of the identified gaps is that the information flow with articles is limited to SVHC contained in concentrations above 0.1%. Although this information at the point of purchase is needed for consumers to exert their market power, they would appreciate information on other substances. In general, it was underlined that supply chain communication does not function well. This is particularly problematic in the waste sector, because waste treatment operators lack information to decide on treatment options, including recycling. While more research is required on the assessment methodologies and on the chemicals life cycles impacts, transparency should be ensured in the decision-making process, from the assumptions used to overcome information gaps to the criteria used in grouping strategies.

Legislative framework - Besides stakeholders pointing out that overarching and consistent legislation restricting the use of chemicals in articles is missing. This was assessed to contribute to an insufficient level of protection of humans and the environment. Furthermore, the waste sector would miss legislation requiring depollution and setting qualitative (substance-related) targets for recycled materials. Corresponding to this gap analysis, stakeholders recommended, among others to:

- develop overarching, consistent legislation on the content of and communication on toxic substances in articles along the supply chain and to consumers,
- include imported articles in all approaches limiting the content of toxic substances in articles; i.e. in particular the REACH authorization scheme,
- (support) the development of approaches to globally standardize communication on substances in

articles that may extend beyond SVHC but should not require full disclosure of content information,
- establish methods and processes to communicate information on toxic substances in articles to the waste sector that are easy to use, fit to every day practices and do not require extensive resources,
- support implementation of a circular economy by implementing qualitative recycling targets, creating markets for secondary raw materials and ensuring economic feasibility of separate waste collection and treatment approaches, including decontamination technologies, where needed,
- identify options to use the principle of extended producer responsibility to enhance the reduction of use and communication on toxic substances in articles throughout the supply chain including the waste sector,
- clarify the legal interlinks between waste legislation and chemicals /products legislation to reduce uncertainty about the applicable requirements,
- increase resources and capacities for the enforcement of provisions on toxic substances in articles and wastes, including analytical methods for compliance checking,
- implement awareness raising, education and training campaigns to support the phase-out of toxic substances and create an understanding of chemical safety in general in supply chains also outside the EU and in the public.

6.3 THE IMPROVED PROTECTION OF CHILDREN AND VULNERABLE GROUPS FROM HARMFUL EXPOSURE TO CHEMICALS (SUB-STUDY C)

Risk assessment & testing methods **-** Participants discussed whether risk assessment methods and overall risk management should be harmonized across legislation and areas, or whether specific assessments depending on the vulnerable group are more appropriate. An integrated approach for screening and testing chemicals that is low cost and yet able to review a large number of chemicals and that takes account attention of the vulnerabilities of certain populations, was discussed. A consensus could not be reached, but overall people agreed that we need to refine current approaches. Participants also underlined that there is a need to translate the scientific evidence into effective tools in order to improve the risk assessment system.

Research **-** Participants agreed that more research is not always the solution. While scientific gaps most certainly still exist, a wealth of information has already been brought together. A problem mentioned in this context was that a large share of the studies tend to focus on a rather limited number of well-known and long-studied chemicals, while studies on chemicals with more recent histories are largely missing. The scientific agenda needs to be rationalised and scientific efforts need to be channelled towards: i) the available evidence; ii) specific vulnerable groups. For that last item, there is a need to perform (more) biomonitoring studies as they are useful tools for understanding the chemical exposure levels, particularly for the foetus and breastfed child. However, it was stressed that such studies do not explain routes of exposure and sources. One of the speakers also pointed out that it would be wiser to focus on human studies, rather than animal studies. In general communication between scientists, regulators and the wider public should be strengthened (see further points on awareness raising).

Legislative framework **-** The participants agreed that the provisions of the EU legislation addressing the issue of vulnerable groups are often vague and/or not binding. The issue is addressed horizontally, leaving room for manoeuvre and failing to provide solid protection of vulnerable groups, particularly children. The majority agreed on the need to ensure more coherence between the legislation. Some participants identified specific pieces of EU legislation that need to be amended (e.g. the food contact materials and the water contact materials legislations). However, participants agreed that in the short perspective, the situation does not require an amendment of all the legislation relevant to vulnerable groups, as this solution will require time, lead to wide legal uncertainty and is politically too sensitive. Participants stressed that for most products, a proper legal framework protecting certain vulnerable

consumer groups does not exist (e.g. products for children, textile, furniture, etc.). Some participants underlined that the precautionary principle should be underpin all the legislation in this matter.

Policies & awareness raising **-** There was a consensus on the necessity of having better information about the routes of exposure, and in particular the need to raise awareness among the general public. However, it was stressed that raising awareness among the public should not result in a shift of responsibilities from politicians to consumers. It is key to involve politicians in awareness raising and prevention initiatives; they will facilitate a better targeting of certain vulnerable groups (e.g. schools, childcare centres, elderly care facilities, etc.). Specific, targeted information (campaigns) should be developed for the vulnerable groups, presented in a constructive way.

6.4 SUB-STRATEGY FOR VERY PERSISTENT CHEMICALS (SUB-STUDY D)

Criteria and evidence **–** Participants agreed that the evidence needed to identify very persistent (vP) chemicals is complex. Established degradation tests e.g. "ready test" and "inherent test" can show which chemicals are not vP. Estimation methods like the USA BIOWIN tool can be useful as training and test sets to predict persistence or screen chemicals. More realistic half-life tests, such as simulation tests of environmental compartments, are time and labour intensive, and costly. Participants highlighted the challenge of testing for persistence in very or extremely persistent chemicals i.e. using a 90-day test of biodegradability and extrapolating test data to determine how long these substances will remain in the environment, because extrapolation is associated with a degree of uncertainty. There were two main views on this challenge, on the one hand participants indicated that there is enough information available: the pursuit of better information or evidence should not impair our ability to take action or regulate. On the other hand, participants noted that we do not have enough information to assess how persistent chemicals actually are, and that in the case of extremely persistent substances there is a need to develop new screening procedures and test protocols, this was highlighted as homework for the scientific/academic community. Participants agreed that, as a first step, it would be useful to take a very pragmatic approach, and suggested that one possible first step would be to develop a list of very persistent chemicals or candidates for this list within the remit of the ECHA.

Regulation and management **-** There was consensus amongst the participants that the current regulatory framework is not adequate for regulating and managing vP substances. There is currently no regulatory paradigm to prevent poorly reversible chemical exposures and regulation is often retrospective i.e. regulation is first put in place after enough evidence is gathered on the environment and health impacts. In addition, the current criteria for persistent, bioaccumulative and toxic (PBT) and very persistent, very bioaccumulative (vPvB) are not particularly useful in predicting planetary boundary threats. For this reason, reliable methods for predicting hazards and risk management are needed. Participants suggested that a few improvements could be made within the current regulatory framework, such as including criteria for P and vP under the Classification, Labelling and Packaging (CLP) legislation; and consideration of vP under Art. 57 (f)[27] as having level of equivalent concern. Workshop participants also pointed out that there is always some leakage during the manufacturing of vPs or manufacturing processes using vPs and suggested creating a system for environmental permits for vP substances as one way to effectively reduce releases into the environment. At the same time, participants suggested that providing incentives for downstream users to avoid vP substances would be effective in reducing release of vP chemicals in combination with environmental permits.

Global perspectives **-** Persistent chemicals are a global problem because of their long-range transport

[27] This article under reach specifies that substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points under article 58 in REAC for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an *equivalent level of concern*.

potential. In practice this means that persistent chemicals have the ability to be transported and in some cases, accumulate in areas far from their point of release into the environment. Participants stressed the importance of maintaining a global perspective, when discussing regulation and management of vP substances. Restricting vP substances in Europe alone, would likely lead to production being moved to other parts of the world e.g. the current case where PFOS production has moved to China following legal action in the EU. Because of vPs long-range transport potential, restricting vPs in Europe alone will also not necessarily reduce exposure. Most the participants agreed, that the starting point should be the Stockholm Convention, but that its coverage of regulated chemicals (i.e. 23 substances) is limited. Participants also discussed what the chain of responsibility should be, and in this respect highlighted several ideas for improvements in global management and governance. There was general agreement that identification of vP substances in imported products was an important first step. Currently it is virtually impossible to know what substances or chemicals are involved or used in manufacturing of imported products. Along the same line, participants suggested that certification schemes could be used to promote higher product standards in articles and promote transparency in supply chains. Naming and shaming was mentioned, but there was broader acceptance for developing a global hub to communicate success stories, including voluntary efforts by industry. The OECD's current work in this area was highlighted as a positive model for communicating success stories and that a logical first step would be to expand upon this model. Finally, participants stressed that it was important to find solutions that benefit multiple targets i.e. providing information and incentives that facilitate downstream users to move away from "high performance" chemicals.

6.5 POLICY MEANS, INNOVATION & COMPETITIVENESS (SUB-STUDY E)

The participants agreed that well-designed **regulation** can promote innovation (Porter and Van der Linde paradigm) but held diverging views on whether the current legislative framework is posing a high administrative burden on SMEs and therefore diverting resources from research and development, ultimately hindering innovation.

An important point is that well-designed regulation needs to be properly enforced: poor **enforcement** is an issue, in particular on imported articles. The work of the Enforcement Forum is a good starting point, but more resources should be dedicated to the co-ordination of enforcement across member states.

The **availability of information** on safer alternatives is an issue: actors along the supply chain willing to engage on the substitution of hazardous chemicals need to be aware of the availability of possible solutions. In this regard, distributors have a potential role in bringing together demand and offer of safer alternatives. Another measure that could foster innovation is the creation of a marketplace for safer alternatives (e.g. the web-based solution currently being developed by Chemsec).

The participants agreed that there are plenty of initiatives trying to promote innovation at European, national and local level, providing funds, knowledge sharing, incubators for start-ups or other networking platforms. However, it would be good to have a better **co-ordination** of these initiatives, which e.g. could be under the OECD umbrella. Moreover, some participants questioned whether it is the responsibility of the public authorities to provide funding to scale up production of innovative solutions, arguing that their role should be limited to facilitate innovation.

In this regard, **economic instruments** such as taxation, public procurement and fee waivers can definitely play a role in providing the market with clear signals towards the changes that are needed to achieve a non-toxic environment. Moreover, innovation should not be seen as the substitution of hazardous chemicals with chemical alternatives only, but product design should start from the question on whether chemicals are necessary to achieve the functionalities required.

Industry stakeholders were of the opinion that free and open markets boost the development of the global economy for industrial and developing countries alike and ensure worldwide availability of products based on the most efficient processes and therefore strongly encourage governments to engage in free trade negotiations with all major trading partners. Importantly, Free Trade Agreements or other (international) agreements must include provisions on **intellectual property rights (IPR) protection**. Industry needs transparency and predictability with regard to IPR protection because of the duration and complexity of innovation processes. A stable regulatory environment allows the long-term planning that is needed to innovate. Furthermore, international agreements should define adequate IPR enforcement rules, as the value of IPRs is strongly linked to their effective enforcement.

6.6 PROGRAMME ON NEW, NON-/LESS TOXIC SUBSTANCES (SUB-STUDY F)

Feedback from stakeholders on issues related to the development of new, non-toxic substances was collected from direct interviews with stakeholders, during the discussions at the stakeholder workshop and from written feedback received after the workshop.

Overall, stakeholders stressed that there is a need for new, non-toxic substances development and that related activities should also take other aspects of sustainability into account. It was emphasised that, with a view to the increasingly complex market of substances and materials, orientation on the term "non-toxic" is of high importance, i.e. explanation would be needed on what are the properties to avoid and the protection goals and how to measure if new substances fulfil the related requirements.

Stakeholders at the workshop agreed that non-toxic substances should satisfy societal needs, be safe in their uses and be "gone" after their use. Achieving these goals would require considering the hazardous properties and the behaviour during the use as well as the waste stage (recyclability) early in the design phase of substances, at least in parallel to the assessment of technical performance criteria.

Stakeholders pointed out the following main barriers to the development of new, non-toxic substances:

- need to change production facilities and equipment potentially requiring large investments;
- making contacts between suppliers (researchers) and users of new, non-toxic substances and overcoming traditionalized supply chain structures;
- fear from change-over costs, in particular if existing (commodity) substances should be replaced
- lack of education and training and (transdisciplinary) cooperation experience;
- low profile and priority of the issue of non-toxic substances in R&D.

The stakeholders proposed, among others, the following activities to respond to these challenges:

- increase legal pressure for substitution (of substance groups) in general;
- make the topic "non-toxic substances" an integral part of all funded research;
- raise awareness and promote non-toxic substance development in ongoing change processes in companies;
- enable basic research for substance innovation and development.

The feedback on the need for targeted research and for better substance design tools was unclear and cannot be interpreted unambiguously.

6.7 EARLY WARNING SYSTEM FOR EMERGING CHEMICAL RISKS (SUB-STUDY G)

The participants to the workshop discussed the creation of an early warning system (EWS), the expectations of its functioning and ability. Stakeholders stressed that an EWS should be flexible and

build on existing experience to avoid duplication of work and should involve the appropriate stakeholders. Furthermore, an EWS should support informed decision making. The expectations were that an EWS should be able to: forecast; prevent; facilitate safe products (use/design); connect data; identify new end-points; be flexible; include vulnerable groups (children, workers); have a multiple compartment (air, water and soil) focus; include post-marketing surveillance; function on proper methods and procedures for signal identification; include measuring strategies such as analytical chemistry; connect to circular economy; facilitate follow-up choosing the best risk management measure or policy options; involve industry and public; include ranking/scoring systems based on for instance (Q)SARs; identify substances with PBT-properties; facilitate informed-decision making; use input from enforcement authorities/inspectors; give for instance a high priority to situations with signals but with little information and consider how to address the situation (e.g., through targeted information gathering); include alternative or new end-points such as neurotoxicity, immunotoxicity, biodiversity loss or ecosystem risk for prioritisation.

Meeting all these expectations is likely to be challenging and going through a procedure capable of achieving all these goals might take too long to address emerging risks. It is essential to find the right balance between timely action and gathering data for building a case. In that sense, the real needs of information should be defined. Overall it should be clear what the aim of the system is, and what it aims to protect. Regarding target audiences, traditionally, the focus is on authorities and policy makers, neglecting other audiences. Examining existing systems that are lacking some of the functionality and purposes of an EWS (e.g. RAPEX) would also be useful. Different methodologies should be identified for each step of the EWS.

6.8 COMMON POINTS

The perspectives shared by the stakeholders during the workshop, through their written feedback, or during interviews were enlightening. Although diverging views exist on the shortcomings of the current legislative and policy frameworks and on the next priorities, it seems clear from the opinions of all represented groups that the current system falls short from providing a holistic framework that ensures the health and well-being of EU citizens. The feedback overwhelmingly underlined that supplementary action is desirable and improvements achievable. The next sections of this report explore those elements for a future strategy of a non-toxic environment.

7 ELEMENTS FOR THE NTE STRATEGY: REDUCING EXPOSURE WHILE MAINTAINING COMPETITIVENESS

7.1 THE NON-TOXIC ENVIRONMENT IN THE GLOBAL POLICY CONTEXT AND IN THE 7TH EAP

Section 5 provides snapshots of the state of play with respect to several key topics related to chemicals and their impact on modern life. On the one hand, these snapshots affirm the importance of the strong foundation in place via current EU regulatory policy on chemicals. On the other hand, they highlight a number of existing and emerging concerns related to exposures to chemicals which are not yet covered or are insufficiently covered by the existing framework of controls, including areas where such exposures carry the potential for harm to human health and the environment. Many of these issues are already identified in the 7th Environment Action Programme (EAP), which commits to developing by 2018 a European Union strategy for a non-toxic environment.

7.1.1 Global policy context

As mentioned in Section 4.2, the chemicals-related objectives of the 7th EAP are not isolated but are embedded in global policy initiatives, first and foremost the WSSD 2020 goal to achieve the safe management of chemicals throughout their life-cycle, as agreed during the World Summit of Sustainable Development in Johannesburg (WSSD). In 2006, governments and stakeholders agreed on the Strategic Approach to International Chemicals Management (SAICM) (UNEP, 2006), a global policy framework to promote safe chemicals management with the explicit aim of implementing the WSSD 2020 Goal on chemicals. The fourth session of the International Conference on Chemicals Management in 2015 endorsed an 'Overall orientation and guidance for achieving the 2020 goal of sound management of chemicals' which takes stock of the progress made towards achieving the 2020 goal[28]. The conference identified the following emerging policy issues: lead in paint, chemicals in products, nanotechnologies and manufactured nanomaterials, hazardous substances within the life cycle of electrical and electronic products, and endocrine-disrupting chemicals. In addition, perfluorinated chemicals and the transition to safer alternatives were identified as an area of concern.

The 7th Environment Action Programme includes a number of specific targets for chemicals up until 2020, and reiterates the EU commitment to meeting the WSSD 2020 Goal specifically [29].

In 2013, the Commission published a report assessing the progress made by the EU towards achieving the WSSD 2020 Goal from the baseline year of 2002 until the end of 2012 (European Commission, 2013)[30]. It identified gaps and developed recommendations to address specific gaps. The gaps were identified against a set of indicators categorised into five different topics, namely:

1. Knowledge, information and infrastructure;
2. Risk reduction;
3. Governance;
4. Illegal traffic in hazardous chemicals, products and waste; and
5. Technical assistance and capacity building.

The report identifies a number of gaps relevant to this study and its sub-study areas, including:

[28] SAICM Document 29 June 2015, available at: http://old.saicm.org/images/saicm_documents/OOG%20document%20English.pdf.
[29] 7th EAP, priority objectives no.3 and 9.
[30] https://publications.europa.eu/en/publication-detail/-/publication/e636b772-1164-4a91-b024-069000bf5626/language-en

Information on chemical substances and their risks

- Lack of consideration of the combination effect of exposure to multiple chemicals, both in chemical risk assessment and horizontally across legislation;
- Gaps in the assessment of environmental impacts for medicinal products;
- Adaptation of risk assessment tools to the special case of nanomaterials needed;
- Low public recognition and understanding of the new CLP hazard symbols, which calls for targeted awareness raising activities.

Chemicals in articles and the Circular Economy

- Lack of transparency concerning research on chemicals;
- Need to significantly decouple production of hazardous chemicals in the EU from overall chemicals production;
- Low awareness of the Eco-label and low overall penetration of the Eco-Label in products and EMAS in activities of companies/governments/other actors.

Vulnerable populations

- Need for further action to protect children from chemicals in products, i.e. heavy metals in toys, textiles including a review of potential risks associated with nanomaterials in products;
- Failure to address the critical window of exposure of pregnant women to reprotoxic substances prior to a declaration of pregnancy;
- Need to revise EU-wide occupational exposure limit values (OELs) on lead, under the Chemical Agents Directive, and to clarify the relationship between OELs and Derived No-Effect Levels (DNELs);
- Gaps in addressing the specific risks to workers from exposure to EDCs and to nanomaterials.

Early warning systems and very persistent substances

- Lack of data on trends in occupational health and disease at EU level to inform policy making;
- Need for more comprehensive and detailed compilation of comparable monitoring data at the EU level;
- Lack of databases on hazardous waste, contaminated sites and the health risks thereof;
- Need for a common information system.

The last two suggestions were in relation to the implementation of the Stockholm Convention and Aarhus Protocol on persistent organic pollutants (POPs), but they are also relevant for other international obligations and to address many of the gaps identified in the sub-studies. And, last but not least, the report finds that even though the precautionary principle is enshrined in EU legislation and influences the design of legislation on chemicals, its application has been compromised by strong vested interests in the EU.

7.1.2 Chemicals under the 7th Environment Action Programme

The sound management of chemical risks is relevant to at least five of the nine high-level objectives of the 7th EAP:

- To safeguard the Union's citizens from environment-related pressures and risks to health and well-being.
- To protect, conserve and enhance the Union's natural capital.
- To turn the Union into a resource-efficient, green and competitive low-carbon economy.
- To improve the knowledge and evidence base for Union environment policy.
- To improve environmental integration and policy coherence.

The non-toxic environment is discussed in paragraph 54 under Priority objective 3 of the 7th EAP: "*To safeguard the Union's citizens from environment-related pressures and risks to health and well-being*". However, toxics-related topics are also mentioned in other places. The box below lists the various mentions of toxics and toxics-related topics. Since the same or similar topics are mentioned in several places, a topic may have more than one reference.

Chemicals-related topics mentioned in the 7th EAP	
Non-toxic material cycles	Par. 40, 43(viii), 54
Continued development of chemicals legislation: REACH, CLP, biocide and PPP regulations (combination effects, nanomaterial, endocrine disruptors)	Par. 50
Expanding the candidate list of REACH	Par. 50
Global goal (WSSD 2020 Chemicals Goal, Rio +20, SAICM)	Par. 50, 100
Hazard based criteria for endocrine disruptors – all relevant legislation	Par. 50, 54(d)
Comprehensive approach to minimising exposure of hazardous substances – chemicals in products	Par. 50, 54(d)
Nanomaterials and similar particles – definition	Par. 50
Risks to particularly children associated with use of hazardous substances incl. substances in products assessed and minimised	Par. 54(d)
Continuing to implement REACH	Par. 54(iv)
Developing by 2018 a union strategy for a non-toxic environment: ■ Innovation and development of sustainable substitutes, ■ Nanomaterials; ■ Endocrine disruptors; ■ Combination effects; ■ Chemicals in products including i.e. imported ■ Non-toxic material cycles, ■ Reducing indoor exposure to harmful substances	Par. 54(iv)
Filling knowledge gaps, accelerating decision making and enable development of chemicals-related acquis regarding relating to EDCs, combination effects, chemicals in products and nanomaterials	Par. 71.3
Considering a Union-wide database on nanomaterials	Par. 71.3
Human bio-monitoring regarding exposure and pollutants, in particular relevant for sensitive population groups, e.g. children	Par. 71.3
In order to develop a comprehensive approach to minimising exposure of vulnerable groups (children, pregnant women…), a chemical exposure and toxicity knowledge base will be established. This, together with development of guidance documentation on test methods and risk assessment methodologies accelerate efficient and appropriate decision-making, which is conducive to innovation and the development of sustainable substitutes including non-chemical solutions	Par. 71.4
Developing a comprehensive chemical exposure and toxicity knowledge base which draws on data generated without animal testing where possible. Continuing the Union's coordinated approach to human and environmental biomonitoring including, where appropriate, standardisation of research protocols and assessment criteria;	Par. 73 (iv)
Global goals (WSSD 2020 Chemicals Goal, Rio +20, SAICM)	Par.100

A number of these topics are already being addressed in other EU initiatives, e.g., the Commission proposal for the criteria to identify endocrine disruptors and the 2012 Communication from the Commission on Combination Effects of Chemicals[31]. The importance of continuing to implement REACH is also stressed by the 7th EAP. Finally, paragraph 54 recognises several additional areas of legislation and policy relevant to "*long term actions with a view to reaching the objective of a non-toxic environment*" important for safeguarding citizens from environment-related pressures and risks

[31] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52012DC0252.

to health and well-being, including indoor and outdoor air pollution; safe drinking and bathing water; the use of plant protection products; nanomaterials; and climate change.
By linking these areas with the goal of the non-toxic environment, the 7th EAP highlights the need for horizontal actions that take into account the interactions present between the many different issues and areas of legislation involved, e.g., ambient air quality, water quality, pesticides, biocides, waste management, and product standards such as for food contact materials. Each of these areas, and the associated environmental and health risks, will need to be part of an integrated and coherent framework for managing chemical pollution.

7.1.3 The objective of a non-toxic environment

The term 'non-toxic environment' has not been defined in the 7th EAP. However, 'environment' should be considered in its broadest terms to include the natural environment, as well as the human, hence including the 'technosphere', i.e. workplaces, indoor environments, cities etc.

A non-toxic environment should be understood as an environment that is free of chemical pollution and of exposures to hazardous chemicals at levels that are harmful to human health and to the environment. This target would take into consideration the need to provide vulnerable groups with as much protection as possible, to take account of potential delays between exposure and disease expression, to prevent accumulations of very persistent substances, and to ensure the quality of the material flows foreseen as part of the Circular Economy.

With these points in mind, the project team has focused on identifying gaps and deficits in the current EU policy for protecting humans and the environment from risks due to chemical exposure, and on possible responses that could form building blocks for a strategy for a non-toxic environment.

7.2 GAPS AND DEFICITS IDENTIFIED IN THE SEVEN SUB-TOPICS

7.2.1 Introduction

On the basis of the 7th EAP, the Commission identified seven areas crucial for the development of the strategy for a non-toxic environment. These are:

a. Substitution, including grouping of chemicals and measures to support substitution;
b. Chemicals in products articles and non-toxic material cycles;
c. The improved protection of children and vulnerable groups from harmful exposure to chemicals;
d. Sub-strategy for extremely persistent chemicals;
e. Policy means, innovation and competitiveness;
f. A programme on the development of new, non/less-toxic substances; and
g. The creation of a joint early warning system for approaching chemical threats to health and the environment.

The project team carried out sub-studies for each focus area to identify gaps and deficits proposed in the literature as well as during the two-day workshop held in Brussels in June 2016. This section prepared by RPA aims to provide a horizontal analysis of the gaps and deficits identified across the focus areas so as to categorise and harmonise the findings.

A first step has been the identification of common categories across the gaps and deficits identified. The analysis allowed defining the following broad categories:

1. Information on hazard, risk and fate of the substance at different stages of the product life cycle;

2. Information on uses/applications of substances and potential alternatives;
3. Analytical tools;
4. Communication and awareness;
5. Resources, guidance and training;
6. Functioning of the market;
7. Functioning of the legislation; and
8. Enforcement.

Tables listing the identified gaps and deficits per sub-study categorised by broad category (Table A) and the identified responses by broad category (Table B) are presented in the annex to this report.

The second step has been the identification of the most problematic areas within each sub-study area:

- For sub-study a (substitution and grouping), sub-study b (chemicals in products and non-toxic circles) and sub-study d (very persistent chemicals): gaps and deficits in the current legislation are the most discussed by literature and by stakeholders.
- For sub-study d, gaps in information on hazard, risk and product life-cycle and deficits in analytical tools have also been frequently indicated.
- For sub-study f (development of new, non/less toxic substances) and sub-study g (early warning system), gaps in communication and awareness and deficits in the provision of resources, guidance and training are the most frequent in the problem discussion.

The analysis also allowed highlighting those broad categories of gaps and deficits that raise less concern within each focus area.

Furthermore, the analysis enabled to identify those broad categories of gaps and deficits that are more common across the different focus areas (horizontal analysis). The aspects that were most discussed across the sub-studies were:

- Deficits in the functioning of the legislation
- Gaps in information on hazard, risk and product life cycle.

It should be noted that the legislation is often considered by stakeholders as the most effective way to require the generation and communication of the information missing. Resources, guidance and training (other category of deficits very common across focus areas) can then be offered to support and improve the functioning of the legislation.

The figure below presents the frequency of gaps and deficits by broad category per sub-study. The colours indicate the level of frequency, blue indicating the lowest, red the highest frequency. Frequency is calculated dividing the number of gaps and deficits in each category by the total number of gaps and deficits per each sub-study. Because some of the identified gaps ticked more than one category the percentages for each sub-study's row do not add up to 100%.

Table 1: Frequency of gaps and deficits by broad category in each sub-study

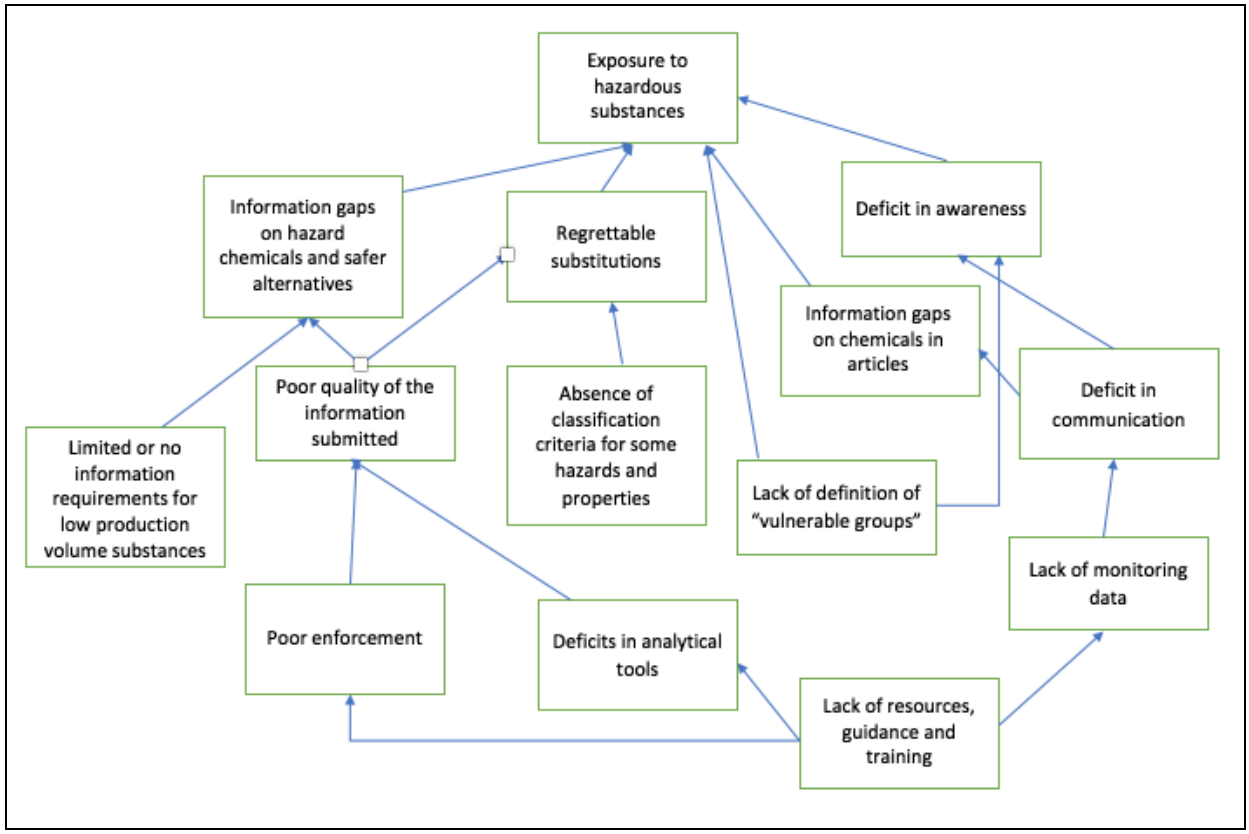
	1. Information on hazard, risk, life cycle	2. Information on uses and alternatives	3. Analytical tools	4. Communication and awareness	5. Resources, guidance and training	6. Functioning of the market	7. Functioning of the legislation	8. Enforcement
Sub-study a: Substitution, including grouping of chemicals & measures to support substitution	13%	7%	7%	13%	7%	0%	60%	7%
Sub-study b: Chemicals in products	33%	29%	19%	24%	24%	14%	67%	10%

	1. Information on hazard, risk, life cycle	2. Information on uses and alternatives	3. Analytical tools	4. Communication and awareness	5. Resources, guidance and training	6. Functioning of the market	7. Functioning of the legislation	8. Enforcement
(articles) and non-toxic material cycles								
Sub-study c: The improved protection of children and vulnerable groups from harmful exposure to chemicals	41%	0%	0%	22%	4%	0%	33%	0%
Sub-study d: Sub-strategy for very persistent chemicals	56%	48%	52%	12%	16%	12%	64%	4%
Sub-study e: Policy means, innovation and competitiveness	13%	13%	0%	13%	38%	0%	50%	0%
Sub-study f: Programme on new, non-/less toxic substances	13%	13%	0%	73%	60%	20%	13%	0%
Sub-study g: Early warning systems for examining chemical threats to human health and the environment	22%	22%	33%	33%	56%	0%	33%	0%

The third step has been to check the identified responses against the broad categories of gaps and deficits defined, in order to verify whether the range of measures proposed in the literature and by stakeholders during the workshop cover all issues highlighted per sub-study area and to enable the project team to identify potential synergies between the identified responses across the sub-study areas. This step is discussed further in section 7.3 below.

All the gaps and deficits identified are interrelated, confounding each other, ultimately contributing to the ongoing exposure to hazardous chemicals. The figure below presents the "gaps and deficits tree", showing the hierarchical relations among them.

Figure 7: Gaps and deficits tree



The following subsections presents the gaps and deficits identified by broad category.

7.2.2 Information on hazard, risk and fate of the substance at different stages of the product life cycle

All sub-studies have identified gaps in the information on hazard, risk and fate of the substance at different stages of the product life cycle. These gaps result from:

- Insufficient legislative requirements (further discussed in Section 7.2.8);
- Poor compliance with the legislation (further discussed in Section 7.2.9);
- Insufficient resourcing and guidance (further discussed in Section 7.2.6); and
- Inadequate analytical tools to generate the information in the first place (further discussed in Section 7.2.4).

With the entry into force of the REACH Regulation, manufacturers and importers have been required to generate and submit physicochemical and (eco)toxicological information of the substances put on the EU market. Information requirements have been differentiated according to the quantities introduced on the market and, therefore, substances which are manufactured or imported in low quantities have no or limited information requirements. The quality of the information submitted so far has been found to be poorer than expected and around two thirds of the registration dossiers have never been updated with new information. Hazard prediction methods alternative to in vivo testing (QSARs, read across) are not sufficiently developed or have been misused by registrants.

The scope of the REACH Regulation does not adequately cover nanomaterials and the lack of classification criteria for some hazards and properties of substances (endocrine disrupting properties, neuro-toxicological effects, PBT/vPvB properties) in the CLP Regulation and the lack of a definition for extremely persistent chemicals hampers the functioning of the chemical legislative framework.

Moreover, persistence is regulated only if bioaccumulability is also present[32] and there is no common framework for a comprehensive screening of substances for persistence.

The information gaps on chemicals in articles (discussed in Section 7.2.3) mean that the legislation does not consider sufficiently the aggregated and multiple exposures to chemicals contained and leaking from articles during the product life cycle and the waste stage, resulting in partial risk assessment and management procedures. The assessment methodologies are still not able to fully capture and measure the combination effects of chemical mixtures and the environmentally induced epigenetic toxicity.

The effects of bioaccumulation of chemicals over long periods are poorly understood and adult onset effects triggered by early life exposures may go undetected. This is of particular concern with regard to vulnerable populations, whose exposure levels may differ significantly from the typical exposure patterns assumed in current risk methodologies. Human biomonitoring (HBM) can be carried out for a limited number of chemicals and can only indirectly support the identification of exposure sources. At the moment, only few EU countries have implemented HBM programmes for monitoring chemical exposure of different groups of the population over time.

Finally, information on the scale of the effects of chemicals on biodiversity and ecosystem services is missing.

7.2.3 Information on uses/applications of substances and potential alternatives

Information gaps on the applications of hazardous substances and on potential safer alternatives derive from:

- Deficits in the information on hazardous properties of the substances (discussed in the previous subsection);
- Inadequate analytical tools to generate the information in the first place (further discussed in the following subsection);
- Deficits in communication and thus awareness on hazards and risks of chemical substances (further discussed in Section 7.2.5);
- Insufficient legislative requirements (further discussed in Section 7.2.8); and
- Poor enforcement of the legislation (further discussed in Section 7.2.9).

In addition to establishing rules for chemical substances and mixtures, REACH also addresses the use of chemicals in articles by setting out requirements for registration and notification of substances in articles, as well as communication requirements for certain substances to the supply chain (Article 33) and consumers (Article 33(2)). Moreover, hazardous substances may be subject to a ban or to certain restrictions regarding their presence in articles, established in REACH or relevant product-specific legislation (e.g. electrical and electronic equipment and cars), restrictions triggered by considerations on recyclability and minimisation of exposure. Under the framework of the Strategic Approach to International Chemicals Management (SAICM), chemicals in products have been identified as a priority policy issue, and the aim has been set to improve the exchange of information on chemicals contained in products and to propose cooperative actions to address gaps in the current levels of information access. To this end, SAICM has set up a "Chemicals in products" programme, which aims at developing practical solutions for information transfer on the presence of chemicals in products for the priority product categories of electronics, toys, building products and textiles.

However, ensuring compliance to these various requirements by obtaining and managing information

[32] With the only exception of the Detergents Regulation, which requires surfactants used in detergents to meet biodegradability standards.

on the presence (and absence) of hazardous substances in articles poses a considerable logistical challenge for actors in the supply chain, especially in the case of complex products made from a multitude of materials and components. In the case of articles, there is no legally prescribed format for the provision of the required information (as e.g. the safety data sheet used for substances and mixtures) and guidance and tools for the chemical safety assessment of articles during their use lives and during the waste stage are not sufficiently developed. Importers of articles produced outside the EU report problems of obtaining the relevant information from their suppliers, in particular in the case of complex supply chains. A multitude of tools and systems to trace substances in articles and handle the information flow along supply chains have been developed by companies, industry sector associations, authorities and international bodies in order to comply with the various requirements under different EU and international legislations, but the systematic use of these tools is still limited to pro-active actors and not widespread across different supply chains. Enforcement of the existing legislative requirements is not harmonized across the European Union and not sufficient to ensure a level playing field between compliant and non-compliant actors. Consumers do not have systematic access to information on toxic substances in articles and thus cannot exercise optimal purchasing decisions.

Public databases of substances searchable by technical functionalities in materials and articles that would enable an easy comparison of the characteristics (including the (eco)toxicological properties) of the chemicals are missing. In particular, this would be of value for very persistent substances, for which information on their uses is lacking, therefore hampering any regulatory effort or substitution initiative.

7.2.4 Analytical tools

Deficits in analytical tools derive from:

- Information gaps on hazard, risk, fate and applications of chemical substances (discussed in the previous two subsections); and
- Insufficient resources, guidance and training (further discussed in Section 7.2.6).

One important factor in the regulation of chemicals is the availability of methods to identify and assess the hazardous properties of chemical substances. To ensure that test methods are internationally and mutually accepted, a test guideline development programme (TGP) has been established under the auspices of the OECD. Despite the progress achieved on the development and validation of test guidelines, there are still some gaps and weaknesses in the current test methods, in particular on:

- The effects of endocrine disruptors (additional hormonal pathways, animal models, assessment of later life stage effects induced by exposure during foetal or pubertal development, appropriate tests for environmental species);
- Chemical exposure from article service life and waste stage, failing to acknowledge cumulative and multiple exposure to chemicals (in particular of very persistent chemicals);
- Combination effects of chemical mixtures and environmentally induced epigenetic toxicity;
- Expensive, time consuming and in some cases/for some categories of chemicals unreliable or insufficient tests on persistence of chemicals (measurement of the half-lives of substances in different environmental compartments).

A recent review of the food contact materials regulation carried out by the JRC has also found a lack of methods to review and follow up on enforcement and compliance, which makes it difficult to demonstrate that national laws ensure safety[33].

[33] https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/non-harmonised-food-contact-materials-eu-regulatory-and-market-situation-baseline-study.

Additional efforts are also required in further developing biological measures of body burden of chemicals. Human biomonitoring is the most reliable indicator of actual human exposure (WHO, 2000), but biomonitoring survey are resource-intensive and expensive. Moreover, only a limited number of chemicals can currently be assessed by biomonitoring[34] and comparability of data from different laboratories and years is problematic. There are also issues in the interpretation of such data, due to the limited availability of epidemiological data and differences and changes in dietary habits across the EU, which can have a higher influence than legislation on exposures than changes in the concentration of specific chemicals in human tissues. The European Human Biomonitoring Initiative (HBM4EU), launched in December 2016, is a joint effort of 26 countries and the European Commission aimed at providing better evidence of the actual exposure of citizens across Europe and any associated health effects[35].

7.2.5 Communication and awareness

Deficits in communication and awareness derive from:

- Information gaps on hazard, risk, fate and applications of chemical substances (discussed in Sections 7.2.2 and 7.2.3);
- Insufficient legislative requirements (further discussed in Section 7.2.8); and
- Poor compliance with the legislation (further discussed in Section 7.2.9).

Article 33 of the REACH Regulation establishes rules for articles containing Substances of Very High Concern (SVHCs) in a concentration above 0.1% (weight by weight). Firstly, suppliers of such articles need to provide the recipient (i.e. industrial or professional users or distributors, but not consumers) with sufficient information to allow safe use of the article. This is specified to include, as a minimum, the name of the substance. For consumers, Article 33(2) establishes the possibility to request similar information from a supplier of an article. This information has to be provided free of charge within 45 days of receipt of the request.

The use of company- or sector-specific restricted substance lists (RSL) is widespread particularly in the areas of textile and footwear, electric and electronic equipment and construction products. In the automotive sector, a Global Automotive Declarable Substance List has been developed. These approaches essentially rely on obtaining suppliers' commitment to either guarantee the absence of certain substances in the goods they supply, or, if the use of regulated substances is unavoidable, to provide information on their use and presence. In addition, information systems have been set up which facilitate the exchange of information between suppliers and customers on chemical content, often specific for a certain sector to ensure sufficient participation. Examples for such systems are e.g. the car industry's International Material Data System, the Bomcheck or Octopus databases, or the Japanese JAMP and ChemSherpa systems, mainly focused on electronics. Other systems are designed to provide information on chemicals typically contained in specific materials. Moreover, authorities and NGOs have devised solutions that assist consumers in requesting information on the presence of SVHCs in articles.

Despite these efforts, there remains the need for an improved flow of information, so that the actors in the waste sector receive adequate information on the presence of hazardous chemicals in articles, allowing better risk assessment and management strategies. Enhanced communication would also contribute in raising awareness of chemical exposure and its potential effects. This is critical for

[34] Around 200 chemical substances. Source: "German experiences with human biomonitoring, its impacts on policy and future perspectives", presentation by Marike Kolossa (Umweltbundesamt) during the conference "From HBM to policy" held in Brussels in October 2010. Available at: http://www.lne.be/en/environment-and-health/humanbiomonitoring-conference/kolossa-gehring.

[35] https://www.hbm4eu.eu/.

ensuring better protection of vulnerable populations, and would ultimately increase market pressure for substitution of hazardous substances with safer chemical or non-chemical alternatives.

Another challenge is presented by the current university system of educating chemists and chemical engineers, which tends to focus on the development of new chemicals to meet certain functional purposes, with insufficient attention to possible downstream impacts due to toxicity or persistence. This contributes to the lack of awareness among company product managers of the opportunities offered by green chemistry. There is also a lack of understanding and communication between researchers of different fields, in particular chemists and toxicologists.

There is also a lack of networking opportunities for actors interested in substituting hazardous chemicals and providers of safer chemical or non-chemical alternatives.

Finally, despite the increasing research on new and emerging risks and the existence of systems such as RAPEX, a centralised system that links all focus areas (food, consumer products, acute poisoning incidences, ecosystems, etc.) and rapidly exchanges information between the relevant actors is missing. Also, once an emerging risk has been identified, there is a lack of communication concerning the applicable risk management measures.

7.2.6 Resources, guidance and training

Deficits in guidance and training are closely related with the progress in developing analytical tools to generate information on the characteristics of the substances and to better assess and manage the risks (discussed in Section 6.2.4) and with gaps in communication and awareness (discussed in the previous subsection). In particular, guidance and training on the following methods and tools should be scaled up and improved:

- Hazard prediction methods alternative to testing and weight of evidence approaches for hazard screening;
- Tools for the chemical safety assessment of articles;
- Guidance on risk assessment of nanomaterials;
- Best Available Techniques guidance documents for industrial activities with control measures for very persistent substances.

More in general, there is a lack of university programmes on green chemistry and the development of non/less toxic chemicals, as well as training of company product managers on the opportunities related to such development. Academia curricula on chemistry should be strengthened with more courses on the (eco)toxicological aspects of chemical substances.

In terms of resources, a better prioritisation and more harmonisation of initiatives at European, national and local levels would greatly benefit the development and the industrial scale up of clean technologies and green chemistry.

7.2.7 Functioning of the market

Market failures are closely linked to information gaps (Sections 7.2.2 and 7.2.3), deficits in communication and awareness (Section 7.2.5), lack of resources, guidance and training (previous subsection), legislative gaps (following subsection) and poor enforcement (further discussed in Section 7.2.9).

Partial or missing information on the properties of chemical substances in different applications (because of the lack of the information or because of deficits in communication) is a major cause of the malfunction of the market, as different actors (chemical manufacturers and importers, formulators, manufacturers of articles, regulators, consumers) cannot make optimal choices. Markets may fail to

incentivise merit goods (safer alternatives), to form (markets for safer alternatives) or to control de-merit goods (hazardous substances), resulting in the failed internalisation of negative externalities by the market actors (e.g. price of articles containing hazardous substances failing to incorporate the cost of managing risks during the product waste stage).

The EU chemical legislative framework was implemented to generate the necessary information to make optimal choices, but partial legislative information requirements (not covering low production volume substances and some relevant health and environment end-points such as endocrine disrupting properties and persistence), the poor quality of the information submitted and the lack of enforcement are hampering the functioning of the market.

While some EU Member States resort to market instruments to address the market failures linked to the production and use of hazardous substances (e.g. Nordic countries applying taxes to the use of pesticides), the use of economic incentives should be encouraged and promoted at European level.

7.2.8 Functioning of the legislation

Stakeholders have identified legislative gaps that need to be addressed in order to solve many of the issues identified. Some of the legislative gaps have already been discussed in the previous subsections (partial information requirements in Sections 7.2.2 and 7.2.3, communication duties in Section 7.2.5).

REACH authorisation generally does not cover imported articles: although ECHA must consider if the use of the substance in articles poses a risk and if so, prepare a dossier which conforms to the requirement of an Annex XV dossier for restriction (Article 69(2)), some stakeholders suggest that the lack of an automatic restriction on imported articles containing Annex XIV substances may result in a potential competitive disadvantage for the companies opting for substitution. Moreover, if a substance is used only as a process chemical or otherwise is not present in the end product, there will be no impact for imported articles but EU manufacturers have to substitute where non-EU manufacturers don't, possibly leading to competitive disadvantage.

The current legislative practice may encourage incremental rather than fundamental change of chemical structure of the potential alternatives, resulting in these exhibiting the similar hazard profiles of the substances substituted (regrettable substitution). Some industry stakeholders noted that, once a substance comes under regulatory scrutiny, the time allowed for finding/developing and switching to suitable alternatives may not be adequate, resulting in regrettable substitutions or in second best solutions (such as minimizing occupational exposure but neglecting environmental fate at the end of life stage). Moreover, once an alternative is developed, where product approval by authorities is necessary (e.g. in aerospace or medical devices), this process can excessively prolong the product time to market.

Moreover, the imperfect synergies between the different chemical legislative acts may result in a limited or inefficient internalization of human health and environmental costs by the chemical or product manufacturers. For example, chemicals regulated by both the REACH Regulation and the Water Framework Directive may leak from products during their life cycle or during the waste stage. However, the costs to clean up such pollution is borne by the wastewater treatment companies and drinking water suppliers and, ultimately, by the citizens rather than the polluter.

Finally, attention to specific windows of vulnerability (e.g. neonates, infants, toddlers and adolescents) in the EU chemical legislation is sometimes missing, especially in those pieces of legislation such as the Drinking Water Directive that are of particular relevance to ensure the protection of certain vulnerable populations from chemical exposure.

7.2.9 Enforcement

Gaps and deficits in the enforcement of the chemical legislative framework have been discussed in Section 5.1.6. Poor enforcement affects all other broad categories of gaps and deficits identified, failing to ensure the generation and communication of information and a level playing field for the actors across the EU market, which currently have different levels of access to information and economic incentives.

7.3 IDENTIFIED RESPONSES TO GAPS AND DEFICITS (BUILDING BLOCKS FOR THE NTE STRATEGY)

7.3.1 Introduction

After identifying the most significant gaps and deficits in the current situation, each sub-study concludes with lists of identified responses to those gaps and deficits. These responses were identified in part through the literature reviews carried out for each sub-study, and in part by stakeholders at the June 2016 workshop in Brussels, with the overall objective in mind of reducing human and environmental exposures to hazardous chemicals to the lowest level possible. The responses can be viewed as potential building blocks for the strategy for the non-toxic environment (NTE).

This section aims to provide a horizontal analysis of the responses identified across the focus areas. It has been prepared by Milieu, with contributions from RPA. The table below presents the frequency of identified responses to various gaps and deficits by broad category per sub-study. Again, the colours indicate the level of frequency, blue indicating the lowest, red the highest frequency. Frequency is calculated by dividing the number of responses identified in each category of gaps and deficits, by the total number of responses per each sub-study. Because some of the identified responses ticked more than one broad category the percentages for each sub-study's row do not add up to 100%.

Table 2: Frequency of identified responses by broad category in each sub-study

	1. Information on hazard, risk, life cycle	2. Information on uses and alternatives	3. Analytical tools	4. Communication and awareness	5. Resources, guidance and training	6. Functioning of the market	7. Functioning of the legislation	8. Enforcement
Sub-study a: Substitution, including grouping of chemicals & measures to support substitution	3%	13%	13%	23%	30%	23%	23%	7%
Sub-study b: Chemicals in products (articles) and non-toxic material cycles	46%	33%	6%	44%	42%	29%	58%	15%
Sub-study c: The improved protection of children and vulnerable groups from harmful exposure to chemicals	17%	0%	17%	24%	0%	0%	38%	3%
Sub-study d: Sub-strategy for very persistent chemicals	46%	37%	46%	24%	24%	17%	63%	12%
Sub-study e: Policy means, innovation and competitiveness	9%	12%	6%	18%	12%	21%	29%	6%
Sub-study f: Programme on new, non-/less toxic substances	10%	20%	10%	50%	60%	30%	40%	0%
Sub-study g: Early warning systems for examining chemical	21%	16%	63%	26%	11%	5%	5%	0%

	1. Information on hazard, risk, life cycle	2. Information on uses and alternatives	3. Analytical tools	4. Communication and awareness	5. Resources, guidance and training	6. Functioning of the market	7. Functioning of the legislation	8. Enforcement
threats to human health and the environment								

The table is based on Table B in the annex to this report, which lists the identified responses by sub-study and shows which gaps and deficits are addressed by each. The following subsections analyse the identified responses and discuss where synergies may be found. Note that parentheses are used to indicate the sub-study and the number of the suggested improvement responses identified, as referred to in Table B in the annex. Further details can then be found in the particular sub-study.

7.3.2 Information on hazard, risk, life cycle

Almost all of the sub-studies suggested practical responses to address gaps with respect to the information base on substance-based hazards, risks and risk assessment. The responses identified related to:

- Filling data gaps concerning substances and any related hazards
- Improvements in risk assessment methodologies
- More systematic monitoring and centralised data collection

Some gaps in data could be addressed by facilitating grouping of similar chemicals by structure (a.27, d.11). Several sub-studies suggested requiring more data, in particular for low volume substances (a.01, b.05, d.08, e.01). Other suggestions focused on speeding up identification of SVHCs by setting priorities for which SVHCs are really important because of hazard and exposure patterns (b.19), agreeing new properties such as mobility for determining which substances might be of equivalent concern under Article 57(f) (b.06), and automatic simulation testing requirements for persistence if initial dossier screening indicates that a substance may be very persistent (d.09). Inclusion of new hazard categories in the CLP Regulation, e.g. EDCs, (developmental) neurotoxins and PBT/vPvB, was also viewed as important (b.4). Several of these suggestions would require new legislation, and – in the case of CLP -- work at international level in order to ensure harmonisation with the GHS.

With respect to risk assessment of chemical substances, several sub-studies stressed the importance of requiring assessment of the impacts of multiple, compound and cumulative (aggregated) exposures (b.11, c.10, c.11, d.5, d.7). This might require additional research on the (synergistic) health and environmental effects of continuous, low-level chemical stress (b.12). Other suggestions in this vein included taking a life cycle approach towards assessing risk from chemical substances, which might require support for further research into chemical product life cycles (e.17), and accounting for health and environmental risks due to exposures to hazardous chemicals in house dust (c.22), substances in materials used in products such as food contact materials and personal care items (c.20, c.21) and during the waste stage (b. 03, b.15, b.47).

Policy instruments to use to achieve this included enforcement of existing requirements, such as ensuring that the chemical safety assessments in registration dossiers included quality information with respect to articles and waste streams. In order to facilitate a comprehensive early warning system, it was also suggested to modify or extend existing exposure and risk assessment procedures by incorporating additional and more specific toxicological end-points, in order to trace adverse effects in a timely manner (g.07).

More systematic monitoring was also viewed as critical, and as part of any effort to establish an operative early warning system. Monitoring with respect to very persistent substances was urged, in order to track the presence of vPs in products, waste streams, humans and other biota, as well as any accumulations in environmental media and humans (d.34). A practical suggestion to facilitate such monitoring was to require producers to deliver validated analytical/detection methods for the chemicals they place on the market, along with technical chemical standards and information on all transformation products, as per pesticides/pharmaceuticals (d.10, e.37), and to design sampling and monitoring programs to look for contamination of natural resources where point sources of discharges have been identified, e.g., PFAS around all airfields (d.36).

Finally, centralised (EU-level) data collection of exposure and hazard information (g.09) was suggested, including on quantities of vP substances produced and used, in order to determine overall loads of vPs in the environment (d.16).

7.3.3 Information on uses and alternatives

One of the puzzles in moving towards reduced exposure to toxic chemicals and the safe materials streams necessary for a viable Circular Economy is to address the current lack of knowledge about which chemicals are used in products and articles, especially imported articles. This gap, as well as a deficit in information on alternatives to support substitution efforts, was viewed as important to overcome as part of an overall strategy. Suggested responses could be grouped as follows:

- Horizontal legislation on toxic substances in articles
- Tools for tracking substances in articles
- Databases on substances in articles, including alternatives
- Quality standards for material flows
- Support for substitution and design of alternatives

Again, a life cycle approach was urged with respect to risks from chemicals used in products (b.01, a.16), including funding of research in this area. One suggestion was to enact some type of horizontal, life cycle based legislation on toxic substances in articles, including provisions regarding content of any toxics in articles and material cycles, and how to communicate that information (b.02). In view of the goal of a Circular Economy, this would need to ensure that risks from 'multiple loops' would be considered in risk assessment and management (b.48), and could include an extended producer responsibility approach. To help close the loops, it was advised to change REACH Art. 2.7d so that recyclers placing materials on the market would be required to register and assess any uses not covered by the main registration (b.35). This might require development of more specific REACH use descriptors (b.10).

Development of tools to track hazardous chemicals in articles was proposed (a.13, e.15), through to end-of-product-life material waste streams (b.46). These could include labelling of products where substances such as vPs were present, together with traceability to prevent passing on accumulations of vP chemicals via materials recycling (d.26), material declaration requirements for toxic substances in materials along the supply chain (b.27), and an obligation to declare content (in concentration ranges/intervals) of all classified substances if exceeding 100 ppm for all consumer products (b.30). Suggestions for addressing knowledge gaps at the end-of-life product stage included revision of the EU rules for classification of waste as hazardous to harmonise with the CLP (b.46) and development of approaches for a better application of information about product composition in waste management (e.g. automatic readable/sensing coding, for use in the daily practice of waste treatment) (b.44).

Databases on substances in materials and/or articles, based either on reporting obligations or published data, were suggested as important tools (b.9) for managing reductions in exposures to toxins. To support substitution efforts, these databases could be enhanced with information on alternatives (a.14, e.16), including non-chemical and low-toxic options. Specific database-related proposals aimed at the

problem of very persistent (vP) substances included to establish central registries of products containing vP substances, along with annual statistical data of the volumes of vP substances produced, used and emitted (d.27), and inventories of all vPs produced, used in products and/or released as emissions or waste, in order to understand overall loads of vPs in the environment (d.38).

Quality standards for the content of toxic substances in materials (virgin and recycled) (b.25) were seen as important for ensuring the quality of material flows. Such standards would have to balance the performance of certain substances such as vPs, against the health and environmental risks of the substance (d.29). They might also be used to enhance depollution via e.g. specific requirements for additional waste streams (b.47), and to set safety limits for use of secondary raw materials in specific articles (b.39). How this could relate to the implementation of end-of-waste criteria (b.25) would need to be defined.

In addition to signalling toxics content, it was also viewed as important to provide positive support for substitution and design of alternatives, including funding (a.25, d.33, e.26), in particular for SMEs. Expanding the scope of the Ecodesign Directive to any article and developing implement guidance and methods to define substance related eco-design criteria for specific product groups (b.23) was suggested. To enhance take-up by product designers and manufacturers, opportunities identified included campaigns to raise awareness on the benefits of – and to stimulate market demand for - safer alternatives (e.18) and implementation of help desks to support substitution activities (b.26).

7.3.4 Analytical tools

The sub-studies identified a number of opportunities for the development or strengthening of analytical tools. Upstream of the data analysis, all sub-studies underlined the need for improved screening tools on hazards, exposure and life cycle impacts of chemicals or articles (a.26, b.07, b.13, c.12, d.35, e.27, f.10, g.08). Hazard screening tools should be developed that help to identify and assess EDCs (c.17), nanoparticles (c.18), persistent chemicals (d.2, d.4), mobile substances (d.35), and chemicals with insufficient evidence of risks (g.03). Exposure screening tools are needed that take into account results from human biomonitoring (c.16) and that consider aspects such as age, consumption patterns, behavioural characteristics, geographical location, lifestyle factors and cultural differences (c.12). Life cycle impacts screening tools would be helpful to assess the consequences of the persistent characteristics of chemicals (d.2, d.4), for linking waste stages to article categories (b.14) and for developing standardised test methods for recycling materials (b.45).

Tools that can combine screening results of these tools were also called for (a.26, e.27, d.3). Such tools were in particular seen as essential contributions to the design of early warning systems capable of detecting, strengthening and acting upon signals (g.01, g.04, g.06, g.08). For example, they were seen as important for bridging the silos of different focus areas, i.e. environment, consumers and workers either by creating a common tool or by enabling information-sharing between different platforms (g.18). Such data analytical tools would benefit from requiring the input of experts in environmental epidemiology, ecology and nature conservation in order to improve the assessment of causality between exposure and impacts of chemicals (g.19).

The development of these analytic tools we seen as dependent on various information-based instruments as well as on support for capacity building. They would in turn accelerate and facilitate the processes of data gathering and analysis.

7.3.5 Communication and awareness

The sub-studies identified over 30 opportunities to respond to current gaps in communication towards and awareness among the industry, the public and policy-makers. The opportunities can be divided in four main categories:

- the development of communication and awareness raising tools;
- the development of strategies to raise awareness on certain points;
- the promotion of dialogue among stakeholder groups; and
- the establishment of platforms that facilitate the exchange of information among relevant stakeholders.

In the first category, four tools were called for: (i) a comprehensive, longitudinal databank including harmonised environment and health indicators, based on human biomonitoring data collected during all life stages (c.15); (ii) an EU substance-regulation navigator that includes implemented and upcoming international and national legislation by substance/application (a.12, e.14); (iii) tools such as the chemical footprint project[36] or ecolabel awards (a.29, b.38, e.33); and (iv) a database and map viewer that cover all contaminated natural resources in the EU (d.39).

Regarding the need to raise awareness and trigger dialogue, a distinction was made between two different audiences: industry and the general public. Depending on the audience, the interests and communication methods will be different. It was suggested to raise the awareness of industry on several issues: the identification of applications for which the use of certain chemical groups raise concerns that are higher than the benefits delivered (a.15); the existence and benefits of safer alternatives (a.17, f.01, f.05); opportunities for the development of new, non-toxic substances (f.05) and on the possibility for functional substitution (a.23, e.24, b.33); on the potential and content of circular economy business models (a.19, e.20); and finally on the content of products across the supply chain (c.27).

Topics where raising the awareness of the public (and policy-makers) were in particular suggested regarding the presence of hazardous substances (including persistent substances – d.25) in household products (c.23); the exposure of vulnerable groups such as women in child-bearing age, pregnant women, children (c.25), workers (c.28) and the elderly (c.29). A specific suggestion was to explore how to reduce chemicals in indoor environments where the elderly live and in kindergartens and schools where children spend a lot of their time, e.g., through better ventilation systems (c.24).

Platforms for facilitating information exchange on new and emerging chemicals (NERCs) (g.05) were seen as particularly important as part of developing an EU-wide early warning system. Key elements of an EWS methodology would be to establish a blue print for a communication plan and options to approach relevant stakeholders (g.12, g.17).

Dialogue should be promoted among actors that are part of the same supply-chain on the hazardous substances used (b.33, e.19), on the benefits and opportunities of developing new, non-toxic substances (f.05), and on NERCs (g.02). Such dialogues could take place and be supported by the establishment of platforms that link the work of scientist and industry on the development of new, non/less-toxic substances (f.07, g.02) and that connect scientist and regulators to ensure that the available information allows meaningful risk assessment and policy making (c.13). This would include collecting information from REACH CSAs on risks for the waste stage and identifying potential priority areas, exchanging information with the waste sector on (specific, article related) information needs, and identifying options to satisfy them (b.47).

Addressing such gaps requires two main types of policy responses: information-based instruments as well as support and capacity building measures. Such policy responses are dependent on the availability of information (see sections on information on hazards, risk, life cycle; information on uses and alternatives; analytical tools) and would hence be complemented by legal requirements on industry and public authorities to communicate information along the supply chain or towards the public (b.38, f.01).

[36] http://www.chemicalfootprint.org/

7.3.6 Resources, guidance and training

The responses in this category of gaps and deficits were quite specific to the respective topic of focus. Each sub-study called for support, capacity building, resources and legislation targeting specific needs, and few opportunities for synergy were found.

For example, sub-study a (substitution) suggested co-ordination of substitution initiatives across Member States around prioritised chemicals of concern (a.07), development of ECHA and Member State competent authorities capacity to support substitution (a.20, e.21), creation of an expert knowledge platform to support authorities and industry with substitution initiatives (a.22, e.23), and supply chain collaboration and engagement through, e.g. shared performance testing and evaluation and the creation of demonstration sites (a.18).

Sub-study b on chemicals in products and the Circular Economy proposed REACH guidance defining chemical product safety, e.g., with respect to environmental protection, including guidance and best practice examples to support implementation (b.37). It also suggested developing an overall approach for the management of waste decontamination based on life cycle thinking. This would need to include guidance concerning obligations for assessment of the waste stage in REACH CSAs and subsequent promotion and enforcement of the use of the ECHA guidance ('Chapter R.18'[37]) (b.14), and clarification of waste treatment priorities on decontamination and related decision criteria (b.41). Other suggestions included developing guidance documents on potential contaminations of secondary raw materials (b.40) and on the identification of substances recovered from wastes, including how to deal with "impurities" (b.36), reviewing existing technologies in order to identify best practices on e.g. molecular recycling of polymers (b.50), and sector-specific manufacturing best practices for articles (b.34).

According to sub-study d, the regulation of very persistent chemicals would require a revision of all BAT guidance documents to take account of all potential releases of vP substances to the environment, and to keep such releases to a minimum (d.18) as well as the establishment of a European infrastructure for the safe transport, disposal of and final destruction (e.g. high temperature incineration) of vP substances/products, at end of product life (d.32). Because very persistent substances are already accumulating in the environment, it suggested designing and implementing programmes for limiting further contamination and for prioritising clean-up – potentially backed-up by liability and redress mechanisms for funding the costs of clean-up (d.40). Such programmes would need to be further supported by the development of and knowledge sharing on remediation methodologies/ technology (d.41).

Sub-study f on a programme for the development of new, non- and less toxic substances called for the development of clear guidance on what is "non-toxic". Such guidance documents and other disseminating tools would allow R&D staff and the market actors to get clear signals on the goals of substance development and certainty about potential future regulatory priorities (f.02). In the same line of awareness and knowledge raising, scientific institutes and Member States agencies could provide education and training on (new), non/less-toxic substances to scientists, workers, company managers, engineers etc. in order to increase the competences and capacities of all relevant actors (f.06). To support all actors in the implementation of programmes on new, non- and less toxic substances, funding should be made available for the development of R&D programmes on the topic (f.08). As for existing research programmes on chemicals, these should systematically integrate the question of the development of non-toxic substances (f.09).

[37] ECHA Guidance on information requirements and chemical safety assessment, Chapter R.18: Exposure scenario building and environmental release estimation for waste life stage.

Related to these needs of developing skills, sub-study e on policy means suggested that overall further investment should be made in skills related to Key Enabling Technologies (KETs), a.o. through partnerships between industry and education providers (e.31).

Regarding ways of addressing current gaps towards the development of early warning systems (sub-study g), the development of data should be supported by Making expertise centres mandatory in every EU member state by means of legislation (g.10). Ultimately a centralised (EU) early warning system should be designed and established based on the different identified steps involved going from signalling through management of NERCs (g.11). A first step would be to design blue prints/options on how to organise an early warning system including estimated costs for the various options (g.14). The design of the early warning system should make it possible to align it with or connect to existing (consultative) structures and institutes as much as possible (g.11)

7.3.7 Functioning of the market

Some of the problems identified in the sections on state of play stem from market failures to incorporate the full costs of toxics or the lack of incentives for implementing alternatives. Several responses for addressing various gaps and deficits pointed to measures to help correct skewed marketplace forces.

Suggestions aimed at sending positive signals included rewarding or incentivising sustainable substitution (e.g. through VAT reduction) (a.09, e.11), reducing regulatory fees for non-toxic substances (f.04), and enhancing government green procurement programmes by favouring the functional substitution of hazardous chemicals (a.11, e.13). Improving access to markets through trade agreements to facilitate investment opportunities in sustainable low, toxic chemistry and substitution was also proposed (e.09, e.30), if care was taken to balance the rights of corporations with the protection of human health and the environment.

Ideas for internalising the external costs of using hazardous substances included promoting taxation of use of hazardous substances among member states (a.10, e.12, f.04) and establishing recycling fees for products requiring specific end-of-life treatment, including decontamination of toxic substances (b.43). It was suggested that parts of the fees could be allocated to setting up related enforcement activities (b.43). Another proposal was to consider cradle-to-grave producer responsibility for vP substances, from production to subsequent use phase, to collection and destruction at the end of the product's useful life (d.31).

Voluntary, self-regulatory measures were also considered potentially useful, including encouraging product designers, manufacturers and retailers to voluntarily reduce or eliminate the use of vP substances in products (d.24) and facilitating public-private investment partnerships for supporting research into safer alternatives and for the provision of technical support to SMEs, in particular on technical feasibility of alternatives (a.21, e.22).

7.3.8 Functioning of the legislation

Quite a few suggestions were focused on strengthening the current regulatory framework for chemical substances. Several proposals were put forward aimed at speeding up the identification of SVHCs (c.09, b.18), including by more use of REACH Article 57(f) possibility of naming additional substances such as vPs as giving rise to equivalent concern (d.01). Ideas for improving the operation of the REACH provisions on authorisation included increase authorities' capacities to handle applications and developing overarching principles for granting authorisations (b.18**)** and refusing authorisations for use of Annex XIV substances for which alternatives are available on the market (a.05, e.05). Imposing an automatic restriction on imported articles containing authorised substances (a.02, e.02) was proposed, as well as the possibility of defining a concentration limit for SVHC in

articles as a general requirement, with even lower limits for substances / articles of particular concern (b.22).

Suggestions relating to REACH's restriction provisions included introduction of options for quick inclusion or revision of substance restrictions upon new evidence in product legislation (b.24), extending the scope of REACH Article 68 to PBT/vPvB or EDCs in consumer products (b.20), and establishing [hazard-based] bans on all unessential releases of vP substances to the environment, e.g., use of PFAS-based foams in fire-fighting training (d.23). It was also suggested to limit the use of persistent substances to certain essential uses which due to technical reasons/functionality absolutely required such persistence (d.28).

Amending CLP to include additional categories for hazards or properties of concern, such as P, vP, PBT, vPvB and M (mobility), was put forward (c.14, d.12), which may require work at international level on the GHS framework. It was also suggested to consider the possibility of an additional classification for extreme persistence for those chemicals that may not degrade for decades or longer (d.14). Significant gap in the EU framework for POPS could be filled by including additional unintentionally produced vP chemicals such as polybrominated dioxins/furans (d.13) and by encouraging more ambitious international implementation of controls over vPs through the Stockholm Convention mechanism (d.15).

From the sub-study on vulnerable groups came several overarching suggestions to improve the EU regulatory framework. Proposals included to agree a comprehensive definition of the term 'vulnerable groups', particularly for those pieces of EU legislation relevant to the protection of vulnerable groups (c.01), to add provisions referring to specific windows of vulnerability, e.g. in the Toy Safety Directive (c.02) or Drinking Water Directive (c.04), and to review legislation related to work, food, products, environment/air for opportunities to ensure consistent coverage for vulnerable groups (c.03). Suggestions aimed particularly at the protection of children, e.g., to reduce and/or phase-out the use of EDCs in medical equipment, particularly for neonates (c.19) and to extend the Toys Directive regime to cover all products aimed particularly at children, such as furniture, bedding, clothing (c.08).

The Drinking Water Directive was flagged as an opportunity for improvement, in particular through a review and updating of the number of chemicals listed in Annex I, part B (c.05) e.g. by adding highly fluorinated (PFAS) and other vP substances to the list. Because of the large number of PFAS, it was suggested to consider a group limit value, similar to the current group limit value for pesticides in drinking water and groundwater protection (d.6). The Food Contact Materials Regulation was also viewed as an opportunity to reduce exposure to hazardous substances, by setting in place specific rules for the 12 types of food contact materials not yet covered at EU-level, and starting with those where chemical contamination problems have already arisen, e.g. printing inks migrating into food, bisphenol A, certain phthalates, PFAS, and other harmful chemicals in paper/board packaging (c.06, c.07).

With respect to vP substances used in production and manufacturing, it was suggested to require all emissions of vPs from all industrial activities to be subject to permit, including those from smaller installations (e.17). Alternatively, the production and/or industrial use of vP substances could be required to take place only in closed systems (d.19). In any case, it was urged to not use emission limit values (concentration levels) for controlling vP substances in discharges, but rather to set fixed maximum amounts for restricting vP substances released to the environment (d.20). It was also proposed to set fixed limits at EU level to amounts of vPs produced/used, as per restrictions for ozone-depleting substances, and allocate allowances via economic instruments such as tradeable permits (d.22)

An overarching legal approach to separation and decontamination of waste streams (b.03) was seen as important to facilitate Circular Economy goals. This would include development of a regulatory system that would incentivise article producers to create minimised dismantling and depollution efforts for the waste sector, e.g. by extending producer responsibility until after waste entered a second

product life (b.42) This improvement opportunity linked back to the proposals to implement more restrictions for SVHCs in articles under REACH or for substances with certain hazardous properties in product legislation (b.20).

Opportunities that did not require new legislation but rather streamlining implementation of existing legislation included several ideas for reducing the administrative burden for the private sector. Extending the available time to identify and move to sustainable alternatives (a.03, e.03) was proposed, along with providing SMEs more time to comply with the legislation (a.06, e.08). To encourage the development of alternatives, it was proposed to lower regulatory burdens for registration and approval for non-toxic substances and to provide longer protection periods e.g. for patents (f.03). It was also suggested to speed up replies to consumer requests for information on substances in products and to support the development of related consumer apps or labelling (b.29).

Possibilities to reduce burdens on regulatory authorities without enacting new legislation included to ease up on requirements to demonstrate risks and to increase opportunities to restrict substances based on a hazard-based, precautionary approach under REACH (b.21), to apply grouping strategies systematically when regulating a substance (a.08, e.07), and to co-ordinate substitution initiatives across Member States around prioritised chemicals of concern (e.6).

7.3.9 Enforcement

Some of the improvement suggestions aimed at enforcement deficits were quite broad, e.g., to dedicate more resources to enforcement of every aspect of the chemical legislation (a.28, b.32, e.32), to continuing support for further Member State work on harmonization and enforcement, including on sanctions (b.31), and to enhance chemical monitoring programmes (a.30, e.34).

Other proposals were more targeted. For example, more Member State enforcement of the REACH provisions on communication of safe use of substances in articles and safe disposal in safety data sheets (b.17) was suggested, with particular focus on the Article 33 obligation on suppliers of articles containing SVHCs above certain concentrations.

Ideas also included ways to improve enforcement efficiency. A suggestion to set limit values (standards) for vPs in products also recognised the need to develop screening and analytical methods for use in checks for compliance with those standards (d.30). Another suggestion related to standards for secondary raw materials was to implement random tests and (unheralded) control measures, and to use enforcement information for policy making (b.32).

7.3.10 Monitoring

In almost all the sub-studies, emphasis is placed on the importance of enhancing the monitoring programmes (a.30; c.15, d. 16, e.34) that have been carried out in the last decades in Europe, on specific substances and populations exposed and with varying geographical scope. Various databases concerning chemicals exposures already exist. For example, the European Commission is developing an EU-wide human biomonitoring (HBM) initiative and the European Commission Joint Research Centre is working on an information platform for chemical monitoring data (https://ipchem.jrc.ec.europa.eu) that will gather together the available experiences in Europe to enhance access to data on chemicals.

Nonetheless, additional monitoring efforts were proposed to address the gaps and deficits they had identified. Sub-study c on vulnerable groups urged development of a comprehensive, longitudinal, human data bank (c.15), including harmonised environment and health indicators; HBM data and human tissue measurements translated into daily exposure estimates; and HBM data collected during all life stages, reflecting total exposures from all sources, complemented with data on individual susceptibility based on gender, age, genetic background and body composition, living environment

(urban vs rural), lifestyle habits, medical history, etc. in order to determine additional risk factors of higher body burden of chemicals.

Sub-study d on very persistent (vP) substances also stressed the need for monitoring to guard against build-ups of vP substances in the ambient environment and technosphere which might lead to irreversible harm. Suggestions included systematic environmental monitoring and surveillance of vPs, including human bio-monitoring and in waste streams, to track presence and mark any accumulations (d.34), and particularly where point sources of discharges have been identified, e.g., PFAS around all airfields (d.36).

And not least of all, sub-study g on an early warning system for examining chemical threats to human health and the environment suggested a number of ways to strengthen the signals picked up by environmental and human monitoring data sources in order to set priorities for assessment, evaluation and initiation of risk management measures (g.08). It called for centralized collection of exposure and hazard information at the EU level (g.09); cooperation and exchange of information on new and emerging risks from chemicals (NERCs) (g.02; g.05); and interlinking and coordinated monitoring of exposures for three focus areas, namely environment, consumers and workers (g.19).

7.4 THE RANGE OF POLICY INSTRUMENTS SUGGESTED

The responses identified for each sub-study also corresponded to a range of policy instruments. It is worth noting that the European chemical legislative framework already uses a similar range of policy means that provides an important base for responding to the gaps and deficits identified in the sub-studies, as summarized in the table below.

Table 3: Overview of current policy instruments

Type	Sub-type	Examples of current use
Legislation	Data gathering	REACH Regulation
	Assessment of data for regulatory controls	REACH & CLP Regulations
	Restrictions & bans	REACH Annex XVII, Ozone Depleting Substances Regulations
	End-of-pipe control	Industrial Emissions Directive, Landfill Directive
	Quality standards	Drinking Water Directive, Water Framework Directive
	Product standards	Toys Directive, Food Contact Materials Regulation
Streamlining legislation		EU 'Better Regulation' Initiative
Economic instruments	Taxes and subsidies	Fertilizer taxation e.g. Denmark, Finland, Norway, Netherlands, Sweden
	Fees and payments	Fees for substance registration under REACH to support ECHA
	Tradable rights	CO2 emissions trading scheme, EU
	Public procurement	Chemicals Action Plans of the cities of Gothenburg and Stockholm
	Liability/insurance	EU Environmental Liability Directive
Information based instruments	Targeted information provision	Children's health public campaign, Denmark REACHReady, UK
	Registration, labelling and certification	EU Ecolabel The Green Dot, EU
	Naming and faming/ shaming	Bathing water interactive map, EU E-PRTR interactive map, EU
Civic, co- and self-regulation	Circular business models	Chemical Leasing, Chemical Management Services, Cradle to Cradle
	Covenants and negotiated	Environmental Covenants, Netherlands Nanomaterials voluntary reporting, UK

Type	Sub-type	Examples of current use
	agreements	
	Self-regulation	ISO14001, global Chemical Footprint BASF Supplier Code of Conduct, global
Support and capacity building	Research and knowledge generation	REACH Regulation requirements for substance testing Horizon 2020
	Demonstration projects/ knowledge diffusion	Eco-Innovation Program Lighthouse Projects, LIFE, Denmark National Demonstration Test Catchments Network, UK
	Network building and joint problem solving	European Technology Platform for Sustainable Chemistry (SusChem), EU ResearchGate, global
Enforcement		ECHA compliance check, Enforcement Forum for REACH and CLP RAPEX
Monitoring		EU Watch List (Water Framework Directive) EU biomonitoring programme

The table below is based on Table C in the annex to this report, which compiles all of the responses identified across the seven sub-studies and the type(s) of policy instruments considered appropriate for addressing particular gaps. It shows the frequency of identified responses by policy instrument. Frequency is calculated dividing the number of responses identified in each category of responses, by the total number of responses per each sub-study. Because some of the identified responses were scored as involving one more policy instrument (e.g. legislation -> monitoring -> enforcement), the percentages for each sub-study's row do not add up to 100%. Rather, the table is an indicator of the frequency for each policy instrument per sub-study, with blue indicating the lowest level of frequency and red the highest level of frequency.

Table 4: Frequency of identified responses by policy instrument.

	Strengthening Legislation	Streamlining legislation	Economic instruments	Information based instruments	Civic and self-regulation	Support and capacity building	Enforcement	Monitoring
Sub-study a: Substitution, including grouping of chemicals & measures to support substitution	10%	17%	17%	37%	7%	33%	3%	7%
Sub-study b: Chemicals in products (articles) and non-toxic material cycles	48%	13%	6%	25%	4%	29%	6%	4%
Sub-study c: The improved protection of children and vulnerable groups from harmful exposure to chemicals	34%	24%	0%	24%	0%	31%	0%	3%
Sub-study d: Sub-strategy for very persistent chemicals	37%	41%	2%	46%	41%	34%	7%	22%
Sub-study e: Policy means, innovation and competitiveness	18%	18%	15%	15%	3%	44%	3%	6%
Sub-study f: Programme on new, non-/less toxic substances	20%	30%	10%	30%	50%	60%	0%	0%
Sub-study g: Early warning systems for examining chemical threats to human health and the environment	5%	0%	0%	53%	0%	53%	0%	0%

The table thus provides an overview of the relative usefulness of various types of policy instruments for addressing the gaps and deficits identified per sub-study. Its policy messages could be summarised as follows:

- A need to strengthen existing legislation, particularly with respect to chemicals in products ('articles'), very persistent chemicals, and the protection of children and other vulnerable groups
- Identification of a need for improved monitoring of very persistent chemicals
- Additional effort and resources needed across the board for improved information, and for the use of information-based instruments
- Not much enthusiasm for the use of economic instruments as a means of achieving the desired policy objectives
- Opportunities for streamlining legislation and for civic and self-regulation by stakeholders, particularly with respect to the development of new, non/less-toxic substances
- A clear need for support and capacity building across all of the sub-study areas

7.5 BRINGING IT ALL TOGETHER

- The findings of the sub-studies summarized in the previous sections indicate the need for an additional, overarching, horizontal policy process or platform with the overall objective of minimising human and environmental exposures to chemicals of concern and drawing on a range of different instruments and measures. The purpose of such a policy process/platform would be to provide: Improved identification and tracking of all substances meeting the criteria for SVHCs and including very persistent substances as well as substances of concern meeting other endpoints not yet adequately addressed, e.g., endocrine disrupters, neurotoxins, immunotoxins, and developmental toxins.
- Improved integration across the many different policy areas that, in one or another, address chemicals of concern and chemical pollution e.g. chemicals legislation, air and water quality legislation, industrial pollution controls, product legislation (toys, cosmetics, pharmaceuticals, pesticides, biocides, etc.), food legislation, waste legislation, etc.;
- Additional hazard identification and risk assessment processes that allow for more rapid screening and identification of potential chemicals of concern and that can cope more efficiently with the huge numbers of existing chemicals as well as the ever increasing numbers of new chemicals being invented and placed on the market;
- Support for improving the functioning of existing legislation and policy approaches e.g. through better information sharing, and more training and capacity building; and
- More focus and clarity on the long-term perspective and goals of sustainable chemicals management, including the international commitments of the SDGs, WSSD 2020 and SAICM.

The risks related to chemical substances may be present at various points throughout a substance's life-cycle: during production, when they are transported, in the manufacture of mixtures and articles, during the use of the mixtures and articles which contain the substances, when they are (eventually) recycled and when they are then discarded. Because of these various stages, it is crucial to manage substances of concern sustainably throughout their life-cycle.

This is particularly relevant regarding very persistent (vP) substances that, once produced, will remain in the environment for a substantial amount of time. Product regulations rarely evaluate the risk of a vP during a product's entire life-cycle: they usually are limited to requiring an assessment of the risk associated with the exposure to the chemical during the use phase. This failure to take account of the substance's fate at the end of a product's life risks build-ups of vP substances in waste materials recycled as part of the circular economy, along with accumulations in the environment, which could form reservoirs for future exposure.

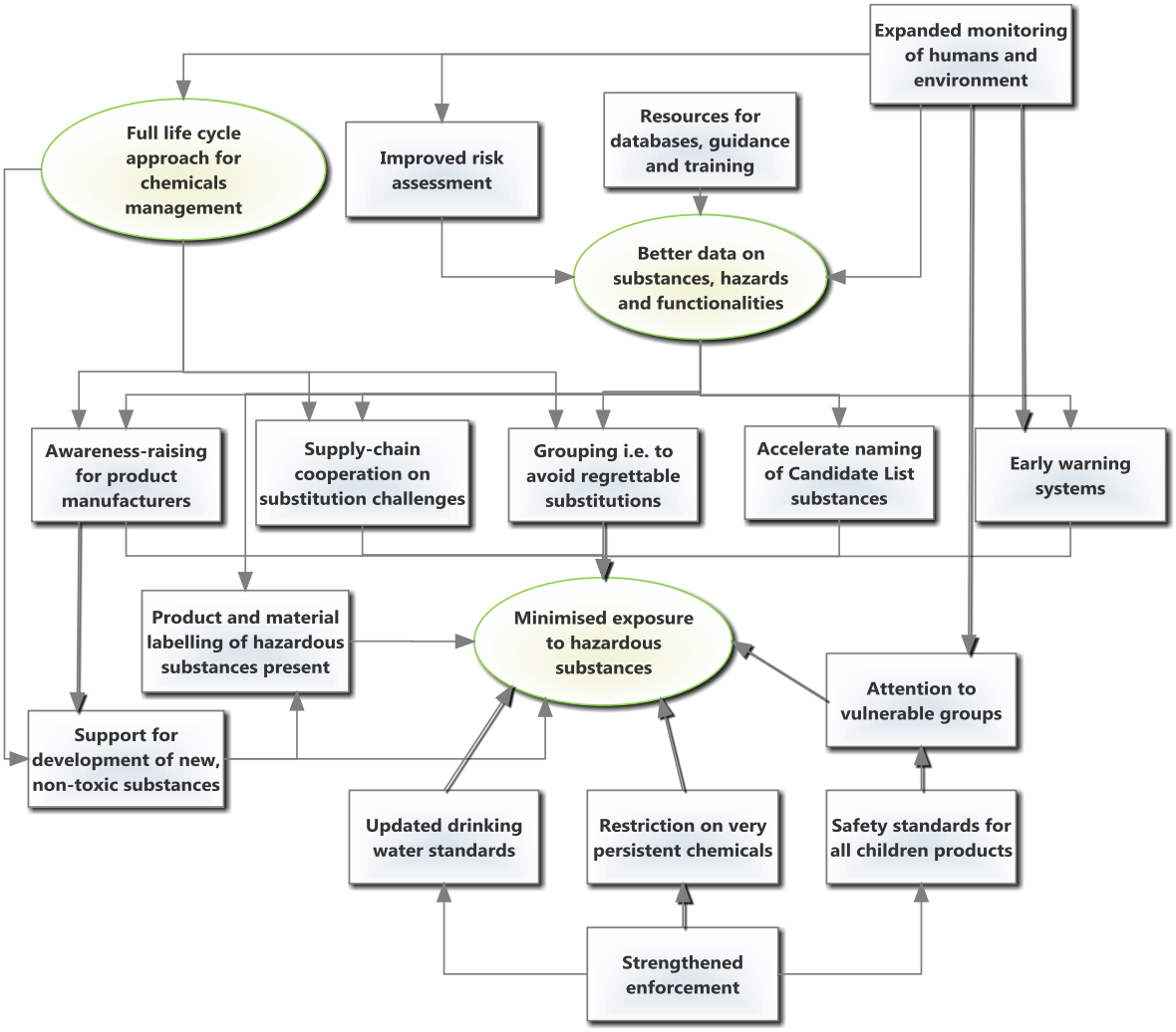
Several sub-studies (and stakeholders) therefore argued for a life cycle approach to chemicals

management. This would include more understanding of chemical product life cycles, in order to identify the responses that might be needed to address the health and environmental impacts of a substance of concern throughout its life cycle, from production through use and including releases into waters and land during use and at the waste stage.

The figure on the next page illustrates some of the key elements identified throughout the sub-studies that could form part of a strategy for a non-toxic environment. Three focal points help to structure the relationship among the various elements, e.g.:

- Full life cycle approach for management of chemicals, including in articles
- Better data on substances, hazards and functionalities/uses
- Minimised exposure to hazardous substances

Figure 8: Overview of elements for a strategy for a non-toxic environment



REACH already recognises the importance of assessing risks from chemical substances from a life cycle perspective. All substances placed on the market in quantities of 10 tonnes per annum or more are required to be subject to a chemical safety assessment (CSA). REACH Annex I, paragraph 0.3 states:

> *"The assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses. The chemical safety assessment shall be based on a*

comparison of the potential adverse effects of a substance with the known or reasonably foreseeable exposure of man and/or the environment to that substance taking into account implemented and recommended risk management measures and operational conditions."

This assessment is to be carried out primarily as part of the description of the 'exposure scenario', and to involve an 'emission estimation' (Annex I, paragraph 5.2.2) that *"considers the emissions during all relevant parts of the life-cycle of the substance resulting from the manufacture and each of the identified uses…cover[ing], where relevant, the service-life of articles and the waste stage."* Note that this is one of the few places in REACH where the service-life of articles and the waste stage are mentioned with respect to a substance's life cycle.

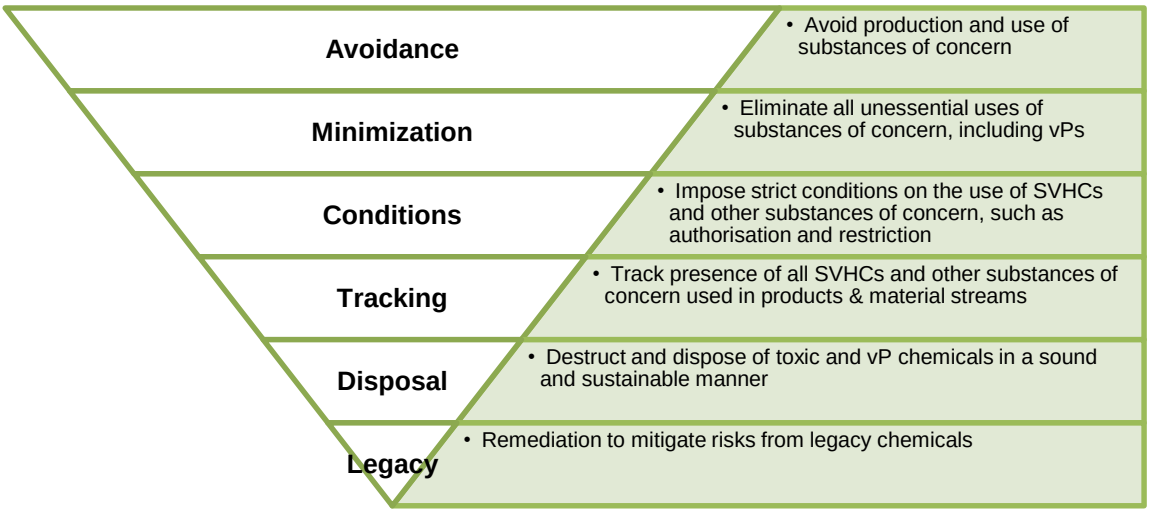
These life-cycle aspects are neglected in many chemical assessment tools, though they are essential for identifying trade-offs, avoiding regrettable substitutions and burden shifting. Even when life-cycle impacts are considered, the available information may not be sufficient for a proper assessment. Moreover, life-cycle assessments are also resource and time intensive and rely on extensive and good quality data that, despite the implementation of the REACH Regulation, are not yet available for most of the chemicals of concern. Introducing additional layers of data demands in a situation where health and environment data is still insufficient for assessments in chemicals policy might not be currently realistic.

Hence it is important to differentiate between a chemical safety assessment, which is often aimed at estimating how much of a substance can be used safely, and a life-cycle **approach,** which aims to minimize all exposures to hazardous substances as much as possible. This involves applying life cycle thinking that prioritises avoidance and minimisation of uses of hazardous substances, with all stakeholders motivated or pushed to design more sustainable substances or find non-chemical solutions.

This involves aligning the design process of articles and substances to the principles of Green Chemistry and to consider life-cycle aspects in the wider context of the chemicals' applications in consumer products and their impacts during service-life and end-of product life. Increased information on the life-cycle aspects of chemicals will also be critical for the goal of a Circular Economy, since waste treatment operators often lack information to decide on a sound basis which treatment options to choose, including recycling.

A strategy for a non-toxic environment could therefore consider a type of hierarchy in chemicals policy and management, similar to that which guides EU waste management policy, as per the figure below.

Figure 9: Hierarchy on uses of chemicals



Such a hierarchy could start with the principle of avoiding the production and use of chemicals of particular concern (i.e. SVHCs and equivalent including very persistent chemicals) as far as possible and limiting any uses to situations where the use is sufficiently well contained and where exposure does not occur. The next step would be minimisation of exposure by different means and applying also to hazardous chemicals of lower concern. In addition, emphasis would be placed on the design of non/less-toxic chemicals and of products that would allow for toxic-free reuse and/or recycling. Finally, it would include workable approaches to address legacy chemicals, including systems for decontamination of recycled materials as well as recovery and destruction of hazardous substances in production wastes and at end-of-life product disposal.

8 CONCLUSIONS

8.1 PROGRESS ALREADY MADE VIA THE CURRENT EU REGULATORY APPROACH

The chemicals regulatory framework put in place by the European Union is widely regarded as the most advanced and comprehensive legal framework for the control of chemicals in the world. It applies to all industry sectors dealing with chemicals and along the entire supply chain, making companies responsible for the safety of chemicals they place on the market.

Because of the REACH Regulation and its registration requirement, significant progress is being made towards filling the previous data gaps concerning the potentially hazardous properties of the more than 100,000 substances on the EU market. Moreover, in theory, the burden for generating this information and for ensuring that the risks linked to substances in commerce are managed safely has shifted from governments to the industry. However, regulators still face considerable hurdles in their efforts to show that a particular substance or group of substances should be subject to authorisation or restriction.

Under its better regulation programme (REFIT), the Commission is carrying out a comprehensive fitness check of all chemicals legislation, except REACH, and a REFIT evaluation of REACH that together will present a stocktaking of chemicals legislation. While this work is ongoing, so far there are no indications of problems that would allow to conclude that the EU legislative framework governing the risk management of chemicals is not fit for purpose on an overall level.

The EU chemicals industry has demonstrated the capacity to remain competitive within this framework and growth over the coming decade is expected to be robust. The use of chemicals is ever increasing. EU production of industrial chemicals is now at 400 million tonnes a year, with some 35,000 chemicals marketed in volumes over 1 tonne a year. However, it is also important to recognise that the production is growing faster in some regions outside the EU. This will have consequences for such aspects as what chemicals will enter the EU market in different kinds of articles.

This poses new challenges for the goal of protecting humans and the environment from chemicals-related harm. Of the chemicals on the EU market today, an estimated 60% by volume are considered hazardous to human health or the environment. Though the data gaps are slowly being addressed, only a few of the large number of chemicals currently on the market have been subjected to a full assessment of the risks they may pose to human health and the environment and impacts, and only some of these are actually controlled under REACH through authorisation or restriction. As the 7th EAP notes, there is particular concern for impacts on children and other vulnerable populations.

An additional challenge is the EU goal of achieving a Circular Economy by e.g. increasing reuse and recycling of material. It will be important to consider how to manage chemicals throughout the material cycle, from manufacturing of the chemicals to manufacturing and use of products, during waste management and recycling as well as in connection to use of recycled materials. If materials contain residues of hazardous substances, these may build up, leading to increasing concentrations of contaminants in recycled materials, and their increased dispersal and presence in the technosphere as well as the natural environment. This is an additional impetus for the sustainable management of chemicals.

8.2 SUMMARY OF GAPS IDENTIFIED AND NEED FOR A STRATEGY FOR A NTE

The seven sub-studies and the June 2016 workshop carried out in the context of this study have identified a range of gaps and deficits in the respective focal areas which are important to consider in

the overall effort to reduce exposure to harmful chemicals. Some of the major knowledge gaps and deficits in legislation identified include:

- Slow progress in identification of Substances of Very High Concern, and in substitution of hazardous chemicals in industrial processes and products
- Lack of information concerning hazardous chemicals in articles, including imported articles
- Insufficient attention to hazardous chemicals in material flows important for a Circular Economy
- Deficits in the framework for protection of children and other vulnerable groups, e.g. from chemicals in products such as textiles and other everyday consumer products
- Lack of consideration of the combination effect of exposure to multiple chemicals, both in chemical risk assessment and horizontally across legislation, as well as cumulative exposure from multiple sources and long-term and low-dose exposure
- Insufficient means to address risks posed by chemicals on the basis of persistence alone
- Lack of monitoring of environmental compartments concerning possible build-ups of contamination and health risks thereof, in particular with respect to water intended for human consumption
- Need for better incentives for development of new, non/less-toxic substances as well as non-chemical solutions
- Need for more comprehensive compilation of monitoring data at EU level and establishment of an early warning system.

Further, the scale of the problems identified in the sub-studies highlight the need for additional action, as per the box below.

The scale of the problem with respect to SVHCs and other chemicals of concern

- As global production of chemicals increases, so does the production and international trade of articles made from these chemicals. The yearly import of manufactured goods to the European Union has almost tripled between 2000 and 2015, including from countries with insufficient regulatory controls over chemicals. In 2016, 3.4 tonnes of products (2.1 raw, 0.4 semi-finished and 0.9 finished products) per capita were imported in the EU, with some 20% from China.
- Human biomonitoring studies in the EU point to a growing number of different hazardous chemicals in human blood and body tissue including pesticides, biocides, pharmaceuticals, heavy metals, plasticisers, flame retardants, etc.
- Over 200 synthetic chemicals have been detected in umbilical cord blood, including ingredients in consumer products, food packaging, and chemical by-products from burning coal.
- Combined exposure to several substances, including substances in articles, can have greater impacts than exposure to a single substance. Combined prenatal exposure to several chemicals led to reduced foetal growth and lower birth rates, indicating the need for a greater safety margin for exposures, in particular for foetuses and neonates.
- The cost to the EU of female reproductive disorders and diseases as a result of exposure to endocrine-disrupting chemicals is estimated at close to €1.5 billion annually.
- Extremely persistent chemicals, such as the more than 3,000 highly fluorinated PFAS on the market today, do not break down in the natural environment. The risk is that concentrations will build up in nature and in the technosphere such that levels of exposures to humans and other biota are irreversible.
- Some 3.5 million sites around Europe are already contaminated by hazardous substances, including vPs. Contamination of natural resources has severe economic consequences, ranging from the extremely high costs of remediation to loss of natural resources such as drinking water, land, soils and fish stocks from productive use.

These findings indicate the need for an additional, overarching, horizontal policy process or platform with the overall objective of minimising human and environmental exposures to SVHCs and other chemicals of concern and drawing on a range of different instruments and measures. The purpose of such a policy process/platform would be to provide:

- Improved identification and tracking of all substances meeting the criteria for SVHCs and

including very persistent substances as well as substances of concern meeting other endpoints not yet adequately addressed, e.g., endocrine disrupters, neurotoxins, immunotoxins, and developmental toxins.
- Improved integration across the many different policy areas that, in one or another, address chemicals of concern and chemical pollution e.g. chemicals legislation, air and water quality legislation, industrial pollution controls, product legislation (toys, cosmetics, pharmaceuticals, pesticides, biocides, etc.), food legislation, waste legislation, etc.;
- Additional hazard identification and risk assessment processes that allow for more rapid screening and identification of potential chemicals of concern and that can cope more efficiently with the huge numbers of existing chemicals as well as the ever increasing numbers of new chemicals being invented and placed on the market;
- Support for improving the functioning of existing legislation and policy approaches e.g. through better information sharing, and more training and capacity building; and
- More focus and clarity on the long-term perspective and goals of sustainable chemicals management, including the international commitments of the SDGs, WSSD 2020 and SAICM.

The overall conclusion is that an additional, more horizontal approach for reducing exposure to hazardous substances, i.e., a strategy for a non-toxic environment, should be set in place as a matter of urgency. In this context, it is important to recall the principles of environmental protection enshrined in the Treaty on the Functioning of the European Union (TFEU), including the principles of prevention and of taking precautionary action when the potential risks are such that to delay action could mean irreversible damage.

8.3 WAYS FORWARD

During this project, a broad outline of the types of measures that could be considered as relevant for a strategy for a non-toxic environment has been emerging. It could include the following themes:

Improve knowledge on chemicals

- Commit long-term to develop chemical knowledge bases (hazardous properties, uses, presence of chemicals in articles, monitoring data);
- Develop and implement an early warning system for identifying new chemical threats;
- Move from the current chemical-by-chemical to groupings of chemicals approaches in risk assessment and risk management.

Promote innovation, development of non-toxic chemicals and non-chemical solutions, and substitution

- Promote innovation: develop non-toxic chemicals as well as non-chemical solutions and promote their use;
- Promote circularity: promote chemical re-use solutions and non-toxic material cycles;
- Support substitution: increase access to knowledge crucial for those who can substitute and support substitution activities.

Reduce chemical exposures and promote circular economy

- Address very persistent chemicals;
- Establish a hierarchy for hazardous substances (e.g. avoidance, minimisation, strict controls, disposal/destruction) and introduce an auditable system of application;
- Establish a system of tracking chemicals in products (articles) and promotion of the development and use of non-toxic materials and articles;
- Improve protection of children and vulnerable groups

Finally, as explained in section 7.5 above, a strategy for a non-toxic environment could also consider moving to a stronger life-cycle approach aimed at minimising exposures to hazardous substances at all chemical and product life stages, from the manufacturing of chemicals, materials and products to the service life and end-of-life of products and to a new life cycle through recycling of materials. It could be translated into the overall principle that hazardous substances of particular concern (e.g substances corresponding with the criteria of SVHC in REACH and equivalent) should as far as possible be phased out in uses which are not sufficiently well contained/controlled during their life cycle. Further, there should be a constant striving towards minimising the exposure to all hazardous substances, including those of lower concern. This would include a range of different activities such as avoiding uses that are not essential, development of non- or low toxic chemicals and non-chemical solutions, product and material design, reducing volumes used, avoiding uses involving large exposure, improving information and different protective measures. Choice of substances, design of products etc. should also meet the needs of reuse and recycling and aim to as far as possible achieve non-toxic material cycles.

In connection to this a type of **hierarchy in chemicals policy and management**, similar to that which guides EU waste management policy, is envisioned. Such a hierarchy could start with the principle of avoiding the production and use of chemicals of particular concern (i.e. SVHCs and equivalent including very persistent chemicals) as far as possible and limiting any uses to situations where exposure does not occur. The next step would be minimisation of exposure by different means and applying also to hazardous chemicals of lower concern. In addition, emphasis would be placed on the design of non/less-toxic chemicals and of products that would allow for toxic-free reuse and/or recycling. Finally, it would include workable approaches to address legacy chemicals, including systems for decontamination of recycled materials as well as recovery and destruction of hazardous substances in production wastes and at end-of-life product disposal.

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European Commission

Study for the strategy for a non-toxic environment of the 7th EAP

Sub-study a: Substitution, including grouping of chemicals & measures to support substitution

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This sub-study report has been prepared by Marco Camboni of Risk & Policy Analysts (RPA).

The views expressed herein are those of the consultants alone and do not necessarily represent the official views of the European Commission.

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Sub-study a: Substitution, including grouping of chemicals & measures to support substitution

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ABSTRACT

The present paper examines the implementation of the substitution principle in European chemical legislation, along with the practices and challenges faced by the companies when substituting hazardous chemicals in processes and products. In particular, it investigates how regulatory incentives results in the occurrence of regrettable substitutions, i.e. the substitution of hazardous substances with substances with similar chemical structure and similar hazard properties or with substances with other effects of similar concern. It explores the extent to which grouping strategies could be used to enhance the efficiency and effectiveness of the regulatory process. Finally, it presents and discusses the measures recommended by the literature and by relevant stakeholders to facilitate and improve the substitution of hazardous substances.

EXECUTIVE SUMMARY

The principle of substituting hazardous substances has been used in international agreements and in European and national legislation as a tool of risk management for many years. The Seventh Environment Action Programme recognises innovation and the development of sustainable substitutes, including non-chemical solutions, as basic aspects of a strategy for a non-toxic environment.

Key findings on substitution

The problem

- The prevailing use of hazardous substances including substances of very high concern and equivalent in industrial processes and industrial and consumer products may lead to human and environmental exposure.
- The presence of hazardous substances in products may cause problems through exposure of humans and the environment during the service life as well as in relation to waste management and recycling once the products become waste.

Gaps and inconsistencies in current policy

- Information on the (eco)toxicological, bioaccumulation and environmental degradation properties of the substances provided in the registration dossiers already submitted appears to be inadequate and is not kept up-to-date in 69 % of the dossers the were subject to compliance check in 2014.
- Substances manufactured or imported in low quantities have no or reduced information requirements.
- There is a lack of information on the uses and presence of hazardous substances in articles, in particular in imported articles.
- Risk assessment methodologies for the article service life and waste stage are not sufficiently developed to assist all actors.
- The available tools for the assessment of alternatives typically combine hazard and risk assessment with economic and technical feasibility, focusing on chemical-by-chemical substitution.
- There is scarcity of information on alternatives.
- The REACH authorisation does not cover imported articles and NGOs and some Member States complain about the lack of speed and ambition of the authorisation process.
- Companies complain about the regulatory uncertainty on available alternatives, the insufficient time to identify and develop suitable alternatives, the excessive lengthening of the time to market for products containing alternatives and, more in general, of the high administrative burden, in particular for SMEs.
- Synergies between chemical policies are still unsatisfactory.
- There are insufficient regulatory signals to investments in innovation.
- Resources dedicated to the enforcement of chemical policy are inadequate.
- There is a lack of resources dedicated to substitution initiatives among Member States, ECHA and the Commission.

Different types of policy means are used to encourage and facilitate substitution, from the mandatory restrictions of certain substances in certain applications, through the development of tools for chemical risk management and for the assessment of potential alternatives, to providing support for research, development and innovation.

The survey of member state competent authorities, industry stakeholders and external consultants confirmed that the legislative requirements are seen as the main driver of substitution, with respondents indicating the placement of a substance on the candidate list for authorisation as the key mechanism that initiates the search for safer alternatives. Economic considerations, corporate social responsibility, internal chemical management policies, supply chain requests and consumers' and

workers' concerns were also indicated as important factors. When asked about the benefits, industry stakeholders reported that replacing hazardous substances improves worker safety and enhances the market reputation of their companies and their clients.

A large proportion of respondents indicated the lack of information on the technical feasibility of alternatives and the actual possibility of developing alternatives able to satisfy the customer performance specifications as important obstacles. Many substances are used for very specific applications and fit into the specific processes of individual companies. General information about potential substitutes may be a good start but ultimately it is not useful for assessing whether the alternatives could perform adequately in a particular process. Moreover, alternative suppliers often do not have knowledge of the process characteristics of their potential downstream users and companies are generally unwilling or unable to share information up and down the supply chain for strategic, competitive and economic reasons. Small and medium-sized enterprises often do not have the resources to deal with the workload and the information and communication management required by the substitution of substances in their products or processes. There is also a deficiency in the communication of information on the presence of hazardous substances in articles, information that could generate pressure on the manufacturers to substitute. Once the substitution of hazardous chemicals has been implemented, one of the main challenges is the increase in production costs, as well as the customer concerns over changes in processes and products.

Many respondents indicated that they have substituted at least one substance with a chemical alternative that was subsequently found to be of concern and therefore subject to regulatory and non-regulatory pressures. These cases of regrettable substitution are often related to groups of substances with similar chemical structure, such as phthalates, bisphenols, brominated flame retardants and highly fluorinated substances. Typically, companies apply alternative assessment methodologies to find less hazardous substitutes. The available tools usually combine hazard and risk assessment with economic and technical feasibility, focusing on chemical-by-chemical substitution, often leading to the replacement of hazardous substances with structurally similar substances which exhibit similar hazard properties, or with substances for which the information on (eco)toxicological properties is limited. An additional constraint is that, despite the REACH registration process, there are still gaps in e.g. (eco)toxicological, bioaccumulation, and environmental degradation information of substances, due to the limited information requirements for low production volume chemicals and to the inadequate quality of the registration dossiers already submitted. Moreover, most tools neglect life-cycle aspects, which are essential to identify trade-offs and avoid burden shifting. When life-cycle impacts are considered, the available information may not be sufficient for a proper assessment.

Public authorities indicated that a major obstacle to supporting and enforcing substitution initiatives is the lack of resources and expertise.

During the workshop on the strategy for a non-toxic environment held in June 2016 in the context of this study, the participants highlighted the shortcomings of the current legislative framework: the REACH authorisation process does not cover imported articles, thus penalising European companies versus extra-EU; once the regulatory action has started, there may be insufficient time to identify and develop suitable alternatives and when these are developed and applied, in certain sectors such as aerospace or the medical devices industry, there may be an excessive lengthening of the products' time to market. More generally, stakeholders pointed to unsatisfactory synergies between chemical legislative acts and to the lack of ambition by the authorities in including new substances in the candidate list for authorisation. Importantly, the consensus was that a better enforcement of the legislation would ensure sufficient regulatory signals to investments in innovation and research of safer alternatives.

The grouping of chemicals may be an effective way to enhance the efficiency and effectiveness of the regulatory initiative in promoting substitution to less-hazardous chemicals. Grouping strategies have been proposed by different stakeholders (SIEFs and registration consortia, regulators, NGOs, retailers, etc.) and carried out by different criteria (chemical structure, functional group, mode of action, particle

size, etc.) for different purposes (to minimise animal testing, to manage the risks associated with chemicals with the same health and environmental effects, etc.). Various pieces of legislation make use of grouping approaches to different extents, but further research is needed on the association between chemical structures and trends in (Q)SAR predictions in order to scale up their adoption and move from the current incremental substitution practice to a more effective substitution of hazardous substances.

Key findings on grouping approaches

The problem

- Some groups of chemical substances (e.g. phthalates, bisphenols, brominated flame retardants, highly fluorinated substances) count hundreds of congeners, with more or less similar chemical as well as health and environmental properties, constituting major regulatory challenges as resources for assessment and controls are limited.
- The practice of adopting structurally-similar alternatives (incremental rather than fundamental substitution) often leads to cases of regrettable substitution.

Gaps and inconsistencies in current policy

- The available tools for the assessment of alternatives typically combine hazard and risk assessment with economic and technical feasibility, focusing on chemical-by-chemical substitution which is not effective or even feasible for some groups of chemicals.
- Additional efforts are required in the research of grouping strategies for regulatory purposes, focusing on the systematic analysis of the structural similarities of substances and trends in e.g. (Q)SAR predictions and other methods supporting such approaches.

Other identified responses span from actions to streamline the existing legislation and strengthen its enforcement (e.g. increase information requirements for low production volume substances; co-ordinated substitution initiatives across Member States, the authorities (i.e. ECHA; the European Commission) and industry around prioritised chemicals of concern; extend the use of grouping strategies to avoid regrettable substitution; dedicate more resources to enforcement) to the use of economic instruments (e.g. tax the use of hazardous substances; enhance government green procurement programmes, considering the functional substitution of hazardous chemicals) and to initiatives that support companies in their substitution efforts (e.g. develop tools to track hazardous chemicals in articles; fund further research into alternative assessment methodologies; scale-up research on grouping strategies based on similarity of chemical structures and trends in (Q)SAR predictions).

ABBREVIATIONS USED

ACEA	European Automobile Manufacturers Association
BPR	Regulation (EC) No 528/2012 concerning the making available on the market and use of biocidal products
CAC	Command And Control legislation
CAD	Chemical Agents Directive – Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work
CBI	Confidential Business Information
ChF	Chemical Footprint
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
CMD	Carcinogens and Mutagens Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
CMR	Carcinogens, mutagens and substances toxic for reproduction
CoRAP	Community rolling action plan
COSME	Competitiveness of Small and Medium-sized Enterprises
CPR	Regulation (EC) No 1223/2009 on cosmetic products
EAP	Environment Action Programme
ECHA	European Chemicals Agency
EEE	Electrical and Electronic Equipment
EH&S	Environment, Health & Safety
ELV	End of Life Vehicle
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FTE	Full Time Equivalent
IED	Directive 2010/75/EU on Industrial Emissions
ILO	International Labour Organization
MSCA	Member State Competent Authorities
NGO	Non-Governmental Organisation
OECD	Organisation for Economic Co-operation and Development
OSH	Occupational Safety and Health
PACT	Public Activities Coordination Tool
PBB	Poly-Brominated Biphenyl
PBDE	Poly-Brominated Diphenyl Ether
ppb	Part per billion
PPP	Plant Protection Product
PPPR	Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market
RAC	Risk Assessment Committee
REACH	REACH – Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMOA	Risk Management Option Analysis
RoHS 2	Directive 2011/65/EU on Restriction of the use of certain Hazardous Substances in electrical and electronic equipment
SAICM	Strategic Approach to International Chemicals Management
SEAC	Socio-Economic Assessment Committee
SME	Small-Medium sized Enterprise
SVHC	Substances of Very High Concern
tpa	Tonnes per annum
UBA	Umwelt Bundesamt (German Federal Environment Agency)
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNIDO	United Nations Industrial Development Organization

UNITAR	United Nations Institute for Training and Research
UVCB	Substances of Unknown or Variable composition, Complex reaction products or Biological materials
VOC	Volatile Organic Compound
WEEE	Waste Electrical and Electronic Equipment
WFD	Directive 2000/60/EC establishing a framework for Community action in the field of water policy
WHO	World Health Organisation

1 INTRODUCTION

The problem

A large number of hazardous chemicals, including substances of very high concern, are used in industrial processes, industrial products and consumer products. These are sometimes associated with human and environmental exposure, and their presence in products may also cause problems in relation to waste management and recycling once the products become waste, e.g. by contaminating recycled materials.

Through the REACH registration process, information on the (eco)toxicological properties of the substances available on the market is being generated. However, the information provided in the registration dossiers already submitted appears to be inadequate to perform a comprehensive hazard and risk assessment for many of the registered substances. Moreover, substances manufactured or imported in low quantities have no or reduced information requirements. Some groups of chemicals have raised particular concerns: for example, phthalates, bisphenols, brominated flame retardants, highly fluorinated substances and more. Each group can count hundreds of congeners and resources for assessment and control are limited.

Different pieces of legislation to varying degrees create incentives to substitute hazardous chemicals in processes and products by restricting the use of certain substances in certain applications, resulting in companies applying alternative assessment methodologies to find less hazardous alternatives. The available tools typically combine hazard and risk assessment with economic and technical feasibility, focusing on chemical-by-chemical substitution. This often leads to cases of regrettable substitution, i.e. the replacement of hazardous substances with structurally similar substances which exhibit similar hazardous properties. In some cases, the substitution occurs with substances for which the information on (eco)toxicological properties is limited.

The objectives of this sub-study are to provide information on:

- The status quo of the application/implementation of the substitution principle, as well as the status of the principle in the field of chemicals in general. A review of legislation and other policy measures, including voluntary initiatives of business and industry, was undertaken to identify the current incentives, driving forces and obstacles;
- The effectiveness and efficiency of regulatory requirements for the substitution of chemicals, including the effects on overall research and development activities in companies;
- The challenges related to the large amount of structurally related chemicals and the management of these in legislation, as well as problems faced by the users of these chemicals and their substitution work;
- The main gaps regarding policy measures, knowledge and access to information.

The description of the current initiatives for the promotion of the substitution of hazardous substances will inform the provision of:

- Ideas for improvement in the short, medium and long term. This includes possible grouping approaches for chemical policy and substitution, which could contribute to streamlining the level of protection afforded to health and the environment by helping to avoid regrettable substitution;
- Possible supportive and enabling measures to encourage substitution by in particular SMEs.

In order to meet these objectives, desk research and three online surveys (one for member states competent authorities, one for industry and one for consultants) on substitution initiatives have been carried out. Appendix 1 details the findings of the literature review, while Appendix 2 presents the

results of the survey.

The desk research is based on the collection and evaluation of available information in the following fields:

- Implementation of the substitution principle and substitution in general in legislation and other policy measures, including the voluntary initiatives of business and industry. The analysis focuses on the practices followed as well as incentives, driving forces and obstacles in applying the substitution principle.
- Approaches to grouping of chemicals by regulators, industry and NGOs. The research identifies the criteria used for grouping the substances, highlighting the strengths and weaknesses of each approach.

A variety of sources have been reviewed in order to obtain a comprehensive view of the policies promoting substitution and grouping of chemicals:

- Information on legislation and policy measures; mainly at international and national level, with searches on public or private initiatives aimed at substitution or grouping of chemicals also carried out at regional level;
- Reports and articles published by academics, research institutes, companies, industry associations, unions and NGOs;
- Guidance and other best practice documents on grouping of substances (risk assessment, categories) and alternatives assessment approaches, including guidance documents developed for assisting companies in complying with chemicals legislative acts (e.g. guidance documents on REACH and CLP);
- Other concurrent studies, such as the study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation and the study on the impacts of REACH on competitiveness, innovation and SMEs.

2 OVERVIEW OF THE STATE OF PLAY OF THE SUBSTITUTION PRINCIPLE IN THE CHEMICAL FIELD

2.1 THE APPLICATION AND IMPLEMENTATION OF THE SUBSTITUTION PRINCIPLE

2.1.1 The Substitution Principle and its interpretations

The literature includes a wide range of definitions of the substitution principle, varying in terms of scope (substance, mixture, product or function), means (substitution by another chemical substance, by technological or organisational measures) and focus on either hazard or risk (Appendix 1 lists some of the interpretations by different stakeholders and provides further discussion on this subject).

'Hazard' and 'risk' are defined in the European chemical legislation by the Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (the so-called Chemical Agents Directive (CAD)): '*'hazard' means the intrinsic property of a chemical agent with the potential to cause harm'*, while *''risk' means the likelihood that the potential for harm will be attained under the conditions of use and/or exposure''* (CAD, Article 2(g)(h)).

While some definitions explicitly refer to the replacement of hazardous substances by less hazardous alternatives (less hazardous or non-hazardous substances, as well as technological or organisational measures) (e.g. Lohse et al, 2003; KemI 2007; IFCS, 2008; Hansson et al, 2011), other definitions interpret substitution as the replacement of one substance by another with the aim of achieving a lower level of risk (e.g. CEFIC, 2005; Aven, 2014)[1]. As risk is the combination of hazard and exposure, risk-based definitions leave open the possibility to minimise either the hazard or the exposure or both.

Hazard-based and risk-based approaches are not mutually exclusive and both are in use in European chemical policy, e.g. the REACH Regulation. Both approaches have their merits: the risk-based approach helps in focusing on and prioritising the substances that have been proved to be problematic and not just classified as having a potential to cause harm. The hazard-based approach lowers the level of complexity of the assessments by not requiring information on exposure and focusing only on the intrinsic properties of the substances and hence their potential to cause harm (ChemSec, 2016). The hazard-based approach is precautionary, meaning that in the presence of uncertainty over the risk, the focus on the hazard is the only certain means to reduce the risk, with some authors arguing that "*the availability of feasible safer alternatives or services should be seen as sufficient rationale under precaution to restrict or phase out the use of hazardous chemicals*" (Hansen et al, 2007 in Lofstedt, 2014, p.546). On the other hand, it may not consider the context in which a substance is used, in terms of exposure, its technical function in the application and the linked socio-economic benefits. Purely hazard-based approaches, without consideration of the use context and available alternatives also bear the risk of leading to regrettable substitution.

With regard to the substitution principle, this is not a new tool in risk management and its first legal use dates back to 1949 in worker's health and safety law in Sweden (Lofstedt, 2014).

At international level, the substitution principle has been discussed since the 1970s. It was first

[1] It should be noted that one-to-one substitution is rarely the case: replacing one hazardous substance from a mixture or an article often requires the substitution or changes in concentration of other substances in the mixture or article. If the overall risk deriving from the exposure to the new mixture or article is not adequately taken into account, the replacement of one hazardous substance may lead to, so-called, regrettable substitutions. This is further discussed in Section 2.3.

included in the Convention on Long-range Transboundary Air Pollution[2] in 1979 and has been subsequently included in all major international agreements on chemical safety (IFCS, 2008a). The Overarching Policy Strategy that forms part of the Strategic Approach to International Chemicals Management (SAICM), developed by the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC)[3] and the Intergovernmental Forum on Chemical Safety (IFCS), has among its objectives,

"to promote and support the development and implementation of, and further innovation in, environmentally sound and safer alternatives, including cleaner production, informed substitution of chemicals of particular concern and non-chemical alternatives"[4].

In order to meet this objective, the Global Plan of Action of SAICM requires the parties to prioritise activities which,

"Ensure that, by 2020, chemicals or chemical uses that pose an unreasonable and otherwise unmanageable risk to human health and the environment based on a science-based risk assessment and taking into account the costs and benefits as well as the availability of safer substitutes and their efficacy are no longer produced or used for such uses"[5].

Table 2 of Appendix 1 to this sub-study provides a non-comprehensive chronological list of the use of the substitution principle in international agreements and in the European and national legislation.

2.1.2 Policy means requiring and promoting substitution

The substitution of hazardous substances is horizontal to many policies dealing with workers' health and safety, products' safety and the environment. Moreover, a range of different measures at local, national and international level promote the substitution of hazardous chemicals. These can be divided into eight different categories:

- Command and control legislation;
- Economic instruments;
- Co-regulation;
- Information-based instruments;
- Civic and self-regulation;
- Support and capacity building;
- Enforcement;
- Monitoring.

The OECD defines command and control (CAC) policy as "*environmental policy that relies on regulation (permission, prohibition, standard setting and enforcement) as opposed to financial incentives, that is, economic instruments of cost internalisation*"[6].

The European chemical legislative framework is built around two key pieces of legislation, REACH

[2] Art. 7 of the Convention on Long-range Transboundary Air Pollution. Available at: http://www.unece.org/fileadmin/DAM/env/lrtap/full%20text/1979.CLRTAP.e.pdf
[3] The participating organisations of IOMC are: the World Health Organisation (WHO), the United Nations Environment Programme (UNEP), the Food and Agriculture Organization of the United Nations (FAO), the International Labour Organization (ILO), the Organisation for Economic Co-operation and Development (OECD), the United Nations Industrial Development Organization (UNIDO), the United Nations Institute for Training and Research (UNITAR), The Global Environment Facility, the United Nations Development Programme (UNDP) and the World Bank.
[4] SAICM Overarching Policy Strategy, IV Objectives, A. Risk Reduction, (j).
[5] SAICM Global Action Plan, Executive Summary 7(d)(i). Overarching Policy Strategy and Global Action Plan available at: http://www.saicm.org/images/saicm_documents/saicm%20texts/SAICM_publication_ENG.pdf
[6] https://stats.oecd.org/glossary/detail.asp?ID=383

and the CLP Regulation. These interact with other legislative acts in the environmental, product safety and health and safety areas, many of which encourage the substitution of hazardous chemicals directly, by explicitly mentioning substitution and/or requiring an assessment of alternatives, and indirectly, by restricting certain uses or requiring expensive risk management measures that effectively incentivise substitution.

Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) came into force on 1 June 2007. REACH aims to provide a high level of protection for human health and the environment through better and earlier identification of the intrinsic properties of chemicals and their uses, while at the same time enhancing the innovative capability and competitiveness of the EU chemicals industry. Furthermore, REACH aims to ensure the free movement of substances and the promotion and development of alternative methods for the assessment of hazards of substances.

The Regulation applies to substances manufactured, placed on the market and used in the EU either on their own, in mixtures or in articles. REACH is based on the principle that it is for industry to ensure the manufacture and place on the market of substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle (Article 1(3)).

The four key elements in REACH are:

- **Registration** of substances manufactured or imported in quantities of more than 1 tonne per year (per manufacturer or importer) (Title II);
- **Evaluation** of the registration dossiers submitted and of the information submitted per substance, prioritizing those substances presenting higher levels of risk (Title VI);
- **Authorisation** of Substances of Very High Concern (SVHC), assuring that the risks of SVHCs are properly controlled and that these substances are progressively replaced, while ensuring the good functioning of the internal market (Title VII); and
- **Restriction** aimed at addressing identified risks on a Community-wide basis (Title VIII).

In particular, the authorisation mechanism aims '*to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution'* (Article 55 of the REACH Regulation).

The regulatory banning of substances and even the anticipation of regulation itself are strong drivers for the substitution of hazardous substances. Once initiated, regulatory processes send signals to the market and act as an incentive for innovation throughout the supply chain.

CIEL (2013) reports that publically available patent records show a surge of inventions (measures such as patent families[7]) to eliminate the use of lower molecular weight phthalates following a series of actions undertaken by regulators starting in 1998 (opinion and recommendation on phthalates by the European Commission Scientific Committee on Toxicity, Ecotoxicity and Environment) and culminating with the listing on Annex XIV of this group of phthalates under REACH. Given the time needed for research and development prior to filing of a patent, it can be assumed that inventors foresaw the enactment of stricter laws when beginning research. Almost half of the patented alternatives to phthalates cite health and environmental concerns (CIEL, 2013). This finding is

[7] Patent families are used rather than individual patents to avoid double counting where an invention has been patented in multiple countries.

corroborated by responses of companies to the prospects of stricter laws on lead, mercury, PCBs and vinyl chloride. It was not until significantly stricter measures appeared likely, such as inclusion in the REACH authorisation list, that major chemical manufacturers and others significantly increased patenting of alternatives. The increase in number of non-phthalate and phthalate-free patents also resulted in the invention of alternatives beyond the share of the market for toys and childcare products, with 95% of the patents not limited to infant and children's products (Godwin, 2011 in CIEL, 2013). Similarly, the case of chlorofluorocarbons (CFCs) used as refrigerants demonstrates how the introduction of progressively stricter rules at global and regional levels encouraged innovation and invention of safer chemicals; helping to reduce the consequences of inaction and disprove the projected cost of action. In this instance, manufacturers researched and developed several alternatives which were not introduced to the market as they were not considered economically viable. However, manufacturers later acknowledged that it was the lack of legally-enforceable standards that prevented safer alternatives from entering the market (Anderson et al, 2007 in CIEL, 2013).

Some stakeholders, although favourable on the principles and objectives of REACH, have pointed to limitations on the scope of the Regulation, for example, with regard to nanomaterials (CIEL, 2012) and chemicals in articles (KemI, 2015; UBA, 2015a). The REACH Regulation has been reviewed in 2012 and is currently the subject of a second review, the results of which will be published in 2017.

With regard to the effects of REACH on substitution activities, CSES et al (2015) report that around 25% of the companies surveyed by the authors reported an increase in budget for research and development. However, around 50% of the sample had transferred their R&D resources to compliance activities. Between 45% and 50% of the companies surveyed agreed that the improved and increased communication in the supply chain required by REACH provides for the potential for more innovation, business development opportunities and more efficient and effective supply chain management practices in the longer term. Many companies took the opportunity of complying with the REACH registration requirements to revise their product portfolios, withdrawing low volume / low value substances, those at the end of their product cycle (economic criterion) and those with an undesirable hazard profile. The study found a gradual increase in the use of product and process orientated research and development (PPORDs), although still mainly by German companies (39%) and large firms (>80%)[8].

For about half of the 31 substances currently in Annex XIV (the authorisation list), no applications for authorisation have been received, and around half of the applications received by August 2015 are so-called "bridging authorisations", meaning that the applicants are working on phasing out the substance from their processes/products but need more time to fully develop an alternative[9].

Furthermore, the inclusion of substances on the PACT, CORAP, the candidate list and ultimately Annex XIV has led to significant levels of activity as regards substitution, withdrawal and replacement.

On the other hand, KemI (2015) considers that the costs of preparing proposals for restrictions under REACH have risen considerably when compared to the past, due to the information required from ECHA's Risk Assessment Committee (RAC) and Socio-Economic Assessment Committee (SEAC) in order to form an opinion. KemI estimates the cost to be between SEK 5 and 10 million (roughly € 0.5-1 million). This has resulted in fewer restriction proposals being submitted, thus slowing down substitution of hazardous chemicals. There is also concern that the authorisation process can become cumbersome and labour intensive, subsequently increasing ECHA's workload. KemI (2015)

[8] For further discussion on the effects of REACH on innovation activities, please see sub-study E.
[9] Presentation by Thierry Nicot - Risk Management Implementation Unit at ECHA. Available at: http://echa.europa.eu/documents/10162/21825501/afa_201502_7_nicot_en.pdf

hypothesises that, due to the more stringent requirements of REACH[10] and despite the increased availability of information on health and environmental risks, many of the restrictions that were mandated from the preceding Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations would not have come about under REACH.

Some environmental NGOs criticised the slow pace in including substances on the candidate list, pointing to the very limited resources dedicated by ECHA and some Member States to achieve the Commission's goal to include all relevant currently[11] known SVHCs by 2020 (Schaible and Buonsante, 2012). In response, ECHA adopted the "SVHC roadmap to 2020 - Implementation Plan" in 2013[12].

The effectiveness of CAC legislation, and therefore REACH, relies on a high level of compliance. In 2015, the German Federal Environment Agency (UBA) screened a sample[13] of registration dossiers to check whether the information submitted fulfilled the legal requirements of the Regulation, concluding that a substantial improvement of the data contained in the dossiers is required (UBA, 2015b). During the Stakeholder Workshop on the "Strategy for a Non-toxic Environment of the 7th Environment Action Programme (EAP)" held on the 8th and 9th of June 2016 in Brussels, the consensus among the participants was that the regulatory framework in place can satisfy regulatory needs if enforcement is ensured. This was also considered valid for the promotion of the substitution of hazardous chemicals, for which the participants highlighted the need for stronger and more consistent enforcement, in particular on imported articles.

As already mentioned, in addition to REACH there are many pieces of CAC legislation that aim to promote substitution, directly or indirectly. A non-comprehensive list of examples from environmental, product safety and health and safety legislation is presented below:

- Directive 2011/65/EU (RoHS 2) on the restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE) restricts the use of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) in EEE when substitution is possible from the scientific and technical point of view. Moreover, it requires to update the list of restricted substances as soon as new scientific evidence is available on more environmentally friendly alternatives;
- Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) is built around the "producer responsibility" principle and, indirectly, promotes the substitution of hazardous chemicals in EEE by making producers responsible for the collection and management of waste and hazardous waste;
- Both Directive 2000/60/EC establishing a framework for Community action in the field of water policy (WFD) and Directive 2010/75/EU on industrial emissions (IED) recall the polluter pays principle (Article 191 of the Treaty on European Union) and indirectly promote substitution by promoting the internalisation of the externalities due to the use and release of hazardous chemicals in the environment;
- Regulation (EC) No 1223/2009 on cosmetic products (CPR) prohibits and restricts the use of hazardous chemicals, in particular carcinogens, mutagens and substances toxic for reproduction (CMR);
- Both Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products and Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market, require active substances with certain hazardous properties to be

[10] According to KemI, this is due not only to the actual legal requirements of the Regulation but also by the working methods of the Committees.
[11] At December 2013.
[12] Available at: https://echa.europa.eu/documents/10162/19126370/svhc_roadmap_implementation_plan_en.pdf
[13] 1932 dossiers of lead and individual registrants covering phase-in substances with a production volume of equal or above 1000 tpa.

considered as candidates for substitution;

- Directive 2009/48/EC on the safety of toys restricts the use of substances with certain hazardous properties and encourages the replacement of dangerous substances and materials used in toys with less dangerous substances or technologies, where suitable economically and technically viable alternatives are available;
- Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (CMD) requires employers to replace, where technically possible, carcinogens and mutagens at the place of work with substances, preparations or processes which pose a lower level of risk. Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (CAD) requires that substitution should be undertaken preferably with a chemical agent or process which, under its condition of use, is not hazardous or less hazardous to workers' safety and health.

At national level, the French National Assembly was discussing a bill (known as the "detox" bill) establishing a list of substances to be substituted, although ultimately it has been dropped. Under the detox bill, manufacturers, importers and formulators of substances and manufactures and importers of articles containing substances would have been required to report quantities and uses of the substances listed and the identities of the downstream users, for the purposes of traceability and risk assessment and for the promotion of their substitution. In order to assist companies with the assessment of alternatives and substitution initiatives, the French National Assembly was also discussing the provision of financial assistance as well as the creation of databases, tools and a voluntary labelling scheme. The Nordic Council of Ministers is discussing a possible recommendation based on the French initiative[14].

Indeed, CAC legislation is often accompanied by other policy instruments, which may belong to one or more of the categories listed at the opening of this sub-Section, to support and encourage companies to achieve environmental objectives. Further examples of policy instruments currently used at European and national levels are provided below.

The OECD defines economic instruments as "*fiscal and other economic incentives and disincentives to incorporate environmental costs and benefits into the budgets of households and enterprises. The objective is to encourage environmentally sound and efficient production and consumption through full-cost pricing. Economic instruments include effluent taxes or charges on pollutants and waste, deposit—refund systems and tradable pollution permits*"[15].

Every Member State of the European Union has a complex system of economic instruments for environmental policy. The OECD and the European Environment Agency maintain a database of these instruments[16]. Within the chemical policy, economic instruments are common for the control of hazardous waste (e.g. the deposit-refund system for lead batteries and accumulators in Denmark and the deposit-return system for lead accumulators and toxic chemicals packages in Poland) and of ozone depleting substances. Other notable examples are the duties imposed by Scandinavian countries on certain chlorinated solvents, pesticides and phthalates.

With regard to taxes and charges, their success depends on a number of factors such as the price impact and signal, the expectations on future price rises, the use or non-use of the revenues in environmental expenditure. However, whether such duties are effective is primarily reliant on their design and the extension of the exemptions granted. Economic instruments should be used not to merely generate economic revenues, but also for the improvement of the environment. Exemptions

[14] Chemicalwatch news 16 June 2016: 'French substitution bill nears collapse'. Available at: https://chemicalwatch.com/48066/french-substitution-bill-nears-collapse
[15] https://stats.oecd.org/glossary/detail.asp?ID=723
[16] Available at: http://www2.oecd.org/ecoinst/queries/Default.aspx

should be granted on the basis of more severe conditions, should be temporary and should be reduced over time (ECOTEC et al, 2001). From an environmental perspective, successful examples of economic instruments are the taxes on the use of pesticides in Scandinavia (that helped phase out approximately 20% of the pesticides and reduce their usage by over 50%) and the Danish deposit-refund scheme for lead batteries and accumulators, which achieved a return percentage of over 99%.

Further examples of economic instruments are the agreements on green public purchasing for local government. In chemical policy, the public procurement strategies adopted by the cities of Gothenburg and Stockholm in Sweden are both noteable (these are further discussed in sub-study E), but many municipalities across Europe have adopted local Agenda 21 strategies, with different degrees of ambition in chemical control objectives.

Legislative binding lists of restricted substances are supplemented by non-legislative lists set up by NGOs or industry actors. Large enterprises and global players have developed standards to ensure quality in the supply chain. These standards are perceived as quasi-legislative and can be stricter and more detailed. They are enforced by the power of the market and so can be even more demanding than the conventional enforcement of legal requirements (Lissner, 2010). Substitution may be driven by chemical manufacturers or by their downstream users. Many large chemical manufacturers have ambitious programmes aiming to identify and prioritise for substitution those hazardous chemicals with the highest potential to cause long-term damage to human health and the environment (e.g. AkzoNobel's Priority Substance Programme[17]). User driven substitution is found where enterprises, commonly those with sector-specific market power, develop a policy of substitution and compel their suppliers to ban or reduce the use of certain hazardous chemicals. Examples are the car manufacturers (Lissner, 2010 reports the use of 'black', 'grey' and 'white' lists of chemicals; the European Automobile Manufacturers Association (ACEA) publishes a list of substances under regulatory scrutiny[18]), the EEE manufacturers (e.g. the Apple regulated substances specification[19]) or large retailers such as Walmart and Target, which announced new initiatives to encourage their suppliers to develop greener formulations[20]; Walmart is prioritising 10 problem compounds for phase-out from the goods they sell, while Target is introducing a system for scoring the environmental performance of its range of goods, heavily weighted towards the toxicity of constituent chemicals. In Europe, Denmark's largest retailer, Coop, has a very ambitious programme on substitution of hazardous chemicals, often acting before any legislation is implemented. Examples of restricted substances are allergenic perfumes and preservatives in its own brand personal care products in 1995, PVC in all packaging in 1999, triclosan in 2005, endocrine disruptors in 2006, sixteen phthalates in 2009, biocides in 2010, nano- and micro-pearls in personal care in 2012 and all fluorinated compounds in food contact materials in 2014[21].

A prominent example of a non-regulatory list of substances to be considered priority for substitution while aiming to speed up the transition to a non-toxic environment is the SIN list, an online tool developed and maintained by the NGO ChemSec[22]. Flynn et al. (2001) argue that the publishing of such lists has encouraged substitution, as companies do not like to see their products stigmatised as potentially harmful to the environment or human health.

Other policy instruments, categorised under support and capacity building, aim to increase the availability of data and information as well as enhance the capabilities of stakeholders in assessing

[17] http://www.cefic.org/Documents/ResponsibleCare/Awards2015/Responsible-Care-Awards2015-Brochure.pdf
[18] Available at: http://www.acea.be/publications/article/substance-pilots
[19] Available at: https://www.apple.com/environment/pdf/apple_regulated_substances_specification_sept2014.pdf
[20] http://healthandenvironmentonline.com/2014/01/27/the-substitution-principle-a-case-for-scepticism/
[21] "Safer products for consumers", webinar by Malene Teller Blume (Manager non-food, quality and social compliance, Coop Denmark A/S, available at: http://echa.europa.eu/view-webinar/-/journal_content/56_INSTANCE_DdN5/title/why-opt-for-substitution
[22] Available at: http://chemsec.org/business-tool/sin-list/

alternatives to hazardous substances. The Swedish government, along with other initiatives aiming to improve monitoring of pollutants and to shorten processing times for pesticides by the Swedish Chemicals Agency, has announced the funding of a chemical substitution centre to help companies eliminate hazardous chemicals from their products.[23] The Danish Environment Protection Agency is funding a four-year long partnership between research centres and consultancies aiming to develop guidelines and support practical substitution of hazardous chemicals by SMEs[24].

Table 1 provides an overview of tools available for chemical risk management and for finding and comparing alternatives. The table is intended to be illustrative, showing the range of tools rather than being fully comprehensive; the tools are organised in alphabetical order. Further details on specific tools are provided in Appendix 1.

Table 1: Overview of existing tools for chemical alternative assessment

Tool	Country	Target audience	Summary
BizNGO Chemical Alternatives Assessment Protocol	United States	Companies and NGOs	BizNGO is a collaboration of businesses and environmental groups working together for safer chemicals and sustainable materials. The Chemical Alternatives Assessment Protocol is a decision framework for substituting chemicals of concern to human health or the environment with safer alternatives.
Catsub	Denmark	Not stated	This database contains more than 300 examples of substitution of hazardous chemicals
Cefic LRI toolbox	EU wide	European and national regulatory agencies, industry and academia	Provides a selection of tools for better research, analysis and visualisation purposes for use in risk assessment and toxicity testing of chemicals, both in preparation of regulatory filings such as REACH, GHS etc. and for R&D purposes
CleanerSolutions	United States (TURI)	Surface cleaning	Gives alternatives to hazardous solvents used in surface cleaning, including a database on potential alternatives. The 'Replace a solvent' site allows for searches for tested alternative chemistry to replace a current solvent cleaner
CLEANTOOL	Europe-wide	Cleaning and degreasing, may require expert use	Tool with accompanying database for finding alternative chemicals for parts cleaning, metal surface cleaning, component cleaning and degreasing. It aims to enhance communications by allowing users to submit data and receive guidance and recommendations.
COSHH Essentials	UK	SMEs	Web-based tool that asks questions about a chemical and how it is used. The tool provides a link to 'Seven steps to successful substitution' where a high hazard chemical or suite of chemicals is entered
EC (2012) guidance	EU-wide	SMEs and companies with limited or some knowledge or experience of chemical risk management	The approach is a systematic but flexible risk-based process to identify chemicals that could or should be substituted. It also covers evaluation of alternatives in terms of risk, technical requirements and practical and cost considerations. The guidance approaches substitution as an element of risk management and part of a company's day-to-day business. Environmental aspects are highlighted but the main focus is on occupational health and safety
German Column Model (Spaltenmodell)	Germany	SMEs	Tool for simple comparison of the differences in hazards and risks of substances. It employs six columns with hazard categories and exposure potential, which the user can fill in according to information from the SDS and the process they are used in. The output is a grading of risk level from

[23] http://www.government.se/press-releases/2016/09/harmful-chemicals-must-be-removed-from-childrens-environment/
[24] http://eng.kemiikredsloeb.com/

Tool	Country	Target audience	Summary
			Negligible to Very High. Gives varying risk rankings in one sheet but does not provide advice on how to proceed
Green alternatives wizard		Research laboratories	Web-based databank that gives general information on potential substitutes for certain substances. It is a tool to reduce the hazardous waste profile in research labs, an effort that ultimately saves money while reducing hazard potentials and the burden to the environment
Green Screen	United States	Companies	Developed by Clean Product Action (CPA), is a hazard-based screening method defining four benchmarks as a roadmap to progressively safer chemicals (starting from chemicals of high concern and ending to safe chemical). Each benchmark includes a set of hazard criteria that a chemical must pass. It can be used for assessing and comparing individual chemicals, but not products or alternative technologies
INERIS	France	Companies	Includes a chemical portal which contains toxicological data and a tool that enables companies to make an inventory of substances they use along with their potential hazards
INRS	France	Companies using chemicals in the workplace	Provides tools to help identify potential areas of exposure in the workplace and to evaluate the use of chemicals by comparing levels of exposure with limit values
Keki-Arvi	Finland	Companies, especially SMEs	Designed to help with risk assessment and with how to avoid risks.
OECD Toolbox	International	A broad range of stakeholders	Lists a number of private or public initiatives, such as hazardous substance lists, standards and methodologies. Includes alternatives assessment tool selector, alternatives assessment frameworks, case studies and other resources, and regulations and restrictions. Brings together a lot of the other tools in one place
P20ASys (Pollution Prevention Options Assessment System)	United States (TURI)	Companies	Tool for checking whether already identified alternatives may have unforeseen negative impacts on the environment or worker/public health. Allows comparison of total environmental and occupational impacts of process changes, not just chemical changes
PRIO	Sweden	Swedish companies but also suppliers to Sweden in other countries	Tool contains a guide and database with around 4,000 dangerous chemicals that the Swedish Government has identified as being of high concern. These are grouped into 'phase out' chemicals and 'risk reduction' chemicals. It can be used for screening and prioritising hazardous chemicals but does not directly provide information on potential alternatives
Stoffenmanager	Netherlands	SMEs	Web-based tools for chemical exposure assessment. It helps in assigning a priority band and gives a list of possible control measures using the STOP-principle (substitution, technical measures, operational measurements, personal protection). Only a limited amount of information is provided for alternatives in the case of substitution. It is a useful tool for more expert users.
SUBSPORT	Germany/ Austria but EU wide	Any company looking to substitute a hazardous substance	An information exchange platform for alternative substances and technologies, developed by a collaboration of NGOs working together with academics, trade unions and government institutions under the LIFE+ Programme of the EU. The portal aims to provide companies, looking to substitute a hazardous substance, with legal information on substitution, a database on restricted and priority substances and analysis of existing substitution tools and case studies, among others.

Tool	Country	Target audience	Summary
Substitution-CMR	France	Companies using one or more of 23 priority substances	Portal containing information, methodologies and datasheets of CMRs, their alternatives and successful cases of substitution. By offering multiple levels of information, it aids those looking for alternative solutions to the use of CMR 1A and 1B substances.
Weber et al, 2014 electronic report	Sweden	All stakeholders	Provides a compilation of information on alternatives to POPs in current uses with the aim of allowing easy updates on POPs free/POPs alternatives. Includes case studies and best practice of chemical and non-chemical alternatives.

In addition to support and capacity building, public authorities grant environmental subsidies in the form of funds for research and development, in particular to SMEs. These may lack the necessary resources to engage effectively in substitution process (Ahrens et al., 2006). At European level, funds for research and development into chemical substitution are awarded mainly through[25]:

- **Horizon 2020:** an EU funding programme for research and innovation running from 2014 to 2020 with an €80 billion budget. The instrument provides full-cycle business innovation support from business idea conception and planning to execution, demonstration and commercialisation. Participants also receive innovation coaching for the duration of their project. Managed by EASME and incorporating the former Eco-innovation initiative;
- **The environment and climate action programme (LIFE):** an EU financial instrument supporting environmental projects throughout the EU. It has a budget of €3.4 billion until 2020 to finance projects that contribute to the sustainability and implementation of the 7th EAP. Environment and health is one of the key themes under LIFE. Calls for proposals under this theme will cover support activities for the implementation of REACH and BPR to ensure safer, more sustainable or economical use of chemicals, including nanomaterials. LIFE will soon be also managed by EASME. The SUBSPORT tool was partly funded through LIFE. However, the period of funding was limited and it was not possible to find other means sufficient to continue the work once funding from LIFE ended;
- **The new cohesion policy**, with a budget of up to €351.8 billion to invest in Europe to achieve the goals of smart, sustainable and inclusive economic growth by 2020.

Other important measures that could promote substitution are chemical monitoring programmes. These can be periodic surveys of concentrations of certain substances in human, animal and plant samples (biomonitoring) or monitoring programmes of emissions of chemicals in environmental media, and initiatives such as chemical footprint. Panko and Hitchcock (2011) define Chemical Footprint (ChF) as "*an indication of potential risk posed by a product based on its chemical composition, the human and ecologically hazardous properties of the ingredients, and the exposure potential of the ingredients during its life cycle. Its analysis should include a comprehensive quantification of the chemicals used, consumed, produced or modified throughout the life cycle of the product of interest, and the risks posed.*" ChF combines life cycle aspects with risk assessment methodologies and other authors are working on the integration of sustainability concepts such as "limit" and "carrying capacity" (e.g. Sala and Goralczyk, 2013).

The Clean Production Action of the Lowell Center for Sustainable Production at the University of Massachusetts Lowell and Pure Strategies started the Chemical Footprint Project, an initiative aiming at measuring and benchmarking the progress of companies to safer chemicals. Corporate chemicals management performance is scored to 100 points through a 20 questions survey, evaluating management strategy (20 points), chemical inventory (30 points), footprint measurement (30 points)

[25] ECHA Newsletter, Funding opportunities for SMEs, accessed at: http://newsletter.echa.europa.eu/home/-/newsletter/entry/2_14_funding-opportunities-for-smes (on 05/08/15)

and public disclosure and verification (20 points)[26].

2.2 DRIVERS OF AND BARRIERS TO SUBSTITUTION

EC (2012) identifies the key drivers for substitution as legislation, pressure from the supply chain and pressure from within the company.

Many authors recognise legislation as one of the major driving forces for the substitution of hazardous chemicals and studies reviewing the functioning of REACH (e.g. CSES, 2012 and CSES et al., 2015) have reinforced this finding. Legislation stands together with a number of other drivers. For each driver however, depending on the perspective adopted and the specific actions and approaches that are taken, there is a corresponding barrier.

Table 2 summarises the findings of the literature review. Further discussion on the points of view and results presented in the literature are provided in Appendix 1.

Table 2: Drivers and barriers to substitution

Factor	Drivers	Barriers
Internal		
Costs	Substitution of hazardous chemicals has the potential to reduce costs, in particular related to alternative risk management measures and to the compliance of legislation	Switching to an alternative substance or technology carries direct costs in the form of capital investment and higher costs of the alternative substance. Even if the substitution may lead to future benefits, these are not easily identifiable in the short term
Company image	Potential to improve reputation and promote 'green' profile	Lissner (2010) found that substitution is rarely user driven if substitution of hazardous chemicals is not crucial for the economic success of an enterprise
Productivity	Involvement of workers can increase morale and buy-in to the process	Impacts may be substantial, particularly when new equipment needs to be installed or when significant downtime is envisaged
Health & Safety policy	The reduction of risks in the workplace and potentially beyond can be the main motive for substitution	Company awareness of the risk may also be low (e.g. ignoring hazards, unknown costs of not substituting hazardous chemicals)
Information and knowledge	Availability of health and safety information can encourage substitution by improving knowledge and understanding of hazards and risks	Companies, in particular SMEs, may not have enough resources to invest in research and development Incomplete information can increase the risk of regrettable substitution Enterprise must employ personnel with the necessary knowledge or substitution is unlikely to occur
Company flexibility	First movers can have significant competitive advantage	When a company has invested in building up know-how about using a particular substance in their process, it is often difficult for them to abandon it for something new which is generally more expensive and often of lesser functionality
Liability and guarantees	Potential to reduce future liabilities by reducing hazard and risk	May be a disincentive where there are concerns that substitutes might not meet existing standards or cause guarantee problems
External		
Bans and restrictions	Restriction of substances leads users to substitute them	A perceived lack of enforcement of legislative requirements may hinder efforts

[26] https://www.chemicalfootprint.org

Factor	Drivers	Barriers
	Restricting substances can be of particular benefit to those companies that are already developing innovative and safer alternatives	to promote substitution
Industry standards	Can drive innovation, e.g. Responsible Care initiative by chemical manufacturers	Laboratories may not be able to introduce substitutes where there is a need to conform to a standard. Changes to the standard may take a long time and be a complex process
Stakeholder requirements	Can apply pressure to substitute from internal (workers, OSH specialists, trade unions) and external forces (NGOs, sector organisations, investment funds, mass media)	Lack of initial identification of chemicals or work processes that could be substituted May be a lack of stakeholder interest, with initiatives towards substitution of hazardous chemicals not gaining enough attention or accolade from public authorities and the public
Financial	Funding can provide the impetus to overcome some of the economic barriers Investors that consider all aspects of sustainability (socially responsible investment) could drive moves to safer alternatives	Lack of available alternatives, or cost-effective alternatives Lack of standards by which to measure a company's steps towards achieving sustainable goals
Supply chain	Customers can apply pressure to substitute	Companies often resist substitution because they are afraid customers will not welcome alternative substances that may change the performance of the products If there is a large number of users and applications of the substance, then the scope of changes required for substitution is broader and substitution is more difficult
Based on information from http://oshwiki.eu/wiki/Substitution_of_hazardous_chemicals; EC (2012); ChemSec, 2016; CIEL, 2013; EEA, 2013; Keml, 2007; Lissner, 2010; Oosterhuis, 2006; Scheringer et al, 2014		

Member State Competent Authorities (MSCA), industry stakeholders and external consultants have been consulted through online surveys on substitution, its drivers, barriers and challenges.[27] Sixteen MSCAs, 105 industry stakeholders and 14 external consultants responded to the surveys.

Legislative requirements were deemed the main driver of substitution by industry stakeholders, with 95% of the respondents specifying REACH as important or very important. In particular, the placement of a substance on the Candidate List was indicated to be a key mechanism that initiates the search for safer alternatives. Over 80% of industry stakeholders reported having substituted hazardous chemicals in the last 10 years.

Economic considerations were also highlighted as a determining factor for substitution (over 85% of the respondents classed them as important or very important), as well as corporate social responsibility, internal chemical management policies and supply chain requests, consumers' and workers' concerns (over 80% of the respondents) (Figure 1). MSCAs' and external consultants' answers mirrored the opinions of industry stakeholders.

Seventy-two percent of the industry stakeholders surveyed reported the improvement of worker safety as one of the main benefits experienced by their companies, with 35% acknowledging that this was also a major benefit for their clients. The replacement of hazardous substances is also seen as a boost to the market reputation of the companies and their clients (Figure 2).

The lack of availability of information on the technical feasibility of alternatives and uncertainty regarding their market potential were indicated as important or very important obstacles by over 90% of the respondents (Figure 3). These factors relate to the concerns of industry stakeholders about the possibility of developing alternatives that are able to satisfy the customer performance specifications

[27] All the findings are presented in Appendix 2.

(89% of the respondents). Many substances are used for very specific applications and fit into the specific processes of individual companies. General information about potential substitutes may be a good start but ultimately it is not useful for assessing whether the alternatives could perform adequately in a particular process. Moreover, alternatives suppliers often do not have knowledge of the process characteristics of their potential downstream users and companies are generally unwilling or unable to share information up and down the supply chain for strategic, competitive and economic reasons.

Small and medium-sized enterprises often do not have the resources to deal with the workload and the information and communication management required by the substitution of substances in their products or processes. The European Commission has launched a project financed through the Competitiveness of Enterprises and Small and Medium-sized Enterprises (COSME), to assist SMEs in finding safer alternatives to hazardous substances, alternative providers and, ultimately, to support them with the substitution implementation.

Figure 1: Drivers of substitution (industry stakeholders' survey)

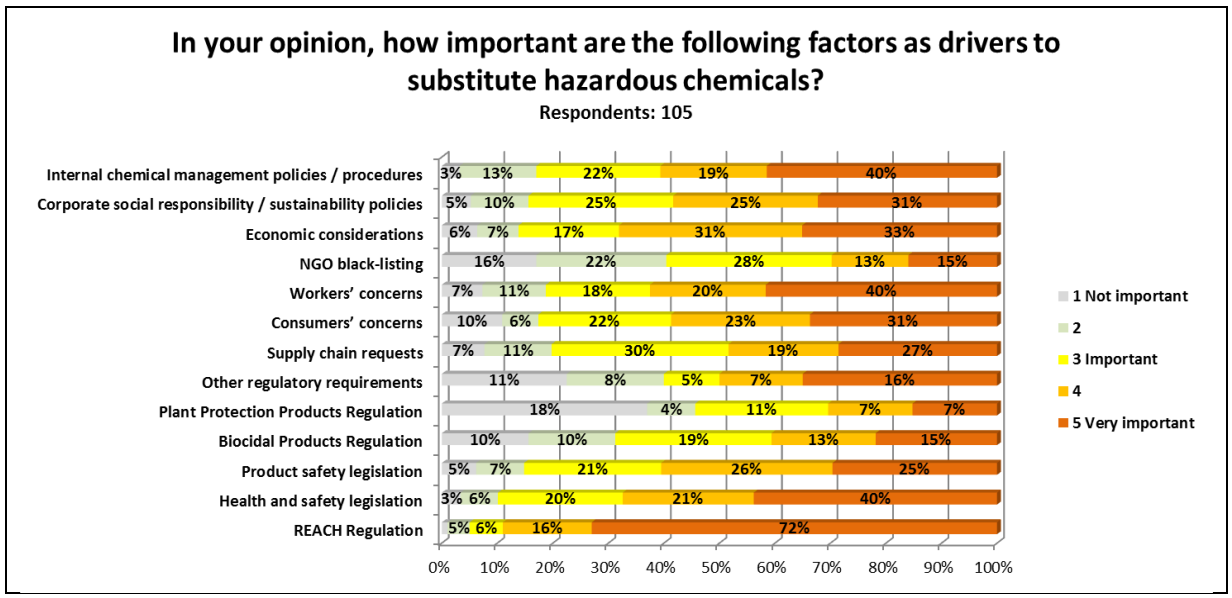
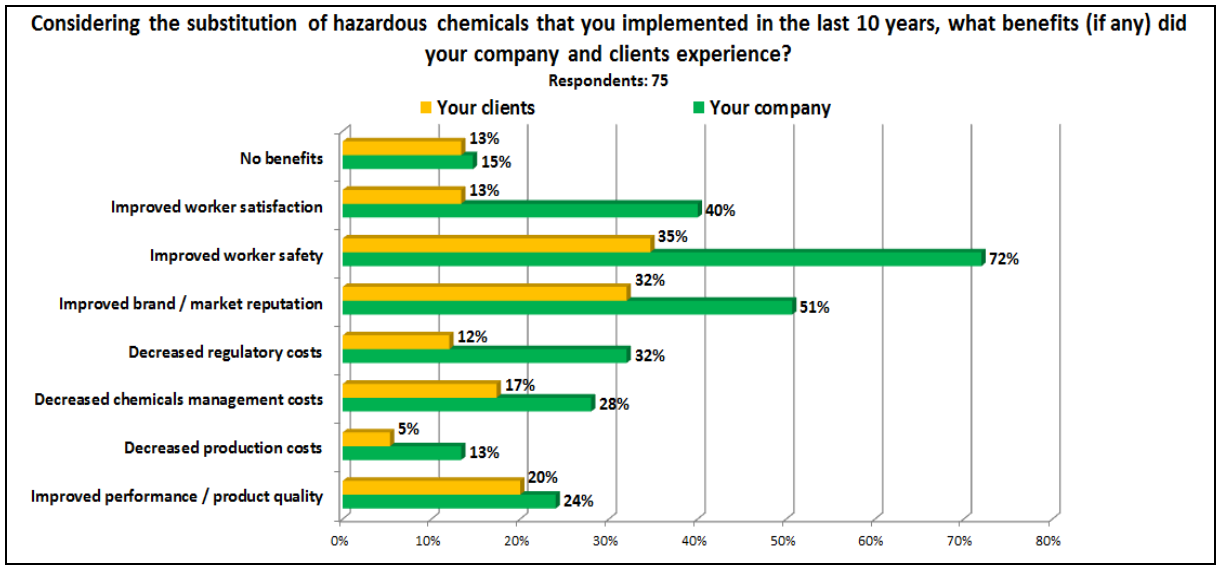


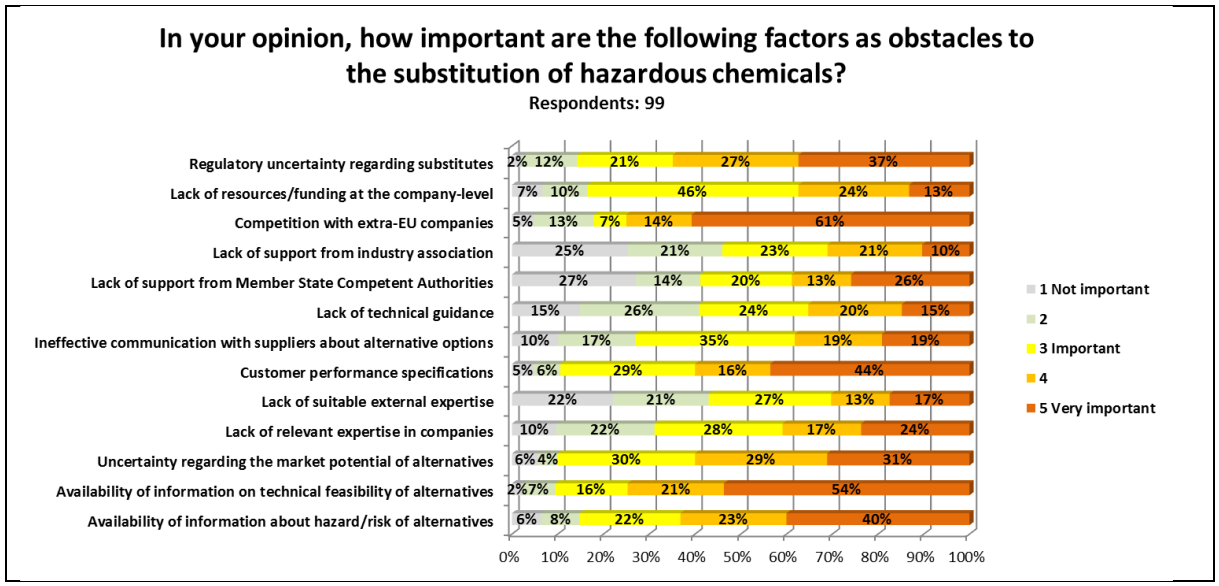
Figure 2: Benefits of substitution (industry stakeholders' survey)



During the workshop on the Non-Toxic Environment organised by Cefic in Brussels on 31 March 2016, it was noted that, sometimes, it may not be possible or be very difficult to develop safer alternatives, for example for process chemicals (e.g. for aprotic solvents). In these cases, longer research and development periods should be granted.

The lack of information on hazards and risks of the alternatives and, therefore, the regulatory uncertainty over potential substitutes, were also seen as important or very important obstacles to substitution (by over 85% of the survey respondents). Eighty-four percent of the survey respondents indicated that they have a limited capability for engaging in substitution initiatives due to a lack of resources at company level. Over 80% of the respondents indicated that competition with companies from extra-EU countries with less stringent legislation is an important obstacle for EU companies willing to substitute hazardous substances, as these competitors do not have the same costs. Respondents called for a stricter enforcement of the legislation on imported articles.

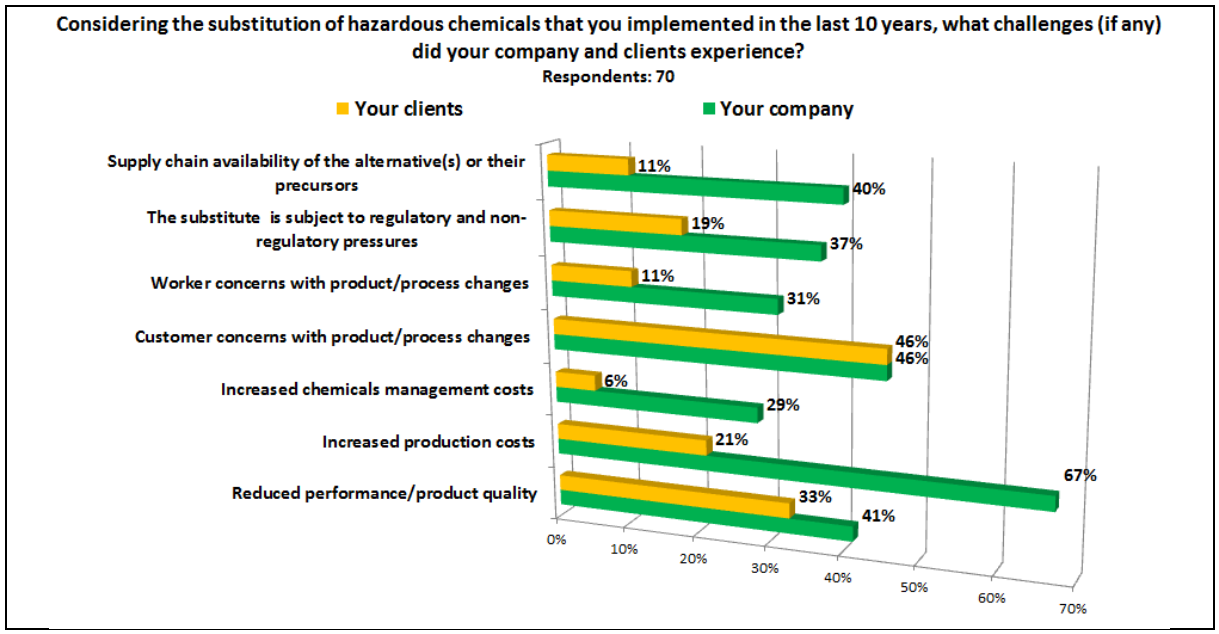
Figure 3: Obstacles to substitution (industry stakeholders' survey)



Once the substitution of hazardous chemicals has been implemented, one of the main challenges (as

reported by over 65% of the respondents) is the increase in production costs, as well as the customer concerns over product/process changes (Figure 4).

Figure 4: Challenges of substitution (industry stakeholders' survey)



It should be noted that over 35% of the respondents indicated that an alternative that has been adopted was also found to be a substance of concern in terms of its hazardous properties and is now subject to regulatory and non-regulatory pressures (e.g. inclusion in the REACH authorisation candidate list, NGOs black-listing): these are cases of regrettable substitutions and are discussed in the following sub-section.

From the MSCAs side, a major obstacle to supporting and enforcing substitution initiatives is the lack of resources and expertise (Figure 5, Figure 6 andFigure 7). Most of the MSCAs consulted reported limited full-time equivalent (FTEs) staff dedicated to supporting substitution initiatives and very few staff with suitable skills to carry out technical feasibility evaluations. However, some respondents also indicated that this should not be the role of the authorities.

Figure 5: Resources dedicated to supporting substitution initiatives

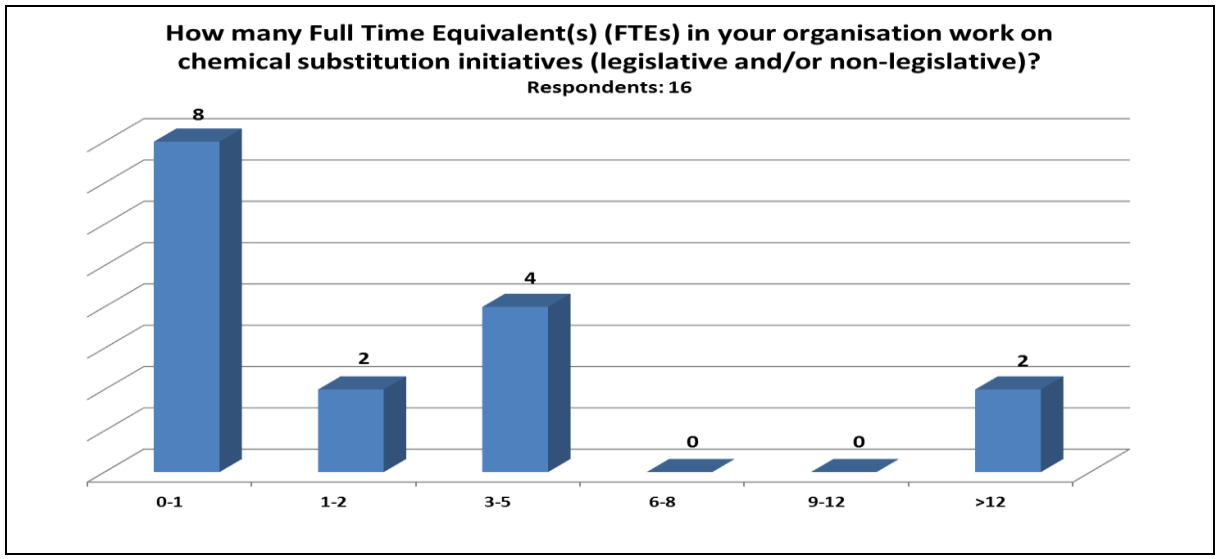


Figure 6: Areas of expertise of staff supporting substitution initiatives

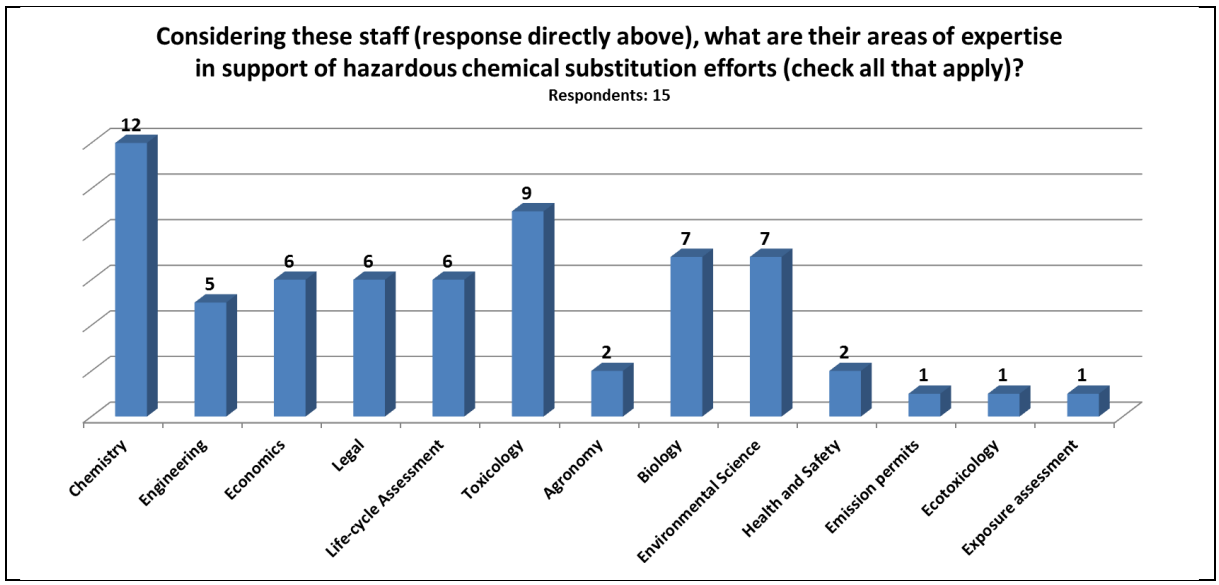
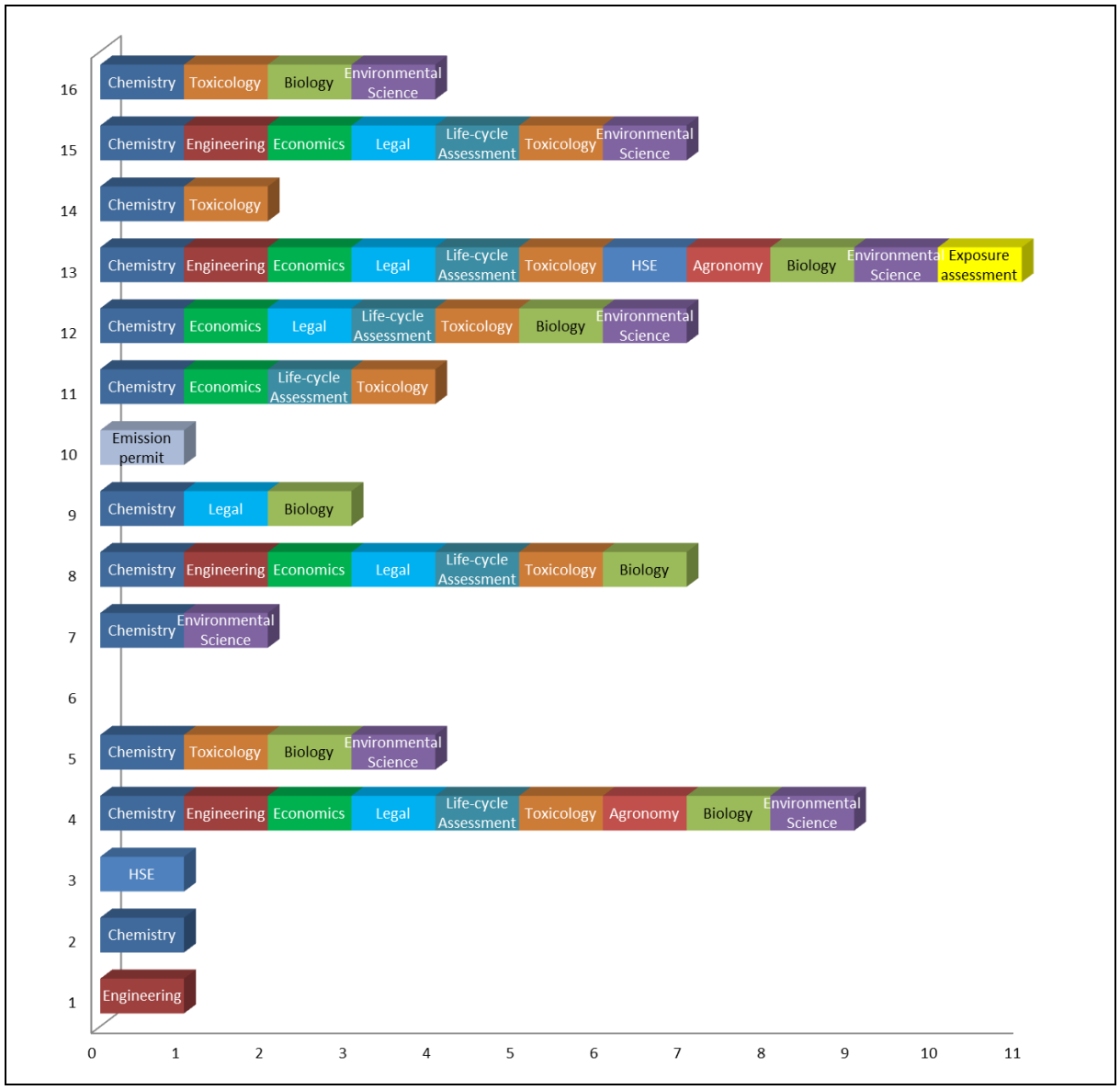


Figure 7: Expertise diversity within respondents



2.3 REGRETTABLE SUBSTITUTIONS

While intended to promote sustainability and reduce negative impacts on human health and the environment, the application of the substitution principle in policymaking may lead to unintended consequences. A regrettable substitution is the "replacement of a toxic substance with one that has unknown – if not greater – toxic effects"[28]. There are numerous examples of situations in which the restriction of certain hazardous substances did not result in their substitution with safer alternatives. Fankte et al 2015 present some well-studied examples (Figure 8; see also Box 1 and Box 2).

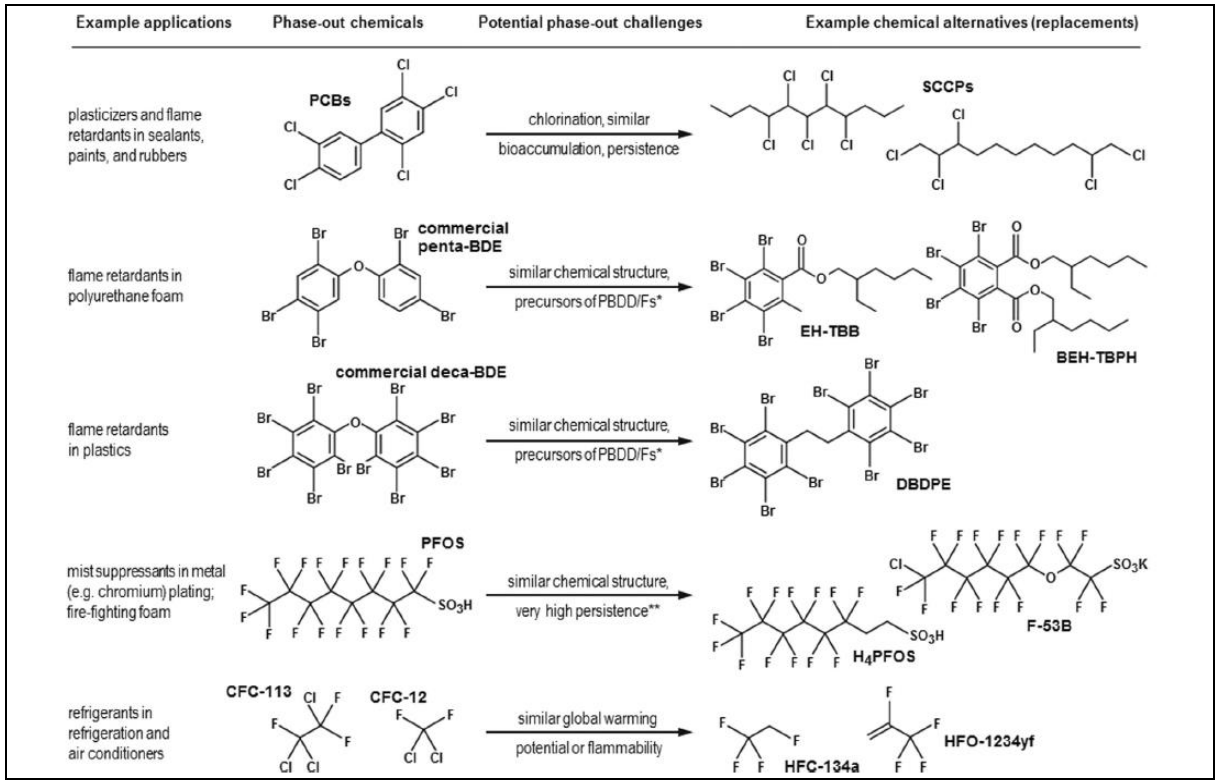
Abelkop et al (2014) note that substituting hazardous substances without the appropriate comparative risk analysis may result in the premature replacement of existing chemicals with those that may be just as hazardous, or may be less toxic but carry a greater potential for release and exposure. Robust

[28] Washington State Department of Ecology. 2015, 'Green chemistry: what is a regrettable substitution?', Available: http://www.ecy.wa.gov/GreenChemistry/faq.html

comparative risk analyses need a high level of information and can be resource and time intensive. However, research is ongoing on user-friendly approaches to develop, evaluate and interpret multiple chemical-product-application scenarios for human exposure that would enable to quantitatively assess exposure in a more rapid and efficient way. Fankte et al (2016) provide a recent example of such a framework.

Lofstedt (2014) argues that substitutes may not serve the same economic utility as the original chemical, thereby generating other types of risks to human health and the environment. For example, the substitution of lead from solders in EEE with lead-free solders had the consequence of creating failures to the board of the components and of operating at higher temperatures, with higher energy consumption. Moreover, EC (2012) notes that lead free solders may need an increased amount of rosin added to the flux, where rosin fumes have been identified as cause of occupational asthma.

Figure 8: **Archetypal cases of incremental substitution for selected phase-out chemicals used in large applications in conmumer products (Fankte et al, 2015)**



Box 1: Bisphenol A

Bisphenol A (BPA) is used in a number of consumer products, particularly those made of clear and tough plastics such as water bottles or food packaging, and in thermal paper such as till receipts[29]. Its first use was as a synthetic oestrogen for women, but from the 1950s it started to be used in plastic materials. In the early 1990s, evidence that BPA may be able to migrate from plastic containers to water and food started to emerge. As a result, industry withdrew BPA from children's products even before regulatory action and replaced it with the structural analogue substances Bisphenol S (BPS) and Bisphenol F (BPF). These displayed the same desired properties of BPA but there was much less knowledge on their hazards and risks. Toxicological studies started to be performed on BPF and BPS and soon toxicologists came to the conclusion that both substances show the same endocrine

[29] The possible regrettable substitution of BPA with BPS has been addressed in the recent Restriction of BPA in thermal paper, see recital 13: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R2235&from=EN

disrupting properties of BPA. It has been observed that BPS affects non-genomic signalling in oestrogen-responsive cells, potentially compromising cell function. Studies have tested BPS and BPF along with BPA in the same assays, allowing for potency and mechanism of action to be compared. Results have shown that both substitutes have potencies in the same order of magnitude of BPA, with the possibility of BPF being more potent. BPS and BPF exhibit an increase in steroidogenic activity which has not been observed for BPA, suggesting that they may pose similar or greater health hazards than BPA. Hence, they are not suitable substitutes.

Box 2: Halogenated flame retardants

Polychlorinated biphenyls (PCBs) and polybrominated biphenyls (PBBs) were widely used as flame retardants until the 1970s. Due to health and environmental concerns, PCBs and PBBs were replaced with polybrominated diphenyl ethers (PBDEs). Production of PDBEs increased rapidly over the next few decades with new emerging markets, including furniture foam, electronics, textiles and baby products (CIEL, 2013).

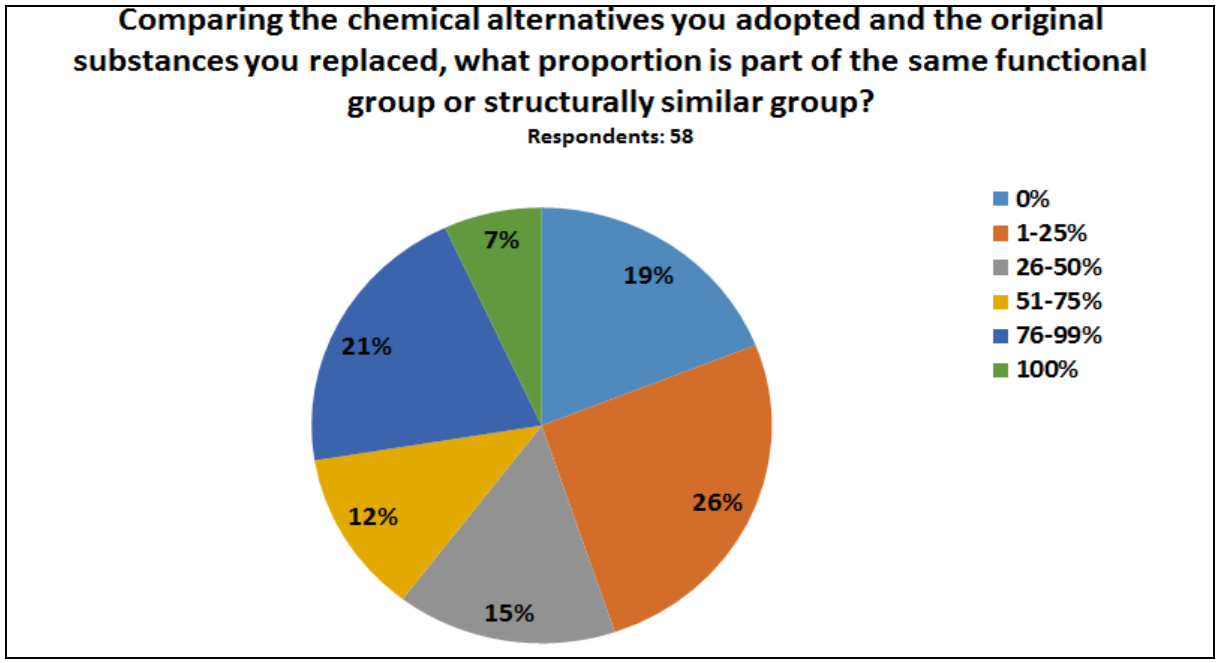
However, PBDEs have been found to have endocrine disrupting properties. They exhibit toxicity at both high and low doses and persist in the environment for long periods of time. As a result, they can accumulate in living organisms and travel long-distances through wind, water and the animals in which they accumulate.

It should be noted that 40% of industry stakeholders consulted estimated that over 50% of the substitutions implemented have been with substances that are part of the same functional or structurally similar group (Figure 9). In general, the substitution of one hazardous chemical in a process, mixture or product may imply the substitution of other chemicals used in the process, mixture or product in order to retain the same desired properties/performance.

In order to avoid regrettable substitution, authorities have resorted to grouping approaches to restrict the use of groups of structurally related chemicals. For example, Article 2 of the 1991 Geneva Protocol concerning the control of emissions of Volatile Organic Compounds (VOCs) or their trans-boundary fluxes requires that "*in implementing the present Protocol, and in particular any product substitution measures, Parties shall take appropriate steps to ensure that toxic and carcinogenic VOCs, and those that harm the stratospheric ozone layer, are not substituted for other VOCs*".

Possible grouping strategies are discussed in the following Section.

Figure 9: Obstacles to substitution (industry stakeholders' survey)



2.4 GROUPING OF CHEMICALS

One of the key issues when considering ways to promote the use of non-hazardous chemicals is that chemical manufacturers and formulators may select alternatives that are part of the same chemical group of the substance to be substituted. The selection of a closely related chemical can be in consideration of the similarity of the characteristics and performance as well as on economic grounds, both for technical reasons (as moving to a similar substance may require less technical adjustment to the production process) and because it avoids investing considerable resources in researching for a non-hazardous and sustainable substitute.

In some cases, a significant proportion of alternatives can have the same functional group or be part of a structurally similar group as the original substance, as it is difficult to find the required functionality, properties and qualities when deviating from certain chemical families or groups. In practice, companies find that product and application innovations come from working closely with customers in understanding their needs and applications, and by making small changes in the composition and purity (e.g. reduced aromatics) of substances and products, which lead to enhanced performance, enhanced health and environmental properties or to opening up new applications.

The grouping of chemicals may be an effective way of promoting substitution to less-hazardous chemicals and may provide additional benefits. Specifically, it may speed up the regulatory scrutiny of chemicals and the transition to less hazardous substances. Grouping strategies have been proposed by different stakeholders (SIEFs and registration consortia, regulators, NGOs, retailers, etc.) and carried out by different criteria (chemical structure, functional group, mode of action, particle size, etc.) for different purposes (to minimise animal testing, to manage the risks associated with chemicals with the same health and environmental effects, etc.).

The OECD defines a chemical category as "*a group of chemicals whose physicochemical and human health and/or ecotoxicological properties and/or environmental fate properties are likely to be similar or follow a regular pattern, usually as a result of structural similarity.*

The similarities may be based on the following:

- *A common functional group (e.g. aldehyde, epoxide, ester, specific metal ion);*
- *Common constituents or chemical classes, similar carbon range numbers;*
- *An incremental and constant change across the category (e.g. a chain-length category);*
- *The likelihood of common precursors and/or breakdown products, via physical or biological processes, which result in structurally similar chemicals (e.g. the metabolic pathway approach of examining related chemicals such as acid/ester/salt)".*[30]

It should be noted that a chemical class is "*a set of compounds sharing a common structural feature to which is attached a variable part (or parts) defining a specific compound of the class. The common feature is often a functional group to which one or a small number of variable parts are attached (e.g. aldehydes, ketones)*".[31]

The category approach is often adopted by industry to reduce the need for unnecessary in vivo testing. Chemicals that are closely related are considered as a group, meaning that not every chemical needs to be tested for each endpoint as those in the group which have already been tested can be used to estimate the endpoints of untested chemicals.

Another common strategy for grouping chemicals and thus avoiding animal testing is the analogue approach, which is used when the target and source chemicals share a known common mode of action.

It is currently unclear if looking at the molecular structure as a basis for grouping is a viable way to go, because small changes in the molecular structure may yield completely different hazard (and function) profiles, while completely different molecular structures may exhibit similar hazard properties.

Other parameters and criteria can be used in combination, or as alternatives, to structural similarity and mode of action to widen or narrow groups of chemicals and to group substances together under a specific regulatory activity for more efficient risk management and legislative processing. ECHA (2015) clarifies that "*each group is defined by different criteria, fitting different regulatory purposes and/or risk management measures*". As for substitution, the concept of grouping similar chemicals by certain properties or characteristics is not new and different grouping strategies have been and are being adopted horizontally across the chemical legislation.

In REACH, grouping of chemicals is actively promoted in the registration process and registrants are invited to use QSARs or read across methods, when possible and suitable.

With regard to the authorisation and restriction mechanisms, while in the authorisation list there are currently two groups of chemicals only (Table 3), around half of the entries in the restriction list refer to groups of chemicals. It should be noted that the authorisation list includes different entries referring to chemicals that could be grouped as chromates and dichromates[32], although not all chromates and dichromates have been listed. The same can be said of the low molecular weight phthalates DEHP, BBP, DBP and DIBP; although these have been restricted in toys and childcare products with some high molecular weight phthalates (DINP, DIDP and DNOP).

The same degree of flexibility in using grouping strategies is present in the CoRAP[33] list and PACT[34]

[30] http://www.oecd.org/chemicalsafety/risk-assessment/groupingofchemicalschemicalcategoriesandread-across.htm
[31] Glossary of Class Names of Organic Compounds and Reactive Intermediates Based on Structure - Commission on Nomenclature of Organic Chemistry (Peter A. S. Smith, Convenor of the Working Group); Commission on Physical Organic Chemistry (Paul Müller, Convenor of the Working Group). Available at: http://www.chem.qmul.ac.uk/iupac/class/intro.html
[32] Any salt or ester of chromic acid.
[33] Community rolling action plan for substance evaluation. Available at: http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

table of substances. In order to maximise efficiency of substance evaluation, some substances for which there is an indication of structural similarity (e.g. o-xylene, p-xylene and m-xylene) may be jointly evaluated; other substances that could be grouped by functional group (e.g. diisocyanates) are evaluated by different Member States and in different years, although some degree of co-operation is to be expected.

Table 3: Groups of chemicals in REACH Authorisation list

Entry no.	Name	EC no.	CAS no.	Intrinsic properties referred to in Article 57
3	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified	-	-	PBT (Article 57 d)
	1,2,5,6,9,10-hexabromocyclodecane	221-695-9	3194-55-6	
	beta-hexabromocyclododecane	-	134237-51-7	
	Hexabromocyclododecane	247-148-4	25637-99-4	
	gamma-hexabromocyclododecane	-	134237-52-8	
	alpha-hexabromocyclododecane	-	134237-50-6	
17	Acids generated from chromium trioxide and their oligomers	-	-	Carcinogenic (Article 57a)
	Dichromic acid	236-881-5	7738-94-5	
	Chromic acid	231-801-5	13530-68-2	
	Oligomers of chromic acid and dichromic acid	-	-	

Notably, Sweden is carrying out a RMOA covering all substances with a harmonised classification as skin sensitising category 1/1A/1B in textile articles.

Indeed, hazard classification and use categories have also been applied to group chemicals. For example, Directive 2004/37/EC regulates the protection of workers from the risks related to exposure to carcinogens or mutagens at work. Use categories are used to regulate broad groups of substances, such as pesticides, biocides or cosmetics. Within these groups, more categories can be identified in combination with other criteria (e.g. in pesticides: fungicides, herbicides, insecticides, etc. grouped by target; these can be further categorised by chemical type, e.g. for insecticides: chlorinated hydrocarbons, organophosphorus, nicotinoids, etc.; in biocides, disinfectants, preservatives, pest control, other biocidal products; these can be further categorised by product-type: human hygiene, veterinary hygiene, food and feed area, etc.; in cosmetics, cosmetic ingredients can be grouped by function: preservatives, UV-filters, colorants, etc.).

Another criterion currently used to group chemicals for optimal risk management measures is particle size. All particles of insoluble materials, even if these materials are not classifiable as dangerous to health, are hazardous, and in many Member States there are general limit values for dust based on respirable or inhalable size criteria. Particle size is also the determinant of a new branch of technology, nanotechnology, which makes deliberate use of materials with dimensions in the order of nanometres. Nanomaterials may show novel physicochemical properties compared to the bulk form of their parent

[34] Public Activities Coordination Tool (PACT) lists the substances for which a risk management option analysis (RMOA) or an informal hazard assessment for PBT/vPvB (persistent, bioaccumulative and toxic/very persistent and very bioaccumulative) properties or endocrine disruptor properties is either under development or has been completed since the implementation of the SVHC Roadmap commenced in February 2013. Available at: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact

substances, and can be used to enhance the performance of materials across several different fields and in a wide range of applications. The same special properties that occur at the nanoscale and can enhance the performance of materials could, however, result in "hazard profiles" that may also be different from that of the bulk form. The nature and extent of these hazards are difficult to predict, and therefore need to be assessed on a case-by-case basis. According to OECD (2016), "*there are plenty of potential nanomaterials of various chemicals and also of the same chemical, with distinctly or slightly different physical-chemical properties contributing to differences in their hazardous properties*". Therefore, many stakeholders are working on grouping strategies of nanomaterials, using criteria such as biopersistence and high-aspect ratio (e.g. Arts et al, 2015).

In relation to toxicology, Hodgson (2004) proposes exposure and use classes. Within exposure classes, Cope[35] distinguishes between toxicants in air, water, soil, domestic and occupational settings. Within use classes, the authors[36] discuss metals, agricultural chemicals (pesticides), food additives and contaminants, toxins[37], solvents, therapeutic drugs, drugs of abuse, combustion products and cosmetics.

Grouping strategies have also been proposed by environmental organisations. Greenpeace put forward eleven groups of chemicals[38] that due to their hazardous characteristics should be eliminated to achieve a non-toxic environment. These are:

- Alkylphenols;
- Phthalates;
- Brominated and chlorinated flame retardants;
- Azo dyes;
- Organotin compounds;
- Perfluorinated chemicals;
- Chlorobenzenes;
- Chlorinated solvents;
- Chlorophenols;
- Short-chain chlorinated paraffins;
- Heavy metals: cadmium, lead, mercury and chromium (VI).

Alkylphenols include octylphenols, nonylphenols and their ethoxilates and are widely used in the textiles industry in cleaning and dyeing processes, although they have been regulated in the EU since 2005 for their PBT properties.

Phthalates are widely used as plasticisers in PVC articles and some of them have been regulated in the EU due to their reproductive toxicity. However, regulatory attention first focused on low molecular weight phthalates (DEHP, BBP, DBP and DIBP) and only later included high molecular weight phthalates (DINP, DIDP and DNOP). Following the restrictions on low molecular weight phthalates, DINP became the preferred substitute for these substances, as its performance in the applications is similar to that of DEHP, with the exception of medical devices (ECHA, 2010). This can be observed in the human biomonitoring data of the German Environmental Specimen Bank[39]:

Göen et al (2011) note that metabolites of all five phthalates monitored (DEHP, DnBP, DiBP, BBP

[35] Cope, W.G., 'Chapter 4 - Exposure Classes, Toxicants in Air, Water, Soil, Domestic and Occupational Settings' in Hodgson (2004).
[36] Cope, W.G., Leidy, R.B., Hodgson, E., 'Chapter 5 – Classes of Toxicants: Uses Classes' in Hodgson (2004).
[37] "*A toxicant is any chemical, of natural or synthetic origin, capable of causing a deleterious effect on a living organism. A toxin is a toxicant that is produced by a living organism and is not used as a synonym for toxicant—all toxins are toxicants, but not all toxicants are toxins."* (Hodgson, 2004, p. 65).
[38] http://www.greenpeace.org/international/en/campaigns/detox/fashion/about/eleven-flagship-hazardous-chemicals/
[39] https://www.umweltprobenbank.de/en/documents/investigations/analytes/analytes

and DiNP) were detectable in over 98% of the urine samples, indicating the ubiquitous exposure of the German population to these substances. In the period 1988-2008, while the internal exposure to DEHP, DnBP, DiBP and BBP decreased substantially, the internal exposure to DiNP increased by a factor of 4. Göen et al (2011) highlight that further investigations will verify the effectiveness of the recent REACH measures (both restrictions and authorisations) on the substances.

Brominated and chlorinated flame retardants have persistent and bioaccumulative properties and some of them are suspected to be endocrine disruptors. Flame retardants are added to products to delay or prevent ignition and spread of fire. They can be used in levels between 1% and 30% of the weight of foam or plastics found in furniture, baby products, electronics, building insulation etc. Many flame retardants are organohalogens (see Box 2). All the chemicals banned under the Stockholm Convention are organohalogens, three of which are brominated flame retardants. There have been cases of regrettable substitution for these banned brominated flame retardants, such as Penta-BDE being replaced by chlorinated tris (TDCPP) which is a known carcinogen. Organohalogens flame retardants are toxic, lipophilic, and resistant to degradation. This means that they are persistent and bioaccumulative in bodies and the environment. Many are semi-volatile and migrate out of products. Biomonitoring studies have found organohalogens flame retardants in the blood and body tissue of nearly all Americans tested, with the highest levels in young children. There are lower concentrations of organohalogens flame retardants in Europeans than in US citizens as EU flammability standards do not always lead to the use of a flame retardant in consumer products. Many organohalogen flame retardants have similar structures to banned chemicals such as DDT, Mirex and PCBs. They have been found to cause adverse reproductive, genotoxic, immunotoxic, neurotoxic, and carcinogenic outcomes in animal studies. Dioxins and furans are produced when products containing flame retardants ignite and these chemicals have their own associated health risks. The toxic gases released from the burning of flame retardants cause the majority of fire related injuries and deaths. The challenge for flame retardant manufacturers and users is not moving from one organohalogens to another, but developing and moving to other chemical or non-chemical solutions, including developing safer alternatives through innovation and green chemistry.

Azo dyes are widely used in the textile industry, but some can break down during use and release carcinogenic aromatic amines. Azo colourants and azo dyes have been restricted in the EU in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity, but can still be used in the likes of tattoos.

Organotin compounds are used as biocides in a wide range of products and due to their PBT properties have been progressively restricted in the EU.

Perfluorinated and polyfluorinated chemicals contain one or more carbon atoms whose carbon-hydrogen bonds are replaced by carbon-fluorine bonds, which are strong and short. Although perfluorinated chemicals have different structures, the perfluorinated group gives these compounds unique properties including oleophobia and hydrophobia which leads to partitioning in protein-rich compartments of the body and subsequent bioaccumulation. Perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) are 8-carbon perfluorinated chain compounds, with PFOS restricted under the Stockholm Convention and REACH. Production of these compounds in Europe and the US has largely ceased since 2002, although they are still produced in other countries. They have been substituted with C6 and C4 perfluorinated groups which are less well studied at present. The problem lies in that many fluorochemicals available in commerce are precursors to PFOS and PFOA as they transform to them in the environment and animals. Fluorochemicals have been detected in surface waters, groundwaters, humans and Arctic animals such as polar bears and seals, which are thousands of miles from manufacturing sources. Twenty-two fluorochemicals have been detected in the blood of fifty non-occupationally exposed Americans ranging in age and gender. For at least half of the compounds detected, there is no publically available toxicological information. A study on adults living near a fluoropolymer manufacturing facility has found positive associations between high PFOA blood levels and testicular and kidney cancers, as well as a biomarker for liver malfunction. In

the same region, women experienced early menopause, and children exhibited increased susceptibility to hypothyroidism, reduced hormone levels and delayed puberty. The health effects of other fluorochemicals are less extensively studied. However, there are a few studies that have shown that shorter chain fluorochemicals have adverse health effects. C4 and C6 perfluorinated carboxylates and perfluorinated sulfonates have been seen to activate a nuclear receptor protein that can induce liver tumours in mice and human cells. Although fluorochemicals have their place in consumer products and exhibit sought after characteristics, the adverse health effects could be considered to outweigh the benefits. Due to a lack of evidence for the health impacts of other fluorochemicals, it would be advisable to substitute fluorochemicals with a different class of compounds.

Chlorobenzenes have been used as solvents and biocides, in the manufacture of dyes and as chemical intermediaries. Due to their PBT properties, they have been restricted in the EU and regulated internationally through the Stockholm Convention.

Chlorinated solvents are used in the textile industry and trichloroethane has been restricted in the EU due to its ozone-depleting, persistent and toxic properties. The main use of solvents is to dissolve materials; they can also disperse and transfer other substances. They are used in many consumer products, from paints to degreasing products. The most common solvents are water, aliphatic hydrocarbons, halogenated organic solvents, citrus or plant oils, oxygenated hydrocarbon solvents, siloxanes and n-methyl pyrrolidone.

Concern arises due to the adverse effects they cause and their rapid evaporation (which can result in inhalation by workers and consumers). Both acute and chronic exposure can have serious health effects. Common adverse effects are neurotoxicity, liver and kidney damage, carcinogenicity and reproductive toxicity.

Solvents perform an essential function in some consumer products and in many cases less harmful solvents or non-solvent based processes can be used instead of solvents that have been identified as hazardous.

Chlorophenols are used as biocides in a wide range of applications and the EU have restricted all products containing pentachlorophenol.

Heavy metals are naturally occurring and share similar properties including electrical conductivity and malleability. In their natural state, they are typically found as ores. Metals are used in numerous consumer and professional products, not only as the primary material but also as minor components such as pigments or to enhance performance. Metals can be released into the environment from mining and processing, and can increase in reactivity when transformed to other chemical forms or when bound to carbon. In their elemental form, metals can bind with organic molecules and bioaccumulate in the food chain. In some cases, human health effects have been noted at parts per billion (ppb) level. Some metals of concern include:

- Mercury can readily cross the blood-brain barrier, it bioaccumulates and chronic exposure can cause nervous system disorders such as memory loss, tremors and numbness.
- Lead targets the brain, nervous system and peripheral sensory system. It can cause blindness, hearing loss and decreased cognitive functions.
- Arsenic is known to accumulate in red blood cells, adhering to proteins in the skin and hair. It is correlated with certain types of skin and lung cancers and can cause anaemia and vascular disease.
- Chromium can cause kidney and lung cancer.
- Cadmium can affect the lungs, causing emphysema, as well as act as a calcium substitute causing osteoporosis/weakness of bone tissue and hence fractures as well as kidney failure.

Another NGO applying grouping strategies to achieve a non-toxic environment is the Green Science

Policy Institute[40]. This NGO promotes the "Six Classes Challenge", suggesting focusing regulatory pressure on six distinct classes:

- Highly fluorinated chemicals;
- Antimicrobials;
- Flame retardants;
- Bisphenols and phthalates;
- Organic solvents; and
- Certain metals and/or metallo-organic compounds.

The Six Classes Challenge seeks to decrease the use of classes of harmful chemicals in everyday products by 50% over 5 years. Most of the groups overlap with the ones suggested by Greenpeace (highly fluorinated chemicals, flame retardants, phthalates, solvents and heavy metals) except from anitmicrobials and bisphenols.

Antimicrobials prevent the growth of microbial organisms, but in contrast with antibiotics, they work outside the body to decrease bacteria levels on surfaces or products that humans come into contact with. Triclosan and triclocarbon are chlorinated chemicals with similar structures that are commonly used as antimicrobials. Triclosan has been used in hospitals, whereas triclocarbon is used in consumer products such as soaps. Triclosan has been detected in 75% of Americans tested, with a correlation between urine and blood concentrations of triclosan and triclocarbon and use of personal care products. This is likely to be due to triclosan and triclocarbon being readily absorbed across the skin barrier. Human health concerns stem from evidence that triclosan is an endocrine disruptor in oestrogenic, androgenic and thyroidal systems. There may also be impacts on the aquatic environment as triclosan and triclocarbon are released from sewage treatment works and are prevalent in the environment. The US FDA and US EPA have determined that more research is required on the safety of triclosan. The EU has determined that the use of triclosan in individual cosmetic and personal care products is not a risk but the cumulative effect from multiple products can be a concern. Triclosan is banned in the EU for use in food contact materials. Some manufacturers of personal care products have announced a phase-out of triclosan from their products. There is concern within the medical community that use of triclosan is promoting growth of resistant bacteria. Triclosan is required in hospitals to prevent bacteria as there are vulnerable people, but it has not been proven to be a benefit in everyday personal care products.

Bisphenols have been indicated as endocrine disrupting chemicals, therefore able to interfere with hormone signalling (see Box 1). One of the aspects of EDCs higher concern is that effects that appear at very low concentrations and exposure during the prenatal and early postnatal development periods may result in effects that manifest in later life and that can be transferred to future generations through epigenetic changes.

Also, large retailers have defined groups of substances to improve their chemical strategies[41]. For example, the Danish Coop has identified twelve kinds of chemicals that are used in everyday products and that pose a threat to human health and the environment:

- Methylisothiazolinone;
- Fluorinated compounds (PFC);
- Substances in cosmetics under suspicion for endocrine disruptor effects;
- PVC and phthalates;

[40] http://greensciencepolicy.org/topics/six-classes/
[41] "Safer products for consumers", webinar by Malene Teller Blume (Manager non-food, quality and social compliance, Coop Denmark A/S, available at: http://echa.europa.eu/view-webinar/-/journal_content/56_INSTANCE_DdN5/title/why-opt-for-substitution

- Chemicals in textiles;
- REACH and the candidate list (SVHC);
- Allergenic scented substances and preservatives;
- Triclosan;
- Cleaning products with chlorine and cationic surfactants;
- Pesticides;
- Polluting washing detergents;
- Bisphenol A and other phenols.

Coop has committed to banning the 11 groups and one additional chemical (Methylisothiazolinone) from its own brand products by the end of 2017, as well as pledging to put pressure on the suppliers of products of other brands to phase out those substances.

The advantage of using grouping strategies for regulatory purposes is that they speed up the legislative processing and make it easier to avoid regrettable substitutions. The Commission has already used the so-called "fast track" restriction procedure outlined in Article 68(2) of REACH (which can be applied to CMRs in consumers' articles) for PAHs (Restriction list entry 50) in consumer articles and toys with rubber or plastic components that come into contact with the human skin or the oral cavity, and it is currently evaluating a fast-track restriction of 58 CMRs in textiles. Both restrictions met the concerns of industry associations: with regard to the restriction of PAHs, the European Tyre and Rubber Manufacturers' Association (ETRMA) argued that the fast-track procedure does not allow for a proper risk assessment[42]; with regard to the restriction of CMRs in textiles, several industry associations published a joint position paper[43] criticising the too wide scope of the restriction, the insufficient consideration of supply chain and business realities, the lack of harmonised and validated test methods to ensure the enforceability of the restriction and the lack of proper risk and socio-economic assessments.

Currently[44], the Registry of Restriction intentions lists three proposals on groups of substances:

- Lead and its compounds in shots over wetlands;
- Lead and its compounds as stabilisers in PVC articles;
- Diisocyanates for industrial and professional uses.

In order to increase the efficiency and effectiveness of the legislation, the extent to which grouping strategies are adopted may need to be scaled up. As discussed in the previous Section, there are numerous examples of regrettable substitutions within groups of chemicals with similar structures and similar hazard properties.

Fankte et al (2015) describe these as cases of incremental rather than fundamental change in the structure of hazardous substances that hampers their successful phase-out and propose the use of the term "lock-in" problem. The authors suggest that several challenges and obstacles are present in the phasing out process of hazardous chemicals: phase-out agreements are often voluntary and do not cover all relevant manufacturers or have a wide range of exemptions. It is also problematic to find a suitable alternative achieving the same performances in the applications, without altering other functions, properties or processes. There are also methodological challenges related to the different assessment criteria applied by the different alternatives assessment tools available that may result in inconsistent results. Most tools also neglect life-cycle aspects, which are essential to identify trade-offs and avoid burden shifting. When life-cycle impacts are considered, the available information may not

[42] Chemical Watch news on 8 November 2012: First 'fast-track' REACH restriction proposal edges forward. Available at: https://chemicalwatch.com/12865/first-fast-track-reach-restriction-proposal-edges-forward
[43] Available at: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8299
[44] August 2016.

be sufficient for a proper assessment.

In order to overcome these challenges, the authors propose to have binding phase-out agreements on groups of substances, which would push all stakeholders to design more sustainable substances. The design process, however, should be aligned with the principles of Green Chemistry and should consider life-cycle aspects in the wider context of the chemicals' applications in consumer products. Moreover, the focus in the alternatives assessment should be on the functions delivered by the substance; what Tickner et al (2015) call functional substitution. This should ensure that entirely new chemical structures and even non-chemical solutions such as new materials or processes are considered in the assessment. When alternatives can only be found in the same structurally similar chemical group, Fankte et al (2015) advance two options: the first option is that, in the absence of comprehensive information on (eco)toxicological properties and environmental fate of the alternatives, it should be assumed that they exhibit the same hazardous properties of the substance(s) to be substituted, based on the similarity in chemical structure. The second option is that the manufacturers of the alternatives generate the information required. The latter is already mandate by the REACH Regulation. However, as noted by UBA (2015b), the information provided in the registration dossiers appears to be inadequate to perform a comprehensive hazard and risk assessment for many substances registered.

KemI (2015) notes that the possibility of recurring to "category" and "read across" approaches to fulfil the test data requirements for the registration process has been widely misused, with registrants not proving proper justification and grouping substances erroneously. In order to improve the inadequate quality of the current registration dossiers and to avoid the future misuse of read across, Kemi (2015) suggests that ECHA should develop guidelines on read across and should explore the feasibility of grouping within the framework of substance evaluation. ECHA is currently studying the possibility of a systematic analysis of the structural similarities of substances in connection with the prioritisation of such substances prior to the substance evaluation stage. Further research on grouping strategies is ongoing at national level too. For example, the Danish EPA explored the possibility of grouping brominated flame-retardants that were found in a survey of consumer products in 2014. Sixty-seven brominated flame-retardants were grouped according to their chemical structures and trends in (Q)SAR predictions for a number of environmental and health effects, resulting in 15 preliminary structural groups and 7 single substances exhibiting peculiar chemical structures and (Q)SAR trends so that they could not be grouped (DEPA, 2016).

With regard to the other REACH mechanisms, Kemi (2015) suggests that the REACH authorisation mechanism should seek "*the application of group-based inclusion of chemically related substances such as metal compounds and salts with the same hazard properties of very high concern"*. Furthermore, "*the inclusion of multi-constituent and UVCB substances containing a substance of very high concern as a constituent under the same rules that currently apply to mixtures, i.e. considered as covered by the SVHC categorisation of the constituent on the candidate list down to the 0.1 % (or 0.3 % as appropriate) concentration cut off."* KemI also proposes to explore the opportunity of facilitating a systematic application of group-based restrictions, investigating ways to overcome the high costs associated with the preparation of a restriction dossier on a group of substances.

More in general, a discussion on grouping strategies should be initiated among member states at the EU political level.

3 AVAILABLE TOOLS TO ADDRESS GAPS AND DEFICITS

Important aspects of a future EU strategy for a non-toxic environment include the enhancement of the application of the substitution principle in the policy context, by creating further incentives for substitution of hazardous chemicals at different levels of the value chain.

The substitution principle is already a well-established aspect of the EU chemicals acquis, having been incorporated in chemical policy, occupational health and safety legislation, product safety and environmental legislation. Different measures are also found at national level, with mandatory reporting schemes, databases to share information on alternatives, guidelines to implement substitution of hazardous chemicals and support for substitution initiatives.

3.1 GAPS AND DEFICITS

On the basis of the literature review, the issues highlighted during the NTE workshop and the results of the online surveys, the following gaps and deficits have been identified (it should be noted that different stakeholder groups have diverging opinions; what is regarded as a deficit by one stakeholder group, may be considered an incentive by another stakeholder group):

1. Gaps in (eco)toxicological, bioaccumulation and environmental degradation information;
2. Information gaps on chemicals in articles;
3. Insufficient risk assessment methodologies. Risk assessment methodologies for the article service life and waste stage are not sufficiently developed to assist all actors;
4. Scarcity of information on alternatives;
5. REACH authorisation does not cover imported articles;
6. Insufficient time to identify and develop suitable alternatives;
7. Excessive lengthening of the time to market for products containing alternatives;
8. Administrative burden;
9. Unsatisfactory synergies between chemical policies;
10. Insufficient regulatory signals to investments in innovation;
11. Regulatory uncertainty as regard available alternatives;
12. Lack of ambition and speed of the authorisation process;
13. Poor enforcement of the legislation;
14. Lack of resources dedicated to substitution initiatives among Member States, ECHA, the Commission;
15. Incremental rather than fundamental change of chemical structure of alternatives;
16. Regrettable substitutions.

3.2 REASONS FOR GAPS AND DEFICITS

3.2.1 Information gaps and insufficient methodologies

Despite the entry into force of the REACH Regulation, there are still gaps in (eco)toxicological information, particularly for low production volume substances. Although substances manufactured or imported in quantities between one tonne and one hundred tonnes per year per manufacturer or per importer will have to be registered by June 2018, the information requirements for these low volume substances do not cover all end-points. Moreover, substances manufactured or imported in quantities below one tonne per year do not have to comply with any registration information requirements. These substances may prove to be a good pool of potential alternatives and the lack of information considerably limits the possibility to carry out robust comparative risk analyses.

Another information gap relates to the uses and presence of hazardous substances in articles. The lack of this information prevents informed choices and affects the efficiency of any prioritisation strategy for the purpose of substitution by downstream users. Although REACH is enhancing the communication of information throughout the supply chain and there are several initiatives aiming to provide information about the content of hazardous chemicals in articles to the public, these initiatives are patchy and may benefit from some form of harmonisation.

A full analysis of the alternatives should take into account not only hazards and risks during the production of the chemicals and their use in the processes/products, but also life cycle impacts and other key aspects, such as the impact on energy consumption. These types of assessments, however, are resource and time intensive and require good quality data that, despite the implementation of the REACH Regulation, are not yet available for most of the chemicals of concern. Moreover, according to the assessment of the analyses of alternatives in the authorisation applications and restriction proposals carried out by the University of Massachusetts Lowell for ECHA, the quality of the analyses could be improved by training, guidance and setting quality standards.

The presence of information gaps on the (eco)toxicological properties of potential alternatives and on their bioaccumulation and degradation behaviour and the insufficient development and adoption of risk assessment methodologies may result in cases of regrettable substitution.

3.2.2 Regulatory issues

REACH authorisation does not cover imported articles: although ECHA must consider if the use of the substance in articles poses a risk and if so, prepare a dossier which conforms to the requirement of an Annex XV dossier for restriction (Article 69(2)). Some stakeholders suggest that the lack of an automatic restriction on imported articles containing Annex XIV substances may result in a potential competitive disadvantage for the companies opting for substitution. Moreover, if a substance is used only as a process chemical or otherwise is not present in the end product, there will be no impact for imported articles but EU manufacturers have to substitute where non-EU manufacturers don't, possibly leading to competitive disadvantage.

The current legislative practice may encourage incremental rather than fundamental change of chemical structure of the potential alternatives, resulting in these exhibiting the same hazard profiles of the substances substituted (regrettable substitution). Some industry stakeholders noted that, once a substance comes under regulatory scrutiny, the time to move to suitable alternatives may not be adequate, resulting in regrettable substitutions or in second best solutions (such as minimizing occupational exposure but neglecting environmental fate at the end of life stage). Moreover, once an alternative is developed, where product approval by authorities is necessary (e.g. in aerospace or medical devices), this process can excessively prolong the product time to market.

Others noted that, particularly for SMEs, the chemical regulatory framework, at both EU and national levels, may be overwhelming and sometimes inconsistent. This results in a relatively high administrative burden of the legislation, which ultimately diverts resources from R&D to comply with the legislation. SME often have an incomplete overview of available alternatives, their advantages and disadvantages from a technical and environmental point of view, and there are often other technical and economic barriers which prevent the take-up of innovative solutions.

Human health and environmental costs may not be internalised by the chemical or product manufacturers. For example, chemicals regulated by both the REACH Regulation and the Water Framework Directive may leak from products during their life cycle or during the waste stage. However, the costs to clean up such pollution is borne by the wastewater treatment companies and drinking water suppliers and, ultimately, by the citizens. As an illustrative example, biocidal products, such as triclosan, are used for their anti-bacteria properties in personal care products and as preservatives in other consumer products. Triclosan has acute and chronic toxic effects in the aquatic

environment, it shows the potential to bioaccumulate, has high mobility in water and soil and is suspected to have endocrine disruptive properties. However, wastewater treatment processes are unable to remove triclosan completely, requiring the implementation of source control measures, such as legislative restrictions. The necessity of its application in most of its current uses have been questioned and concerns have been raised over it contribution towards antimicrobial resistance of bacteria.

Another issue that was highlighted by some stakeholders is that the granting of authorisation for the use of substances in applications for which safer alternatives are available, may stifle, rather than reward, innovation. Some others pointed to the fact that even when companies substitute hazardous substances with less hazardous substances, there is a certain regulatory uncertainty over the chosen alternatives as there is no guarantee that these safer (but nevertheless hazardous or potentially hazardous) alternatives will not come under regulatory scrutiny in due course.

Environmental organisations are concerned about the lack of ambition and rhythm in adding new substances to the Authorisation list.

3.2.3 Lack of resources

Very few resources are currently dedicated to substitution initiatives among Member States, ECHA and the Commission. This may be linked to the budgetary limitation at both national and EU level and has already been identified as an issue, for example, regarding effectively fulfilling European Agencies mandates[45]. At Member State level, the engagement in substitution initiatives is not homogeneous, with some Member States very active and others, even those with a sizeable chemical industry, focusing mainly on traditional risk management activities and dedicating scarce resources to substitution initiatives or to supporting green chemistry solutions.

3.3 AVAILABLE TOOLS TO ADDRESS GAPS AND DEFICITS

The gaps and deficits identified in current policy are not new. To a smaller or larger extent, member states and stakeholders have identified the gaps and developed, or are developing, measures to address these gaps. The catalogue of available tools listed below comprises of existing measures practiced in Member States and/or by other stakeholders as well as measures described in the reviewed literature.

A number of ongoing initiatives within the Commission are currently assessing the performance of chemicals legislation. These include the fitness check of all chemicals legislation except REACH and the REACH review, which are both due in 2017. The results of this study also provide useful input to those initiatives.

The catalogue of available tools to respond to gaps and deficits identified is a comprehensive inventory of all possible measures identified during the work of this study. The appropriateness of those tools and their potential impacts have not been assessed as part of this study. This needs to be done in a further step, taking into account the tools identified in the better regulation agenda.

Through literature review and stakeholders' consultation, we identified the following available tools, presented by type of instrument:

[45] Position paper of the EU Agencies Network, 8 July 2013. Available at: http://www.europarl.europa.eu/meetdocs/2009_2014/documents/budg/dv/agencies_position_paper_/agencies_position_paper_en.pdf or Chejmical Watch web article on 13 January 2015: "Dancet fights staff cuts slated for 2016 - Reductions jeopardise Echa's ability to manage REACH registrations, says agency head". Available at: https://chemicalwatch.com/22508/dancet-fights-staff-cuts-slated-for-2016

Strengthening and streamlining existing legislation

1. Increase information requirements for low production volume substances;
2. Impose an automatic restriction on imported articles containing substances subject to authorisation;
3. Extend the available time to identify and move to sustainable alternatives;
4. Shorten product safety assessment processes by public authorities (e.g. product approval for aviation or medical devices);
5. Refuse authorisations for the use of Annex XIV substances for which alternatives are available on the market;
6. Reduce the administrative burden for SMEs (e.g. more time to comply with the legislation, lower fees);
7. Co-ordinate substitution initiatives across member states around prioritised chemicals of concern;
8. When regulating a substance, consider systematically the application of grouping strategies;

Economic instruments

9. Reward/incentivise sustainable substitution (e.g. VAT reduction);
10. Promote taxation of hazardous substances among member states;
11. Enhance government green procurement programmes, considering the functional substitution of hazardous chemicals;

Information based instruments

12. Develop an EU-level substance-regulation navigator, including implemented and upcoming international and national legislation by substance/application;
13. Develop tools to track hazardous chemicals in articles;
14. Enhance the available databases with information on alternatives;

Support and capacity building

15. Start a public debate, involving all relevant stakeholders, on the identification of applications for which the use of certain chemical groups raise concerns that are higher than the benefits delivered;
16. Fund further research into chemical product life cycle risk assessment;
17. Raise awareness on the benefits of – and stimulate market demand for - safer alternatives;
18. Enhance supply chain collaboration and engagement through, e.g. shared performance testing and evaluation and the creation of demonstration sites;
19. Promote circular economy business models (e.g. chemical leasing);
20. Develop ECHA and Member State Competent Authorities capacity to support substitution;
21. Facilitate public-private investment partnerships for supporting research into safer alternatives and for the provision of technical support to SMEs, in particular on technical feasibility of alternatives;
22. Create an expert knowledge platform to support authorities and industry with substitution initiatives;
23. Raise awareness over functional substitution (rather than chemical-by-chemical substitution);
24. Create a system for consistent definitions, classification and characterisation of functions of chemicals;
25. Encourage the design of chemical alternatives in accordance of the green chemistry principles by creating academia curricula and funding green chemistry;
26. Develop rapid and efficient (high-throughput) quantitative screening tools combining hazard, exposure and, possibly, life cycle impacts to avoid burden shifting and regrettable substitution;
27. Scale-up research on grouping strategies based on similarity of chemical structures and trends in (Q)SAR predictions;

Enforcement

28. Dedicate more resources to enforcement of every aspect of the chemical legislation;

Monitoring

29. Encourage initiatives such as the chemical footprint project;
30. Enhance chemical monitoring programmes.

3.4 INTERVENTION INSTRUMENTS

For each gap, one or more available instruments to address those gaps have been identified. Some of these instruments may address several gaps and deficits, others would need to be combined to effectively fill the gap. Some of these instruments may be implemented in the short (1 or 2 years) or medium term (3 to 5 years), while others would need a longer time horizon (over 5 years) because they are likely to involve new legislation or amendments to the current legislative framework.

Table 4 below qualifies and discusses shortly each idea.

4 CONCLUSIONS

There has been much debate in recent years about the application of the substitution principle for hazardous chemicals.[46] Öberg (2014) and Lofstedt (2014) argue that the substitution principle is under-researched and there is no clear consensus on how to best apply it.

Overall, Lissner (2010) found that practitioners and specialists are sceptical about general legal substitution requirements and prefer case-by-case decisions. Lofstedt (2014) agrees that substitution should be examined on a case-by-case basis. Economic factors are strong motivational factors, while regulatory and technological considerations can be initial triggers and supportive factors. As a result, there is not a uniform approach to assessment and evaluation of the motivation, drivers, barriers, costs and successes of substitutions. The complexities and difficulties need to be taken into account in the support tools and decision criteria that aim to support substitution (Lissner, 2010). Lofstedt (2014) considers that there is a need for rigorous academic and regulatory analysis and examination before it can be used and promoted in a satisfactory way. Lofstedt calls for more emphasis on risk analysis instead of hazard classifications as the basis for substitution, incorporation of risk/risk trade-offs into risk management decisions and increased transparency in the risk management process, among others.

Hansson et al (2011) have suggested a set of methods to promote substitution, focused particularly on increasing the availability of data on toxicity, chemical composition and the availability of information about technical functionality. This was based on their observation that there is a need for manufacturers and end-users to have access to information in order to make informed decisions on the substitution of a hazardous substance with a safer alternative. Access to such information is currently enabled by ECHA with its data dissemination portal and the classification and labelling inventory (CLI). The former includes all non-confidential information from the REACH registration dossiers submitted by the industry so far and there are various data fields such as substance, tonnage or hazard classification. The latter includes classification and labelling information for hazardous substances and substances subject to REACH registration. It contains both harmonised as well as self-classification data, as submitted by manufacturers or importers of each substance.

That decisions should be as well informed as possible is a view supported by Olofsson (2014). However, she also points out that, while the best available knowledge should be used for decision-making, ideology always plays a role and it is better if it is transparent rather than disguised as scientific evidence. Therefore, Olofsson concludes that whether a decision on substitution is based on risk assessment or hazard classification is secondary. What is most important is that the decision is based on the best possible evidence available. The controversy surrounding chemical regulations and the substitution principle will eventually draw media attention and may be subject to political opportunism and lobbying from industry and NGOs. Therefore, argues Olofsson, the real challenge is to find ways, despite this, to operate the substitution principle in an effective and sustainable way. To reach such a goal, more research will be needed as Lofstedt suggests, particularly on the social, political and economic aspects of the substitution process. Transfer of knowledge between REACH and EU environmental and work environment legislation could also increase the information pool and promote substitution. Relevant pieces of legislation are the Industrial Emissions Directive and the Water Framework Directive (KemI, 2015).

Dudley (2014) also comments that there is uncertainty regarding the result of government interventions to effect societal improvements. This is the case with simple hazard classifications, but also because predicting the risk of different substances is not sufficient for sound policy. Sound policy decisions must also weigh other factors such as those related to economics, engineering, ethics, law and politics. She also argues that unilateral decisions on substitution of hazardous chemicals stifle

[46] For the review of the literature on substitution of hazardous chemicals please see Appendix 1.

innovation and learning and fail to account for the diversity of affected populations. Dudley concludes that the best use of the substitution principle may be to help everyone understand the complexity of risk management decisions.

Overall, literature identifies a need to move towards a policy which combines legal provisions that are strict enough to provide a strong incentive for proactive substitution and supportive and enabling factors, such as increasing the knowledge base, providing access to knowledge and information, developing and making available tools for substitution, comparative assessment and possibly also more direct support in actual substitution activities. ChemSec (2016) identifies that anticipation of regulation is a strong driver for innovation with regulatory processes sending signals to the market and acting as an incentive for innovation. Promotion and use of the substitution principle need to reflect the need for regulatory impetus, but that this needs to be supported by processes that improve access to information that is useful at the practical level so that ongoing innovation can be encouraged (EC, 2012).

To the problems highlighted by the literature, the gaps and deficits suggested by the consulted stakeholders also need to be addressed in order to foster a more effective substitution of hazardous chemicals, in the interest of health and environmental protection, and a more stable and reliable framework for investments in innovative alternatives. This may also be an important contribution to create non-toxic material cycles and a circular economy.

These problems relate to the large number of hazardous substances used in industrial processes and products and consumer products, which may result in multiple exposures during the production, use and waste stage of the substances.

The current legislative framework, in particular the REACH authorisation process, tends to follow a chemical-by-chemical approach when regulating substances of concern. This often results in cases of regrettable substitution, as companies tend to favour substances with not only similar chemical structures and technical properties, but also similar (eco)toxicological characteristics and the same bioaccumulation and environmental degradation behaviour.

- Available tools for dealing with these gaps and deficits have also been suggested by different stakeholders (authorities, industry, NGOs and academia), both during the consultation process and in the literature. These range from measures to strengthen and streamline the legislative framework (a process started since the first review of the REACH Regulation in 2012) to the provision of support, training and information. In particular, the promotion of functional substitution and the scaling up of the adoption of grouping strategies may ensure a more effective and efficient phasing out of substances of concern.
- Economic instruments, better enforcement and the enhancement of the monitoring programmes have also been suggested as initiatives that would benefit the transition towards a non-toxic environment.

The appropriateness of those tools, and their potential impacts, need to be assessed in a further step, taking into account the tools identified in the better regulation agenda.

Table 4: Ideas for improvement

Gap / Deficit	Reason for Gap/Deficit	Identified Responses	Qualification	Discussion
Gaps in (eco)toxicological, bioaccumulation and environmental degradation information	Limited information requirements Inadequate quality of the registration dossiers submitted	a.01. Increase information requirements for low production volume substances	Medium term Strengthening of existing legislation	Low production volume substances may prove to be a good pool of potential alternatives and the availability of information would enable robust comparative risk analyses.
Information gaps on chemicals in articles	Lack of reporting requirements for information on the toxic content of substances in materials and articles to authorities and in the supply chains, information on functionalities of substances in materials is regarded as confidential. Lack of structured and accessible information on toxic substances in materials and articles.	a.13. Develop tools to track hazardous chemicals in articles	Short-medium term Information based instrument	This would increase the availability of information to all actors, allowing for better risk assessment and management, better prioritisation of regulatory activities and may encourage substitution. The creation of a market demand would generate a bottom-up pressure on chemicals manufacturers to communicate the presence of hazardous substances in articles.
		a.29. Encourage initiatives such as the chemical footprint project	Medium term Coregulation	
		a.17. Raise awareness on the benefits of – and stimulate market demand for - safer alternatives	Short-medium term Information based instrument	
Insufficient risk assessment methodologies particularly for article service life and waste stage	Frequently, Chemical Safety Assessments under REACH ignore life cycle stages other than manufacture and use in the production process, such as the waste stage.	a.16. Fund further research into chemical product life cycle risk assessment	Short-medium term Economic instruments Information based instruments Support and capacity building	Life cycle risk assessment would enable better risk management and would ensure the avoidance of cases of regrettable substitution. The development of the authorities' capacities would enhance the regulatory action.
		a.20. Develop ECHA and Member State Competent Authorities capacity to support substitution	Short-medium term Support and capacity building	
Scarcity of information on alternatives	There are few and limited databases of information on alternatives and no marketplaces dedicated to	a.14. Enhance the available databases with information on alternatives	Short-medium term Information based instrument	These initiatives would help manufacturers in developing alternatives and downstream users in

Gap / Deficit	Reason for Gap/Deficit	Identified Responses	Qualification	Discussion
	safer alternatives.	a.18. Enhance supply chain collaboration and engagement through, e.g. shared performance testing and evaluation and the creation of demonstration sites	Short-medium term Information based instrument	searching for alternatives.
		a.21. Facilitate public-private investment partnerships for supporting research into safer alternatives and for the provision of technical support to SMEs, in particular on technical feasibility of alternatives	Short-medium term Support and capacity building	
		a.22. Create an expert knowledge platform to support authorities and industry with substitution initiatives	Short-medium term Support and capacity building	
		a.21. Co-ordinating substitution initiatives across member states around prioritised chemicals of concern	Short-medium term Support and capacity building	
		a.23. Raise awareness over functional substitution (rather than chemical-by-chemical substitution)	Short-medium term Information based instruments Support and capacity building	
		a.29. Encourage initiatives such as the chemical footprint project	Medium term Coregulation	
		a.24. Create a system for consistent definitions, classification and characterization of functions of chemicals	Short-medium term Information based instruments Support and capacity building	
REACH authorisation does not cover imported articles	Legislative gap	a.02. Impose an automatic restriction on imported articles containing substances subject to authorisation	Medium term Strengthening of existing legislation	The use of a substance subject to authorisation in an imported article will be restricted by default in such articles, hence achieving equal treatment of all

Gap / Deficit	Reason for Gap/Deficit	Identified Responses	Qualification	Discussion
				articles. This would ensure a level playing field and protect competitiveness of European companies
Insufficient time to identify and develop suitable alternatives	Due to the lack of information on alternatives, stakeholders may not have sufficient time to develop suitable alternatives	a.12. Develop an EU-level substance-regulation navigator, including implemented and upcoming international and national legislation by substance/application	Medium term Information based instruments	Supporting stakeholders in finding information on alternatives and focusing on functional substitution (beyond chemical substitution) will help in phasing out hazardous chemicals more effectively
		a.14. Enhance the available databases with information on alternatives	Short-medium term Information based instruments	
		a.03. Extend the available time to identify and move to sustainable alternatives	Medium term Streamlining legislation	
		a.18. Enhance supply chain collaboration and engagement through, e.g. shared performance testing and evaluation and the creation of demonstration sites	Short-medium term Information based instruments	
		a.23. Raise awareness over functional substitution (rather than chemical-by-chemical substitution)	Short-medium term Information based instruments Support and capacity building	
		a.24. Create a system for consistent definitions, classification and characterization of functions of chemicals	Short-medium term Information based instruments Support and capacity building	
Excessive lengthening of the time to market for products containing alternatives	Safety assessment processes of products for certain sectors may require several months	a.04. Shorten product safety assessment processes by public authorities (e.g. product approval for aviation or medical devices)	Medium term Streamlining legislation	This would encourage companies in considering safer alternatives even in those sectors with very strict and demanding technical

Gap / Deficit	Reason for Gap/Deficit	Identified Responses	Qualification	Discussion
				performances and safety standards
Administrative burden	Complex legislative requirements	a.06. Reduce the administrative burden for SMEs (e.g. more time to comply with the legislation, lower fees)	Medium term Streamlining legislation	Apart from a direct support by, for example, further lower fees for SMEs, all other initiatives would contribute in easing the administrative burden. More efficient grouping of substances would help in saving companies' resources.
		a.26. Develop rapid and efficient (high-throughput) quantitative screening tools combining hazard, exposure and, possibly, life cycle impacts to avoid burden shifting and regrettable substitution	Medium term Support and capacity building	
		a.21. Facilitate public-private investment partnerships for supporting research into safer alternatives and for the provision of technical support to SMEs, in particular on technical feasibility of alternatives	Short-medium term Support and capacity building	
Unsatisfactory synergies between chemical policies	Complex legislative framework	a.15. Start a public debate, involving all relevant stakeholders, on the identification of applications for which the use of certain chemical groups raise concerns that are higher than the benefits delivered	Short term Information based instruments	The identification of chemical groups of concern would enable to prioritise these across different pieces of legislation. The promotion of substitution would eliminate the problems at the source rather than requiring end-of-pipe controls by different sectorial legislation.
		a.10. Promote taxation of hazardous substances among member states	Short-medium term Economic instruments	
		a.07. Co-ordinate substitution initiatives across member states around prioritised chemicals of concern	Short-medium term Streamlining legislation	
Inadequate regulatory signals to investments in innovation	The authorisation of the use of Annex XIV substances when alternatives are already available on the market.	a.05. Refuse authorisations for the use of Annex XIV substances for which alternatives are available on the market	Short term Streamlining legislation	Beyond restricting hazardous substances in certain applications and easing the identification

Gap / Deficit	Reason for Gap/Deficit	Identified Responses	Qualification	Discussion
		a.17. Raise awareness on the benefits of – and stimulate market demand for - safer alternatives	Short term Information based instruments	and communication of information, policy-makers need to incentivise sustainable substitution by e.g. reducing VAT on products with safer alternatives and by systematically consider safer alternatives in public procurement processes.
		a.21. Facilitate public-private investment partnerships for supporting research into safer alternatives and for the provision of technical support to SMEs, in particular on technical feasibility of alternatives	Short-medium term Support and capacity building	
		a.09. Reward/incentivise sustainable substitution (e.g. VAT reduction)	Short-medium term Economic instruments	
		a.11. Enhance government green procurement programmes, considering the functional substitution of hazardous chemicals	Short-medium term Economic instruments	
Regulatory uncertainty as regard available alternatives	Insufficient (eco)toxicological information of potential alternatives; insufficient risk assessment methodologies; substitution with substances with a similar chemical structure.	a.14. Enhance the available databases with information on alternatives	Short-medium term Information based instruments	The passage from incremental to fundamental change in the chemical structure of the substances should ensure the sustainable substitution of the hazardous substances. The promotion of functional substitution may also encourage the adoption of non-chemical alternatives.
		a.08. When regulating a substance, consider systematically the application of grouping strategies	Short term Streamlining legislation	
		a.24. Create a system for consistent definitions, classification and characterisation of functions of chemicals	Short-medium term Information based instruments Support and capacity building	
		a.23. Raise awareness over functional substitution (rather than chemical-by-chemical substitution)	Short-medium term Information based instruments Support and capacity building	
		a.03. Extend the available time to identify and move to sustainable	Medium term Streamlining legislation	

Gap / Deficit	Reason for Gap/Deficit	Identified Responses	Qualification	Discussion
		alternatives		
		a.01. Increase information requirements for low production volume substances	Medium term Streamlining legislation	
		a.27. Scale-up research on grouping strategies based on similarity of chemical structures and trends in (Q)SAR predictions	Short-medium term Economic instruments	
		a.25. Encourage the design of chemical alternatives in accordance of the green chemistry principles by creating academia curricula and funding green chemistry	Short-medium term Support and capacity building	
Lack of ambition and speed of the authorisation process	Limited use of grouping strategies for the inclusion of substances in Annex XIV	a.15. Start a public debate, involving all relevant stakeholders, on the identification of applications for which the use of certain chemical groups raise concerns that are higher than the benefits delivered	Short term Information based instruments	Inclusion of groups of substances with similar properties in Annex XIV would ensure a more effective and efficient functioning of the Regulation
		a.08. When regulating a substance, consider systematically the application of grouping strategies	Short term Streamlining legislation	
Poor enforcement of the legislation	Lack of resources	a.28. Dedicate more resources to enforcement of every aspect of the chemical legislation	Short term Enforcement Economic instruments Support and capacity building	Better enforcement ensures the right signals are given to investors when deciding on the research and development of safer alternatives
Lack of resources dedicated to substitution initiatives among member states, ECHA, the Commission	Resources have been dedicated to other aspects of the chemical legislation	a.17. Raise awareness on the benefits of – and stimulate market demand for - safer alternatives	Short term Information based instruments	Co-ordination of the initiatives and prioritisation of groups of chemicals of concern would ensure the efficient use of available resources.
		a.22. Create an expert knowledge platform to support authorities and industry with substitution initiatives	Short-medium term Support and capacity building	

Gap / Deficit	Reason for Gap/Deficit	Identified Responses	Qualification	Discussion
		a.08. When regulating a substance, consider systematically the application of grouping strategies	Short term Streamlining legislation	
		a.20. Develop ECHA and Member State Competent Authorities capacity to support substitution	Short-medium term Support and capacity building	
		a.07. Co-ordinate substitution initiatives across Member States around prioritised chemicals of concern	Short term Streamlining legislation	
Regrettable substitutions	Limited use of grouping strategies	a.09. Reward/incentivise sustainable substitution	Short-medium term Economic instruments	The regulation of groups of substances with similar properties instead of a substance-by-substance mode of action would ensure the fundamental change in chemical structures used instead of an incremental change. Moreover, moving the focus on functional substitution would ensure the consideration of non-chemical alternatives too.
		a.10. Promote taxation of hazardous substances among member states	Short-medium term Economic instruments	
		a.17. Raise awareness on the benefits of – and stimulate market demand for - safer alternatives	Short term Information based instruments	
		a.18. Enhance supply chain collaboration and engagement through, e.g. shared performance testing and evaluation and the creation of demonstration sites	Short-medium term Information based instruments	
		a.19. Promote circular economy business models (e.g. chemical leasing)	Short-medium term Information based instruments Support and capacity building	
		a.21. Facilitate public-private investment partnerships for supporting research into safer alternatives and for the provision of technical support to SMEs, in particular on technical feasibility of alternatives	Short-medium term Support and capacity building	
		a.11. Enhance government green	Short-medium term	

Gap / Deficit	Reason for Gap/Deficit	Identified Responses	Qualification	Discussion
		procurement programmes, considering the functional substitution of hazardous chemicals	Economic instruments	
		a.22. Create an expert knowledge platform to support authorities and industry with substitution initiatives	Short-medium term Support and capacity building	
		a.29. Encourage initiatives such as the chemical footprint project	Medium term Coregulation	
		a.08. When regulating a substance, consider systematically the application of grouping strategies	Short term Streamlining legislation	

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APPENDIX 1: LITERATURE REVIEW

A1.1. GENERAL LITERATURE REVIEW ON THE SUB-STUDY AREA

A1.1.1. Defining the substitution principle

The literature includes a wide range of definitions of the substitution principle, varying in terms of the scope (substance, mixture, product or function), means (substitution by another chemical substance, by technological or organisational measures) and focus on either hazard or risk. Table 1 presents some of the interpretations by different stakeholders.

Table 1: Definitions from the literature on substitution and the substitution principle

Definition	Reference
Substitution means the replacement or reduction of hazardous substances in products and processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organisational measures [key element is functional equivalence, i.e. achievement of the same functionality by less hazardous means]	Lohse et al, 2003 in Hansson et al, 2011; Keml 2007; IFCS, 2008
Substitution is the replacement of one substance by another with the aim of achieving a lower level of risk	CEFIC, 2005 in Lofstedt, 2014; Aven 2014
Informed substitution is the considered transition from a chemical of particular concern to safer chemicals or non-chemical alternatives	Auer, 2006 in Hansson et al, 2011; Keml 2007
Substitution of a hazardous substance or product signifies its replacement by a less hazardous substance, product or process	Ahrens et al, 2006 in Hansson et al, 2011; Keml 2007
The substitution principle is a policy principle that requires the replacement of hazardous (or potentially hazardous) chemical substances by less hazardous alternatives. It should be interpreted as promoting the substitution of the use of a hazardous chemical by some (chemical or non-chemical) method that reduces the potential for damage to health or the environment. More generally speaking, applications of the substitution principle should be based on the best available evidence. This evidence can be sufficient to warrant a substitution even if quantitative risk estimates cannot be made	Hansson et al, 2011
Substitution is the replacement of a substance, process, product or service by another that maintains the same functionality	UK Chemicals Stakeholder Forum, 2010 in Hansson et al, 2011
The replacement or removal of chemicals in processes or products. Replacement of hazardous chemicals can be achieved by changing materials, changes in processes or by using new technology	ChemSec, 2016
Substitution is one way of eliminating or reducing the risks from chemicals to health and safety at the workplace. Substitution is a way of reducing identified chemical risk at source by: replacing a chemical used with a less hazardous one; using a safer physical form of a chemical, such as larger particles sizes or pellets; changing a process or technology using safer alternatives	EC, 2012
Substitution is the replacement of a substance, process, product or service by another that maintains the same functionality	Taylor et al (2010) in EC (2012a)
If risks to the environment and human health and safety can be reduced by replacing a chemical substance or product either by another substance or by some non-chemical technology, then this replacement should take place. All decisions on such substitutions should be based on the best available evidence. This evidence can be sufficient to warrant a substitution even if quarantine risk estimates cannot be made	Keml (2007)
[Substitution is] the replacement or reduction of hazardous substances in products and processes by less hazardous or non-hazardous substances, whilst achieving an equivalent functionality via technological or organisational measures	EIM, 2006, referenced in Oosterhuis, 2006

Definition	Reference
An alternative is used to denote a chemical, material, product, produce design, system, production process or strategy that can replace listed persistent organic pollutants or candidate chemicals, or materials, products, product designs, systems, production processes or strategies that rely on persistent organic pollutants or candidate chemicals, while maintaining an acceptable level of efficacy	Weber et al, 2014

Some of the definitions are very narrow or specific; others are wider and/or more flexible in terms of defining substitution in the broader sense, i.e. including non-chemical solutions. For example, Oosterhuis (2006) states that '*the hazardous substance does not necessarily have to be replaced by another substance. It can also be substituted by other means of fulfilling the function it had. Thus, a hazardous cleaning agent (e.g. a chlorinated solvent) can be replaced by a less harmful one, but [it] is also conceivable that the product or production process is redesigned in such a way that the cleaning step can be omitted*'.

Hansson et al (2011) suggest that a definition that is restricted to just material production and maintenance of functionality without consideration of environmental objectives should be rejected. They also note that '*if risks to the environmental and human health and safety can be reduced by replacing a chemical substance, mixture or product either by another substance, mixture or product or by some non-chemical technology, then this replacement should be made*'.

Tickner et al (2015) promote "Functional substitution" as a combined approach to risk assessment. Their proposal is to combine the way chemists and product designers look into the function of a chemical with alternative assessment considerations of health, safety and environment, focusing on health and innovation. The approach identifies three distinct conceptual levels of substitution (Tickner et al, 2015):

- Chemical function: This is mainly driven by the chemical's structure. For some functions, different types of chemicals may be suitable, but there are cases when functions are linked to specific, inherently hazardous chemical structures, making substitution difficult;
- End use function: This relates to the specific purpose of the chemical in a product or process. Aside from direct chemical replacements, there is broader spectrum for substitution with engineering or design alternatives (e.g. instead of using an alternative plasticiser for a phthalate in PVC for food packaging, switch to an alternative packaging material such as HDPE that does not require plasticisers);
- Function as service: This calls for re-examination of the whole 'service' that a chemical provides in a material, product or process.

Aven (2014) argues that the substitution principle is another example of the precautionary principle, since it is about being cautious in the face of risk and uncertainties. He suggests a definition that is \ flexible enough to include substitution not just of one chemical with another, but also the potential of substitution based on changes in process. This could result in elimination of hazardous substances in line with the EC (2012), a principle that there is a hierarchy of measures to reduce chemical risk, starting with elimination, followed by substitution and then protection. Overall, the definition used by Aven is:

'Substitution is the replacement of a substance with the aim of achieving a lower level of risk'

The definition is also neutral in terms of being hazard or risk based: within the topic of substitution, hazard and risk are not mutually exclusive and both are indeed used by the REACH Regulation in its different mechanisms. By and large, hazard-based substitution is preferred on precautionary grounds, when '*a phenomenon, product or process may have a dangerous effect, identified by a scientific and objective evaluation, if this evaluation does not allow the risk to be determined with sufficient*

certainty'[47]. Indeed, the availability of evidence is very important. Hansson et al (2011) note that '*all decisions on substitutions should be based on the best available evidence'*. Similarly, Olofsson (2014) claims that *'substitution should be based on the best possible evidence, but whether that is achieved through hazard categorisation or risk assessments is secondary and will vary according to the available data and a number of other circumstances*'.

KemI (2015) argues that use of Risk Characterisation Ratios (RCRs) to determine whether the risk arising from a substance is adequately controlled (in the case of substances with DNELs) or properly controlled or managed in the case of non-threshold substances, may be preventing the adoption of a preventive approach as far as restriction under REACH is concerned (e.g. by intervening before use of a problematic substance becomes widespread or before new applications are developed which could result in 'unacceptable risk'). This could mean that action against hazardous substances may not be taken until they actually present an unacceptable risk in the form of measurable damage to human health and the environment. KemI argue that it can be said that the interpretation of 'unacceptable risk' conflicts with the precautionary principle.

A1.2. HISTORICAL USE OF THE SUBSTITUTION PRINCIPLE

The substitution principle is not a new tool in risk management: Table 2 provides a non-comprehensive chronological list of the use of the substitution principle in international agreements, European and national legislation.

Table 2: Historical uses of the substitution principle in legislation and conventions

Year	Event	Location	Reference
1949	Law on worker's health and safety included first use of term substitution principle	Sweden	Nilsson, 1997, 2007 in Lofstedt, 2014; ChemSec, 2016
1972	Law on health and environmentally dangerous products was the first to use the principle	Sweden	SOU 1972 in Lofstedt, 2014; ChemSec, 2016
1975	Council Directive 75/442/EEC on waste	European Union	Lissner, 2010
1976	Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations	European Union	Lissner, 2010
1979	Convention on Long-range Transboundary Air Pollution (LRTAP) (entered into force in 1983)	Global	IFCS, 2008
1986	Substitution principle used in relation to phasing out of hazardous substances in the Ordinance of Hazardous Substances	Germany	Ahrens et al, 2006 in Lofstedt, 2014
1987	The Montreal Protocol on Substances that Deplete the Ozone Layer (entered into force January 1989)	Global	IFCS, 2008
1989	EC first uses substitution principle in health and safety sector (Directive EEC 89/391, occupational health and safety framework)	European Union	Nilsson, 2010, in Lofstedt, 2014; EC, 2012a
	Massachusetts Toxic Use Reduction Act (TURA) requires manufacturers to identify alternatives to reduce waste and the use of a number of chemicals every 2 years	US (Mass.)	Oosterhuis, 2006
1990	Law on chemical products consolidated the use of the substitution principle	Sweden	Proposition 1989/1990 in Lofstedt, 2014; ChemSec, 2016

[47] EC, 2000, 'The precautionary principle', available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3Al32042

Year	Event	Location	Reference
1991	Directive 91/322/EEC on establishing indicative occupational exposure limit values		EC, 2012a
	Geneva Protocol concerning the Control of Emissions of Volatile Organic Compounds or their Trans-boundary Fluxes (entered into force September 1997)	Global	IFCS, 2008
1992	Agenda 21: - Chapter 19: Environmentally sound management of toxic chemicals, including prevention of illegal international traffic in toxic and dangerous products - Chapter 20: Environmentally sound management of hazardous wastes, including prevention of illegal international traffic in hazardous wastes	Global	IFCS, 2008
1993	Call for promotion and use of substitution principle on international stage and substitution principle became synonymous with Product Choice Principle	Sweden	SOU 1993 in Lofstedt, 2014; Swedish Chemical Agency, 2008a in ChemSec, 2016
1994	Intergovernmental Forum on Chemical Safety (IFCS) – Forum I Resolution on Priorities for Action in Implementing Environmentally Sound Management of Chemicals	Global	IFCS, 2008
1996	Council Directive 96/61/EC concerning integrated pollution prevention and control	European Union	Lissner, 2010
1997	Intergovernmental Forum on Chemical Safety (IFCS) FORUM II Agreed action items and recommendations programme area e - strengthening of national capabilities and capacities for management of chemicals	Global	IFCS, 2008
1998	Substitution principle applied to hazardous substances in EU regulations (Directive 98/24/EC on protection of health and safety of workers from risks related to chemical agents at work and in biocides directive (98/8/EC)	European Union	Ahrens et al, 2006 in Lofstedt, 2014; Swedish State Studies SOU 2012, in Lofstedt, 2014
	Directive 98/70/EC (leaded petrol ban)	European Union	EC, 2012a
	Aarhus Protocol on Persistent Organic Pollutants (POPs) (entered into force October 2003)	Global	IFCS, 2008
	Aarhus Protocol on Heavy Metals: (entered into force December 2003)	Global	IFCS, 2008
	Rotterdam Convention On the Prior Informed Consent Procedure for certain hazardous Chemicals and Pesticides in international trade (entered into force in 2004)	Global	IFCS, 2008
	OSPAR Hazardous substances strategy	Global	IFCS, 2008
1999	VOC Solvents Emission Directive (199/13/EC) (organic solvents emissions)	European Union	EC, 2012a
	Council Directive 1999/13/EC on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations	European Union	Lissner, 2010
	Swedish Environmental Code, Ch.2, Sec.6 considers the substitution principle (under the term 'product choice principle') as one of its cornerstones	Sweden	Oosterhuis, 2006
2000	European Court of Justice finds in favour of Swedish Chemicals Agency vs Toolex Alpha AB regarding use of substitution principle over company's use of trichloroethylene in industrial processes	European Union	Nilsson, 2010, in Lofstedt, 2014
	Directive 2000/53/EC on end-of-life vehicles	European Union	Lissner, 2010

Year	Event	Location	Reference
	Directive 2000/60/ES establishing a framework for Community action in the field of water policy	European Union	Lissner, 2010
	Montreal Protocol (substances depleting ozone layer)	Global	EC, 2012a
	Directive 2006/15/EC on establishing a second list of indicative occupational exposure limit values	European Union	EC, 2012a
	Water Framework Directive (2000/60/EC) (priority substances and other pollutants)	European Union	EC, 2012a
	Intergovernmental Forum on Chemical Safety (IFCS) – Forum III Priorities for Action beyond 2000	Global	IFCS, 2008
2001	Danish OSH legislation (Exec. Order 292 of April 26, 2001 on Work with Substances and Materials) requires replacement of hazardous substances or materials by less hazardous ones, even if effects of hazardous substances are insignificant. Law provides for exemptions if substitution is technically impossible or prohibitively expensive.	Denmark	Oosterhuis 2006
	Substitution principle is prominent in European Commission's 2001 Chemical White Paper	European Union	EC, 2001, in Lofstedt, 2014
	Stockholm Convention of Persistent Organic Pollutants adopted (entered into force in 2004)	Global	Weber et al, 2014
2002	Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment	European Union	Lissner, 2010
	Directive 2002/96/EC on waste electrical and electronic equipment (WEEE)	European Union	Lissner, 2010
	RoHS Directive 2002/95/EC (electronic equipment) restricts the use of certain materials	European Union	EC, 2012a
2003	Intergovernmental Forum on Chemical Safety (IFCS) – Forum IV Agreed action items and recommendations on Acutely Toxic Pesticides	Global	IFCS, 2008
2004	Directive 2004/37/EC on carcinogens and mutagens at work requires prioritising the consideration of replacing carcinogens and mutagens by less hazardous substances, mixtures or processes	European Union	
	Metals Directive 2004/107/EC (ambient air quality)	European Union	EC, 2012a
	Regulation (EC) No 850/2004 on Persistent Organic Pollutants (POPs) is the legal framework for implementation of Stockholm Convention (for limiting POP contamination) in the EU	European Union	
2006	Directive 2006/15/EC on establishing a second list of indicative occupational exposure limit values	European Union	EC, 2012a
	REACH Regulation (1907/2006) aims to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances	European Union	
	Strategic Approach to International Chemicals Management	Global	IFCS, 2008
	Intergovernmental Forum on Chemical Safety – Forum V Agreed actions and recommendations on Toys and chemical Safety	Global	IFCS, 2008
2009	Ozone layer regulation (1005/2009/EC)	European Union	EC, 2012a
	Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market requires active substances with certain hazardous substances to be considered as candidates for substitution	European Union	

Year	Event	Location	Reference
2011	RoHS Directive (2011/65/EU) states that potential substitution for safer alternatives should be examined for the listed hazardous substances	European Union	
2012	Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products requires active substances with certain hazardous substances to be considered as candidates for substitution		
2014	7th Environmental Action Programme enters into force. Requires a strategy to be developed by 2018 for a non-toxic environment that is conducive to innovation and the development of sustainable substitutes	European Union	

A1.3. STAKEHOLDERS AFFECTED BY SUBSTITUTION OF HAZARDOUS SUBSTANCES

The key players can be divided into: those who would undertake substitution, those who require (or would like) substitution to take place, those who support substitution efforts and those who benefit from substitution. These can be grouped as follows (based on Oosterhuis, 2006; EC, 2012a; OECD, 2013; Tickner et al, 2015; SCP/RAC, 2014):

- **Those who undertake substitution**: within these companies, there are likely to be technical and non-technical decision makers, the former being, for example, corporate materials managers and EH&S specialists who have in-depth understanding of alternatives assessments and who would seek assistance in making trade-offs, and the latter being, for example, business managers, CEOs SMEs, retailers, workers and product designers who have little to basic knowledge of alternatives assessments and are looking for simple, easily digestible information to aid decision making. Companies undertaking substitution include:
  - Raw material suppliers;
  - Chemical manufacturers;
  - Blenders, resellers and distributors: they tend to aim for added value through providing specific chemical service solutions. As they are more service-oriented they tend to react strongly to customer demand. They also tend to be more agile in terms of reactions to changes in demand and are more likely to proactively search for solutions with end users. As they are not strongly tied to specific manufacturing processes or chemical raw materials, they can be well placed to provide information and act as partners in substitution efforts;
  - Downstream users of chemicals: they are mostly interested in the function that the chemical performs and the cost-effectiveness of the alternatives. Supplier assistance is an important factor helping substitution for SMEs that have very limited knowledge and information about chemicals. However, in general only specialised suppliers have the necessary knowledge to provide their customers with safer products.

- **Those who require (or would like) substitution to take place**: these stakeholders include regulators, influencers (e.g. NGOs, trades union) and purchasers, both corporate and consumer. For example:
  - Representatives from European workers federations, industry associations, professional organisations, research organisations;
  - Occupational health authorities and authorities concerned with chemical safety more broadly;
  - Supranational organisations:
    - United Nations: promoter of chemical safety;

        - OECD: information provider;
        - OSPAR: international agreements for industry specific requirements on substitution;
        - European Union: legislator, policy setter and information providers;
    - National and local authorities;
    - Buyers and consumers seeking simple product level information to inform their purchasing decisions;

- **Those who support substitution efforts**: practitioners, e.g. consultants, businesses, and governments with in-depth expertise in alternatives assessment and experience in a relevant technical field who seek access to robust technical data sources to help those undertaking or requiring substitution:
    - government agencies conducting alternatives assessments as part of a regulatory process.

- **Those who benefit from substitution**: this entails the downstream beneficiaries of substitution who are not directly involved with the substitution process:
    - Society as a whole
    - Environmental media.

A1.4. PROS AND CONS OF REGULATORY REQUIREMENTS ON SUBSTITUTION

Table 3 and 4 summarise, respectively, the pros and cons of regulatory and non-regulatory approaches highlighted in the literature on substitution.

Some authors (e.g. Costanza and Perrings, 1990) have explored the use of assurance bonds: a government body would estimate the externalities and impose a fee on the entities carrying out activities which are potentially harmful for human health and the environment. The bond would be refundable if those entities show lower damages than those assumed by the government body when setting the bond. As a result, the burden of proof would lie with the user of the resource, providing a strong incentive to research the future health and environmental costs of activities and to improve performance in terms of these factors. Where a company cannot afford the bond, it would not be permitted to undertake the activity. In practice, assurance bonds would be very difficult to implement, as a high level of information would be necessary to estimate the potential externalities resulting from the production and use of chemicals. Moreover, new technologies such as nanomaterials would be overburdened, as the risks are even more uncertain and so the bonds would discourage investments.

Table 3: Pros and cons of regulatory approaches

Approach	Pros	Cons	Reference
Ban of dangerous substances	Strongest driver: substitution must occur including for long-established and profitable substances	May not stimulate sufficient innovation if accompanied with a large number of exemptions. Stalled regulation may inhibit innovation while there may also be little incentive to innovate further once compliance is achieved May redirect personnel from research to compliance	Oosterhuis, 2006; ChemSec, 2016; Abelkop & Graham (2014)
Lists of unwanted substances	Also strong driver, but less so for long-established and profitable substances	Generalising nature of lists can stigmatise all use of the listed chemical and not just those related to potential releases, exposures and risks	Abelkop & Graham (2014) ; ChemSec, 2016

Approach	Pros	Cons	Reference
Required substitution plans	Continuous programme helps maintain focus on innovation		Oosterhuis, 2006
Positive lists of substances by application	Improve the reputation of companies using the substances in the lists	Limit innovation	
Economic instruments	Enables internalisation of health and/or environmental costs Costs can be avoided by undertaking substitution Burden of proof can be moved to polluter	May require considerable monitoring, which may be beyond capacity of public bodies May discourage investment in risky activities if technologies are overburdened	EEA (2013)

Table 4: Pros and cons of non-regulatory approaches

Criterion	Pros	Cons	Reference
Control of substances			
Non-legislative restriction of dangerous substances		Dependent on strength of the supply chain actors requiring safer alternatives	Lissner (2010)
Non-binding lists of unwanted substances	Gives an indication on the substances that authorities considered as problematic and may urge companies to proactive substitution on the fear that these substances will be regulated in the future. Encourages substitution to avoid products being stigmatised	May stigmatise chemicals in applications for which industry has risks under control	Løkke (2006)
Increasing the availability of data and information			
On hazardous properties	Companies are in better position to choose better alternatives Raises awareness of potential hazards and risks	Information is often considered too technical to have practical application	Keml, 2007; EC (2012)
On chemical composition of materials		Information is often considered too technical to have practical application	EC (2012)
On technical functionality		Information is often considered too technical to have practical application	EC (2012)
Information exchange platforms	Detailed case-by-case approaches supported by practical tools can help to overcome complexities Enables communication between users	Information is often considered too technical to have practical application	EC (2012)
Green chemistry			
Proactive replacement of hazardous substances	Potential growth area for investment	There are active initiatives, but these usually/largely focus on the perspective of identifying alternatives from a (eco)toxicological point of view, along with the concepts of increased use of bio-based materials and low energy consumption.	Clutter (2012 in CIEL, 2013); Keml, 2015

A1.5. GUIDANCE FOR ASSESSING SUBSTITUTES

A1.5.1. Overview

When assessing the potential for substitutions, a common method is to compare the current technology with one favourite alternative option using a basic process model and a number of decision criteria. Typical criteria include (Lissner, 2010):

- Risks: health risks caused by chemicals, other health risks, environmental risks;
- Technical suitability: compliance with product and process specifications, adaptations needed
- Work organisation: changes needed;
- Cost: material costs, material consumption, equipment and investment costs, energy, labour costs, organisation costs, transport costs, insurance costs, storage costs;
- Cost of different risk management measures;
- Waste, sewage water: disposal equipment and organisation, disposal costs;
- Other influencing factors: corporate image, employee satisfaction, sustainability, planning reliability;
- Shift of risks: to environment, to consumers, etc.

This approach requires information on all of the above criteria, hence, approaches to information and data sharing can have a significant positive effect on the potential for substitution. This information can be provided on hazardous properties of substances, chemical composition of materials, technical functionality and through sources such as information exchange platforms and helpdesk functions. The tools identified and described in Box 8 often fit into more than one of these categories, reflecting the number of different pieces of information that may be required and the various ways that this information can be presented. The 7th EAP also recognises that the establishment of a chemical exposure knowledge database, along with the development of guidance on test and risk assessment methods, will hasten decision making favourable to the innovation and development of sustainable substitutes, including non-chemical solutions (Annex, point 71 (4)).

EC (2012a) found that companies, authorities, organisations and experts stated that guidance on substitution is generally far too theoretical to have practical application, especially for SMEs. Ideally a tool to help with identification and assessment of substitutes needs to be available through one single portal. This needs to address the five most common requirements found in EC (2012a):

- How to find adequate information on chemicals being used;
- How to identify the most dangerous chemicals based on hazard and use cases;
- How to prioritise chemicals for risk reduction through substitution;
- How to find alternatives;
- How to compare properties and risks of identified alternatives.

EC (2012a) also added that to be effective, guidance and tools need to be accompanied by dissemination. Lissner (2010) found that practitioners and specialists prefer a detailed, case-by-case approach to substitution supported by practical tools. These approaches can help overcome the many difficulties that are seen in the practical application of substitution at the workplace. Lissner (2010) recommends that tools need to be sector specific and suited to the information needs of enterprises.

The Massachusetts TURA requires manufacturers to identify the use of a number of chemicals as well as alternatives to reduce waste every 2 years. According to Tickner & Geiser (2004)[48], between 1990 and 2000, 550 firms that have continuously participated in the program have reduced the use of targeted chemicals by 40%.

[48] Quoted in Oosterhuis (2006).

A1.5.2. Examples of Guidance and Information Sources

Danish Environment Agency's List of Undesirable Substances (LOUS)

The Danish EPA List of Undesirable Substances (LOUS) is intended as an informative tool for industry about substances of concern whose use should be reduced or ended. It is the responsibility of industry to substitute these chemicals. A substance is included in the LOUS if it exhibits a number of undesirable effects and is used in significant quantities in Denmark. Inclusion criteria for substances in LOUS and the REACH candidate list overlap greatly.

LOUS 2009 comprised 40 substances which have been documented as dangerous or identified as potentially problematic using models (QSAR)[49]. The first LOUS was published in 1998, with revised lists being published in 2000 and 2004. Some selection criteria have changed in later years and substances may be removed from the list as consumption patterns change.

The Danish EPA allocated €6.4 million in order to perform surveys and develop management strategies of substances in the LOUS between 2012 and 2015, with the aim of assessing the need for risk management of substances or substance groups. The final report for the 4th round of surveys was published in February 2015.

The selection criteria for the inclusion of substance in the LOUS are:

- Properties of concern according to the EU list of hazardous substances
- Properties of concern identified using computer-based model calculations outlined in the Danish EPA's advisory list for self-classification of dangerous substances.
- PBT/vPvB substances identified by the EU
- Substances on the EU Priority list of substances for further evaluation of their role in endocrine disruption
- Substances that are the subject of particular focus in Denmark.
- Substances used in quantities exceeding 100 tonnes per year in Denmark.

The EU list of hazardous substances is the starting point for identifying substances that may be added to LOUS. There is a particular focus on CMR substances but those that pose a serious health risk through long-term exposure, are highly toxic to aquatic organisms or can cause adverse long-term effects in the aquatic environment are also deemed necessary to include on the list. Once a substance has been identified due to its properties of concern, the Danish Product Register is consulted to ascertain the quantities being used and for what purposes. The focus of this consultation is on tonnage thresholds and to find any reason for including/ excluding individual substances from the LOUS.

When substituting chemicals, the technical applicability and the assessment of the effects on human health and the environment should be carried out. Any substitute should be less harmful than the original. In order to assist companies in avoiding regrettable substitution, the Danish authorities also developed a List of Effects.

EC (2012) guidance on minimising chemical risk to workers' health and safety through substitution

The EC (2012) guidance aims to provide workplaces with a common approach to chemical substitution, with particular emphasis on SMEs and companies with limited or some knowledge or

[49] Danish Environment Protection Agency. 2011, List of |Undesirable Substances 2009. Available: http://www2.mst.dk/udgiv/publications/2011/05/978-87-92708-95-3.pdf

experience of chemical risk management. The guidance does not cover innovation or R&D processes required for more challenging substitutions, such as substitutions in chemical reactions or of complex process industry use of chemicals.

A checklist is used to identify if substitution is likely to be an option, followed by an approach based on the 'Plan-Do-Check-Act' model. At this stage, the approach splits into two (EC, 2012):

- **A short process in four steps** intended for those with little experience of chemical risk assessment and management to give a fast overview of the potential for substitution. It is suggested that this approach should be used by smaller businesses and workplaces where few chemicals are used or chemical use is more generic (there are many ways of doing a task or process such as cleaning, lubricating or painting);
- **A more detailed seven step process** intended for workplaces where more hazardous chemicals or larger quantities are used. It is suggested that this approach should be used where the company has some experience of chemical risk assessment management, a detailed assessment of the potential for substitution is desired and/or the process or task where the chemical is used is more complex or very specific. This approach includes the recommendation to check for alternatives when changing anything but also to identify and keep up to date with alternatives as part of maintaining business plans.

EC (2012) identifies the importance of providing guidance that includes hazard identification, exposure estimation and risk assessment within the same document for a substitution guide to be effective.

SUBSPORT (Substitution Support Portal)

SUBSPORT is a free, multilingual platform for information exchange on alternative substances and technologies, as well as tools and guidance for substance evaluation and substitution management. SUBSPORT aims to be a first point of contact for any company looking to substitute a hazardous substance and requiring support to fulfil substitution requirements within the EU. It is also intended as a resource tool for other stakeholders such as authorities, environmental and consumer organisations, and scientific institutions. The platform provides a range of services in four languages (English, French, German and Spanish). These include:

- **Legal information on substitution** throughout the European Union and, in part, on an international and national level;
- A **database of restricted and priority substances** that are legally or voluntarily restricted or subjects of public debates (only in English);
- A compilation of **prevalent criteria** for the identification of hazardous substances;
- A description of **existing substitution tools** to compare and assess alternative substances and technologies;
- A **database comprising case studies** from companies and literature;
- **Substitution training programmes** (alternatives identification and assessment training);
- **Interactive elements** for discussion, networking, exchange of information and experience as well as for portal updates.

An example of the guidance provided by SUBSPORT is its six-step web-based guide that can be used as a quick screening tool to assess the suitability of hazardous chemical alternatives. The guide provides a range of tools to assist in each step of the evaluation of alternatives with a focus on safety, practicality, and continued improvement.

SUBSPORT was partly funded through LIFE (as well as BAuA (Federal Institute for Occupational Safety and Health, Germany), and the Federal Ministry of Agriculture, Forestry, Environment and Water Management (Austria)). The period of funding was limited and after this, it has not been

possible to find other sufficient means to continue the work. Similar problems are probably relevant for other, similar activities. LIFE offers opportunities to fund the development of projects/solutions but a major problem is the lack of continuity/long perspective in funding of e.g. substitution support activities (DG ENV, Pers. Comm.)

Toxics Use Reduction Institute, USA (TURI)

The Toxics Use Reduction Institute (TURI) was established by the 1989 Toxics Use Reduction Act (TURA) as a state agency of Massachusetts. TURI is based at University of Massachusetts Lowell and its main purpose is to research, test and promote alternatives to toxic chemicals used in Massachusetts. TURI provides a number of tools and guidance documents to help businesses and communities reduce their use of toxic chemicals. The institute operates in assessing, developing, and evaluating initiatives that reduce toxins used in industry and communities[50]. More specifically, the institute operates in the following areas:

- **Training** – skills and capacity building of managers, technicians and consultants e.g. training for professionals to become Massachusetts-certified Toxics Use Reduction Planners.
- **Grants** - TURI awards grants to businesses, community organizations and academia that support technology purchases, demonstrations, research and projects that reduce toxic chemical use in Massachusetts.
- **Toxic chemicals –** construction of chemical fact sheets that describe the hazards, uses and alternatives for selected chemicals.
- **Research –** collaboration with industry and universities to identify and promote innovation in science and technology.
- **Home and community –** assist organisations to raise awareness of the hazards of toxic chemical use and introduce safer alternatives in neighbourhoods through support for education and training.
- **Policy** - TURI's policy program assesses, develops, and evaluates initiatives that reduce toxins used in industry and communities.

In the context of this study, TURI's Alternatives Assessment Process Guidance could be of value. The Guidance is a result of a 2006 study by TURI to assess the suitability of alternatives to five common hazardous chemicals. The guide focuses on economic feasibility but does not provide a measure for the assessment of the relative safety of alternatives.

Lowell Center for Sustainable Production

Based at the University of Massachusetts Lowell and affiliated with TURI and the Department of Work Environment (also at the University of Massachusetts), the Lowell Center for Sustainable Production focuses on developing, piloting and promoting concepts of sustainable production and consumption. The centre works in partnership with individuals, businesses and communities, organizations, and governments to achieve the following aims:

- Increase knowledge and understanding of sustainable production through collaborative and interdisciplinary research, applied field projects, and information exchanges.
- Educate and build support for actions and policies that encourage sustainable production and consumption.
- Create cooperative solutions to complex problems by providing technical support, guidance, and vision.

Currently, the centre is carrying out several solutions-orientated and collaborative research initiatives with a focus on sustainable production and consumption. These initiatives range from developing

[50] TURI, Who We Are, accessed at: http://www.turi.org/About/Who_We_Are (on 30/07/15)

chemicals policy strategy to more specific research areas such as sustainability in hospitals. Table 5 lists each of these initiatives along with a brief description of the respective objective/activities.

Table 5: Lowell Center for Sustainable Production Research Initiatives

Research Initiative/Project	Objective
Chemicals Policy and Science Initiative	To develop scientific tools, strategies, and concepts that promote more precautionary and comprehensive chemicals policies
Clean Tech Project	To identify specific opportunities and benefits to making Massachusetts a leader in clean technologies that serve the world, and to recommend a path to get there
Environmental Health Program	To develop strategies and policies to prevent exposures and reverse rates of chronic disease
Environmental Management Systems	To help public entities improve and sustain environmental performance
Safe Home Care Project	To improve safety and health in home care through investigation of the challenges, hazards, and promising practices in delivery of increasingly complex care in homes; identification of effective, preventive interventions; and development and distribution of educational materials for home-care workers, agencies, and other beneficiaries
Sustainability Action Summer Institute	To train participants in concepts, tools, and skills needed for promoting more sustainable forms of production and consumption
Sustainable Hospitals Program	To assist healthcare providers to identify safer materials and practices that are favourable for the environment, workers, and patients
Sustainable Products Project	To promote the sustainable design and development of safer, healthier, and greener products
Source: adapted from http://www.sustainableproduction.org/proj.futu.php	

Within the context of the substitution of hazardous chemicals, the Lowell centre has a number of useful guidance documents. For instance, the centre's 'Alternatives Assessment' framework aims to provide a relatively quick assessment of safer and more socially acceptable chemicals, materials and products of concern. The framework uses a modular approach to evaluate the hazardous properties of chemicals with publicly available tools. Furthermore, its "Designing Safer Alternatives: Chemicals, Materials and Products" report contains summaries of alternative assessment methodologies (taken from a meeting with North American and European experts in alternatives assessment, life-cycle assessment, policy, and substitution) which form the basis of the 'Alternatives Assessment' framework.

OECD's substitution and alternatives toolbox

The OECD's web-based Substitution and Alternatives Assessment Toolbox[51] provides valuable information, listing various external resources and approaches aimed at supporting decision-making for the substitution of chemicals of concern. The Toolbox and its four constituent parts are listed in the table below alongside their potential relevance for the study.

Table 6: OECD's substitution and alternatives toolbox

Section	Description	Relevance
Alternatives Assessment Tool	A list of assessment tools and	Over 30 databases and tools listed

[51] OECD Substitution and Alternatives Assessment Toolbox, accessed at: http://www.oecdsaatoolbox.org/

Section	Description	Relevance
Selector	databases, which allow for the identification and assessment of chemicals of concern	(e.g. Chemspider, eChemPortal, SIN list etc.) along with descriptions and website links. Potential to identify key stakeholders and initiatives across the EU.
Alternatives Assessment Frameworks	An inventory of identified frameworks for alternatives assessment	Provides descriptions of and links to 24 substitution frameworks (e.g. BizNGO Alternatives Assessment Protocol, TURI Alternatives Assessment Process Guidance etc.) Potential to identify key stakeholders and initiatives across the EU.
Case Studies and Other Resources	Alternative or chemical hazard assessments that have already been conducted by manufacturers, academic institutions, NGOs or government bodies	Links to 32 case study reports/databases on substitution. Potential to identify successful examples of substitution cross the EU.
Regulations and Restrictions	A table of restricted substances lists and related laws and regulations organized by geographic scope	Lists and provides links to key EU and national legislation with regards to hazardous chemicals and substitution. Potential for identifying policy gaps at the EU and national level.
Source: based on information accessed at http://www.oecdsaatoolbox.org/		

Table 7 compares each of the identified tools against the five requirements identified by EC (2012). EC (2012) concludes that many of the databases available that provide information about substances are useful sources of information but are better suited to use by experts.

Table 7: Comparison of tools against most common requirements

Tool	Information on chemicals being used	Identification of most dangerous chemicals based on hazard and use cases	Prioritisation of chemicals for substitution	Identification of alternatives	Comparison of properties and risks of identified alternatives
BizNGO	X	X	X	X	X
Catsub				X	
Cefic LRI toolbox	X	X			
CleanerSolutions				X	
CLEANTOOL				X	
COSHH Essentials	X		X		X
EC (2012) guidance			X	X	
German Column Model (Spaltenmodell)		X			
Green alternatives wizard				X	
Green Screen	X	X	X	X	X
INERIS	X		X		

Tool	Information on chemicals being used	Identification of most dangerous chemicals based on hazard and use cases	Prioritisation of chemicals for substitution	Identification of alternatives	Comparison of properties and risks of identified alternatives
INRS	X	X			
Keki-Arvi					
OECD Toolbox				X	X
P20ASys (Pollution Prevention Options Assessment System)					X
PRIO	X	X	X		
Stoffenmanager			X		
SUBSPORT	X	X		X	
Substitution-CMR	X			X	
Weber et al, 2014 electronic report	X				

A1.6. SUBSTITUTION IN PRACTICE

A1.6.1. Barriers to substitution

Lack of Incentive

Abelkop & Graham (2014) argue that one of the weaknesses in the current environmental regulatory regime is that, once compliance is established, industry has little or no incentive to make further investments in safety innovation (above and beyond what is motivated by common law liability concerns). KemI (2015) considers that the way REACH authorisation provisions are worded narrows down examination of alternatives to a small group of substances already familiar to the applicant. There is thus the possibility that other materials, techniques or other types of substances will be excluded from the analysis.

Abelkop et al (2014) believe that the process of proving safety (or acceptable risk) in chemicals policy should continue to shift from government to industry. As this shift occurs, industry will always have at least some incentive to find chemical innovations that are easier to defend in terms of safety. REACH moves in this direction to some extent but arguably in an overly burdensome way. Canada's Chemicals Management Plan does shift some burden to industry but Abelkop et al (2014) contend that this is not undertaken with sufficient vigour. Abelkop et al (2014) add that there may be little or no incentive for industry to make further investments in safety innovation above and beyond that which is required by the legislation.

Financial aspects are likely to be one the key barriers, but this can also be an important driver. Investment and operational costs of the alternative do not necessarily have to be lower than the costs of the current practice, since considerations such as better product quality and other drivers described above may justify the higher costs. Furthermore, it is expected that an increase in production volumes of alternatives will lead to lower production costs in the long-term as part of the learning process in production. In the short term, decrease in prices tends to slow down, but in the long term the costs of the alternative will drop (Oosterhuis, 2006).

However, loss of company reputation can be a significant driver for substitution. Consider, for example, the case of the toy manufacturer Mattel which saw its stock price drop significantly after it had to issue a recall due to lead being detected in paint used on their products. Similarly, the stock price of a US laminate flooring company fell significantly after it was exposed as having high levels of formaldehyde in its floors. The stock fell even further after a CBS news report (ChemSec, 2016).

There are four key aspects of the economics of substitution that should be considered in designing economic instruments to incentivise substitution. These are (ChemSec, 2016):

- New alternatives are often initially more expensive but prices tend to decline as supply increases;
- The use of hazardous chemicals involves additional costs, including protective measures and equipment for workers, healthcare, handling of hazardous waste and wastewater, special requirements for transport and storage and environmental remediation. New innovations may help reduce these costs and potentially reduce energy or water needs;
- Anticipation of a regulation which further drives development of new products; and
- The market for safer alternatives is growing since they are more likely to be safe from potential future regulations and are increasingly requested by consumers and investors.

Lack of information

Abelkop et al. (2014) argue that there are multiple market failures in relation to chemical risk management. These include gaps in information, information asymmetries at different levels, and externalities in the form of uncompensated damages to human health and the environment. Lofstedt (2014) suggests that these market failures can be addressed by policy-makers using the substitution principle. For example, he recommends greater use of risk–risk comparisons of existing chemicals and potential alternatives. Such analyses require phases of information gathering and evaluation prior to the application of risk management.

E.g.: Hansson *et al.* (2011) recognise that REACH can provide the access to information that they consider crucial to promotion of the substitution principle, but they also argue that more data is needed than what is currently required by REACH. They consider that the Regulation is more heavily focused on substances and less on products (articles in REACH terminology) as far as substitution is concerned. REACH uses a criterion-based approach (i.e. it focuses on the properties of substances and not on specific substances). Its advantage is that it includes processes both for identifying and restricting hazardous chemicals. The disadvantage of such an approach, as has been observed, is that it tends to become complex as well as time- and resource-intensive.

According to KemI (2007), a lack of reliable and comparable data for chemical substances for alternative substances and technologies was (at the time of the report) an important barrier; also, many companies did not have access to adequate information about the chemical contents of products they were using, making it difficult to deal systematically with substitution. EC (2012) found that the level of ability or knowledge devoted to systematic risk reduction reduces with the size of the enterprise. Tools to help businesses, authorities and associations to compare substances tend to be used by enterprises with a well-developed OSH-infrastructure and high awareness. Most smaller companies and other enterprises not affected in their core business tend to rely on information given by the supplier or on easily accessible and visible tools such as classification and labelling (Lissner, 2010).

Lack of information in the public domain on the chemicals used as substitutes to the hazardous substance can also be a significant barrier. Scheringer et al (2014) calls this the ‘lock-in’ problem. These substitutes are chosen because of their structural similarity with the hazardous substance. They have probably been in the market for a long time in small quantities, so their properties and environmental fate have not been investigated in detail. Their manufacturers may hold such information, but it is not publicly available. In markets where such ‘lock-in’ problems are present, there is usually conflict between established companies manufacturing the “old” chemical and new

non-established manufacturers of alternative, innovative substances (Scheringer et al, 2014). The disclosure of information can be a strong driver to promoting innovation, however, there are known abuses of confidential business information (CBI) privileges that can mask the identity of chemicals that are subject to health and safety studies. Moreover, for low tonnage production chemicals, manufacturers do not have to provide the same level of (eco)toxicological information. This represents a significant barrier to the identification of hazardous substances and the development and entry of safer alternatives (US GAO in CIEL, 2013).

Implementation and enforcement

KemI (2015) identifies that there is currently a very large number of hazardous substances and of potential substances of very high concern, particularly when compared with the actual number of substances banned completely or restricted from use in products for consumers. Procedures of identifying SVHCs and proposing new restrictions and substances for the authorisation list are relatively slow and may mean that several SVHC may continue to be in use for many years. KemI advocates for promotion of voluntary substitution from the industry. Short term measures to promote substitution could be (KemI, 2015):

- KemI to assist in the preparation of better guidance documents (as is ongoing right now under ECHA's leadership);
- Improve quality of supervision of REACH in each member state, in terms of quality of CSRs and communication of information along the supply chain;
- Promote initiatives that build up and make available knowledge that will support companies working on substitution (e.g. information on alternative substances and technologies);
- Creation of a database at EU level with information on restrictions on use, concentration limits, etc. for chemical substances.

In the longer term, measures could include (KemI, 2015):

- Provision within REACH that SVHCs are not substituted by substances with same type of properties;
- Establish support for and promote R&D concerning chemicals of low health and environmental concern, as well as new technical solutions aiming at improving the supply of alternatives, thus facilitating substitution.

Lack of enforcement of regulation can also negate the driver for substitution. EC (2012) highlighted that substitution of substances classified as Car1, Car2, Mut1 or Mut2 under the Carcinogens and Mutagens Directive was a particularly poorly enforced area and, as a result, substitution is scarce. Lissner (2010) found that the requirements and legal frameworks regarding substitution are relatively similar across different Member States. A survey carried out by Lissner (2010) found that 73% of respondents agreed with the statement that 'Substitution is important for improving working conditions in practice'. A further 16% disagreed and 10% were neutral. However, many of the respondents also highlighted the limited impact of substitution in risk reduction at workplaces. This was considered to be because it was rarely undertaken in a systematic and proactive way. German and Dutch OSH practitioners considered 'In practice it is hard'. A lot of companies abandon this strategy because it costs too much (e.g. the whole production line should be adapted) or the appropriate products/substances are not available'.

A1.7. GREEN CHEMISTRY

Hazardous chemicals can be replaced based on economic and technological considerations and decisions. This can include the customising of chemical products (Lissner, 2010). Investors see 'green chemistry' as one of the most promising areas for investment (Clutter, 2012 in CIEL, 2013), with estimates that the market potential could increase from US$2.9 billion in 2011 to US$98 billion

by 2020 (Pike Research, 2011 in CIEL, 2013). Even at this rate though, green chemistry would only account for 15% of the 2020 market (CIEL, 2013).

If existing chemicals (or preferably uses of chemicals) are divided into two categories, those of higher and lower concern with respect to safety, an annual fee could be charged on the sale of chemicals of higher concern. Green chemistry then becomes an industrial strategy to avoid those fees while the government can use the fees it collects to pay for the administration of regulatory programmes as well as basic research to advance the tools of green chemistry (Abelkop et al, 2014).

A crucial part of Quality Management System is compliance with legal requirements, which supports the responsible use of chemicals. Removal and strict regulation of chemicals are part of these approaches (Lissner, 2010). This is particularly true for large corporate actors and global players whose businesses are especially vulnerable to negative public pressure or scandals related to chemicals in their products. This introduces pressure into the supply chain (Ahrens et al, 2005 in Lissner, 2010).

However, Lissner (2010) finds that more generally supply chain relationships involve a complex collection of economic and social features that result in aspects that work in a specific situation but are not necessarily transferable to another. In addition, many supply chain relationships have been demonstrated to be detrimental to the health and safety of workers and often unhelpful in promoting good practice (Walters and James, 2009 in Lissner, 2010).

A1.8. GROUPING OF CHEMICALS

Chemicals can be grouped as a result of similarities in physico-chemical, (eco)toxicological and/or environmental fate properties, or because they follow a regular pattern as a result of structural similarity. The principle of grouping is based on data gap filling. As the number of chemicals in a group increases, the easier it is to develop hypotheses for specific endpoints and observe trends within the group, leading to a more robust evaluation. There are two forms of grouping: category and analogue. Both approaches make it possible to extend the use of measured data to similar, untested chemicals providing reliable estimates for classification and labelling and/or risk assessment without the need for further testing. A chemical can potentially belong to more than one group. A multifunctional compound would be present in a group based on each of its functional groups, as they will affect its properties. The rationale for grouping is generally based on:

- Common functional group(s);
- A common mode or mechanism of action (MoA)[52] or adverse outcome pathway (AOP)[53];
- Common constituents or chemical classes, e.g. similar carbon range numbers (this is particularly important for complex substances such as substances of unknown or variable composition, complex reaction products or biological materials (UVCBs);
- The likelihood of common precursors and/or breakdown products via physical or biological processes that result in structurally similar chemicals;
- An incremental and constant change across the category, often observed in physico-chemical

[52] The sequence of events leading from the absorption of an effective dose of a chemical to the production of a specific biological response in the target organ. The mechanism by which an active substance produces an effect on a living organism or in a biochemical system. It is considered to be the identification of a specific molecular target to which an active substance binds or whose biochemical action it influences; a general recognition of the broad biochemical pathways which are inhibited or affected by a substance in terms of mode of action. OECD. 2012. Appendix I: Collection of working definitions. Available: http://www.oecd.org/chemicalsafety/testing/49963576.pdf

[53] A linear sequence of events from the exposure of an individual to a chemical substance (molecular initiating event) through to an understanding of the adverse (toxic) effect at the individual level (for human health) or population level (ecotoxicological endpoints). This incorporates the toxicity pathway and mode of action. OECD. 2012. Appendix I: Collection of working definitions. Available: http://www.oecd.org/chemicalsafety/testing/49963576.pdf

properties e.g. boiling points.

The OECD has developed guidance on how to proceed in the grouping of chemicals, so that data can be interpolated and extrapolated between substances, reducing the need for additional testing and providing information based on a larger body of data than the one available on just one compound[54]. Moreover, new approaches to defining chemical categories are emerging, grouping the substances in terms of "similarity" of descriptive characteristics (the so-called "similarity descriptors" approach), mode/mechanism of action or chemical / biological interaction[55]. The work in this focus area will list and analyse the different approaches to grouping, as these will inform the analysis of possible improvement opportunities.

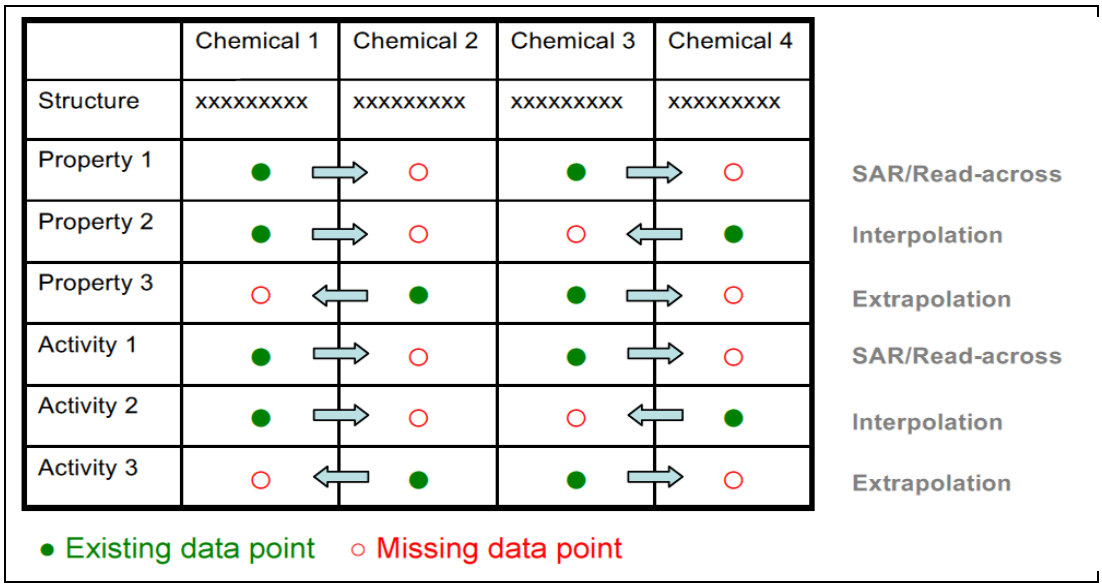
The assessment of a large number of chemicals through grouping is more efficient and accurate than the assessment of single chemicals as:

- The identification of chemicals as members of a group provides an insight into the potential effects of a chemical that may be overlooked;
- The use of a category approach could provide significant advantages in the evaluation of chemicals that are considered difficult as they present technical difficulties when carrying out standard test protocols;
- Category proposals can be expanded via the inclusions of chemicals that may be addressed under various global programmes.

Although grouping of chemicals is viewed as a step towards good chemicals management, there are some caveats. There can be high costs associated with grouping due to generating or gaining access to good quality data for the group, and characterising the target chemical and its analogues, including their impurity profiles, although these costs should be lower than those associated with performing *in vivo* studies[56]. It can be difficult to formulate the data for some endpoints as they are less well understood, putting strain on data gap filling techniques.

[54] https://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf
[55] https://www.concawe.eu/uploads/files/1.Whelan-ConcaweSymposium-Day2-Feb2015.pdf
[56] OECD. 2014. Guidance on Grouping of Chemicals: Second Edition, Available: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono%282014%294&doclanguage=en

Figure 1 - Graphical representation of a chemical group and some approaches for filling data gaps[57]



The analogue approach allows for comparisons of a very limited number of chemicals. Where there is a need to fill in the data gaps for one specific chemical (target), empirical data from a similar (or group of similar) chemicals (analogue/source) can be used to predict the endpoint for the target chemical. The analogue approach is useful when the target and source chemicals share a common mode or mechanism of action (OECD, 2014). In the analogue approach, data gap filling is usually achieved through extrapolation. (Q)SAR tools can be used in conjunction with extrapolation in order to form a more robust evaluation.

The category approach allows for the identification of consistent patterns of effects within a category, increasing the confidence in reliability of results for all individual chemicals within that category, as compared with evaluation of data on a chemical-by-chemical basis. A category of chemicals is one where the chemicals share physicochemical, (eco)toxicological or similar structural properties. The category approach assesses the properties of an individual chemical on the basis of the evaluation of the category as a whole, rather than measured data for an individual chemical. It is designed to provide information to characterise the group as a whole and not fill every data point for every chemical. In contrast with the analogue approach, trends in the group may be analysed. Both structural similarities and differences must be considered as they may affect the endpoint of interest, those that are not considered to have an effect on an endpoint may be called "allowed differences". Endpoint justifications and supporting information is expected to be multifaceted. Evidence may include bridging studies that are not endpoint related, MOA, AOP, computational theoretical studies, common bioavailability metabolism and reactivity profiles. The category approach commonly uses interpolation, with extrapolation used when there are limited members in the category.

Subcategories may occur where:

- Some members of the group meet the criteria for one particular hazard but others meet the criteria for a different hazard. This can be qualitative, in the case of degrees of hazard potential or regulatory classifications, or quantitative, where the numerical values of the endpoint include values on either side of the breakpoint; or
- There is a peak in activity or a breakpoint in a trend; or

[57] ECHA, 2008, 'Guidance on information requirements and chemical safety assessment. Chapter R.6: QSARs and grouping of chemicals', available at: https://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf

- The trend analysis applies to a subcategory of the group but not the whole group.

An example of this would be glycol ethers where some show reproductive toxicity and others do not.

Howard (2014) highlights that decisions on chemical substitution are made rapidly and he provides the example of flame retardants, exploring how Chemical Alternatives Assessment (CAA) on a hazard-based approach could be used for determining possible suitable substitutes through grouping of substances.

Flame retardants pose numerous risk management problems as they belong to several classes of chemistry and structure, are high production chemicals and, due to functional necessity, are designed to be persistent. Flame retardants are known to migrate from the products where they are used, with polybrominated diphenyl ethers being observed in environmental and biological monitoring. The largest volume of available data is for PBDEs due to their early identification and widespread use. Most PBDE substitutes are of recent origin and far less well studied with information on toxicity uncommon and data for exposure being even rarer. It has been reported that exposure information exists for only 20% of chemicals for which hazard data exists and in most cases this exposure data is limited to basic descriptors such as production volume. Penta-BDE use has been phased out in order to reduce consumer exposure. The most commonly used alternatives were tris(1,3-dichloro-2-propyl) phosphate (TDCPP) and Firemaster 550 (FM550).

Chemical Alternatives Assessment is one method in the process of alternatives assessment. It is being used by the European Union and other government bodies such as the United States Environmental Protection Agency (US EPA). Alternatives assessment encompasses a wide-range of decision-making tools. Lavoie *et al* (2010) describes CAA as applying a hazard framework to inform decision-making around chemical substitution. Although there may be variations in alternatives assessment processes, they share the following key features:

- The aim is to avoid regrettable substitution
- CAAs compare numerous options at once, whereas risk assessment (RA) typically treats chemicals on a case-by-case basis
- CAAs are intended to be quicker and simpler than RA, focusing on hazard evaluation and avoiding the complexities of exposure assessment
- CCAs are intended to lower risks through the selection of chemicals and processes with the lowest available hazard profiles.

The transparency of the process is critical and stakeholder involvement is an important way of reaching the goal of continuous improvement. Alternatives assessment can address a diverse range of endpoints when performed by different users. These may include physical and chemical hazards, fate and transport in the environment, and life-cycle impacts. The tools employed to assess an endpoint may include comparison of "red lists" of chemicals of concern, literature-based hazard screening, or comprehensive evaluation of risk. All CAAs should start with an assessment of the need for the chemical function, for example whether flame retardants are effective at improving fire safety characteristics. The Design for the Environment (DfE) has a CAA process for informing chemical substitution decisions. It is primarily concerned with human health and environmental toxicity endpoints over the entire lifecycle. Persistence and bioaccumulation are also considered. The aim of this CAA is to provide information describing alternatives to stakeholders, particularly manufacturers, for substances which have already been identified by other actors, be that the EPA or internationally, for substitution or regulation. Although the US do not use CAA to make regulatory decisions, other bodies do. The EU has listed hexabromocyclododecane (HBCDD) in the authorization list, meaning that US manufacturers must find an alternative to stay competitive in the global market. The DfE process includes extensive industry consultation to ensure that all appropriate chemicals are addressed and those assessed are suitable for functional use in terms of efficacy and practicality. It can be said that the aims of the DfE process are aligned with those of industry, as both would rather find a suitable substitute than have additional regulation.

The aim of a Risk Assessment is to identify the risks expected to be associated with different uses, which may be able to be mitigated through exposure controls. Chemicals Alternatives Assessment takes the view that risk can be more effectively lowered by reducing the hazard. This hazard-based approach aligns CAA with many of the principles of green chemistry: whereby the chemical product should have minimal toxicity, synthesis should involve minimal toxicity and prevention is better than clean up. Risk Assessment and CAA reflect different views when it comes to exposure. Assessment of real-world exposures is difficult and the variability and unknowns in exposure assessment are major sources of uncertainty in risk assessment. The risk assessment view is that exposures are controllable in many cases. The hazard-based-approach believes that some exposure is likely to occur and that reducing the hazard is more effective than reducing the risk.

When comparing a number of alternatives, "*the most valuable endpoints are those that reveal significant variation in toxicity among alternatives*" (Lavoie et al, 2010). This makes them distinguishing factors and helps to differentiate between safer and less safe options. Distinguishing characteristics are dependent on a number of factors. For flame retardants, persistence is not considered a distinguishing characteristic as virtually all flame retardants are persistent. As such, human and environmental toxicity are considered distinguishing characteristics. This means that the emphasis is on those endpoints for which hazard rankings differ. In order to lower the hazard to lower the risk, the exposure should stay constant. Lavoie *et al* (2010) propose that exposures within a functional use class are roughly constant as they are expected to have similar patterns of use, consumer contact and disposal. Due to similar physical properties and chemical structures, the exposure potential across the class would also be similar, in which case a risk assessment can be simplified to a hazard assessment. The category of flame retardants for furniture foam is very broad, containing assessments for halogenated organics, non-halogenated phosphate based organics, metal and metal-oxide-based inorganics, polymeric flame retardants and intumescent expandable graphite. The fate and transport parameters to be considered for these groups are wide and can make comparison of exposures difficult. Drop-in substitutes are therefore considered by industry. Drop-in functionality is often based on bulk properties like viscosity rather than structure. A chemical can be considered an exposure analogue when it is a drop-in solution, meaning exposure potential is no longer a distinguishing characteristic and so hazard considerations can be an effective way to reduce risk. Structural similarity may not result in the same hazard endpoint.

For many chemicals, there is little hazard or exposure data, even when the structure is known. One of the main issues is the use of confidential data which may only be available to regulators and not external stakeholders. The DfE employs models which use data from structural analogues of known chemicals and information about specific structural alerts based on known moieties to fill data gaps. It is not only chemicals for which there is little hazard or exposure data, even less is available for products. In hazard assessment, practical considerations must also be taken into account, such as different toxicity via route of exposure as, in the example of aloe vera, carcinogenicity classification due to intestinal cancer in rats caused by ingestion may not be relevant for decisions based on dermal application.

APPENDIX 2: SURVEY RESULTS

A2.1. INTRODUCTION

The purpose of the survey was two-fold:

- To help the European Chemicals Agency better understand the current capacity of companies to substitute hazardous chemicals and to help determine capacity building needs. This is part of the project, "Improving the Analysis of Alternatives and practical ways of promoting innovation and substitution in the EU" managed by the University of Massachusetts Lowell.

- To provide input to DG Environment's study into "the strategy for a non-toxic environment of the 7th Environment Action Programme (EAP)", specifically a sub-study on substitution, managed by Milieu and Risk & Policy Analysts Ltd.

As these studies had some degree of commonality and surveys of the same group of stakeholders were being conducted at the same time, the two web-based questionnaires were combined to maximise efficiency for participants.

The survey of industry and consultancy representatives was launched on 24 March 2016 and closed on 12 May 2016 and was administered online by RPA.

Responses from 105 industry representatives and 18 consultants were received. Two companies submitted multiple responses but from different departments/national offices[58] and thus have been considered separately. In addition to individual companies, three industry associations responded to the industry survey and one association responded to the consultant survey. Among consultant survey respondents, the majority have worked with a number of industries on applications for authorisation and other related chemical substitution initiatives.

Of the 81 industry respondents providing details on their size, 70 were large companies (86%) and 11 were SMEs[59] (14%) (Figure 1). However, the three industry associations responded to this questionnaire on behalf of their members and indicated they were representing SMEs. Eighty companies provided details about their sector of activity, with around 35% of the responses provided by manufacturers of chemicals and chemical products, nine from the wholesale and retail sectors and the rest coming from a wide range of downstream sectors (Table 1). Responses were received from 16 different countries, with companies located in Germany, France and the UK providing over 50% of the responses (Figure 2).

[58] Respectively, three responses from three different national offices of a company operating in the manufacture of basic chemicals and three responses from three different departments of a company active in the manufacture of air and spacecraft and related machinery.

[59] Companies with ≤250 employees and ≤€50 million in turnover. Six companies that indicated to be SMEs have been considered large companies because part of large groups of enterprises, in accordance with the EU definition of small-, medium-sized enterprises.

Figure 1: Are you a small- or medium-sized enterprise (≤250 employees and ≤€50 million in turnover)? – Respondents: 81

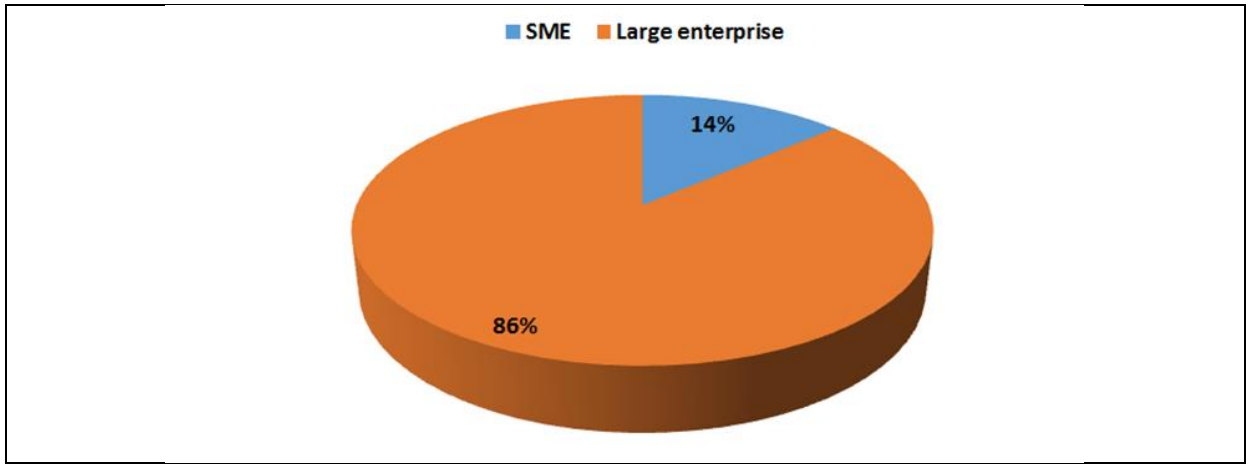
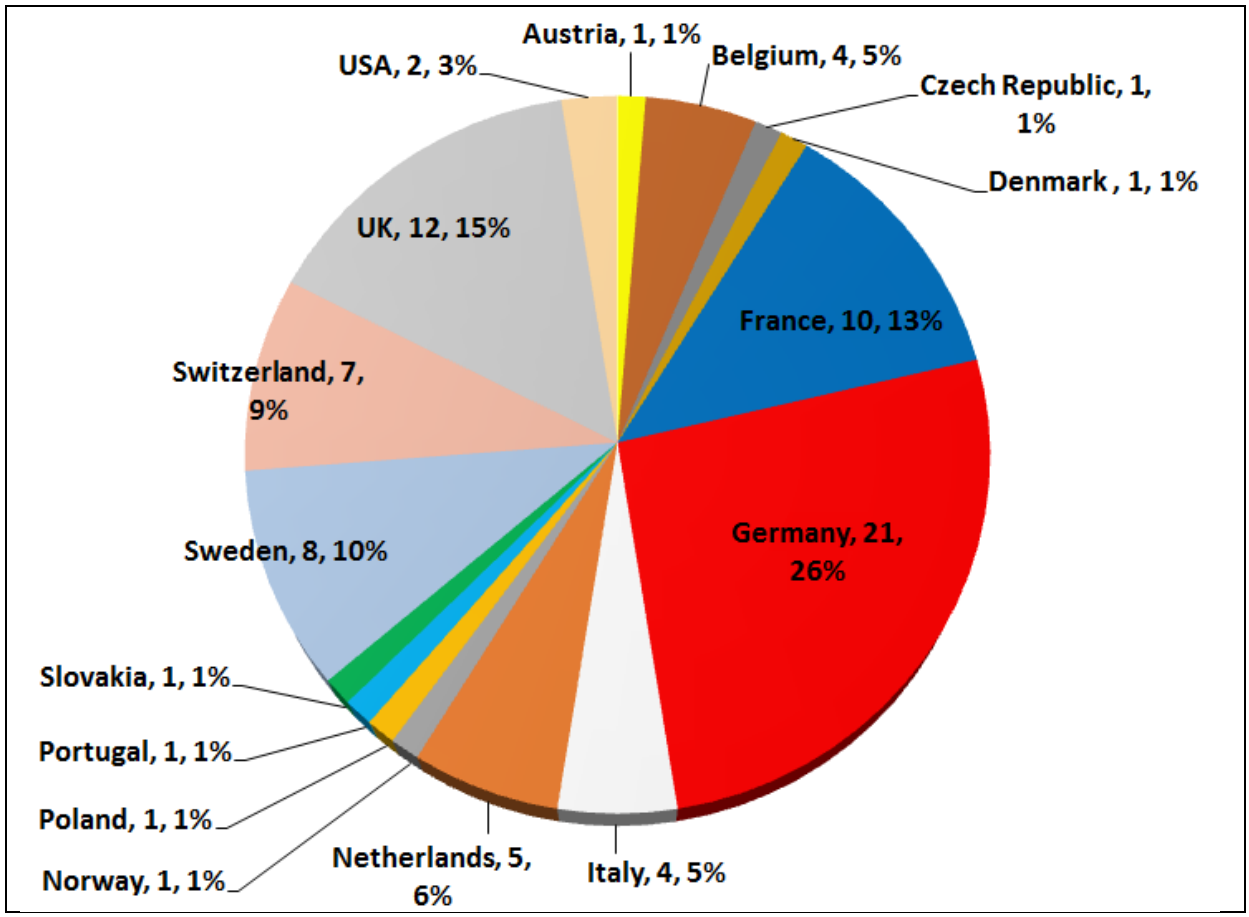


Table 1: Two-digit NACE codes of the primary business sector – Respondents: 80

	Description	No.
B06	Extraction of crude petroleum and natural gas	1
B07	Mining of metal ores	1
C13	Manufacture of textiles	1
C20	Manufacture of chemicals and chemical products	28
C21	Manufacture of basic pharmaceutical products and pharmaceutical preparations	4
C22	Manufacture of rubber and plastic products	4
C23	Manufacture of other non-metallic mineral products	1
C24	Manufacture of basic metals	2
C25	Manufacture of fabricated metal products, except machinery and equipment	6
C26	Manufacture of computer, electronic and optical products	2
C27	Manufacture of electrical equipment	3
C28	Manufacture of machinery and equipment n.e.c.	4
C29	Manufacture of motor vehicles, trailers and semi-trailers	4
C30	Manufacture of other transport equipment	7
C32	Other manufacturing	1
D35	Electricity, gas, steam and air conditioning supply	1
F41	Construction of buildings	1
G46	Wholesale trade, except of motor vehicles and motorcycles	4
G47	Retail trade, except of motor vehicles and motorcycles	5

Figure 2: Responses by country of origin – Respondents: 80



A2.2. DRIVERS AND OBSTACLES TO THE SUBSTITUTION OF HAZARDOUS CHEMICALS

Q1. In your opinion, how important are the following factors as drivers to substitute hazardous chemicals?

Regulatory pressure is the most important factor driving substitution: of the 100 industry representatives providing a response to this question, 95% believe that the REACH Regulation is important to driving substitution of hazardous chemicals (with 73% of respondents indicating it is ***very important***); health and safety and product safety legislations are deemed important by well over 80% of the respondents (Figure 3).

In particular, the placing of a substance in the candidate list for authorisation (Annex XIV of REACH) has been indicated as the mechanism triggering consideration of substitution. Some companies indicated they are also looking at PACT and CORAP, although due to the uncertainties over the outcomes and timescales, proper consideration of substitution starts at a later stage.

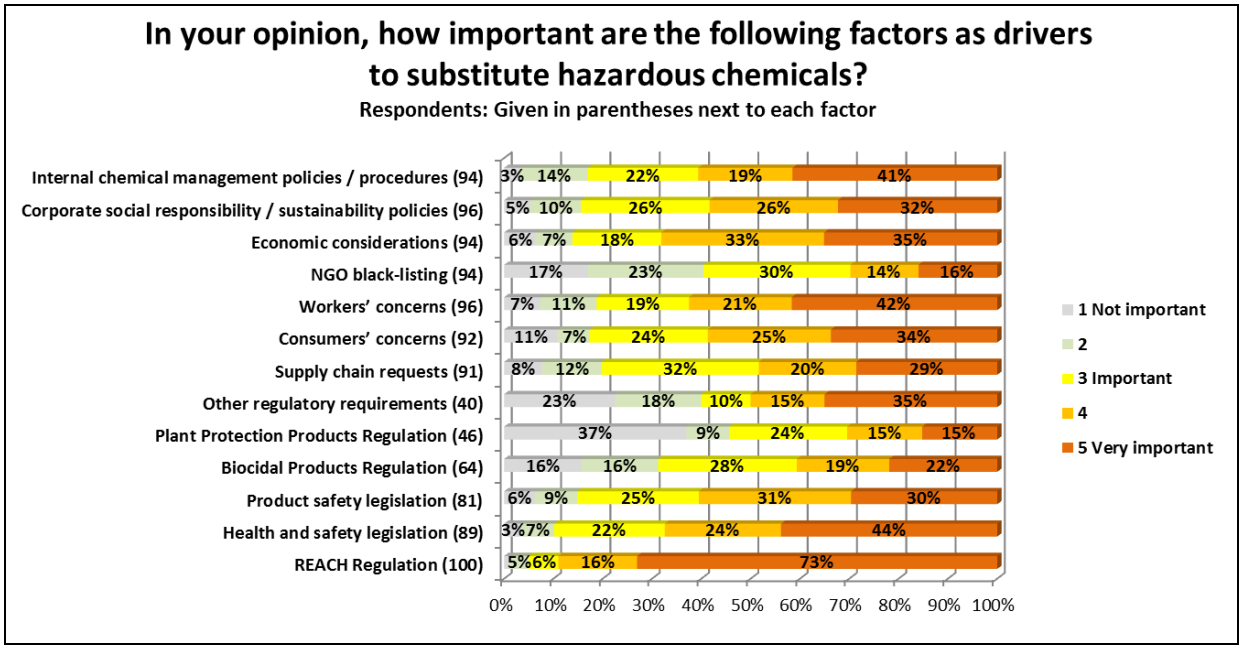
Over 80% of the respondents consider supply chain requests, workers' and consumers' concerns important or very important in driving substitution. Consequently, internal chemical management procedures and sustainability policies at corporate level are also seen as determining factors in leading companies to consider how to better substitute hazardous chemicals. Indeed, a respondent noted: "*Chemical companies are and have always been striving to improve product performance, product/feedstock/process costs, sustainability, health and environmental safety, and to meet regulatory requirements. This is not only because workers' safety, consumers' safety and*

environmental protection are at the heart of the chemicals business, but also because innovation is essential to allow companies to grow and remain competitive. Investment in R&D leading to the development of new substances is vital for companies to maintain their market shares and attract new customers with safe and high-performing products".

Some of the respondents pointed out that NGO black-listing can be an unfortunate driver, as they deem the criteria utilised to identify the substances to be included in the lists to be less rigorous than REACH and purely based on hazard without consideration of actual risk.

The consultants that provided responses to the survey agree that REACH is a very important driver of substitution, mainly due to its broad scope. Other regulations act as important drivers as well, but they put pressure on different actors of the supply chain and are therefore perceived as more or less important by these.

Figure 3: In your opinion, how important are the following factors as drivers to substitute hazardous chemicals? – Respondents: 100



Q2. In your opinion, how important are the following factors as obstacles to the substitution of hazardous chemicals?

The availability of information on the technical feasibility of alternatives and on their hazards and risks, combined with the subsequent uncertainties over their market potential and their regulatory fate have been listed as important or very important obstacles by over 85% of the respondents (Figure 1-4).

The lack of resources at company level, competition with extra-EU companies and ineffective communication with suppliers about potential alternatives have also been indicated as important or very important by over 70% of the respondents.

A respondent noted: "*It takes years and significant financial and human resources to research, develop, manufacture, test and assess, support applications and uses development and to distribute new chemical products (this statement is from the perspective of production of high volume commodity chemicals; for low and medium volume chemicals these statements will apply to a lesser degree). The low success rate in the development of new products, because they do not meet market expectations in terms of safety, performance and affordability, is an obstacle not only to substitution, which should not*

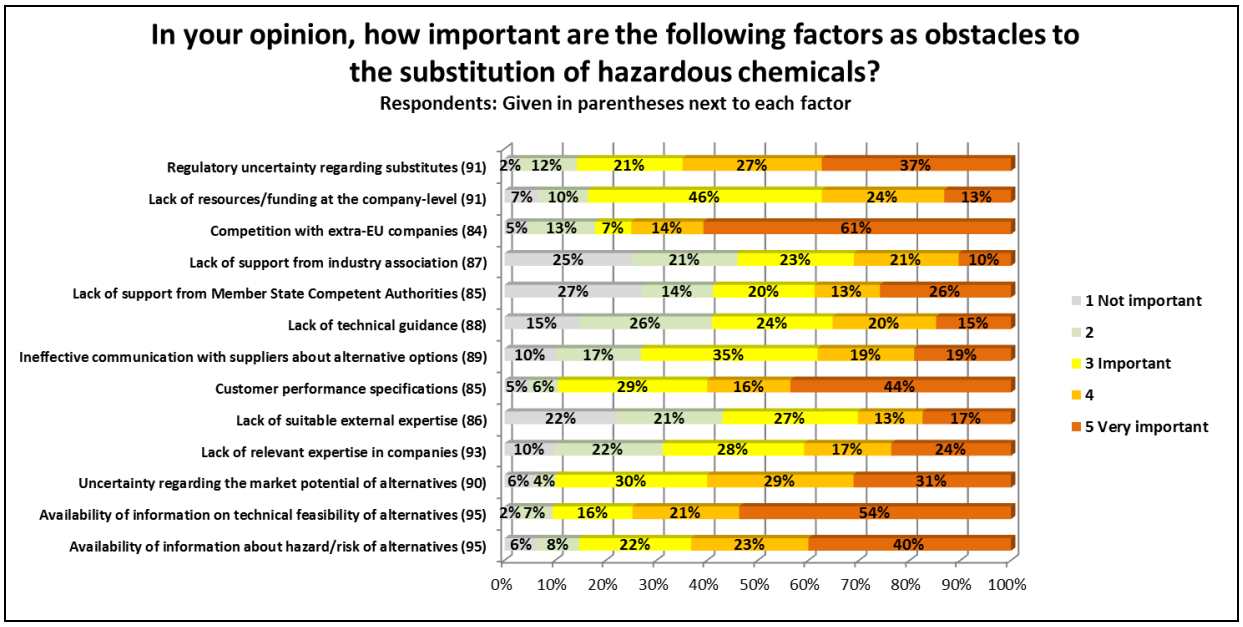
be a goal in itself, but also to the marketing of innovative chemical products (…) Requiring substitution of a well-tested chemical that can be used safely by a less tested alternative based on hazard is contrary to the logic of safe substitution (…) Regulating chemicals can only be done based on a robust assessment of the available data, taking into account the potential risks of the substances and the amount of scientific evidence available".

One consultant noted that: "*…many substances are used for very particular reasons which are specific to the process of the individual company. General information about potential substitutes is not useful for assessing whether they could perform adequately in a particular process. Alternatives suppliers are often unsighted about the process characteristics of (potential) downstream users. Companies are generally unwilling or unable to share information up and down the supply chain for genuine strategic, competition and economic reasons*".

Other industry respondents commented on the availability and prices of potential alternatives, noting that substitution is particularly challenging for SMEs.

Some other representatives noted that the REACH authorisation mechanism can be an obstacle in itself in the moment that an authorisation is granted for substances for which alternatives have been developed by other companies, as their efforts toward substitution are not adequately rewarded. Inadequate enforcement of the existing legislation has also been indicated as a major problem by both industry and consultants, exposing "virtuous" companies to the competition of firms unlawfully using banned chemicals.

Figure 4: In your opinion, how important are the following factors as obstacles to the substitution of hazardous chemicals? – Respondents: 95

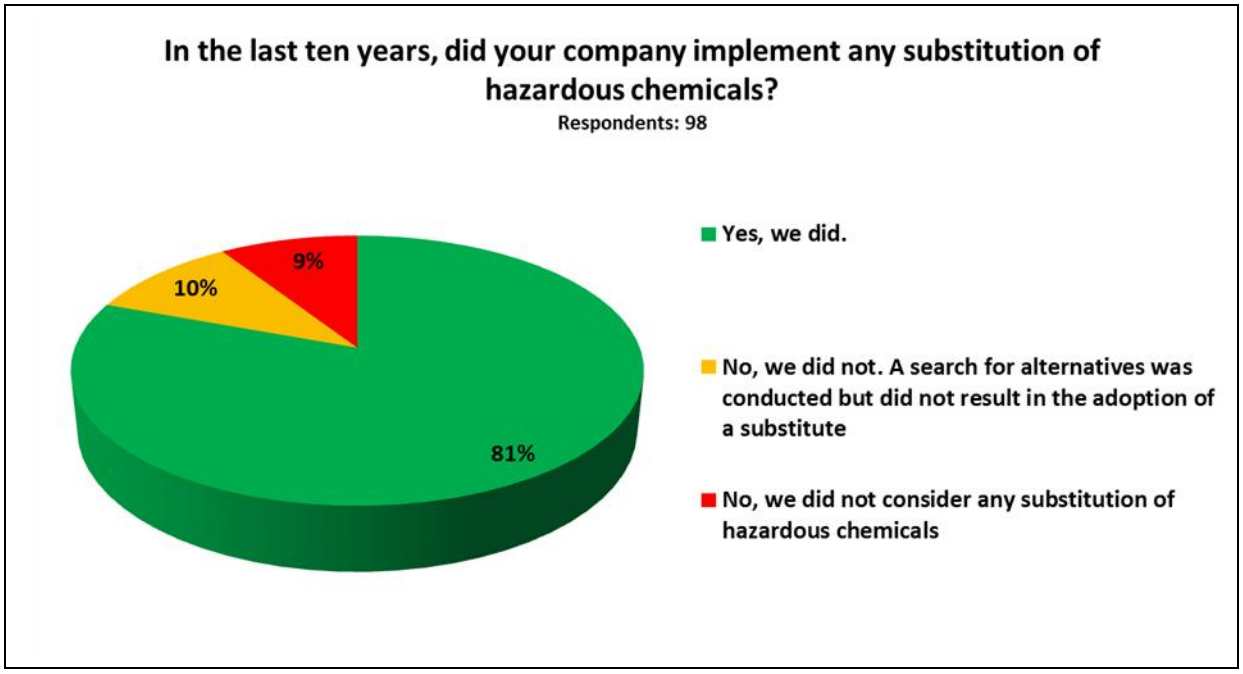


A2.3. EXPERIENCE WITH SUBSTITUTION

Q3. In the last ten years, did your company implement any substitution of hazardous chemicals?

Of the 98 respondents to this question, 81% indicated that they have implemented the substitution of hazardous chemicals in the last ten years. Of those who did not, 10% indicated that this is due to a failure to find a suitable alternative, despite searching for one. Nine percent indicated not to have considered substituting hazardous chemicals (Figure 5).

Figure 5: In the last ten years, did your company implement any substitution of hazardous chemicals? – Respondents: 98



The substituted substances more frequently cited were phthalates, heavy metals, brominated flame retardants, chlorinated solvents and nonylphenols. One respondent noted that their company is particularly pro-active in chemicals safety and follow a "cradle to cradle" methodology to prevent the use of hazardous substances. Other respondents stressed the complexity, duration and resources required to successfully develop and implement a substitute across the entire supply chain, noting that it is not always possible to find a suitable substitute. A company operating in the nuclear safety sector noted that it was possible to find a substitute for a fire resistant fluid used in the control systems of nuclear power stations that was identified as SVHC; however, the respondent claimed that only boric acid (identified as SVHC) is capable of absorbing neutrons in pressurised water reactors or spent fuel cooling ponds, and therefore there are no suitable substitutes. In his words: "*the slight increase in chemical safety is far outweighed by the negative impact on nuclear safety. As such we believe that, in some instances, controlling the chemical risk via good procedures and PPE results in a much greater degree of general health and safety*". A respondent lamented that, after having invested considered amount of resources in finding suitable alternatives, these are now object of regulatory scrutiny, creating significant uncertainty and lack of predictability for investment in existing products and new alternatives. A SME added that, although they are willing to research safer alternatives, the administrative burden of legislation is diverting resources from R&D to regulatory compliance. The European Tyre and Rubber Manufacturers Associations (ETRMA), reflecting upon the experiences of their members in substituting aromatic oils in tyres, summarised these with the following points:

- "SMEs could never have initiated such replacement projects alone without involving experts along the entire supply chain;
- Economic and research support was needed;
- Time is very important and the time needed can only be estimated for the best case scenario;
- Industry has been active in finding safer alternatives even before REACH and this is a clear example of how the industry anticipated regulations;
- The success of a research for substitutes cannot be guaranteed upfront;
- Public funding support to SMEs, and not regulatory pressure on them, turned out to enable the substitution process".

Another industry association noted that substitution should be considered long with other options in a Risk Management Options Analysis: "(…) *the need for substitution will be particularly evident where the risk cannot be eliminated, sufficiently reduced, or controlled so that the benefit of the continued use of the (hazardous) substance or technology for society outweighs the risks of this continued use for society. In such a case, best practice would be to investigate other opportunities for substitution via an effective analysis of alternatives (AoA), to be conducted by users of the substance or technology of concern, on a consistent basis".*

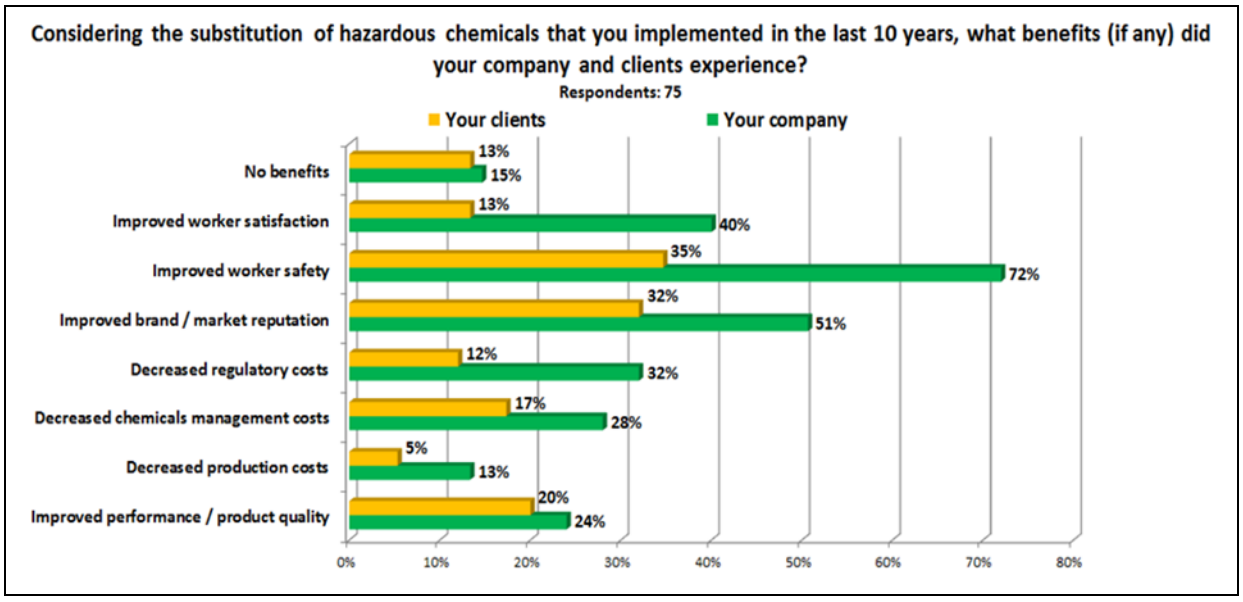
A2.4. EXPERIENCE WITH SUBSTITUTION ASSESSMENTS & USE OF ANALYSES OF ALTERNATIVES

Q4. Considering the substitution of hazardous chemicals that you implemented in the last 10 years, what benefits (if any) did your company and clients experience?

The three most widely achieved benefits for companies responding to the survey are: improved worker safety (72% of respondents); improved brand/market reputation (51%); improved worker satisfaction (40%). Only 15% of respondents indicated that they did not enjoy any benefits because of substitution of hazardous chemicals. A significant number of companies enjoyed decreased costs: 32% indicated their company had enjoyed a decrease in regulatory costs; 28% experienced a decrease in chemicals management costs; 13% benefitted from decrease production costs. Thirty-five percent indicated that their clients benefitted from improved worker safety whilst 32% indicated that their clients experienced improved brand/market reputation. Only 13% of respondents indicated that their clients did not experience any benefits because of the substitution of hazardous chemicals.

Two consultants noted that their clients and the clients of their clients benefitted from the research and development of safer alternatives, because they were able to develop products with improved performances.

Figure 6: Considering the substitution of hazardous chemicals that you implemented in the last 10 years, what benefits (if any) did your company and clients experience? – Respondents: 75



Q5. Considering the substitution of hazardous chemicals that you implemented in the last 10 years, what challenges (if any) did your company and clients experience?

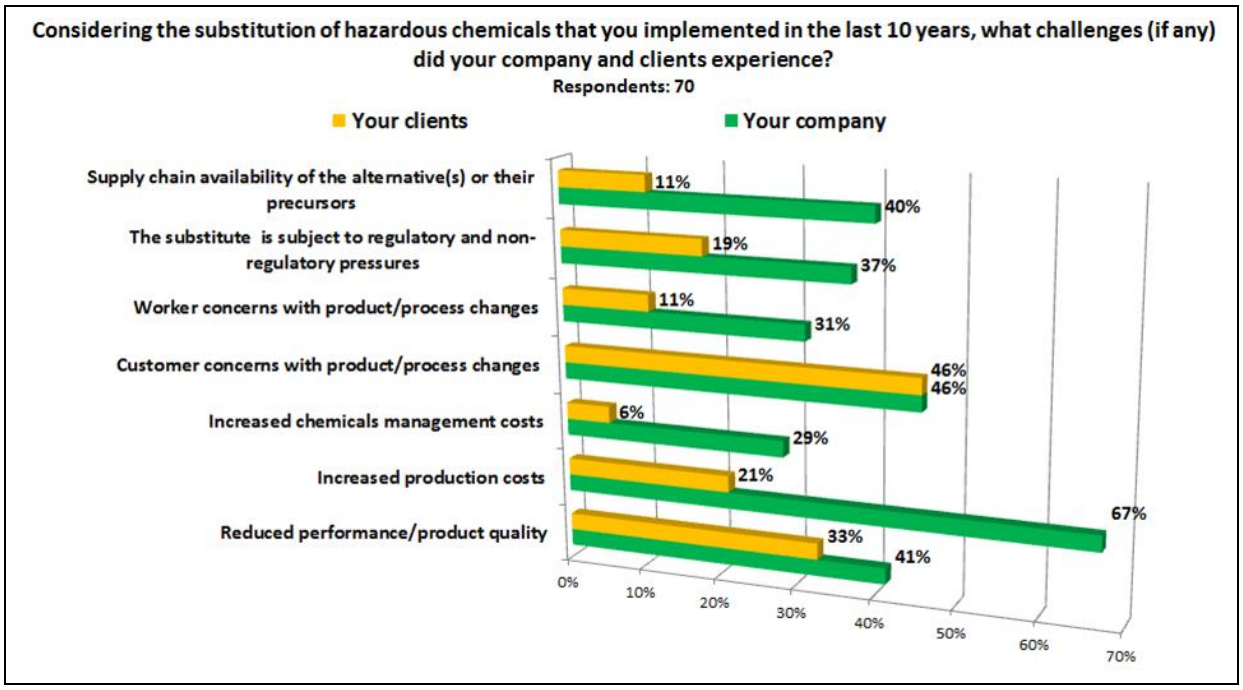
Sixty-seven percent of the 70 respondents to this question indicated that substitution led to increased production costs, while only 21% indicated that their clients face increased production costs,

signalling that they absorbed most of the substitution costs and did not pass these to their customers. Respondents to the survey seemed to indicate that upstream actors in the supply chain (manufacturers of chemicals and manufacturers of articles containing chemicals) face most of the challenges. However, similar percentages of respondents indicated that reduced performance/product quality and, subsequently, customers' concerns with product/process changes are worries for all actors in the supply chain, independently from their position (Figure 7).

Some respondents signalled the regulatory environment as a challenge, mentioning that, for example, three different national regulations on construction products emission control exist in Belgium, France and Germany. The constant regulatory scrutiny over the same substances has also been cited as a challenge, where respondents asked for more predictability by limiting the opening of new regulatory procedures, if not in the event of new data. One respondent noted that awarding long authorisation periods to substances for which safer alternatives have been developed by other companies stifles, rather than rewards, innovation.

Many respondents pointed to the limited availability of alternatives, in terms of number of substances, quantities on the market and number of suppliers; all of which increase the price of alternatives in general.

Figure 7: Considering the substitution of hazardous chemicals that you implemented in the last 10 years, what challenges (if any) did your company and clients experience? – Respondents: 70

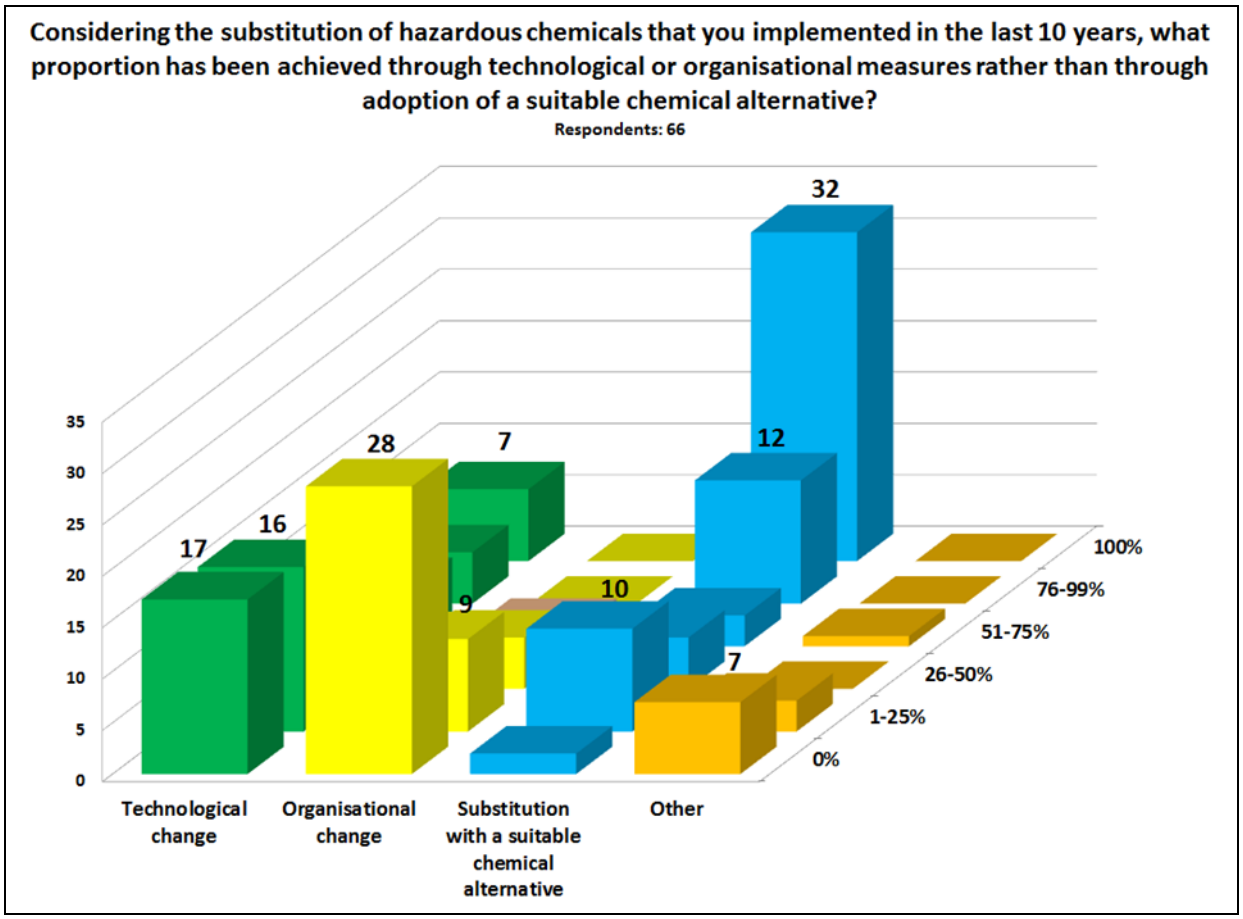


Q6. Considering the substitution of hazardous chemicals that you implemented in the last 10 years, what proportion has been achieved through technological or organisational measures rather than through adoption of a suitable chemical alternative?

Respondents noted that the substitution of hazardous chemicals requires the adoption of suitable alternatives in combination with technological and organisational changes. Substitution through the mere adoption of technologies or organisational measures is rare: only 12 respondents indicated that they achieved substitution through technological change for more than 75% of their substitution cases and only 16 respondents indicated to have substituted hazardous substances through the adoption of organisational change in some cases (less than 50%) (Figure 8).

Some examples of technological changes that eliminated some of the chemicals involved were provided by the respondents: laser cutting, laser cleaning and laser printing. Broadly, however, technical and organisational measures are used to reduce the use and the exposure to hazardous chemicals.

Figure 8: Considering the substitution of hazardous chemicals that you implemented in the last 10 years, what proportion has been achieved through technological or organisational measures rather than through adoption of a suitable chemical alternative? – Respondents: 66



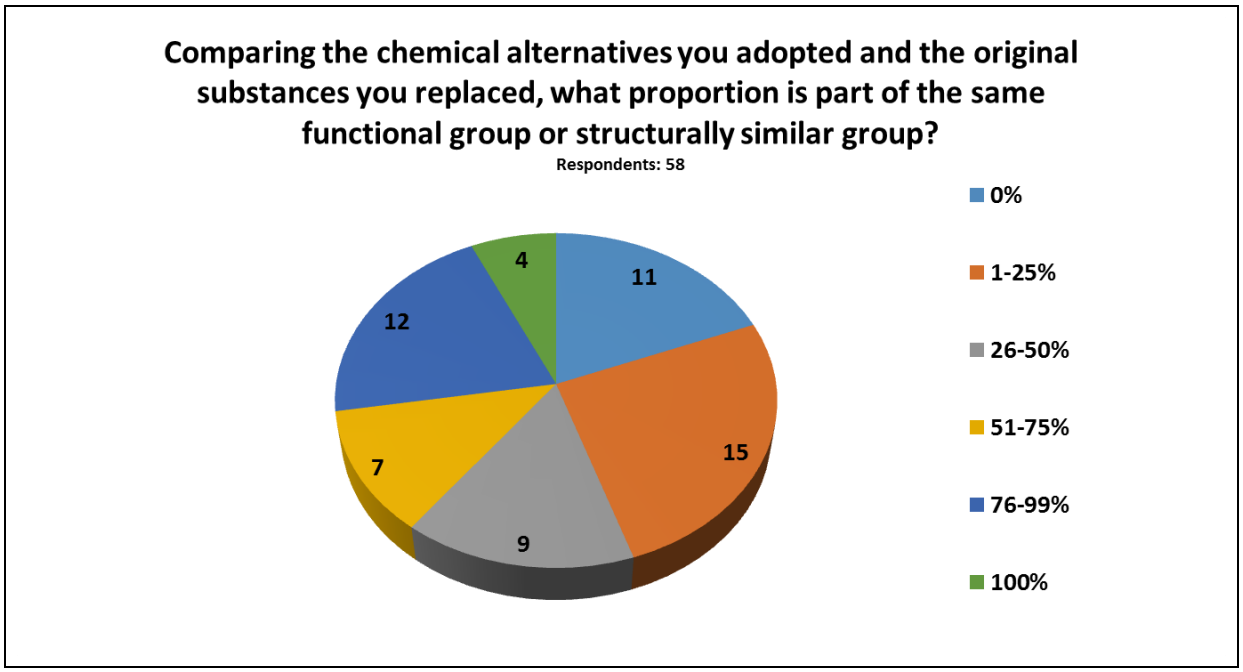
Q7. Comparing the chemical alternatives you adopted and the original substances you replaced, what proportion is part of the same functional group or structurally similar group?

Around 40% of industry stakeholders (23 on 58 respondents) consulted estimated that over 50% of the substitutions implemented have been with substances that are part of the same functional or structurally similar group (Figure 9).

Many respondents noted that the substitution of one hazardous chemical in a process, mixture or product often implies the substitution of other chemicals used in the process, mixture or product in order to retain the same desired properties/performance. A respondent added: "*A significant proportion of alternatives are part of the same functional group or structurally similar group as the original substance. This is due to the fact that years of research have allowed companies to identify and select products that have specific properties and answer specific needs, and it is difficult to find these properties and qualities when deviating from a certain chemical family or group. For many types of chemicals, companies are exploring and developing "variations on a theme", which can however still bring major benefits to society and contribute to further innovation (…) In practice we find that product and applications innovations come from working closely with customers in understanding their needs and applications, and by making small changes in the composition and*

purity (e.g. reduced aromatics) of substances and products, which lead to enhanced performance, and/or enhanced health and environmental properties, including the facilitation of compliance, or opening up new applications".

Figure 9: Comparing the chemical alternatives you adopted and the original substances you replaced, what proportion is part of the same functional group or structurally similar group? – Respondents: 58



A2.5. ANALYSIS OF ALTERNATIVES

Q8. Which of the following components of analysis of alternatives or substitution assessment were particularly challenging for your company and where capacity-building support and technical assistance is therefore a priority need?

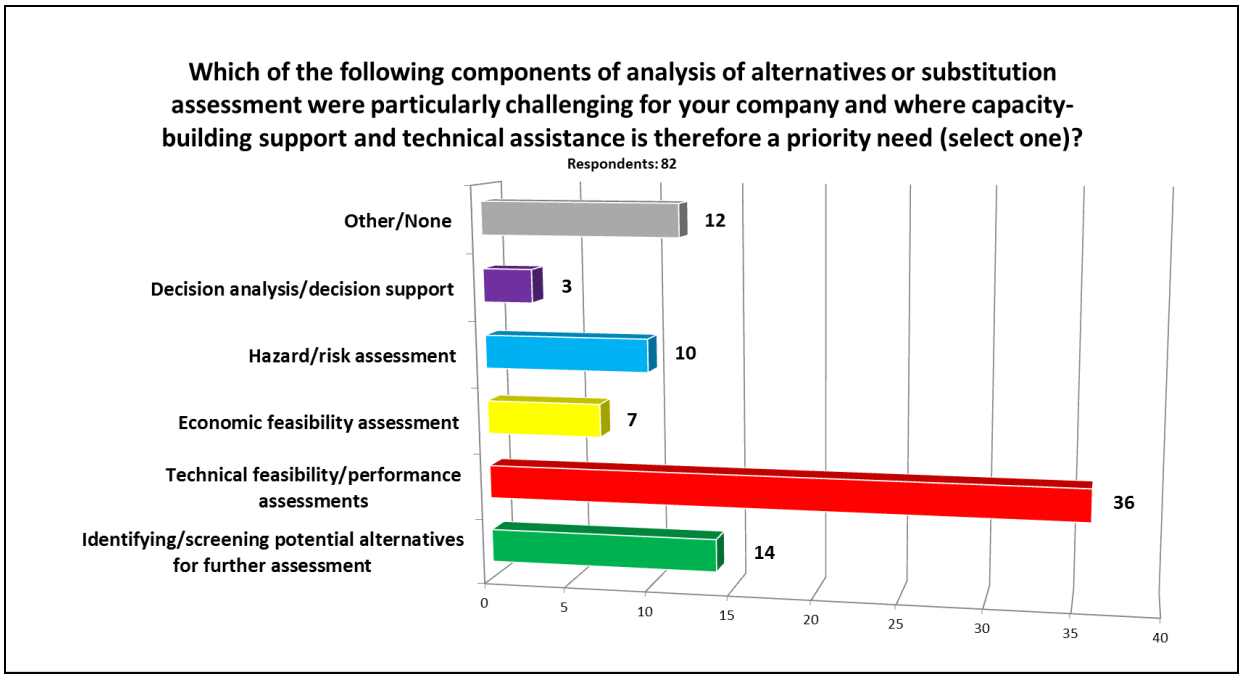
Technical feasibility and performance assessment of alternatives has been indicated as being particularly challenging by 44% of the 82 respondents (Figure 10). Many participants of the survey pointed to the fact that the chemicals to be substituted have been in use in many cases for decades and risk management measures were developed and implemented to reduce exposure. The introduction of alternatives, even of alternatives with lower hazard profiles, requires the complex evaluation of the potential exposure to the new chemicals at each stage and the satisfaction of the customers' specifications; it needs the assessment of the impacts on all the actors in the supply chain. A respondent noted: "*A key challenge for our company is the lack of regulatory predictability and of a stable environment for investment, with chemicals being constantly submitted to further regulatory scrutiny despite having been demonstrated to be safe in recent in-depth regulatory assessments (…) It should also be noted that access to raw materials in the relevant quantities and at the right cost is also extremely important. For example a major commodity chemical can require as many as 6 raw materials or feedstocks, each with its own complex supply chain, which has been developed over many years with huge investment*".

The identification of potential alternatives was found to be problematic by 14 respondents, with some noting that it is not always possible to find safer alternatives that achieve the same performance level.

In general, participants of the survey noted that substituting hazardous chemicals is a complex process requiring considerable effort and commitment in terms of time and resources: "*Authorities could promote a more systematic consideration of alternatives, by providing users guidance about how to*

document the analysis of alternatives and the justification of their ultimate decision of substituting or not".

Figure 10: Which of the following components of analysis of alternatives or substitution assessment were particularly challenging for your company and where capacity-building support and technical assistance is therefore a priority need? – Respondents: 82

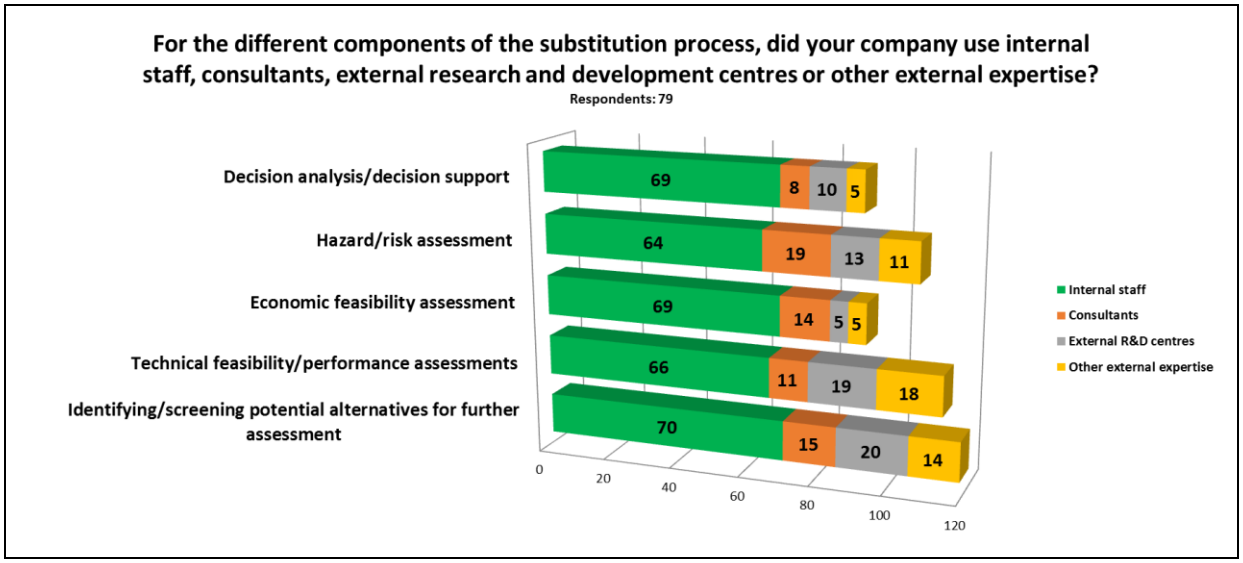


One consultant suggested that decisions on substitution should be taken following a more "holistic approach", considering not only product performance and hazard and risk information, but also other environmental parameters, such as energy, resources' use, waste generation, etc.

Q9. For the different components of the substitution process, did your company use internal staff, consultants, external research and development centres or other external expertise?

The results indicate that most companies rely on internal staff to deal with all the different aspects of the substitution process. Consultants are also used, particularly for hazard and risk assessment. Respondents also indicate their use of external R&D centres, particularly for technical feasibility and performance assessments, as well as for identifying and screening potential alternatives for further assessment. Some respondents operating in downstream sectors stressed the importance of the information and expertise provided by the chemical suppliers, others noted that collaboration with customers is essential as technical feasibility needs to be evaluated at customers' facilities.

Figure 11: For the different components of the substitution process, did your company use internal staff, consultants, external research and development centres or other external expertise? – Respondents: 79

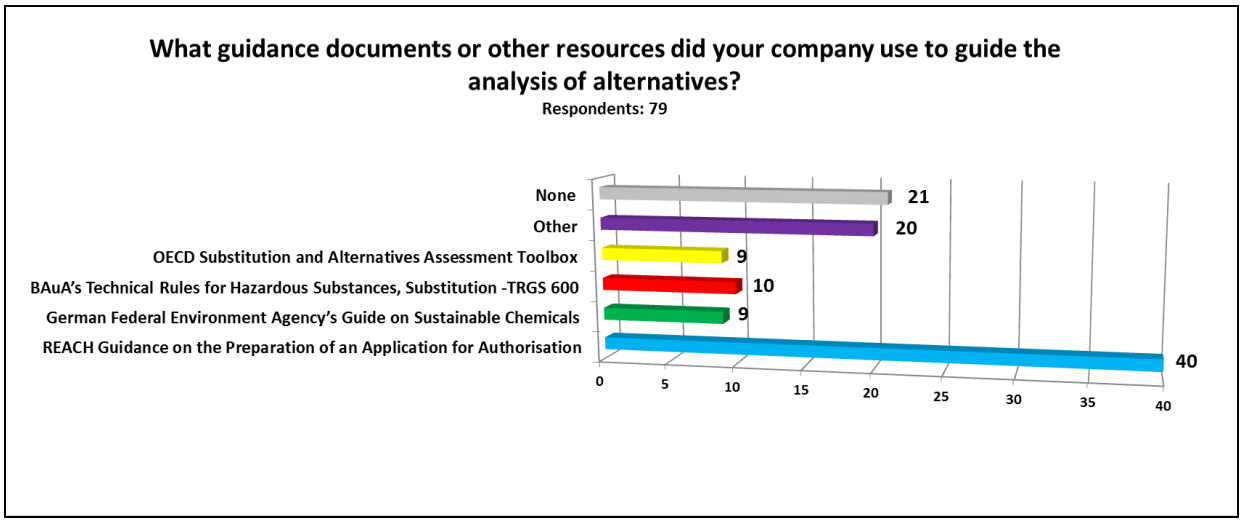


Q10. What guidance documents or other resources did your company use to guide the analysis of alternatives?

Over 50% of the respondents used the REACH Guidance on the Preparation of an Application for Authorisation. Other respondents followed the OECD Substitution and Alternatives Assessment Toolbox, the BAuA's Technical Rules for Hazardous Substances or the German Federal Environment Agency's Guide on Sustainable Chemicals.

Many participants to the survey indicated using internal guidelines while for certain downstream sectors, any change to the approved design needs to follow certain procedures established by notified bodies.

Figure 12: What guidance documents or other resources did your company use to guide the analysis of alternatives? – Respondents: 79



A2.6. ENHANCING SUBSTITUTION EFFORTS

Q11. What actions would you like to see from regulators or publicly funded organisations to

better support and encourage substitution efforts?

Sixty percent of the 90 respondents to this question would like financial support for the research and development of safer alternatives. Forty-five percent would like regulators to develop enhanced technical guidance materials on analysis of alternatives: one respondent suggested a web-based "chemicals encyclopaedia" with frequently updated information on chemicals' uses in certain product categories, legislative status, potential alternatives, etc.

Over 40% of respondents would like regulators and publicly funded organisations to convene supply chain and sector dialogues to identify, evaluate and adopt substitutes. The same proportion would also like these bodies to coordinate research activities on substitutes. These initiatives were deemed important by the representatives of SMEs participating in the survey: one noted that without financial support, a common understanding of the supply chain and communications among the others, substitution for SMEs remains an impossible task.

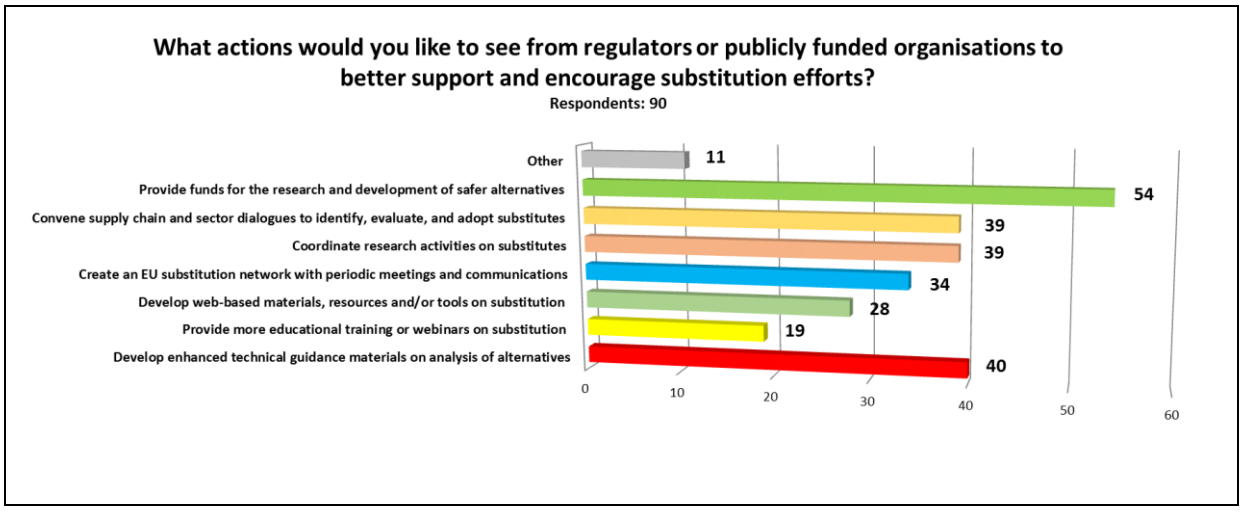
Some respondents were not in favour of having co-ordinated research, for different reasons: one noted that since a safer alternative may give a competitive advantage, the co-ordination of research activities is of limited interest; another noted that there would be issues with patents and intellectual property protection.

One respondent commented that the initiatives suggested would be suitable for the substitution of mixtures and some "less technical" ingredient such solvents, but would not work for substances with highly technical and proprietary functions, such as catalysts, cross-linkers, light assorbers, etc.

Many stressed the importance of reasonable transition timeframes and adequate sunset dates. In general, legal certainty, proportionality and enforcement were seen as fundamental principles that would support industry in their substitution efforts.

One consultant noted that financial support should go in particular to SMEs, as they have the largest potential to produce quick and effective change.

Figure 13: What actions would you like to see from regulators or publicly funded organisations to better support and encourage substitution efforts? – Respondents: 90



European Commission

Study for the strategy for a non-toxic environment of the 7th EAP

Sub-study b: Chemicals in products and non-toxic material cycles

Written by Antonia Reihlen (Ökopol)
August 2017

This sub-study report has been prepared by Antonia Reihlen (Ökopol).

The views expressed herein are those of the consultants alone and do not necessarily represent the official views of the European Commission.

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Chemicals in products and non-toxic material cycles (sub-study b)

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ABSTRACT

This report describes the various aspects of the production and use of chemicals in articles and material cycles. It outlines the challenges in three main areas: regulation of the content of toxic substances in articles; communication on the content of toxic substances in articles and material cycles and the related potential risks; and information gaps as well as organisational problems arising from the avoidance of toxic substances in a circular economy.

The analysis of chemicals, products and waste policies shows the lack of a consistent approach to limiting the content of toxic substances in articles and materials. In addition, legal requirements regarding communicating information on (toxic) substances along the supply chain and to consumers are limited in the substances they cover, making little information available to authorities and stakeholders engaged in setting risk management priorities. Finally, the routines and infrastructure of the waste sector are inefficient in decontaminating material streams from legacy chemicals contained in articles.

A number of options to further develop the policy framework have been identified and developed, with the aim of moving towards a non-toxic environment. These encompass legal measures, the implementation of economic incentives, supporting research, and increased efforts in the communication of substances and technologies.

EXECUTIVE SUMMARY

This report describes the various aspects of the production and use of chemicals in articles and material cycles. It characterises challenges of regulating the content of toxic substance in articles; communication on the content of and potential risks from toxic substances in articles and material cycles; and the communication as well as organisational problems arising from the avoidance of toxic substances in a circular economy.

The overall aim of achieving non-toxic[1] articles and material cycles is to prevent their related risks for human health, for the environment, and to improve resource efficiency through the recycling of article wastes. Combining the goal of a non-toxic environment and a circular economy requires:

- improving article design and thereby as far as possible preventing the inclusion of toxic substances in articles with the aim of reducing the exposure throughout the life cycle and increasing the recyclability of the articles or the materials of which they are composed, and;
- collecting and separating wastes that contain toxic substances with the aim of decontaminating material streams and ensuring high quality recycled materials generated from article wastes.

The issue of non-toxic articles and material cycles is complex because three different but interconnected regulatory areas are relevant i.e. chemicals legislation, article-related legislation, and waste legislation. Furthermore, a large number of different types of actors are involved in article production and in waste treatment. Finally, numerous types of articles and waste streams, which have complex compositions, need to be considered.

Key findings on chemicals and articles and the circular economy

The problem

- Toxic substances are included in articles and may be released at any lifecycle stage, resulting in exposures and potential risks for humans and for the environment. This is true for new/currently produced articles, as well as for articles already present in society.
- The scale of the problem is significant. The following examples involve two substances from problematic substance groups widely used in articles. The annual amount of DEHP (a phthalate used as plasticiser in PVC, now listed in REACH Annex XIV as a SVHC substance subject to authorisation) included in articles on the EU market (produced in the EU or imported), which is estimated to 210,000 t/y (KEMI, 2015). Further, 7 t/y of BDE (a flame retardant listed as a POP) included in plastics waste from WEEE in the Netherlands, and 22% of this is estimated to be recycled and used in new products (Leslie, 2013).
- Linking the incidence of the health and environmental damage observed to exposures to single articles or article categories is challenging due to the complex exposure situation and a lack of basic exposure data. Furthermore, the extent of risks varies with the type of substance, type of article, and its actual use situation. However, there is evidence that many substances, including such with known toxic effects, are released from articles and are present in the human body and the natural environment.
- Toxic substances contained in end-of-life articles eventually reach the waste stage and may contaminate recycled material streams, enter into a second service life, and potentially occur in unsafe uses, as has been demonstrated e.g. for brominated flame retardants from recycled plas-

[1] In this sub-study, the term 'non-toxic' is used to describe substances that have no or at least a low toxicity, i.e. hazard which are not severe. It implies the ultimate goal of replacing as far as possible substances in articles and materials that could cause harm to humans and/or the environment. It also implies a procedural approach, that addresses substances with the most severe hazards first, i.e. SVHC properties, and eventually includes further hazards. Exposure considerations would modify the priority with which substances are addressed.

Key findings on chemicals and articles and the circular economy

tics used in thermos cups (Samsoneka, 2013).

- Information about the content of toxic substances in articles is largely missing, both for specific articles and at a general level. This lack of data renders it extremely difficult for:
  - Regulators to carry out overall risks assessment, determine the scale of risks, and to choose regulatory risk management measures;
  - Economic operators and consumers to make informed choices about how to avoid toxic substances in articles;
  - Waste treatment operators to separate and treat end-of-life articles in a manner that prevents contamination of recycled materials.

Gaps and inconsistencies in current policy

- The methodology of current regulatory risk assessment under REACH and other chemicals legislation does not ensure that risks relevant for articles can be identified, because:
  - Information on relevant substance properties is partly not available or considered on a routine basis (e.g. PBT/vPvB if registered in low volumes, endocrine disruption or neurotoxicity as not sufficiently covered by information requirements under REACH, nanomaterials as the testing regimes are not adapted to them);
  - Long-term and low-dose effects, cumulative and combined exposures as well as combination effects are not sufficiently well addressed;
  - The exposure assessment is generic and requires information on substance uses and releases from articles, which are frequently not available.
- Legislation preventing the presence of toxic substances in articles (where possible) is scattered, neither systematic nor consistent and applies only to very few substances, articles and uses, often with many exemptions.
- Legal information requirements on toxic substances in articles are vague and cover only a few substances (of very high concern) under certain conditions, hence rarely resulting in useful information. If information on toxic substances does exist it is frequently insufficient to support:
  - Article producers in gaining full knowledge about the presence of toxic substances in the complex objects they assemble and place on the market. Consequently, they can hardly ensure material compliance, improve product design regarding the reduction of toxic substances or provide information to their customers;
  - Waste treatment operators in separating waste streams or components thereof that include toxic substances from other waste streams that are not contaminated.
- Legislation and current practices in the waste sector were generally designed to safely treat the large wastes streams and quantitatively recover materials, if possible, rather than to decontaminate waste streams from (articles/materials containing) individual toxic substances in a manner intended to generate recycled materials free from them.

The following issues indicate the scale of the problem in the context of a non-toxic environment:

- The overall volume of (toxic) substances included in articles is large, and increases in line with global trade volumes of articles.
- The majority of supply chains are globalised, complex and dynamic. This makes the management of toxic substances in articles difficult, including the efficient communication on these.
- A large share of articles on the EU market are imported. These may include SVHCs (and biocides) that are subject to authorisation in the EU, which may create additional risks and represents an economic disadvantage for EU article producers.
- The composition of articles is complex, making it challenging to identify the content and release potential of toxic substances, or to assess the risks from articles.
- Several studies illustrate that large amounts of toxic substances are present on the EU market,

giving rise to exposures during their service life in articles, and causing problems during waste management and recycling, which may result in (risks of) harm to human health or the environment.

- Release of toxic substances from articles contributes to a continuous, long-term, and low-level exposure to a mixture of different hazardous chemicals, which causes or exacerbates adverse effects on human health and the environment.
- Frequently, only minimum information on the chemical content of articles is communicated along the supply chains, sometimes due to confidentiality concerns. This information may not be sufficient to ensure legal compliance and the assessment and potential management of risks for workers, consumers and the environment.
- Information on the use (amounts) of toxic substances in articles at a general level is missing, due to the limited scope of the legal notification and communication provisions on hazardous substances in articles. This hinders assessment of the scale of risks from toxic substances in articles, as well as impacts on targeted decision-making in respect of risk management measures.
- The sheer variety of articles represents a challenge for sorting and separate treatment.
- A systematic regime preventing (certain) toxic substances from entering waste streams does not exist in either waste legislation or articles legislation.
- Toxic substances, which have been restricted in the meantime, are still included in materials and articles manufactured in the past (legacy chemicals). They may leak from articles/materials that are still in use, emit during waste processing or enter a second service life, if integrated into recycled materials.
- The use of toxic substances in articles may lead to their continuous presence in the material streams if they are subject to recycling. According to modelling studies, it may take centuries to decontaminate a recycled material stream from a particular substance.
- The waste sector lacks information on the content of toxic substances in end-of-life articles and material streams, because only few and insufficient mechanisms exist to facilitate effective information flow from article producers to the waste sector exist at present.
- Information on certain hazardous substances, such as PBT/vPvB and POPs, are not systematically communicated in the waste chain.
- Toxic substances in recycled materials may occur in articles. Although the quality of virgin and secondary materials used for the production of articles should be identical, several cases of recycled materials containing banned substances have been observed. This suggests that enforcement of the requirements is insufficient, in particular for recycled materials.
- Although the Waste Framework Directive generally requires the 'depollution of waste streams', this is put into practice for very few types of waste streams.

Toxic substances included in articles may cause exposures to humans or the environment if they are released during the articles' service lives, waste treatment or recycling resulting in one - or several - further life cycles. While risks may stem also from acute exposure, concerns chiefly relate to aggregated and cumulated, long-term exposures to chemicals of both humans and the environment, in particular of aquatic life.
At the waste stage, different articles (and materials) converge into waste streams. This leads to a dilution and dispersion of toxic substances in waste streams. Toxic substances in waste materials could cause risks to workers and the environment, if released during waste treatment. Furthermore, if carried over into a new product life cycle, risks to consumers and the environment may occur. The presence of toxic substances in wastes might also compromise the quality and technical functionality of a material, leading to downgrading.

The exposure levels to chemicals from articles are likely to increase, considering the globally increasing production volume of chemicals and articles. The yearly import of goods to the European Union has almost tripled between 2000 and 2015, with a large share being imported from countries with less severe legislation on chemicals control.

A number of studies discuss the presence of toxic substances in articles and biomonitoring data show

they can be found in human body tissue, in wildlife and the different environmental compartments. Some exposure levels are of concern and have been demonstrated to cause damage, e.g. to unborn life.

Intentionally added toxic substances usually fulfill particular functions in articles and materials. Where this is the case, information on their content in materials and articles is generally available and can be provided along the supply chain. In addition, their content may be unintended, e.g. as residues of processing aids, or contaminations from the carry-over from materials or products of other batches processed in the same machinery. In such cases, information on the substances' content is not normally available. Toxic substances in wastes or – after recycling - in products made from recyclates, could stem from either of the sources mentioned above, or from different articles mixed together during waste management and recycling.

There are three distinct categories of challenges that need to be addressed in order to achieve non-toxic articles and material cycles:

- Toxic substances are contained in articles causing risks to humans and the environment throughout the life cycle.
- (Legacy) chemicals enter the waste stage with articles and may cause risks during waste treatment or if included in articles (second service life).
- There is a lack of information on (toxic) substances in articles and in waste streams.

Possible paths to address these challenges include developing the legal framework in the field of chemicals, products (articles) and wastes, and implementing additional measures, e.g. in the area of enforcement, economic incentives, capacity building and awareness raising, etc. Instruments from all three policy areas target different stages of the articles' life cycle and these would influence each other, given the partial circularity of material flows. Nevertheless, one particular policy area may be better suited to address one problem than another. For example, waste management is the most powerful tool to remove hazardous substance from material cycles, while restrictions of toxic substances in articles legislation could prevent the influx of new toxic substances.

Chemicals policy

The main pieces of chemicals legislation that may influence the content of and information availability on toxic substances in articles considered in this study are: the REACH regulation, the regulation on classification, labelling and packaging of substances and mixtures, the regulation on biocidal products (BPR) and the regulation on persistent organic pollutants (POPs). Legislation on mixtures is not considered in the study, as long as they are not used for the production of articles.

Chemicals policy sets the framework for the placing on the market and use of chemicals. REACH and the BPR, among others, define requirements to generate data on substance properties and its uses, and to apply it for hazard identification and risk/safety assessment. The CLP regulation defines rules and procedures for the identification and communication of chemical hazards, including notification to the EU-wide classification and labelling inventory. Information on hazardous properties of substances and mixtures and their safe use are to be communicated via safety data sheets along the supply chain, according to REACH and the BPR. In addition, REACH, the BPR and the POPs regulation include several risk management measures, such as substance approval, restrictions, authorisation or notification.

Specific provisions exist on the communication of substances of very high concern (REACH) and biocidal active substances (BPR) contained in articles. However, the communication obligations are much less extensive than those for chemical mixtures.

International, European and national stakeholder groups work on chemical safety, including on the communication on toxic substances in articles. Part of their work is to develop tools to identify if substances have properties of (very) high concern, to create communication standards and tools, and to propose actions to increase awareness and responsible use of substances in articles.

The current legal framework exhibits shortcomings that affect the risk management of and communication on toxic substance in articles. These include a lack of requirements for generating information necessary to identify SVHC, if registered in low volumes. In addition, there are deficits in the chemical safety assessment methodology regarding the exposure assessment for articles and the integration of combined and cumulative exposures. Furthermore, the risk management measures partly do not cover imported articles (authorisation) and restrictions are not systematic and cover few substances in a small number of articles.

Product policy

Article-related legislation considered in the study include the General Product Safety Directive (GPSD), the Construction Products Regulation (CPR), the Ecodesign Directive, the Toy Safety Directive (TSD), the directives on medical devices, legislation on food contact materials and the Ecolabel Regulation.

The General Product Safety Directive requires that all products placed on the market are safe. However, the definition of safety does not include the environment and the GPSD does not define, how chemical safety should be assessed. Similarly, other article-related legislation does not define a methodology to assess the chemical safety of articles.

The Toy Safety Directive is the only piece of article-related legislation that restricts the content of toxic substances via a substance list and via excluding the content of substances with certain properties (CMR) under certain conditions.

All other legislation in this policy area requires that articles placed on the market do not cause any risks to humans and the environment, which is regarded as ensured either if existing standards are implemented (CPR, medical devices) or if only substances are used in the production of the article that are approved for use (plastic food contact materials).

In principle, the Ecodesign Directive allows restricting chemical substances but this is currently not the case. There are ongoing discussions of using this option to restrict substances in articles in in the future. Avoiding the use of specific toxic substances in articles may be a condition to obtain (certain) ecolabels; this is a voluntary activity of the article producers.

Chemicals legislation, such as Annex XVII of REACH, includes several restrictions of substances that relate to their content in articles. In addition, the use of biocides in articles may be limited during the approval of active substances or product authorisation under the BPR.

Articles-related legislation does not require communication on the content of (certain) toxic substances in articles. The only related requirements exist according to REACH Article 7 and 33. They cover only a small number of substances and are not yet sufficiently implemented. In addition, communication is required for biocide active substances under the BPR under certain conditions (treated articles).

Stakeholders implement numerous initiatives to identify substances in articles (e.g. reports on analytical campaigns), to incentivise substitution with safer alternatives, or to communicate about the issue. At the international level, the project 'Chemicals in Products', which is part of the international chemicals strategy (SAICM), managed by UNEP, aims to identify challenges and opportunities in communicating about substances in products (including articles) along complex international supply chains, as well as to define any such communication standards.

Several deficits exist in product policy with regard to a non-toxic environment. These include the lack of a comprehensive risk assessment methodology for articles that sufficiently considers the fact that low-level, long-term exposures to a multitude of substances occur from articles. In addition, there is no consistent approach to restricting the use of toxic substances, e.g. based on hazards and/or generic

exposure and risk considerations. Furthermore, it is insufficiently transparent for the supply chain actors, which toxic chemicals are contained in articles, limiting their abilities to improve article design. Consumers lack information on toxic substances in articles to guide their purchasing decisions and articles handling, except for the information they obtain according to REACH article 33. Finally, articles legislation does not sufficiently implement standards for the recyclability of articles, regarding both the content of toxic substances and the separability of articles and materials.

Waste Policy

Legislation particularly considered in this policy area include the Waste Framework Directive (WFD), the Directive on the Restriction of certain Hazardous Substances in electrical and electronic equipment (RoHS) as well as the Directive on Waste Electrical and Electronic Equipment (WEEE), the Directive on End-of Life Vehicles (ELVD), the Packaging Directive and the Batteries Directive.

All waste legislation bases on the hierarchy of waste management, which prioritises waste prevention, including reduction of the hazardousness of wastes as most important waste management principle. Where waste generation cannot be prevented, material recycling should have priority over thermal recovery and the last option should be the (safe) disposal of wastes.

The waste management sector handles a broad range of heterogeneous waste streams consisting of a large variety of articles and materials and, where possible, extracts them as a whole or transforms them into secondary raw materials for which there is a demand. Reuse and recycling of wastes closes the material cycles and are therefore a core element of the circular economy.

Waste legislation includes several instruments that influence the content of toxic substances in articles. RoHS, the ELVD and the Batteries Directive restrict the content of certain toxic substance. The Packaging Directive requires a general minimisation of the content of toxic substances. Although part of waste legislation, these requirements apply to the article producers.

For certain waste streams, such as steel, copper and glass, end-of-waste criteria exist, which define, among others, the quality of waste materials that may be used as input and the quality of the secondary raw material that may be placed on the market as a product (and not a waste). These criteria delineate the border between waste and chemicals legislation.

The Batteries Directive requires communication of the content of specific toxic substances. The ELVD requires that vehicle producers provide relevant information, including on hazardous substances, to the dismantling companies. Labelling requirements exist in the Batteries Directive and the WEEE Directive with regard to the disposal of the articles.

The presence of toxic substances in end-of-life articles may hinder the implementation of the circular economy and the intended increase in material recycling. This is due to challenges in identifying materials/articles containing toxic substances in the waste streams, separating them from the waste streams that are free from them and ensuring separate treatment, while meeting the qualitative recycling targets and ensuring economic operation of the waste sector.

Communication on the presence of hazardous substances in end-of-life products is crucial for informed waste management decisions on pre-treatment needs and the recycling potential of wastes. However, such information is not available in a manner easily applicable to daily waste management practice. For example, no information is currently available for waste treatment companies on whether or not an end-of-life flatscreen TV contains mercury or LED backlights. Such information gaps mean that waste treatment companies must invest greater effort (each flat screen must be separated and the backlight must be checked), thus incurring higher costs. There is as yet no effective system to ensure that the stakeholder responsible (in this case the producer) bears the costs, in line with the 'polluter pays principle'.

In addition, the heterogeneity of waste streams poses a challenge for waste management (e.g. where some end-of-life products in a waste stream contain brominated flame retardants and others do not),

not least because of missing information about such products, or the inability of the day-to-day processes of waste management to detect the presence of toxic substances in products and materials.
Waste legislation contains some communication tools on hazardous properties due to the presence of hazardous substances (e.g. European List of Waste, requirements of the Waste Framework Directive Articles 17 and 19 on Member States approaches). The effectiveness of these tools is however limited for heterogeneous waste streams, e.g. from complex end-of-life products.

Conclusions on opportunities towards a non-toxic environment
A number of approaches to further develop the policy framework for a non-toxic environment have been identified, including legal measures, the implementation of economic incentives, supporting research, the development of substances and technologies, and increasing communication.

From a structural perspective, an overarching, life cycle and materials-based approach regulating the content of and communication on toxic substances in articles and material streams should be developed and implemented, either as overarching legal approach or by amending existing regulation.

Chemicals legislation and its implementation could be improved, among others, by extending information requirements in a way to ensure that SVHC properties of substances relevant for article use can be identified. Further measures include developing better approaches for the safety assessment of substances in articles and implementing restrictions based on hazard and generic exposure considerations. This should be complemented by research on substitution options for toxic substances, a potential centralised information collection and publication of information on substances in articles, or awareness raising campaigns on the consumers' right-to-know of SVHC in articles according to Article 33(2).

Improvements in the area of product policy may include, complementing approaches in chemicals legislation, the development of methods and guidance for an appropriate assessment of safety/risks from substances in articles. In addition, chemical safety of articles should include the management of environmental risks from toxic substances in articles. Furthermore, mechanisms to include and review restrictions are needed to address specific risks as well as provisions to inform consumers of the toxic substances content in articles in order to enable their informed decision-making.
The legal provisions should be complemented by training and education of article designers regarding the use of less toxic substances as well as improved materials and the design for recycling. Economic measures to increase substitution and decrease the use of toxic substances could include taxation or fees.

Waste legislation could be amended with strengthened quality requirements for recycled materials, e.g. by including qualitative recycling targets that complement the existing quantitative ones. Dealing with legacy chemicals poses significant challenges and apparently requires different approaches for simple and complex articles. Simple article may be sorted before shredding and, if containing unwanted toxic substances, be separated from material streams destined for recycling. For complex articles, approaches to include markers into materials might be applicable to enable identification of contaminated materials in a post-shredder fraction. Additionally, measures complementing legislation could include the use of economic instruments and would require technology research and development to enhance efficient sorting and decontamination processes for materials.

ABBREVIATIONS USED

Art.	Article
ANEC	European Association for the Co-ordination of Consumer Representation in Standardisation
BOG	Break Out Group
BPR	Biocidal Products Regulation
CAS	Chemical Abstracts Service
CEFIC	European Chemical Industry Council
CiP	Chemicals in Products
CLI	Classification and Labelling Inventory
CLP	Classification, Labelling and Packaging
CLS	Candidate List Substance
CMR	Carcinogenic, Mutagenic or Toxic for reproduction
CPR	Construction Products Regulation
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DG	Directorate General
EEE	Electrical and Electronic Equipment
EFIC	European Furniture Industries Confederation
ELV	End-of-life Vehicles
EPR	Extended Producer Responsibility
EU	European Union
FCM	Food Contact Material
FCMR	Food Contact Material Regulation
FR	Flame Retardant
GPSD	General Product Safety Directive
ICCA	International Council of Chemical Associations
LoW	List of Waste
MedD	Medical Devices Directive
OPS	Overarching Policy Strategy
PBT/vPvB	Persistent, Bioaccumulative and Toxic / very Persistent and very Bioaccumulative
POP	Persistent Organic Pollutant
RAC	Risk Assessment Committee
RAPEX	Rapid Exchange of Information System
REACH	Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals
RoHS	Restriction of Hazardous Substances
SDS	Safety Data Sheet
SEAC	Socio-Economic Analysis Committee
SEV	Substance Evaluation
Subst.	Substance
SVHC	Substance of Very High Concern
TSD	Toy Safety Directive
WEEE	Waste Electrical and Electronic Equipment
WFD	Waste Framework Directive
WoE	Weight of Evidence

1 INTRODUCTION

This report outlines the status quo in legislation, policy and stakeholder activities in the field of toxic substances in articles and non-toxic material cycles. Its aim is to set out various policy options to achieve non-toxic articles and material flows. The study takes an integrated, life cycle perspective and analyses potential shortcomings and opportunities regarding the content of toxic substances in materials and articles from a number of different perspectives, i.e. chemicals management, product design and waste treatment. It also focuses on the availability of information on the content of toxic substances in materials and articles.

The sub-study b on non-toxic products and material cycles is linked to all other sub-studies conducted in the context of the study supporting the development of a non-toxic environment strategy. It outlines these links, together with the crucial intervention points in the life cycle of substances and products to decrease emissions of, and exposures to, toxic substances.

The tasks and objectives of sub-task b are to:

- Outline the effects on human health and the environment of the content of toxic substances in articles and material cycles;
- Identify gaps and deficits in existing legislation, policies, measures and activities of stakeholders preventing the production and use of non-toxic products and the resulting non-toxic material cycles;
- Highlight commonalities and conflicts in the policy, goals and instruments of chemicals, articles and waste both within themselves and in relation to each other, with regard to non-toxic products and material cycles;
- Assess options to tackle the identified gaps and deficits in knowledge and communication on the presence/absence of substances in articles and waste streams;
- Address decision criteria and instruments for sorting/pre-treatment and recycling of end-of-life products in order to obtain clean material cycles at an acceptable cost and effort for all stakeholders;
- Outline short-, medium- and long-term responses (from literature and stakeholders) that would bring benefits and support from at least by some of the stakeholders in more than one of the policy areas.

This sub-study relates to the discussions on the further development of the circular economy, which includes, inter alia, work on the analysis of interfaces between chemicals, articles and waste legislation and options to reduce the presence of toxic substances in articles and material streams.

Three types of issues and challenges can be distinguished in relation to non-toxic articles and material cycles:

- Risks to human health and the environment from the use of toxic substances in articles, and related opportunities to prevent such risks, either by restricting substance uses or by reducing exposure levels through risk management measures;
- A lack of information on the presence of toxic substances in articles and wastes, including a lack of communication;
- Risks and technical challenges related to the decontamination of waste streams from toxic substances by the waste sector.

1.1 OVERVIEW OF THE CURRENT POLICY AND LEGISLATIVE FRAMEWORK

The issue of non-toxic articles and material cycles relates to, and is influenced by, three regulatory

areas: chemicals legislation, articles related legislation, and waste legislation. Each of these legal areas has overarching legislation, i.e. REACH and the CLP regulation (chemicals), the General Product Safety Directive (articles), and the Waste Framework Directive (waste), as well as specific legislation, such as the Biocides Regulation (chemicals), the Toy Safety Directive (articles), the RoHS Directive or the End-of-life Vehicles Directive (waste).

Each legislative area contributes to a framework for the production of non-toxic articles and generation of material cycles free from toxic substances to the greatest extent possible. The following description presents the general approach of the legislation but does not include individual requirements. The main gaps and deficits, i.e. where legislation does not (sufficiently) ensure the production of non-toxic articles and maintain clean waste streams, are outlined in the following section.

Chemicals legislation contributes to ensuring that:

- the **hazardous** properties of substances potentially contained in articles **are identified and that this information is available** to all parties concerned (registration/active substances approval, substance evaluation, SVHC identification and candidate listing, notification of classification, and labelling);
- **unsafe uses** of toxic substances in articles **are identified** via generic risk assessments **and prevented** via the limitations of their use[2] (chemical safety assessment and discouraged uses, biocide product approval for use in articles, communication of binding conditions of use through safety data sheets or article labels, restrictions and authorisation procedures);
- recovered substances and mixtures are placed on the market only if information exists and they are safety assessed. According to REACH, recovered substances must either be demonstrated to similar to a registered one or be registered. Safety information in form of safety data sheets must be provided with recovered materials, if they are classified as hazardous;
- **information** about the presences of **substances of very high concern (SVHC) in articles above 0.1% is available** to everyone handling, using, and regulating articles (REACH Article 33 and Article 7, as well as labelling of treated articles under biocides legislation). The information should be sufficient to enable:
  - economic actors to comply with legal requirements, protect their workers from potential risks during processing, and to consider it in their product design processes;
  - consumers to make informed choices and to potentially avoid articles containing SVHC;
  - regulators to assess and identify risks from SVHC in articles at an aggregated level, and to implement corresponding measures, if necessary.

Articles related legislation contributes to ensuring that:

- **all articles** placed **on the market are safe for human health** during normal and reasonably foreseeable use (General Product Safety Directive);
- **the content of substances** that are **of particular concern** in articles with sensitive exposure potential or with regard to the treatment of waste **are restricted** (specific restrictions, e.g. Toy Safety Directive, RoHS or positive lists (food contact materials));
- information on the **content of certain substances** (e.g. sensitisers in toys) and on **proper disposal of an article** to ensure that it enters the correct waste treatment stream (e.g. electronic devices) **is communicated** to consumers.

This also ensures a level playing field with regard to the content of the restricted toxic substances, given that articles legislation applies to imported and EU produced articles alike.

[2] There may be options to limit exposure through article-integrated risk management measures but it is unlikely either that a registrant will identify this as a risk management measure or communicate it along the supply chain.

Waste legislation contributes to that:

- incentives are created to **prevent hazardous wastes** (waste treatment hierarchy, extended producer responsibility, End-of-life Vehicles (ELV), and Waste Electrical and Electronic Equipment (WEEE)) and to increase recycling of materials (collection and recycling targets);
- **infrastructure and management routines exist to** collect, sort, and **treat large volumes of waste** efficiently, including recycling materials to the greatest extent possible, technically and economically (Waste Framework Directive);
- **hazardous wastes** are identified and related information is used to decide on the appropriate treatment technology, as well as the application of stricter management and documentation requirements (waste classification and related requirements for hazardous wastes);
- **toxic substances** are separated from specific waste streams (i.e. hazardous mixtures from vehicles, batteries) and are either finally disposed of by incineration or landfill.

Use restrictions to prevent toxic substances from entering articles could originate from chemicals, articles, or waste legislation. Chemicals legislation generally takes a top-down view, integrating worker, consumer, and environmental concerns in generic risk assessment and management approaches that cover the entire life cycle. By contrast, articles legislation focuses on consumer health issues and the service life of articles. Existing restrictions triggered by the waste sector, such as those contained in the ELV and WEEE Directives, consider problems encountered during waste treatment that may relate to environmental and health risks, or problems in waste material management and contamination.

Specific requirements to decontaminate waste streams exist only in the ELV and WEEE Directives. In addition, the end-of-waste criteria indirectly imply these provisions by defining the quality of the input and output materials for recycled materials that become a product. However, these criteria apply to very few materials. Due to requirements of chemicals legislation, decontamination of materials may be necessary, if the recycle material should be placed on the market in case substance bans and use restrictions exist (e.g. REACH authorisation, POPs regulation) because these also apply to secondary materials

1.2 RELEVANCE OF THE ISSUE

1.2.1 The production and trade of goods are increasing

The production volume of chemicals and articles are increasing in the EU and at global level[3]. An estimated 35,000 chemicals are on the EU market in volumes above 1 tonne per year, and over 60% (by tonnage) of these are hazardous to human health and/or the environment[4].

The yearly import of manufactured goods to the European Union has almost tripled between 2000 and 2015, including from countries with insufficient regulatory controls over chemicals. In 2016, 3.4 tonnes of products (2.1 raw, 0.4 semi-finished and 0.9 finished products) per capita were imported in the EU. About 20% of these were imported from China (value of € 344.7 billion)[5].
According to Eurostat data, in 2015, products worth more than 3 trillion EUR have been produced and sold within the EU market while during that same period products worth more than 1.7 trillion EUR have been imported into the EU-28 from third countries. A high share of these products are articles in terms of REACH.[6]

Unfortunately, overview information on the total amounts of (specific) toxic substances contained in

[3] European Commission, 1992; European Commission, 2001.
[4] Eurostat, 2015.
[5] Eurostat, April 2017.
[6] Schenten and Führ, 2016

the articles produced or imported in the EU is missing due to a lack of respective statistics[7].

1.2.2 Articles contain toxic chemicals

Hazardous chemicals are contained in a vast array of consumer articles, from clothing, furniture, buildings and infrastructure, electronics and vehicles to tinned food linings, medical devices and toys. A literature overview[8] concludes that studies on the content of substances in articles usually focus on those that are either use restricted, subject to authorisation or included on the REACH candidate list. These publications mostly refer to articles with high exposure potentials to consumers and/or vulnerable groups (such as children). Consequently, textiles, toys and plastic articles are highly represented in these studies, while other articles, such as construction materials or furniture, are less widely discussed.

As no specific information is available, examples of substances and articles illustrating the scale of the problem are provided. All of the substances mentioned in these examples may cause severe damage (CMRs, EDCs or PBT/vPvBs) and are likely to be released from articles, due to a comparably high mobility and a generally loose binding to the matrices they are normally included in.

KemI has estimated the supply of phthalates[9] in a number of article categories for both the Swedish and EU markets[10]. They used consultant reports on the use of the plasticiser DEHP in Sweden, statistical data, and made various assumptions to close information gaps for their estimations. They concluded that the EU production of DEHP fell from 282,000 tonnes in 2007 to 118,000 tonnes in 2012, demonstrating the impact of regulation. They estimated that approximately 120,000 t/y of DEHP are used in the production of articles in the EU. The total amount of DEHP contained in articles that are placed on the EU market (including import) was estimated at 210,000 t/y.

In another study, KemI[11] estimated the use of substances with adverse effects on health in construction products. Forty-six carcinogens were identified in the products analysed, as well as phthalates and endocrine disrupters, of which many are classified as volatile or semi-volatile. Based on information from construction products databases and trade statistics, KemI estimated the amounts of hazardous substances placed on the market in specific construction products (flooring, carpets and panel materials). They concluded that, for example, 36,000 tonnes of the plasticiser DINP[12] is placed on the flooring market in Sweden each year, along with 22,000 tonnes of phenols[13] in wooden panels. Furthermore, styrenes[14] are placed on the market as part of floorings (2,6000 t/y) as well as bisphenol A[15] (2,000 t/y). The release of these substances from construction products could cause or contribute to a considerably high exposure of humans and the environment.

[7] Production and trade statistics mostly relate to trade values rather than volumes; furthermore, information on the composition of articles, which could be linked to volume information, is not available.
[8] Reihlen A., Wirth O., Camboni M., 2013.
[9] Phthalates are used as plasticisers. Many of them are reprotoxic and some are endocrine disrupters. Several phthalates are included on the REACH candidate list.
[10] KemI, 2015.
[11] KemI, 2016.
[12] DINP is increasingly used as a softener in plastics. It has reprotoxic effects but is currently not classified. It is use restricted in childcare articles and toys.
[13] Phenols are a group of substances characterised by an aromatic ring and one or more hydroxyl groups. They are used as reactant of phenolic resins in the production of wood panels. The non-reacted phenols may emit during service life of the panels. Phenols are toxic if swallowed, in contact with skin and if inhaled. They are also suspected of causing genetic defects and damage to organs through prolonged or repeated exposure.
[14] Styrene is a PBT, may cause damage to the inner organs through prolonged or repeated exposure and is suspected of causing harm to the unborn child. It is used to produce polystyrene, which may be included in flooring for insulation purposes. Unreacted monomers may emit during service life.
[15] Bisphenol A is used, among others, to produce polycarbonate. It is an SVHC on the candidate list and has recently been confirmed to be an endocrine disrupter.

The IVM Institute for Environmental Studies[16] analysed the flow of the flame retardants pentaBDE and octaBDE in waste plastics from WEEE, ELV and other plastic wastes in the Netherlands. These brominated biphenyl ethers (BDEs) are listed as persistent organic pollutants (POPs) under the Stockholm convention, hence referred to as POP-BDEs.
Overall, BDEs were found in few individual parts in these waste streams, with the majority being plastic parts from WEEE rather than from ELV. However, in shredded plastics, these POP-BDEs were frequently detected with levels up to 330µg/g. A mass flow analysis for the Netherlands shows that approximately seven t/a of these POP-BDEs reach the waste stage in plastics from WEEE and approximately 0.2 t/a from ELVs. The corresponding material flows are 72,000 t/a from WEEE and 20,000 t/a from ELV.

A recent Swedish market survey illustrates by analogy the variety, number and complexity of products containing hazardous substances (Kemi 2016). Biocides prevent harmful organisms from causing adverse effects on humans, products, animals or the environment, and are hence by definition more or less toxic.
The study searched for articles treated with biocides and identified a wide range of treated articles marketed with a claim such as "antibacterial", including sanitary products, electronic products, kitchen utensils, textiles, leisure equipment, home products, baby products, pet accessories etc. Only 18% of these products were labelled according to the legal requirements, i.e. named the active substance(s) contained in the articles.
A more common situation is; however, that articles contain biocides but no biocidal functions are explicitly claimed. Due to the lack of labelling requirements for these articles, they were much more difficult to identify in the study.
A conclusion of the study is that large quantities of biocides are used, without any knowledge of or information on the active substances and quantities involved as well as what exposure of humans and the environment the use results in.

Further to the content of toxic substances in articles for which no regulation exists, there are also articles on the market, which do not comply with existing restrictions; i.e. that contain restricted substances above the legally defined threshold values. This is evident, for example, from the notifications provided to the RAPEX system. According to the RAPEX database, approximately 25% of all product warnings made by the enforcement authorities are due to the content of toxic substances.[17] Not all of these notifications relate to articles; nevertheless, they concern only a small share of potential risks from articles, as they represent the findings only of those articles, which have been controlled.

These examples show that significant amounts of hazardous substances, including restricted ones, are contained in different materials and articles on the EU market.

1.2.3 Toxic substances in articles may cause damage to human health and the environment

Articles contribute to a continuous, long-term, and low-level exposure to a mixture of different hazardous chemicals that may, individually or in combination, cause damage to human health and the environment. While there are few studies that cover the entire evidence chain of a chemicals-induced damage, i.e. from the content and release of substances from articles to the resulting exposure and observed damage, evidence exists of the individual stages.

Examples of publications that include several stages of the evidence chain are:

- EU risk assessments

[16] Leslie et al., 2013.
[17] European Commission, 2016.

- to justify restriction proposals under REACH[18];
- to identify if substances may be used in food contact materials.

- Risk assessments conducted by Member State authorities, e.g. the
  - Danish Surveys of Consumer Products[19];
  - KemI reports on risks from substances in articles, such as textiles[20] and construction products[21].

The Surveys on Consumer Products by the Danish Environment Ministry identify and discuss the content of, and risks from, substances in consumer products, including articles. Most of these surveys have a similar structure and include a general literature overview detailing those substances that have already been detected or are expected in an article, a description and justification of the substances analysed, the samples purchased and the analytical methods used. The results are presented, showing the concentrations of different substances in these articles. Some studies also include an assessment of risks for the substances in these articles.
Reports on the content and release of substances from articles are also available from the Swedish Chemicals Agency (KemI), as well as Environmental Agencies and Ministries of other EU Member States, such as Germany, or EEA countries, e.g. Norway.
Due to the campaign focus of NGOs, several studies are available on toxic substances in textiles, e.g. by Greenpeace or ChemSec but also for other article types.
There are also databases providing information on the substance content in articles, e.g. under the Children's Safe Products Act in Washington State.

Proof of substances releases from articles is also available from of ample testing results, e.g. migration tests for food contact materials, evaporation studies for construction products, leaching tests for waste classification etc. Generally, these analyses show that substances are released from article matrices and that the extent of emissions varies greatly, both in terms of the materials into which they are integrated and the conditions under which they are used.

There is also evidence of exposure to toxic substances, e.g. from bio-monitoring data, samples from indoor air or substance concentrations in food or water. Information from these sources clearly indicates the presence of toxic substances in the (living) environment and organisms, but does not easily allow tracing the origin of these substances.
In particular house dust presents information on actual exposures, as it accumulates substances emitted from the house's interior, as well as from the indoor use of mixtures. Mitro et al.[22] reviewed recent U.S. studies on the content of several groups of toxic substances in house dust, among others of phthalates and brominated flame retardants, which are mainly used in articles and unlikely to be found in consumer mixtures for indoor use. They conclude that house dust is a reservoir for (toxic) substances, which proves that substances emit from products, including articles, and provides hard evidence for cumulative exposures.

At the waste stage, substances may emit from the material matrices in a manner similar to emissions during service life. In addition, the (potential) destruction of the matrices during recycling processes or final disposal may increase the level of release, either due to an increase of the materials surface area (milling, grinding, shredding etc.) or due to a destruction of the matrix and related bindings of the

[18] ECHA, *Submitted Restriction proposals*; There are 31 submitted restriction proposals, of which 24 include use in articles. Risk assessments conducted under the Existing Substances Programme frequently relate to the uses of substances as intermediates, solvents or in mixtures. The risk assessment reports (RARs) for some substances also cover the service life of articles but these assessments under the former EU chemical policy are less detailed then those conducted in restriction proposals under REACH.
[19] Ministry of Environment and Food of Denmark, *Danish surveys on chemicals in consumer products*.
[20] KemI, 2015.
[21] KemI, 2016.
[22] Mitro et al., 2016

toxic substances. For example, when waste paper is recycled, toxic substances may leach to the pulper and enter waste water.

Workers in the waste sectors handle different types of end-of-life articles and are potentially exposed to the full gamut of substances used in these articles. A Swedish study[23] on the exposure of workers in EEE recycling plants identified high dust levels at the plants. Workplace air measurements and biological data revealed that the workers were exposed to several heavy metals and organic substances, including brominated flame retardants. Combined and cumulative exposures occurred, due to the presence of several (end-of-life) articles and substances (absorbed or integrated into dust).

A research programme by the German Institute for Occupational Health and Safety[24] conducted workplace measurements at different recycling plants (EEE, vehicles, paper, textiles and plastics) and identified significant exposure levels to particles, as well as heavy metals. Apart from demonstrating that risks from chemicals in (end-of-life) articles can – and do - occur, these results stress that the release potential of a substance from a matrix may not always be decisive for worker risks, as the release could occur also with particulate matter from article processing or specific waste treatment processes.

Biomonitoring data show that hazardous substances are present in the human body and in wildlife. Furthermore, several studies have been published with respective evidence of exposure levels of concern.[25]
Unacceptable risks were demonstrated for certain substances in the past and are currently being derived in restriction proposals, such as the existing one for nickel in jewellery or the currently discussed one on PFOA and their precursors, which are used in several article categories.

The combined exposures giving rise to risks of harm to human health are documented for some substances in human biomonitoring studies. These indicate the occurrence of a growing number of different hazardous chemicals in human blood and body tissue including pesticides, biocides, pharmaceuticals, heavy metals, plasticisers and flame retardants. The concentration of these substances in the human body is linked to health damage, in particular if exposure occurs pre-natal (e.g. Govarts, 2016; Hass, 2017; Danish EPA, 2017).

In conclusion, there is evidence of the content of toxic substances in article, there is evidence indicating that they are released during service life and the waste stage, there is evidence of exposure levels of concern in humans and the environment from (bio)monitoring data and there is evidence of adverse effects of chemicals to human health and the environment.

A comprehensive and fully proven chain of evidence between the content of toxic substances in articles, their emissions, the exposure levels and a damage to human health or the environment is difficult to establish. This is due to the numerous factors determining the exposure levels and effects of toxic substances, including exposures from sources outside a study design or empirical assessments as well as and combination effects with other substances.

The low number of proven, comprehensive chains of evidence should not be interpreted as proof of the absence of risk from substances in articles. In contrast, the available evidence indicates a need for action and resources may rather be invested in prioritising action areas than gathering further proof of risks.

[23] Julander et al., 2012.
[24] Hebisch R. and Linsel G., 2012.
[25] Govarts et al., 2016; Hass U., et al., 2017 or Danish EPA, 2017

1.2.4 Toxic substances in articles may undermine the goals of a circular economy

Chemical contaminations of articles may hinder recycling and present new, unexpected exposure situations if contaminated recycled materials are used in products for which the use of included substances are not foreseen. While problems from toxic substances in article wastes can partly be addressed by preventing their inclusion in new articles, long-lived products may contain and hence re-introduce legacy chemicals into secondary materials. The elimination of toxic substances from material cycles may take a long time. The core concerns are that the content of toxic substances in waste materials may:

- cause risks to the environment and workers during waste processing (c.f. Section 1.2.3);
- lead to unforeseen consumer exposure situations during a second service life;
- remain in the material cycles for a long time, in particular if used in articles with long life-spans and
- contribute to a decreased quality of waste materials, resulting in downcycling of materials (or thermal recovery).

Articles entering the waste stage are diverse in their composition, including their toxic substances content. While this is obvious for different article types, difference may occur for the same article type but from a different producer and may even significantly differ for the same articles manufactured by the same producer, if he changes the design, e.g. due to new legislation.

The sheer variety of articles causes challenges for sorting and separate treatment, which is a precondition for decontaminating material cycles. Furthermore, the waste volumes increase, with a time lag, with increasing volumes of articles (c.f. Section 1.2.1). However, the increase in waste amounts treated in the EU does not necessarily correspond with the volume of goods used in the EU, because several types of articles are exported as well as particular (waste) materials they are composed of.

Recycling of materials from end-of-life articles (and sometimes also processing conducted to enable the reuse of an article), may involve shredding and other (intense) mechanical processes. This may lead to the formation of dust[26] during waste treatment, which may cause risks to workers (c.f. Section 1.2.3). In addition, recycled materials may have an increased surface area as compared to the virgin material/article giving rise to higher substance releases during the second/further service life. For example, if mineral wastes are crushed and used in path construction, the surface area available for leaching to the ground from rainwater is increased.

There are studies available providing evidence that toxic substances are re-introduced into articles made from secondary raw materials. These second service lives may lead to critical exposure levels, in particular if the "new" uses differ from the original ones.

The IVM Study[27] (c.f. above) analysing the flow of pentaBDE and octaBDE in waste plastics shows that 22% of the POP-BDEs recovered with materials from WEEE and 14% recovered from ELVs end up in recycled plastic materials. In addition, 19% of the POP-BDEs are included in vehicles as second-hand parts (reuse).

The IVM also identified POP-BDEs in some new products from recycled plastics, all of which were produced outside the EU. The authors conclude POP-BDE-containing recycled plastics re-enter the EU via products containing these recycled plastics. However, the levels of POP-BDEs in products were stated to be lower than in the early 1990s, indicating some success for the relevant policies. Nevertheless, the example also shows that banned substances will prevail in waste streams and recycled

[26] EU Commission, JRC, 2015.
[27] Leslie et al., 2013.

materials for a long time.

Another study found that brominated flame retardants are included in thermos cups, which are made from recycled plastics[28].

Toxic substances in articles and materials may remain in the material cycles for a considerable time, even if measures are taken to prevent their use or to decontaminate waste streams.
Pivnenko et al.[29] modelled the concentration of Bisphenol A, diethylhexyl phthalate (DEHP) and mineral oil hydrocarbons (MOHs) in recycled paper over time. They identified the conversion process as the main source of (toxic) chemicals in paper products, for example the printing and gluing processes. The models used for the analysis are based on information on paper flows, their chemical content and transfer factors for different recycling processes, which were collected from public sources, industry associations and independent research. Three scenarios were modelled to identify the most effective waste management option. Preventing the input of these substances proved to be most effective, although it resulted in a time lag of up to 30 years for full removal of the substances from the waste streams. Better decontamination technologies, as well as better separation of paper streams (avoidance of recycling of contaminated papers) showed some effect but markedly less than the preventative approach and at the cost of recycled volumes (lower recycling rates). The study shows that toxic substances could also occur in materials originally regarded as comparatively free of them, and that related decontamination scenarios take time to show effects.

A decrease in the quality of recycled materials as compared to virgin materials could result from the (accumulating amounts of) contained toxic substances. For example, toxic substances may accumulate in polymers if it is not possible to "reuse" the contained additives in the recycled materials, due to a lack of knowledge on the material composition. Then, new additives are introduced at each new cycle, regardless of the residual content of additives used in earlier cycles. The extent to which this accumulation may lead to a decrease in technical quality and an increase in exposure levels has not yet not been systematically assessed.

Problems with recycled materials associated with the content of toxic substances in articles are particularly relevant because of the current weaknesses in end-of-life product management; i.e. the fact that different materials are frequently mixed rather than being kept separate, contaminating 'clean' material streams. In the case of construction and demolition waste, insufficient sorting 'at source', together with a lack of selective demolition or controlled deconstruction, results in a contamination of 'clean' materials streams, hereby keeping the contaminated materials, which could/should be phased-out in the materials loop[30].

1.2.5 Little information if available on the content of toxic substances in articles

Information about the content of toxic substances in articles is largely missing, both for specific articles and at a general level. This lack of data renders it extremely difficult for regulators to carry out overall risks assessment, determine the scale of risks, and to choose regulatory risk management measures. In addition, economic operators and consumers lack data to make informed choices about how to avoid toxic substances in articles or to protect themselves against potential risks. Finally, waste treatment operators lack information that would help them identify end-of-life articles that, due to their content of toxic substances, should be separated from materials intended for recovery in order to prevent contamination of recycled materials.

The collection of information on toxic substances in articles (within supply chains and at EU-level) is

[28] Samsoneka, 2013.
[29] Pivnenko et al., 2016.
[30] BIO IS, 2011.

challenging. The complexity of individual articles makes estimating or measuring the content of toxic substances an extensive task. There is a large number of (different) articles on the market, which are produced by sometimes very complex, dynamic and global supply chains that fall under different legal requirements. Few requirements exist to communicate information on substances in articles to authorities and/or centralised databases as well as to and within the waste sector. The information gap between articles and wastes determines the lack of information on the composition of secondary raw materials.

Most articles consist of a number of different materials which themselves include a large number of chemicals that constitute their matrices, such as polymers or metals. Chemicals may also be included as additives to provide a particular functionality to a material, such as flame retardance or general stability. They may also be present as contaminations from the production process. The possible combinations of chemicals in articles and complex objects are infinite.

The supply chains of many articles are complex and frequently include economic actors from different regions of the world. In addition, supply chains are not static over time, but change dynamically depending on prices and product availability. The various supply chain actors may have to follow different legal requirements, which may result in a lack of a legal basis to request information on substances in articles.

Due to the large number and variety of substances that could be present in articles, their identification via chemical testing is cumbersome and costly. Therefore, it is normally used to verify a suspicion rather than as a standard routine.

Another aspect hindering communication on substances in articles are confidentiality concerns. Due to fear of losing sensitive business know-how on (innovative) uses of substances in materials and articles, the economic actors frequently communicate as little information as possible. Sometimes this is even less than legally required or than is necessary to assess potential risks from hazardous substances in articles for workers, consumers or the environment.

The insufficient communication in the supply chains is one of the causes for a lack of overview data on the content of toxic substances in articles, as well as on their release potential from articles (i.e. how they are integrated into article matrices, under which conditions articles are used etc.). However, the main reason for the lack of such data are the very limited provisions requiring the submission of information on hazardous substances in articles to authorities, such as under REACH Article 7(2).

The lack of information on substances in articles in the supply chains carries over to the waste sector. In addition, the waste sector lacks information on the substance content of (end-of-life) articles because only few legal and practical mechanisms are in place to create such information flow from article producers. The existing requirements and mechanisms are part of the "extended producer responsibility" for EEE and vehicles. Finally, the chemical composition of waste articles may differ from that of the articles placed on the market, for example due to chemical reactions during service life (intended or unintended), weathering or aging (contact with oxygen or sunlight) or modifications during the use-phase (e.g. renovation or repainting of buildings).

Within the waste sector, no information on the content of toxic substances in waste streams are communicated. Instead, waste codes are assigned according to the EU list of waste, which identify the hazardousness of a waste. The substance categories PBT/vPvB and POPs, which may be particularly relevant for risks from articles and article wastes as well as "persistence in material cycles", are not specifically considered.

In summary, due to the complexity of the production and disposal of articles, the related (supply chain) management and a lack of respective requirements, the information flow along the supply chains and to the authorities is insufficient for risk assessment and risk management. The communica-

tion problems are enhanced by a lack of related, globally harmonised communication standards as well as language and cultural barriers.

The lack of quantitative and qualitative knowledge regarding the actual content of hazardous chemicals in articles and resulting exposures hinders efficient priority setting, risk assessment and risk management by authorities and provides little incentive for substitution and development of less toxic products within industry.

1.2.6 Risk assessment insufficiently addresses toxic risks from articles

Another aspect of non-toxic articles and material cycles are related to risk assessment methodologies. Criticism on the methodology regards a lack or insufficient consideration of:

- specific hazardous properties, such as endocrine disruption or neurotoxicity;
- the large variety of emission sources, including different types of articles;
- combination effects from simultaneous exposures to several substances, including internal exposures;
- low-level long-term exposures, which are typical for some (substances in) articles and
- exposures from substances recovered from waste and entering a second and further service lives

Assuming that substances are released from materials/articles, and knowing that they are used in a variety of products, it follows that in most cases several emission and exposure sources of one individual substance exist. While there are mechanisms in EU regulatory risk assessment to take account of the total exposures from all potential sources, these cannot be applied to the full extent due to the lack of information on the use of substances (c.f. above) and are regarded as not conservative enough.

Currently, none of the available risk assessment methodologies considers all of the above-mentioned points of criticism but some consider aggregated and cumulative exposures.
While assessment methods developed at a workshop of the WHO/IPCS[31] or one by the US EPA[32] include an approach for aggregated and cumulative exposures from all emission sources, these appear to be understood as production processes and the use of mixtures, rather than exposures from articles.
In the REACH chemical safety assessments, aggregated exposures should be considered for consumers and the environment (i.e. regional and continental background concentrations). Furthermore, substance evaluations should address related concerns[33]. Risks from cumulative exposures are not considered under REACH.

The REACH restriction proposal on phthalates by ECHA and Denmark[34] is based on a risk assessment showing potential risks for consumers from exposure to four phthalates with similar modes of action from numerous sources in the indoor environment. It also shows that substances may emit from articles over the entire product life cycle and that exposure could remain even after the article is removed from the indoor environment via contaminated house dust.

Several studies on mixture toxicity identified human health effects of substances acting in combination, where the individual exposure levels were below their effect thresholds. For example, one study[35] analysed challenges and approaches to the assessment of aggregated and cumulative exposures, with several endpoints and internal exposure levels. In the introduction, several studies are quoted that identify effects from combined exposures of substances present in individual concentrations below their

[31] Meek et al., 2011.
[32] U.S. EPA, *Exposure Assessment Tools by Tiers and Types - Aggregate and Cumulative.*
[33] ECHA, 2014.
[34] ECHA, 2016.
[35] Silins et al., 2011.

effect thresholds. Other studies highlight that continuous, low-level exposures to a mixture of chemicals and can constitute a continuous stressor for humans and the environment[36].

A new section on the internet portal hosted by the Danish National Food Institute covers information on the mixture effects of chemicals, including evidence of small doses of chemicals in combination having toxic effects[37].

1.2.7 Conclusions on the scale of problems

The number of possible combinations of (toxic) substances, matrices and applications in articles as well as related waste treatment options is very high. Each of these combinations has specific characteristics with regard to the release of substances, making general statements on 'the risks' from toxic substances in articles and materials impossible. However, it is evident that any reduction in the use of toxic substances in, and the complexity of, articles would reduce the overall toxicity of articles and material cycles and thus reduce the related risk, including from combined exposures.
In conclusion, the issue of 'chemicals in products and non-toxic material cycles' is relevant to the strategy for a non-toxic environment as:

- Many hazardous chemicals are used in the production of articles, with an overall increasing global production volume of manufactured goods indicating an increase of the problem scale
- There is ample evidence that chemicals are emitted from articles during and at the end of their service life, resulting in exposure levels of concern that could cause damage to human health and the environment
- Resource shortage and the goal of closing material cycles require (better) management and communication on articles and wastes.

1.3 DEFINITIONS AND USE OF TERMS

This sub-study uses the term 'toxic substance' to refer to substances which:
- fulfill the criteria for classification as hazardous to human health or the environment according to the EU Classification, Labelling and Packaging (CLP) Regulation (hazardous substances); and/or
- fulfill the criteria as persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to the Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Annex XIII; and/or
- have any other properties of similar concern to human health or the environment.

The terms used here are the legal definitions under REACH and the Waste Framework Directive (WFD). For REACH, these are - in particular - the terms substance[38], mixture[39] and article[40].
Under the WFD, these are, particularly, the terms waste[41], hazardous waste[42], waste management[43],

[36] Kortenkamp et al., 2007; Ashford, N. and Miller, C., 1998.
[37] Chemical Watch, 2016.
[38] REACH Article 3(1): 'substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition'.
[39] REACH Article 3(2): 'mixture: means a mixture or solution composed of two or more substances'.
[40] REACH Article 3(3): 'article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition'.
[41] Waste Framework Directive (WFD) Article 3(1): 'waste means any substance or object which the holder discards or intends or is required to discard'.
[42] WFD Article 3(2): 'hazardous waste means waste which displays one or more of the hazardous properties listed in Annex III'.

reuse[44], recycling[45] and disposal[46].

The term 'product' is used in its economic context, meaning anything placed onto the market by a company. It therefore covers substances, mixtures, primary and secondary raw materials and articles.

The term 'material' refers to substances and mixtures or waste streams from the perspective of the circular economy. This includes virgin or primary materials, which originate from natural sources or synthesis, and secondary materials, which originate from recovered waste.

The term 'aggregated exposure' addresses situations where a total exposure level to a single substance stems from several sources. The term 'cumulative exposure' is where several substances from several emission sources are present, creating exposure to a mixture.

1.4 SCOPING AND WORK FOCUS

The sub-study focuses on articles as defined under REACH Article 3(3)[47], as the information provision and content of chemicals in articles is less regulated than that of substances and mixtures. Chemicals legislation covers mixtures (chemicals products including two or more chemical substances) and includes comprehensive provisions on the information flow on toxic substances. By contrast, the content of, and information flow on, toxic substances in articles is less well regulated and poses more challenges for non-toxic material cycles.

The analysis of the status quo and policy instruments does not focus on substances with any particular properties but, rather, assumes that addressing 'toxic substances' generally is sufficient for the identification of gaps, deficits and remedial options.

As the sub-study focuses on toxic substances in articles and material cycles, issues to do with wastes that contain toxic substances are addressed here. This includes considerations on separating wastes contaminated by toxic substances from those that contain no such substances. Energy recovery or saving critical resources from recycling is outside the scope of this study, as is production wastes (e.g. galvanic sludge), with the focus instead placed on post-consumer waste.

Substitution is the most profound and comprehensive measure to eliminate toxic substances from articles and material cycles. The study thus aims to identify available tools to promote the prevention of toxins in articles (and thereby material cycles). However, as it may not be feasible in the short-term (or indeed possible in the long-term) to avoid the use of toxic chemicals in some applications (for example because their functionality is linked to certain hazardous properties (e.g. persistence)), the report also identifies tools to reduce emissions from articles and material cycles.

[43] WFD Article 3(9): 'waste management means the collection, transport, recovery and disposal of waste, including the supervision of such operations and the after-care of disposal sites, and including actions taken as a dealer or broker'.
[44] WFD Article 3(13):'reuse means any operation by which products or components that are not waste are used again for the same purpose for which they were conceived'.
[45] WFD Article 3(17): 'recycling means any recovery operation by which waste materials are reprocessed into products, materials or substances whether for the original or other purposes. It includes the reprocessing of organic material but does not include energy recovery and the reprocessing into materials that are to be used as fuels or for backfilling operations'.
[46] WFD Article 3(19): 'disposal means any operation which is not recovery even where the operation has as a secondary consequence the reclamation of substances or energy. Annex I sets out a non-exhaustive list of disposal operations'.
[47] REACH Article 3(3): 'article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition'.

2 CONTEXT OF THE STUDY

2.1 THE GLOBAL CONTEXT

The EU strategy for a non-toxic environment, including issues related to non-toxic articles and material cycles, is implemented in the context of the Global Sustainable Development Goals, which were first discussed and agreed at the Global Summit for Sustainable Development in Rio de Janeiro in 1992. Chapter 19 of the agreed action ('Agenda 21') contains cornerstones for the safe use of chemicals, including basic chemicals management elements such as hazard assessment, classification and labelling, information exchange on hazards and risks, and risk reduction measures. In 2002, the global community agreed to minimise the adverse impacts from chemicals on human health and the environment by 2020. Agenda 2030, the most recent policy commitment on the Global Sustainable Development Goals, reiterates its commitment to the safe use of chemicals and minimisation of adverse impacts.

In 2006, the International Conference on Chemicals Management confirmed these same goals, creating the Strategic Approach to International Chemicals Management (SAICM) to support their achievement. SAICM should interlink and coordinate activities for the improvement of chemicals management at global level, including the identification of gaps and deficits and the implementation of actions to close these gaps. SAICM should also enhance the implementation of international chemicals conventions.

The SAICM's Overarching Policy Strategy (OPS) reiterates the importance of reducing chemical risks and impoving knowledge and information on chemicals. The latter objective is specified in point 15:
'(b) To ensure, for all stakeholders: (i) That information on chemicals throughout their life cycle, including, where appropriate, chemicals in products, is available, accessible, user-friendly, adequate and appropriate to the needs of all stakeholders. Appropriate types of information include their effects on human health and the environment, their intrinsic properties, their potential uses, their protective measures and regulation.'

The Global Plan of Action accompanying the OPS also requests that all articles be accompanied by relevant information for users, workplaces and disposal sites. In this regard, a need for better communication on substances in articles (and wastes) was identified at global level ('emerging policy issue' under SAICM). In response, the Project 'Chemicals in Products' (CiP) was initiated which is working to identify issues and develop potential solutions to these issues.

2.2 INFORMATION NEEDS IN THE SUPPLY CHAIN

The role of information in respect of substances in articles and material cycles cannot be underestimated, as it is a crucial aspect of identifying risk management needs and subsequently implementing them. Due to the high number of substances, mixtures and articles on the market, as well as the resulting secondary material and waste streams, information management is necessary for efficient and effective chemicals management, as well as implementing a circular economy. Increasingly globalised trade and related movement of goods add challenges to information management, as different legislation applies and cultural differences in communication must be integrated.

While particular stakeholders may have specific information needs, some are generally applicable along the supply chain. These can be regarded as 'universal', as they stem from the understanding that any economic actor should be responsible for worker safety, the environmental protection related to article production, and the safety of their products for consumers. The relevant information needs are not specific to any legal requirements, therefore, but may be expressed in various pieces of legislation.

Generally speaking, information on the content of toxic substances in input materials allows economic actors to make an informed choice about their raw materials supply and to assess whether or not the toxic substances could cause risks for their workers, the environment or consumers. Quantitative risk assessments are only possible if the amount or concentration of these substances is known, as well as information on substance hazards. However, as much of this information is publicly available it does not necessarily have to be provided along the supply chain. Finally, information on the release potential of substances from articles may be necessary to enable risk assessments to be carried out. The actual need is case-specific and depends on the conditions of use, the toxicity of the substance concerned, etc.
In principle, all actors could be made aware of the potential risks and necessary risk management measures from substances in articles if these types of information were made available. While it is actually provided in the supply chain for chemicals, similar information on amounts, release potential and/or hazards is not usually provided for articles and is almost completely absent for waste.

Those further down the supply chain frequently have less awareness and knowledge of chemicals than those active in the chemicals sector. In view of the request that information be '*user-friendly, adequate and appropriate to the needs of all stakeholders' (*c.f. OPS, Section 2.1) greater aggregated and practical information is needed for downstream users, the waste sector and consumers. Decisions on the appropriateness and adequacy of information depends on the sector, the use of substances and articles, and the knowledge and capacities of the users and consumers, and is disputed between the different stakeholder groups, in particular with regard to consumer information (e.g. the discussions at the Stakeholder Workshop carried out as part of this project).

As indicated by Beatrice Kogg and Åke Thidell[48], there are information needs beyond those of chemical hazard and release data, such as the identification of product producers up the supply chain to enable traceability, supply chain information to identify production pathways or responsibilities in the product chain, as well as information on safe handling and precautionary measures. While this information may have different purposes, contexts and aims, it is not essential to the implementation of chemicals risk management for articles and material cycles.

The waste sector, particularly when implementing recycling processes, has a specific need for the 'location' of a substance in a (complex) article, in order to separate article / material streams prior to processing, and to control the flow of those (toxic) substances, which could cause risks in their second life cycle. These may manifest in financial business risks, as has been shown in product recalls. In addition, workers in recycling installations may be exposed to toxic substances in wastes during sorting or shredding processes. Enabling risk assessment at workplaces and designing appropriate risk management measures for these workers would also require (more/better) information on the substance content in wastes.

The information needs and flows along the substance life cycle is described and discussed further (including communication instruments and their legal basis in the EU) in Section 3.3 of this report.

[48] Kogg, B. and Thidell, A., 2010.

3 OVERVIEW OF THE STATE OF PLAY OF THE SUB-STUDY AREA

To accommodate the complexity of the sub-study area, different perspectives are presented here, starting with some specific cases on the content of toxic substances in articles and material cycles, and then followed by a general view of the life cycle of substances, materials and articles. The most relevant intervention points are identified, together with the legal instruments currently in place to regulate the content of, and information on, toxic substances in articles and material/waste streams, as well as policy measures and stakeholder activities working towards a non-toxic environment.

3.1 CASES OF THE CONTENT OF TOXIC CHEMICALS IN ARTICLES/WASTES

Three main cases of toxic substances' origins in articles / material streams are presented, each with different levels of information available on the substance content.

Case 1) Intentionally added toxic substances
Toxic substances are added to the production of materials and (as constituent of materials) into articles, because they fulfill a specific function in the (raw) material, the semi-finished or finished (complex) article, or in the production processes. The presence of these toxic substances is thus intended and the relevant information is, in principle, available in the supply chain. This includes residues of processing chemicals in the (final) article. The degree to which the different actors actually generate and collect this information, communicate it along the supply chain, and make it available to consumers and/or authorities differs depending on the substance hazards, the material and product type, the legal requirements and the respective policies of the actors, as well as the type and complexity of the supply chain (e.g. if it involves suppliers in several countries acting under different jurisdictions).

Case 2) Toxic substances as contaminants
Toxic substances may also be included in products as contaminants, principally from two sources:

- Impurities in the intentionally used substances and (secondary) materials that are included in the products or used in the processing aids.
- Residues from (production) processes or caused by contamination from the manufacturing of other products using the same machinery or production facility (this has been reported for PFCs in textiles), contaminations from transport (e.g. biocides used in transport containers) or from packaging (e.g. printing inks migrating through the packaging materials).

The types and concentrations of toxic contaminants may vary greatly for different product types but also within the same group of products. This depends on the contamination sources and the scale of variations between supply chains and production pathways. The content of toxic contaminants in products is normally unknown and is researched only upon suspicion of irregularities, and/or where restrictions exist.

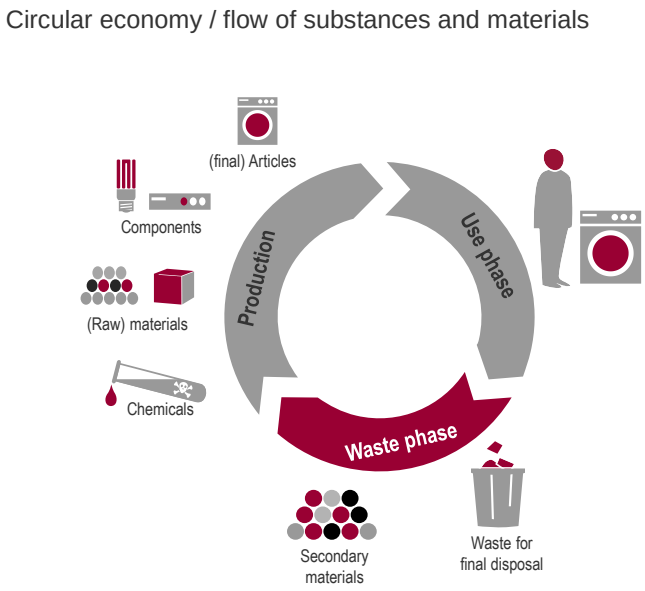
Case 3): Toxic substances in wastes
In contrast to the first two cases, article wastes are not homogenous but are normally composed of, or originate from, a number of different article types from different producers and with different use histories. Substances in these end-of-life articles may have been intentionally added, may have entered them as contaminations or may even have been added during the article service life.
Due to the non-homogeneous composition of wastes not normally easily miscible, it is difficult to identify the content of toxic substances in post-consumer article wastes, with some exceptions in the

area of plastic recycling[49].
If waste streams are subject to recycling, the waste treatment operators can be regarded as manufacturers of substances and mixtures or as article producers, thus being required to fulfill the applicable requirements to place their products on the market, e.g. classification, labelling and communication of all substances present in their products (substance/mixture/article).

3.2 OVERVIEW OF THE FLOW OF (TOXIC) SUBSTANCES

Figure 1 depicts the flow of chemicals in articles and materials streams and illustrates the scope of this sub-study of the Non-toxic Environment Study. Chemicals and raw materials are used to produce articles, which are discarded as waste at the end of their service life. Wastes could be disposed of or entered into recovery and reuse processes, which may entail the collection, separation, decontamination and recovery of materials or articles and their components (which may also be articles). They are reintroduced into the life cycle as secondary raw materials, reusable articles, or article components.

Figure 1: Flow of (toxic) chemicals in articles and material streams



The use of substances and mixtures, as well as their addition to materials and articles, falls under chemicals legislation. The placing of articles on the market may be affected by such legislation (e.g. REACH Article7, Article 33, Annex XVII), by product legislation (e.g. Toy Safety Directive (TSD)), or by waste legislation (e.g. Directive on End-of-life Vehicles (ELVD)). Waste legislation applies to all end-of-life articles and materials falling under the definition of 'waste' and all processes undertaken for their treatment, until the waste starts being a product (mixture/materials/articles) again (reuse or recycling) or is finally disposed of (incineration, landfill). Intervention points to manage the content of toxic substances in articles and material cycles exist at the 'entry' to and 'exit' from each life cycle stage.

[49] An exception may be very homogeneous waste streams from specific collection systems, e.g. in the area of food packaging; here, too, however, the probability of the content or absence of certain substances can be determined but certainty can only be obtained by measuring. Due to the non-homogenous nature of wastes and the large products they may contain, it may be difficult to make representative measurements of substance contents.

3.3 OVERVIEW OF THE FLOW OF INFORMATION ON (TOXIC) SUBSTANCES

The registration under REACH requires that registrants compile information on the toxicity and ecotoxicity of substances. Data generated under REACH is also used under the CLP Regulation to classify and label substances. Classification and labelling information is communicated via product labels or in safety data sheets (SDSs) along the supply chain. However, these requirements apply only to substances and mixtures, but not to articles.

REACH defines the requirements for providing and compiling SDSs for substances and mixtures (REACH Annex II). Substance information must be included where specific concentration thresholds are exceeded, either for the hazardous property generally or specifically for a single substance. Information on substances below these concentration thresholds are not included in the SDSs for mixtures, and are not communicated along the supply chain[50].

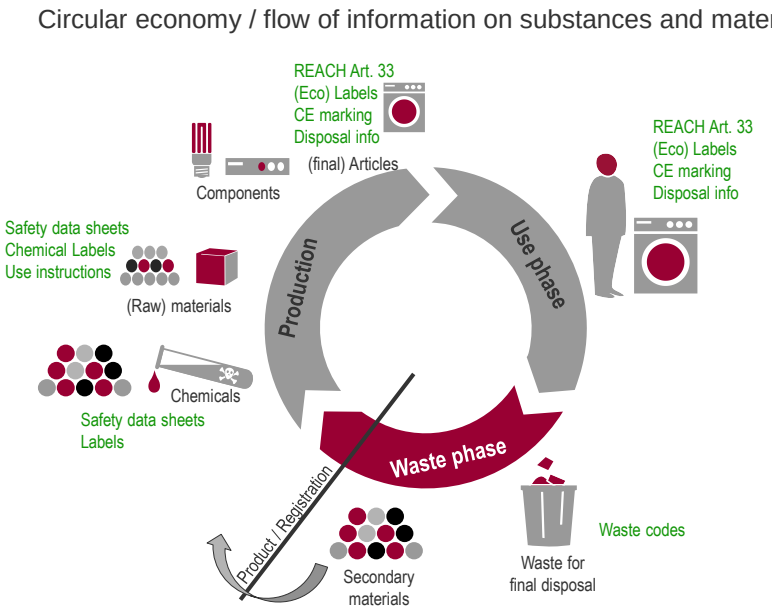
For articles, information on SVHC according to REACH Article 57 (as identified under REACH Article 59 (CLS)) must be communicated along the supply chain if their concentration exceeds 0.1% in that article. Information on biocide active substances used to treat articles must be provided on the product labels under certain conditions (Article 58(3) Biocides Directive). Information on the substance content in articles may be provided indirectly, e.g. if CE labels are applied or products have an ecolabel[51].

Wastes are classified according to the EU List of Waste (LoW), which differentiates between waste origins, waste types and potential hazardousness (mirror entries with an asterisk). Information on the content of hazardous substances may be used to identify a relevant waste code, but this is often not the case for article wastes. Consequently, in many cases, no information is provided on the substance content in end-of-life articles. Figure 2 gives an overview of the possible information flows on toxic substances along the entire life cycle.

[50] Information on the presence of classified substances in non-classified mixtures is 'lost' as no SDS is required. Similarly, information on the presence of classified substances included in mixtures in concentrations below the threshold for identification in classified mixtures is 'lost' because the substances do not have to be named in section 3 of the SDS (composition information) of mixtures.

[51] All EU ecolabels exclude, at a minimum, the presence of REACH candidate list substances.

Figure 2: Information flow with (toxic) substances in the article and waste chain



3.4 CHEMICALS LEGISLATION

This section summarises the main article and waste related requirements of chemicals legislation. While the fitness check of chemicals legislation considers a very wide range of (downstream) legislation, this sub-study examines only the most relevant legal acts. This is because only requirements affecting either affect the actual content of substances in articles (and related wastes) or the information flow on substances in articles, are relevant here. Pesticides legislation, for example, is not included because this group of mixtures is not used to produce articles.

The focus of this section is to identify gaps and deficits, as well as relevant stakeholder activities related to chemicals legislation that relate to the goal of non-toxic articles and materials cycles.

3.4.1 Overview

The following legislation is relevant to the production of non-toxic articles:

- REACH[52];
- Regulation on classification, labelling and packaging (CLP)[53];
- Regulation on Persistent Organic Pollutants (POPs Regulation)[54];
- Biocidal Products Regulation (BPR)[55].

Legislation on mixtures is considered if it is relevant for the content of toxic substances in articles and/or for information transfer in the supply chain.

[52] REGULATION (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.
[53] REGULATION (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
[54] REGULATION (EC) No 850/2004 on persistent organic pollutants and amending Directive 79/117/EEC.
[55] REGULATION (EU) No 528/2012 concerning the making available on the market and use of biocidal products; the BPR includes provisions for substances and mixtures, as well as articles in general, and is also considered part of the product safety policy area.

Chemicals legislation covers the manufacture and import of substances and mixtures, their placing on the market, their use (including article production), and communication in the supply chain for substances, mixtures and CLS in articles (Article 33 and Article 7(2)). Chemical safety assessments (CSA) must cover article service life and the waste stage, if appropriate. Chemicals legislation applies to both secondary materials and articles produced from waste and those that ceased to be waste. This imposes an obligation for recyclers to register recovered substances[56] or, if they produce articles, to comply with REACH Articles 7 and 33. Substances recovered from wastes may also be subject to the restriction and authorisation process.

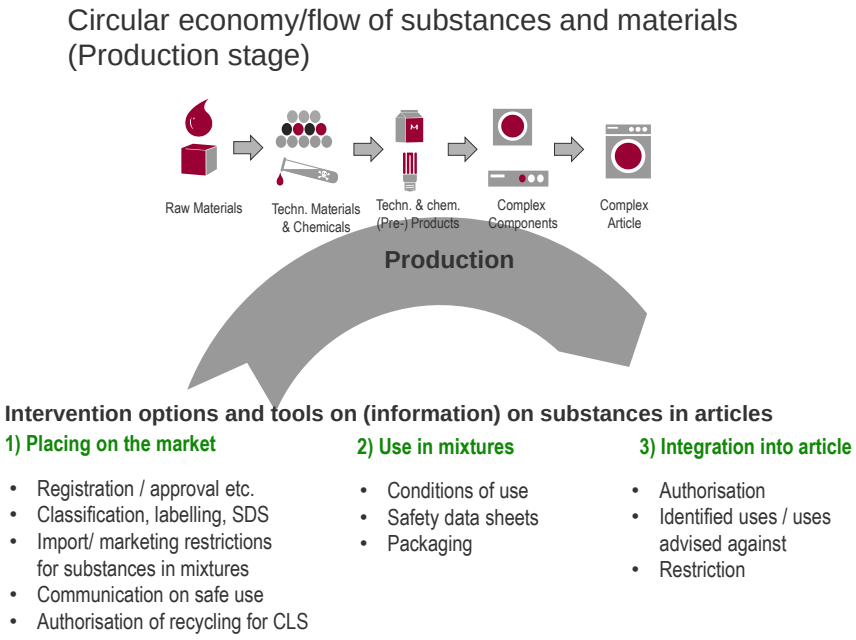
The following types of instruments exist in chemicals legislation to regulate the content or communication of toxic substances in articles, including secondary raw materials or articles produced from wastes:

- Registration/application for approval: actors may only manufacture/place on the market substances for which hazards have been identified and safety is demonstrated for all uses and along the entire life cycle (e.g. REACH registration, approval/authorisation under the BPR). Chemicals legislation thus ensures the availability of an information basis for chemicals management and, to a certain extent, prevents unsafe uses (e.g. non-approval for use in articles under BPR; use advised against under REACH) that have been identified 'top-down'.
- Classification: rules and obligations on the generation, interpretation and translation of hazard data into standardised communication on chemical properties (e.g. CLP Regulation, REACH Annex XIII) ensure a common language on chemicals along the supply chain.
- Labelling and SDSs: formats and requirements for communication on (the safe use of) chemicals in the supply chain (e.g. REACH Articles 30, 31 and 32; REACH Annex II, CLP Regulation), including for (substances contained in) mixtures are well-established and legally defined.
- Classification, labelling and SDSs of mixtures: classification, labelling and communication rules for mixtures are also relevant for secondary raw materials such as recycled plastics as soon as they enter the market as products. This is because they then fall under chemicals legislation. Recyclers of plastics, for example, must therefore classify and label the polymer before it is placed on the market and provide SDSs, if required.
- Marketing and use restrictions: bans and restrictions on the import, manufacture, use and placing on the market of substances individually, in mixtures and in articles (e.g. POPs regulation, REACH Annex XVII, BPR) directly limit the presence of toxic chemicals in products.
- Authorisation: a substance on REACH Annex XIV may only be used (for the production of articles in the EU) if authorisation is granted. Authorisation therefore directly influences the content of toxic chemicals in products and processes (e.g. REACH, BPR), although it cannot limit the content of (toxic) substances in articles produced outside the EU.
- Binding conditions of use: information on the uses of substances - including conditions on their application - are generated and communicated by the market actors (e.g. REACH exposure scenarios, uses advised against, conditions prescribed in authorisations and restrictions, conditions of biocidal product authorisations). This influences both risk management and the exposure levels of humans and the environment to chemicals. It may also limit the number/type of users/uses. Conditions of use may indirectly influence the content of substances in articles (e.g. uses advised against).
- Enforcement: Member States are required to enforce all legal provisions of chemicals legislation, ensuring compliance and implementation of all provisions.

Figure 3 illustrates the intervention points of the legal instruments in the life cycle.

Figure 3: Legal instruments relating to substances for use in articles

[56] An exemption exists for recovered substances in Article 2.7(d).



3.4.2 Instruments and tools of chemicals policy

Table 1 provides a list of regulations, including those instruments outlined above. The first column indicates the number of the intervention point shown in Figure 3, the second specifies this intervention point, the column 'legislation' indicates the legal act containing an instrument, while the final column briefly describes how the legal instrument is designed in that legal act.

Table 1: Examples of the influence of legislation on chemicals on the content of, or information on, substances in articles/materials

#	Possible intervention point	Legislation	Instrument and content relevant to toxins use in articles and communication
1	Manufacture of substance as such or in mixtures	REACH	Registration of substances above 1 t/a; chemical safety assessment (CSA) if above 10 t/a, exposure assessment if classified as hazardous or PBT/vPvB; provision of (e)SDS Registration of substances as such or in mixtures from recycling processes (possible exemptions), provision of SDS for hazardous substances or mixtures, labelling
		CLP	Classification and labelling (C&L); notification to C&L inventory for virgin substances and/or substances as such and in mixtures recovered from wastes
		BPR	Approval of active substances for use in biocidal products after review of approval dossier, classification and provision of SDS for hazardous substances and mixtures, labelling
	Import of substance as such or in mixture	REACH	Registration of substances above 1 t/a; CSA if above 10 t/a, exposure assessment if classified as hazardous or PBT/vPvB; provision of (e)SDS for hazardous substances or mixtures, labelling
		CLP	Classification and labelling of substances and notification to C&L inventory; classification and labelling of mixtures including secondary raw materials
		BPR	Approval of active substances for use in biocidal products after review of approval dossier, classification and provision of SDS for hazardous substances or mixtures, labelling
	Import of substance in article	BPR	Import restricted to approved substances listed in the Annexes to the BPR, labelling of the content of biocide active substances on the product (packaging), safe use information, if necessary Substances intended to be released from articles must be registered SVHC in concentrations above 0.1% and included in total amounts exceeding 1 t/a must be notified
	Authorisation of substances in recycling processes	REACH	If substances on Annex XIV are contained in waste materials and these are used as input materials to a recovery/recycling process, an authorisation must be granted for this use, except where exempted, as well as any further uses down the supply chain, until it is incorporated into an article
2	Use of substance to formulate mixtures	REACH	Use restrictions, identified uses from (e)SDS; provision of (e)SDS for mixtures, labelling
		BPR	Only approved active substances may be used in biocidal products, provision of SDS for products, labelling
	Integration of substances into/onto articles	REACH	The use of a substance in an article may be limited due to an authorisation need, use restrictions or limitations from the (e)SDS not supporting the use as identified use or indicating it as use advised against
1, 2, 3	Import, manufacture and use of substances as such, in mixtures or articles	POPs	Bans or use restrictions if substances are listed in the Annexes of the POPs convention/ included in POPs regulation. Provisions to limit/end recycling of wastes and destroy stock piles may exist

As chemicals legislation generally takes the form of regulations, it is directly applicable in all Member States. While implementation of the legislation on enforcement and sanctions differs between the Member States, the Forum for Exchange of Information on Enforcement (Forum) aims to harmonise approaches. The REACH and CLP Regulations are currently under assessment in the EU's REFIT Programme and the Commission is to report on their implementation every five years.

Some Member States have additional or complementary restrictions on the content of substances in articles. The Nordic countries oblige those who place substances and mixtures on the market to report data on the uses of their chemicals and publish this information in the relevant product registers.

France and Belgium have established similar registers for the use of nanomaterials.

3.4.3 Criticisms of the legal framework for chemicals

Numerous publications discuss the operation of the current legal framework. The following selection summarises the gaps and deficits identified in these publications. In the main, these authors state that emissions and exposures from chemicals are not sufficiently controlled, and/or information on substances is insufficient for adequate risk management along the supply chain. Concerns in respect of confidential information required under chemicals legislation are also raised, as these represent barriers to transparency on chemicals in products and material cycles imported into the EU market.

In its report on the operation of REACH and CLP, the European Chemicals Agency (ECHA)[57] includes criticisms of the content of substances in articles and wastes, and the related information availability. It states that the quality of registration dossiers needs further improvement, in particular on use and exposure information. Similarly, the information requirements for SVHC identification should be reviewed, and it considers the restriction process too slow, with only three restriction proposals processed in 2016. In addition, several Member States struggle with the preparation of restriction dossiers and the identification of restriction candidates in its current interpretation, as well as the demands for demonstrating unacceptable risks.

Molander[58] analyses the effectiveness of REACH's design in covering risks from substances in articles, concluding that data requirements for low volume chemicals are insufficient to identify SVHC. Therefore, registrants should take non-standard test methods into account more than is currently the case. This is particularly relevant as the communication requirements for articles with identified SVHC remain limited. Molander also points to the failure of the authorisation process to cover the substance content in imported articles.

Führ et al.[59] state that the information and CSA tools available to registrants may not be sufficient to identify all risks from substances in articles and to ensure safe use. The authors also highlight a potential gap in legislation in respect of the notification of CLS in articles under REACH Article 7(2). Due to the use of rough and broad use descriptions[60] for articles in the registration dossiers, importers may frequently claim an exemption from notification of SVHC. Therefore, information on SVHC in imported articles is patchy.
Another problem mentioned in the study is the break in the information chain when chemicals are present in articles, and the limited information communicated on CLS in articles. Merely communicating CLS names would not allow informed decisions and safe handling by supply chain actors or consumers. Führ et al. also criticise the authorisation process' failure to cover imported articles, potentially leading to the presence of CLS in such articles, in contrast to the articles produced by EU actors.

KemI[61] describes the exposure to hazardous substances in articles as an acknowledged problem for human health and the environment, where exposure to many substances occurs simultaneously and the effects are partly unknown. It claims that the legal framework is not sufficiently protective, as SVHC may be present in articles, such as in imported articles. It points to the low number of substances on which information is to be provided with articles, and states that the information on substances in articles is insufficient to enable informed (consumer) decisions. Finally, it asserts that stakeholder awareness of substances in articles remains too low to (easily) drive change.

[57] ECHA, 2016.
[58] Molander, 2015.
[59] Führ et al., 2015.
[60] The system of use descriptors for articles was revised in the meantime. As yet there are no reports on the degree of improvement achieved from the new, more detailed system of describing articles.
[61] KemI, 2011.

In their assessment[62] on the level of protection from hazardous substances in consumer articles envisaged by legislation, Brunn Poulsen and her colleagues conclude that insufficient information is available from REACH due to the tonnage trigger for hazard data. Registration data may be of insufficient quality, given the reliance on industry self-assessment. The REACH implementation in general, and the risk management procedures, in particular restrictions and authorisations, are too slow to ensure sufficiently high consumer protection. REACH Article 33 defines the communication requirements or CLS but does not place any such restrictions on articles. The authors of the study state that the REACH CSA does not take sufficient account of the emission of substances from various sources (aggregated exposures) or the possibility of combined exposures to multiple substances from various sources (cumulated exposures), potentially leading to an underestimation of risks.

3.4.4 Discussions and conflicting policy goals

Conflicts and diverging views arise in respect of the evaluation of risks, the need for risk management and/or the phasing-out of substances, as well as the most efficient and effective risk management option:

- Hazard-based versus risk based approaches – prioritisation of substances for risk management may be carried out based on hazard (e.g. inclusion on the candidate list, inclusion of active substances in the annexes of the BPR) or based on risks (e.g. CSA, substance evaluation). This has been discussed extensively among all stakeholders, e.g. in the context of the REACH review 2012[63].
- All parties involved are aware of the lack of information on substances in articles and the related challenges to comply with legislation and/or make informed choices on input materials and product design. A conflict of interests arises because industrial actors are hesitant to provide information on the composition of their products, fearing a loss of confidential know-how. In addition, communication on substances in materials and articles should not be resource intensive, for example, efforts to set up communication or establish communication systems. The interests of protection of confidential business information and low resource investments conflict with those of downstream users who want greater transparency on product composition(s) in order to choose materials or articles that are free from toxic substances, to comply with legislation and to produce safe(r) products. They also conflict with the interests of regulators and the public who wish to know the chemical content of articles. Finally, their interests do not always match the need for information to increase recycling and production of secondary raw materials.

3.4.5 Policy initiatives influencing the content of, and information on, chemicals in articles and material cycles

The use of chemicals in articles may be 'steered' by policy initiatives in the chemicals area. Mechanisms for such steering might be common goals in chemicals management, awareness raising (of risks from toxic substances and benefits of substitution), requirements from investors, consumer pressure, etc. The most relevant activities identified are listed below.

3.4.5.1 UN sustainability goals / SAICM

The UN sustainability goal of minimising the undesirable impacts from the use of chemicals is confirmed in the 2030 Agenda[64]. The International Conference on Chemicals Management agreed to enhance policy integration and to improve mainstreaming of the management of chemicals and waste, including cooperation from all actors.

[62] Brunn Poulsen P., Strandesen M. and Schmidt A., 2010.
[63] See for example the national discussion in Germany: Reihlen, A. and Jepsen, D., 2013 and VCI, 2012.
[64] United Nations, 2015.

In the field of chemicals information, three aspects are included in the 'Overall orientation and guidance'[65]:

- Cooperation of all actors to gather and make available information on chemicals along their life cycle, including in products (articles) and for the waste stage;
- Industry should consider whether its current approach to confidentiality is appropriate, i.e. if more information could actually be made available, in particular on the content of chemicals in articles;
- SAICM stakeholders should consider participation in the CiP project.

3.4.5.2 International conventions

EU chemicals legislation implements international chemicals conventions, such as the POP Convention and the Montreal Protocol on substances that deplete the ozone layer or the GHS. All measures agreed at international level are therefore eventually transferred to the EU regulatory system. EU initiatives to integrate new substances or activities in the conventions frequently follow regulatory actions within the EU. In some cases, international conventions prescribe risk management measures which are not yet in place in the EU. Given the interlinked standards, no significant additional incentives are expected to be imposed by the conventions on the EU in respect of management of toxic substances in articles and material cycles.

3.4.5.3 Examples of national approaches

Sweden
The Swedish Government passed a bill establishing a non-toxic environment as one of its overall goals[66], which KemI implements via action plans. The 2015-2020 action plan includes enhanced enforcement of banned or restricted substances in articles, support of international efforts to improve information provision on substances in articles (CIP) and research on possibilities to reduce substance emissions from recovered/recycled materials.

Denmark
In 2013, the Danish government agreed to launch strong chemicals initiatives (2014-2017) to protect humans and the environment from chemical risks[67]. They envisage answering the challenges of lack of information (access) on substances of concern in consumer products, challenges in differences of risk perception, and the (partial) knowledge and implementation gaps in legislation. The proposed initiatives include assessment of risks from hazardous substances in consumer products and an examination of whether their presence prevents recycling, increase of consumer product control effectiveness, the development of environmentally sound products, and information provision to consumers. More information on legal requirements should be provided to companies, in particular SMEs, and enforcement should be strengthened by improving cooperation with tax and border controls.

Product registers of the Nordic Countries
In the Nordic Countries, manufacturers and importers of chemicals are obliged to report information on their products, including their uses[68]. Although the types of articles and materials in which substances and mixtures may end up does not have to be provided directly, information on sectors of use and the functions of chemicals may be used to assess the types of products in which they may occur. Information from the registers is publicly available via the SPIN (Substances in Preparations In the Nordic countries) database.

[65] SAICM, 2015.
[66] KemI, 25.05.2015, *A non-toxic environment.*
[67] Ministry of Environment and Food of Denmark, *Chemicals initiatives 2014-2017.*
[68] Ahrens, A. and Reihlen, A., 2007.

3.4.6 Stakeholder initiatives and activities in the chemicals area

This section describes activities that 'start' from the perspective of chemicals and/or are initiated by chemicals manufacturers or importers and are thus considered as part of a 'top-down approach to chemicals management'.

3.4.6.1 Responsible Care and Product Stewardship Programme

The chemical industry has committed itself to implementing a 'Responsible Care and Product Stewardship Programme'. The 'Global Product Strategy' is a policy initiative aimed to support SAICM implementation[69]. The European Chemicals Industry Association (CEFIC) provides several tools and guidance documents on its website to implement the programme, in particular for SMEs[70].

The Responsible Care programme aims to initiate and monitor continuous improvement of the environmental, and health and safety performance of the chemical industry and its products. The Product Stewardship Programme should strengthen the responsibility of the chemicals manufacturers, importers and distributors for product safety along the supply chain by providing risk assessment and communication tools and other measures. Although the programme extends over the entire life cycle of chemical products, the use of substances in articles and disposal considerations have been of low relevance until now, with only the risk assessment frameworks and recommendations addressing service life.

3.4.6.2 SIN (Substitute it Now) List

The SIN List[71] includes substances which ChemSec, the list's owner, evaluates as fulfilling the criteria of REACH Article 57 (SVHC). ChemSec recommends substituting these chemicals as soon as possible. Stakeholders widely acknowledge the SIN List as an 'early warning system' and companies use it to screen their substance portfolio to prepare for potentially upcoming regulations. ChemSec also provides a tool to avoid 'regrettable substitution', whereby it assesses the similarity of substances to chemicals on the SIN List. Similar critical molecular structures are used as to infer similar hazard properties and thus indicate the potential for regrettable substitution. As the SIN List influences company decisions on the use of substances, it contributes to substitution of (potential) SVHC in articles.

3.4.6.3 'Green chemistry'

Stakeholder activities aiming to prevent risks from chemicals in articles are also rooted in designing substances which are inherently safe, i.e. have properties that do not pose risks to human health or the environment. More information on the development of green or sustainable chemicals is provided in sub-study f on an EU programme for the development of new, non-toxic substances.

3.5 ARTICLES LEGISLATION

3.5.1 Overview

This section gives an overview of legal instruments in the policy area of articles, which influence the content of toxic substances in articles or define information requirements on substances in articles. The policy area differs from chemicals and waste policy as it focuses on the article (service life) and related risks. The actors affected by legislation are those placing articles on the market. The following

[69] ICCA, 2006.
[70] CEFIC, *Responsible care for SMEs.*
[71] ChemSec, *SIN List.*

legal acts are analysed for their provisions on hazardous substances in articles:

- General Product Safety Directive (GPSD)[72].
- Construction Products Regulation (CPR)[73].
- Ecodesign Directive[74].
- Toy Safety Directive (TSD)[75].
- Directive on Medical Devices[76] and its daughter directives (MedD).
- Regulation on Food Contact Materials[77] (FCM) and related directives for specific materials.
- Ecolabel Regulation[78].
- Biocidal Products Regulation (BPR).
- REACH.

According to the **General Product Safety Directive (GPSD),** only safe products may be placed on the market. Product safety is defined with regard to the health of the user of the product and mainly concerns mechanical or electrical safety rather than chemical, long-term risks[79]. The definition of product safety does not include the environment. A product is 'safe' if little or no risk to human health could occur upon normal and reasonably foreseeable use.
Product safety under the GPSD is implemented by deeming a product 'safe' if it conforms to EU law, national legislation or standards applicable to the product. In the absence of the aforementioned binding and non-binding standards, other rules or codes of practice should guide the determination of product safety.

Annex I of the **Construction Products Regulation (CPR)** defines 'Basic Requirements for Construction Works', including the construction products used. Accordingly, construction works should not pose threats to human health or the environment throughout their life cycle, i.e. no emissions of dangerous substances should occur to indoor and outdoor air or water. EU standards may specify these general provisions for certain product types. The development of standards should take account of horizontal norms, which specify the identification and treatment of various risks (e.g. to surface water/groundwater and indoor air). The CPR requires inclusion of SDS information or information on CLS under REACH Article 33 in the Declaration of Performance (CPR Article 5(5)).

The **Ecodesign Directive** establishes a legal framework under which minimum criteria for the environmentally friendly design of energy using products are developed and implemented as regulations, limiting market access to those compliant products[80]. The scope of the Directive allows the inclusion of minimum criteria for other environmental impacts, such as the use or release of toxic substances[81]. In principle, the standardised method used for the assessment of different ecodesign options could include an assessment of the content of toxic substances and possible emissions. To date, the regulations derived under the Directive focus on energy aspects and do not consider toxic chemicals.

The **EU Ecolabel Regulation** sets out the development of award criteria for the EU Ecolabel for a product group, including consideration of the use and release of hazardous substances and their substitution (Article 3(3)a and 3(3)b). Article 6(6) of the EU Ecolabel Regulation explicitly excludes sub-

[72] DIRECTIVE 2001/95/EC on general product safety.
[73] REGULATION (EU) No 305/2011 laying down harmonised conditions for the marketing of construction products.
[74] DIRECTIVE 2009/125/EC establishing a framework for the setting of Ecodesign requirements for energy-related products.
[75] DIRECTIVE 2009/48/EC on the safety of toys.
[76] COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices.
[77] REGULATION (EC) No 1935/2004 on materials and articles intended to come into contact with food.
[78] REGULATION (EC) No 66/2010 on the EU Ecolabel.
[79] However, according to RAPEX notifications, risks from chemicals in articles are of high relevance (approx. 25% of all notifications) for product safety and might therefore deserve more explicit reference in the product safety definition of the GPSD and related instruments.
[80] Alternatively, industry could propose other measure to achieve the same goals, such as voluntary commitments.
[81] There are several initiatives from stakeholders to implement this option, including a proposal for a related methodology. Whether or not these approaches will be implemented remained unclear at the time of writing this report.

stances fulfilling the criteria of REACH Article 57[82]. No guidance exists for applicants for an ecolabel wishing to check the absence of SVHC: no lower concentration limits are specified, no information sources are recommended, nor is advice given as to the type of assessment the applicant should make.
A horizontal approach to address hazardous substances in ecolabel criteria is currently under discussion. This considers the limited access of market actors to information on the (chemical) composition of their articles, leading to challenges in defining the 'bill of materials' of an article.
Annex II, part III of the **TSD** specifies the chemical requirements for toys (substances, mixtures and/or articles):

- Toys should not pose any health risks during normal and reasonably foreseeable use;
- Legal provisions applying to mixtures or articles apply (e.g. CLP);
- No CMR (1A, 1B or 2) may be included in toys (with some eceptions);
- Some fragrances listed in the annex may not be contained in toys, unless their presence cannot be avoided and remains below 100 mg/kg; some fragrances need to be identified on the product;
- The fragrances listed in the Directive must be declared if contained in toys;
- Contained substances listed in the Directive must meet specific migration limits.

Toy manufacturers must ensure that their products fulfill the provisions of the TSD by means of a safety assessment and/or a conformity procedure prior to placing on the market. The procedures may take different forms: if standards or norms exist, compliance with these is regarded as ensuring toy safety and a CE marking can be applied. If the product is not manufactured according to existing standards and norms, or if no such rules exist, a safety assessment should be carried out.

The **Medical Devices Directive** defines 'essential requirements' for medical devices to be safe, including consideration of the toxicity of the materials used. Conformity assessments are required and are implemented based on existing standards, norms or other rules for the safety of medical devices existing at EU or Member State level. Product standards, however, do not include any limit values for specific substances or substances in certain hazard categories but, rather, describe risk assessment procedures.

The **BPR** requires that articles can only be treated with biocides that are authorised for use in the EU, i.e. that have been assessed as 'safe' for this use by the Member State or EU authorities. The provisions cover imported articles. In addition, anyone placing on the market those articles treated with biocides must, under certain conditions, to provide the following information on the label[83]:

- The fact that the article is treated with biocides;
- The biocidal properties the article is expected to have;
- The names of all active substances present;
- The names of nanomaterials contained, followed by '(nano)';
- Instructions for safe handling and use.

Placers on the market of treated articles are required to answer consumer queries on the content of biocidal active substances in the article within 45 days and free of charge (Article 58(5)).

Several obligations under **REACH** directly address the production and import of (substances in) articles and communication on CLS in articles. Producers and importers of articles are required to:

- Register substances in articles intended to be released, if the total amount exceeds 1 t/a (Arti-

[82] 'The EU Ecolabel may not be awarded to goods containing substances […]' referred to in Article 57 of Regulation (EC) No 1907/2006 […].
[83] This obligation is restricted to those cases where the article is claimed to have a biocidal property due to that treatment and/or the approval conditions of the biocide active substance require indication on the label.

cle 7(1)) or upon request if they are not intended to be released (Article 7(5)).

- Notify ECHA of CLS above 0.1% (w/w) contained in their articles, if the total amount in all produced/imported articles exceeds 1t/a and none of the exemptions[84] apply.
- Communicate information on the CLS and on safe handling and use to the recipients of their articles, if one is contained in concentrations above 0.1%. This information is also to be provided to consumers on request within 45 days and free of charge (Article 33).

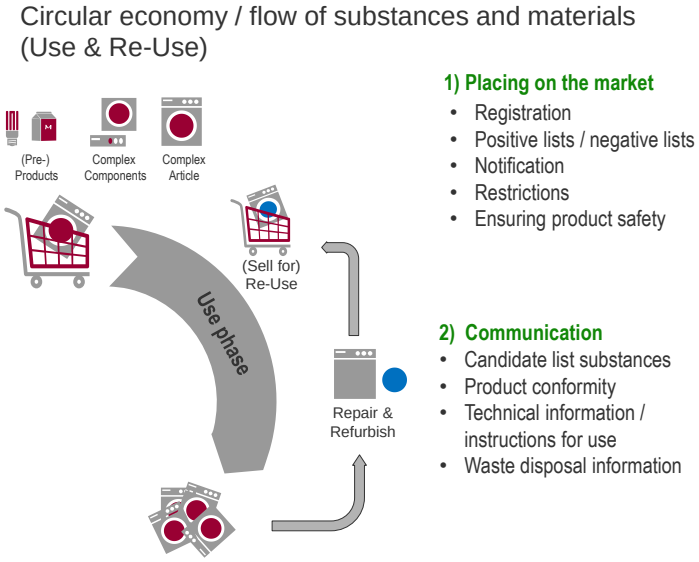
The **Regulation on Food Contact Materials** (FCMR) requires that all food contact materials (FCM) placed on the market are safe. Among others, FCM should not release substances to food at levels hazardous to human health. For plastic materials intended to come into contact with food, an authorisation process is established by Regulation (EU) No 10/2011 requiring that they only contain substances included on its positive lists and in accordance with any restrictions specified. The list of authorised substances for use in plastic FCM is published in an online database[85]. The Regulation on Plastic FCM defines migration limits and requires supply chain actors to communicate a declaration of compliance along the supply chain in order to document implementation of the requirements and to ensure traceability.

Regulation (EC) No 282/2008 defines requirements for the use of recycled plastics in FCM. The EU Commission must authorise the recycling processes that use and produce recycled plastics for food contact materials, which includes compliance with requirements on (the substance contents of) input materials and output materials, quality management routines and product sampling and testing.

Legislation on food contact materials also includes specific restrictions for epoxy resin derivatives, nitrosamines and nitrosable substances, as well as for specific types of FCM, such as kitchenware from polyamides.

Figure 4 illustrates the legal instruments outlined above.

Figure 4: Legal instruments influencing content of, and information on, toxic substances in articles



[84] A notification is not required if the substance is already registered for the use, or if exposure can be excluded.
[85] https://webgate.ec.europa.eu/sanco_foods/main/?event=substances.search&substances.pagination=1

3.5.2 Instruments and tools in product policy

The following table lists different types of instruments for regulating the content and communication of toxic substances in articles. It specifies the legislation containing the instrument(s) and provides some examples of the mechanisms.

Table 2: Legal instruments to regulate the content of, and information on, toxic substances in articles[86]

#	Mechanism	Legislation	Instrument and content relevant to toxin use in articles and communication
1	Registration	REACH Article 7(1) and Article 7(5)	Substances as such or in mixtures intended to be released from articles must be registered, if their total amounts in the articles exceeds 1 t/a. A CSA is required if the amounts exceed 10 t/a ECHA may decide a substance included in articles, which is not intended to be released, must be registered if the amounts exceed 1t/a in all articles, if there is a suspected release which could cause risks
	Positive lists / authorisation	BPR	Articles may only be placed on the market if the biocidal products they have been treated with are authorised within the EU. All active substances must be listed in one of the annexes of the BPR
		FCMR	Only substances approved for FCM may be used/contained in plastic food packaging.
	Notification	REACH Article 7(2)	ECHA must be notified of any CLS in articles in concentrations above 0.1%, if the total amount in all articles exceeds 1t/a. Exemptions apply if the substance is already registered for the use or if exposure can be excluded
	Restriction	REACH Annex XVII	Several restrictions on content of substances in articles; bans or concentration limits are specified based on an assessment of risks
		TSD	Restriction of content for CMRs (i.e. by classification) and additional lists (sensitisers, heavy metals) with bans or concentration limits
		FCMR	Specific restrictions for specific substances in separate legislation, e.g. nitrosamines and nitrosable substances
		POPs	Ban/use restriction for listed substances
		BPR	Substance approvals may include restrictions related to the use of active substances as such or in biocidal products for the treatment of articles
		Ecolabel	'CLS-free' as precondition for ecolabel award, further restrictions may be specified in the requirements for the different product groups
		Ecodesign	Requirements on the absence of CLS or other substances of concern may be included in the implementing directives in the future. This would correspond to the definition of minimum requirements for placing on the market
		Medical Devices, CPR	Legislation defines requirements to design products for which risks are minimised, including from chemicals. If existing, standards, norms or national legislation could include restrictions on specific product types
2	Conformity assessment	TSD	Comparison with product standards, norms and/or national legislation via self-assessment and/or external certification of product safety
		Medical Devices, CPR	Conformity with standards and rules, if existing; certification of conformity to be provided
		GPD	All products placed on the market to be (chemically) safe; only includes health hazards
		Ecodesign	Depends on potential implementing directives
	Communication in the supply	BPR	Labelling of biocide active substances in treated articles; answering consumer queries within 45 days and free of charge
		REACH	Communication of SVHC in articles in concentrations above 0.1% to recipients

[86] Italics indicate that the existence of requirements either depends on further implementing instruments or may be implemented in the future.

#	Mechanism	Legislation	Instrument and content relevant to toxin use in articles and communication
	chain/to consumers other than CE marking	Article 33	(consumers only on request)
		CPR	Provision of information on hazardous substances (classified according to CLP or SVHC) with the construction product as part of the conformity declaration
		FCMR	Documentation of conformity to be communicated along the supply chain
Legislation on voluntary instruments			
2	Communi-cation	EU Ecolabel	Ecolabel to show products comply with the ecolabel requirements, which include 'CLS-free' and potentially more substance related obligations

3.5.3 Criticisms of the current legal framework

There follows some of the main criticisms identified from publications addressing the operation of the legal framework on the (chemical safety) of articles. This is not a comprehensive description of opinions on the functioning of the legal requirements but, rather, pinpoints the critical issues whose improvement would contribute to a non-toxic environment.

The Austrian Consumer Council commissioned a series of five studies to analyse product legislation with regard to its appropriateness and suitability to protect consumers from chemical risks, with a focus on children's products.
Their first two studies[87] analysed several pieces of legislation, including REACH, the TSD, RoHS and FCMs, and the conclusions can be summarised as follows:

- There are few restrictions of the use of chemicals in consumer products. Existing legislation covers only a small number of product types and specific substances.
- The FCMR is the sole piece of legislation to include a positive list system.
- Most product safety requirements are not defined using specific limit values but via general phrases such as 'must be safe', which are difficult to implement and enforce.
- Most legislation was implemented after damage occurred, i.e. the regulatory system on consumer products/articles is not based on risk assessment and proactively avoiding damage.
- Market surveillance is not sufficient and information generated by inspectors is not used to inform decision-making.
- Multiple exposures and combination effects are not considered in the current system[88], leading to an underestimation of the actual risk.
- There is a large knowledge gap on the content of chemicals in articles.
- Nanomaterials require additional specific regulation(s).
- Only the TSD and the RoHS Directive include procedures allowing quick amendments of requirements on substances in articles.
- Product standards do not set (sufficiently strict) restrictions on chemicals.

The Austrian Consumer Council concludes that consumer safety is not sufficiently ensured. They discuss several improvement options, including expansion and revision of existing product legislation, introduction of horizontal legislation on chemicals in products, extension of REACH to better address substances in articles, or extension of the Ecodesign Directive to include chemical restrictions, finding this latter to be the most promising option. Finally, they recommend strengthening existing requirements, introducing a comitology procedure in all product legislation, strengthening market surveillance and introducing a regulatory, horizontal approach to chemicals in products.

[87] Brunn Poulsen et al., 2010 and Brunn Poulsen and Strandesen, 2011.
[88] There is one exception in the TSD for multiple exposures, where a fraction of the acceptable daily intake is used to derive limit values.

Strandesen and Brunn Poulsen[89] propose changes to legislation for different consumer products and make some general recommendations, including expansion of the TSD to all products that come into contact with children. They emphasise that a horizontal, regulatory approach is needed for substances in articles via an expanded Ecodesign Directive, including a comitology procedure, market surveillance, a chemicals declaration scheme in articles and a ban of PBT/vPvB and CMRs in consumer products.
The fourth and fifth study[90] commissioned by the Austrian Consumer Council examined the legislation relating to products aimed at children in more depth, concluding that new restrictions should be introduced, with the limit values for existing restrictions made stricter. The existing requirements in legislation and in standards are insufficiently protective for babies and young children, nor do existing restrictions cover the entire range of substances that could pose risks. The study highlights children as a vulnerable group, making the limitation of exposure to toxic chemicals necessary, even where individual substances in articles do not pose a risk by themselves.

The European Association for the Coordination of Consumer Representation in Standardisation (ANEC)[91] criticises chemicals regulation in articles as insufficient, as:

- it covers only some substances/materials/articles.
- it frequently omits limit values.
- it does not ensure a sufficiently high level of protection.

The restriction process under REACH is characterised as laborious without the possibility of generic restrictions (e.g. prohibition of CMR in textiles) and articles deemed to be insufficiently covered (imports). ANEC therefore concludes that REACH does not close the existing gaps in articles legislation.
ANEC also criticises the TSD, stating that the substance-related requirements are insufficient to ensure toy safety because the allowed CMR content is too high and several other hazard categories are not addressed at all. They also state that the provisions of the Medical Devices Directive are insufficient when it comes to protecting human health and the environment.

Führ et al.[92] criticise the article related requirements under REACH as insufficient to ensure a high level of protection. This relates to the lack of coverage of (imported articles) in the authorisation scheme, and particularly to the lack of efficient and effective communication on substances in articles. Article 33 is regarded as insufficient because only the substance name is communicated and consumer requests may be answered with a delay of 45 days, weakening its influence on purchasing decisions.

In its report on the operation of REACH[93], ECHA states that the registration dossiers contain little information on substances in articles and that far fewer notifications (under Article 7(2)) are received than expected. There seems to be a lack of understanding in relation to assessing and describing the safe use of substances in articles. Finally, ECHA holds that the communication on CLS in articles does not work, and that most consumers are not aware of their right to ask for information relating to SVHC in articles.

KemI[94] also states in its report that the article related provisions of REACH are insufficient:

- REACH Article 33 is unclear, in particular regarding the extent of efforts made by suppliers to provide information, as well as the type of information regarded as 'sufficient to enable safe use'.
- The delay for consumers in obtaining information on SVHC in articles would weaken the substi-

[89] Strandesen and Brunn Poulsen, 2012.
[90] Brunn Poulsen, 2013 and Brunn Poulsen, 2014.
[91] ANEC, 2014.
[92] Führ et al., 2015.
[93] ECHA, 2016.
[94] KemI, 2015.

tution incentive intended to be posed by this provision.

- The limitation of the consumers right-to-know includes very few substances of which even fewer are used in consumer articles and the limited number of substances fulfilling the criteria of REACH Article 57 listed on the candidate list.
- Information generated under REACH Article 7(2) is insufficient (few notifications, partly due to the exemptions for notification and the imprecise descriptions of registered uses).
- Lack of implementation of the requirements in the supply chain, in particular SMEs lack support.
- An insufficient knowledge base on substances in articles in general.
- Information on SVHC in articles does not reach the waste processors and recycling organisations; SDSs are not available to those in the waste sector.

KemI criticises the current implementation of the restrictions process as too slow and resource-intensive. Further issues include: information on the occurrences, releases and risks from substances in articles is difficult to obtain, in particular as regards substances in articles; the term 'unacceptable risk' lacks a clear interpretation; and the approach to restrict substance groups is under-exploited.

3.5.4 Discussions and conflicting policy goals

The content of, and information on, toxic substances in articles is usually discussed in the context of specific article types or groups, e.g. toys, consumer textiles, construction products, etc. The overarching issues within the current debate can be summarised as follows:

- According to industry, information on (toxic) substances can be confidential and disclosure endangers the companies' competitive position. In addition, they face difficulties in obtaining information from non-EU suppliers. Consumer and environmental groups, regulators and other organisations state that disclosure of the content of toxic substances in articles should not be regarded as confidential but, rather, as necessary to ensure consumers' right to know[95]. In addition, all stakeholders are of the opinion that the communication efforts are not justified by the expected benefits for human health and the environment. This conflict was also evident in the breakout group discussion during this project's stakeholder workshop in June 2016.
- As toxic substances are frequently integrated into or onto the article matrix, they may be released at low levels during article service life and thus not present an immediate risk to humans or the environment. This leads industry and several public authorities to disagree with merely hazard-based restrictions of substances in articles. In contrast, civil society groups and other authorities argue in favour of hazard-based restrictions, based on potential releases during the waste stage, the existence of aggregated and cumulated exposures, and precaution. These actors also plead for less labour intensive restriction justifications. Another argument for hazard-based approaches is that in the circular economy, substances may enter uses for which they were not originally foreseen.
- Humans and the environment are exposed to a multitude of substances from a large number and variety of articles. Stakeholders hold different views on the ways in which the various emission sources and combined exposures should be considered in substance risk assessments. These differences may depend on the types of articles in question (e.g. outdoor articles vs. toys).
- The use of toxic substances usually facilitates certain functions; whether or not these functions are strictly necessary is a matter of societal values, giving rise to contrary opinions, particularly where the function improves 'only' the ease of use of a product[96].

[95] For example, SAICM asks stakeholders to challenge their current approach to confidentiality in its recently published guidance for the achievement of the 2020 sustainability goals.

[96] Occasionally, the presence of a substance does not support a particular function. One example is antimicrobials used in consumer textiles, which should prevent the formation of odours but which are rapidly washed off or are not functional in dry environments (KemI PM 8/15 http://www.kemi.se/global/pm/2015/pm-8-15-antibacterial-treatment-of-clothes.pdf).

3.5.5 Policy measures related to toxic substances in articles

This section describes examples of initiatives and measures on toxic substances in articles by international or regional organisations, governments and authorities. Actions may target particular article types and/or directly address article producers, importers and retailers.

3.5.5.1 UNEP / SAICM

In May 2009, the second international conference of chemicals management initiated the chemicals in products project (CiP). This analyses existing information systems on chemicals in products, identifies stakeholder information gaps, and develops recommendations for improvement. Several activities have already been completed, such as those reported in SAICM (2015)[97]:

- A survey among national focal points to identify:
  - Information systems on chemicals in articles;
  - Stakeholders' information needs on chemicals in products;
  - Priority products or sectors.
- An analysis of existing information systems;
- Case studies to review the information exchange on chemicals in products in the sector(s), illustrate the specific information needs and identify relevant gaps, as well as to derive measures to overcome obstacles in information provision and access;
- An international workshop to discuss the project results;
- Development of information materials on the business case for knowing chemicals in products;
- Development and implementation of a chemicals in products programme, together with the establishment and maintenance of a programme website;
- Starting a pilot project on chemicals in textiles in China.

At the fourth international conference on chemicals management, a programme guidance document was agreed for CiP implementation[98]. This outlines the key objective of facilitating high quality information exchange within supply chains and to non-supply chain actors. It defines stakeholder roles, programme scope, and the approach to confidentiality. A separate implementing guidance[99] exists for supply chain and non-supply chain actors, with examples of information systems available, help on selection of substances and articles, and the information required.

Several reports have come from the CiP project (e.g. survey of 2009[100], Kogg and Tidell[101] and a synthesis report[102]). Conclusions drawn in respect of information needs point to the absolute necessity of information to trace the products' supply chain and enforce compliance with product requirements, such as information on the presence, hazardousness and quantities of substances in products, as well as information on safe handling and disposal of products containing hazardous substances. The varied interests and knowledge of stakeholders demands information in different forms and levels of detail.

The reports identify the following priority products: children's products, food packaging, construction material, electrical and electronic equipment (EEE), and cosmetics/personal care products. Various types of information systems on chemicals in products are described, mainly from Japan, the U.S. and Europe. These are divided into different systems for information provision:

- From supplier to client in the supply chain and vice versa;

[97] SAICM Secretariat, 2015a and SAICM Secretariat, 2015b.
[98] SAICM Secretariat, 2015c.
[99] SAICM Secretariat, 2015d.
[100] Becker M., 2009.
[101] Kogg, A.; Thidell, A., 2010.
[102] UNEP / DTIE 2011.

- From producer to consumer;
- From producer to waste sector;
- From non-market actors to the general public.

Information systems covering entire supply chains are rare (e.g. International Material Data System (IMDS)) and most existing systems are narrow in scope (e.g. cover very few substance). Overall, the systems appear insufficient to satisfy the existing information needs.

The reports identify legal and product safety requirements, market pressure from consumers, and general considerations on public relations/avoidance of scandals as key drivers for comprehensive information management.

The reports highlight that:

- No agreement on harmonised systems for information provision is expected, in view of the complexity and variety of products and supply chains;
- Two levels need to be addressed – information on the actual content of chemicals in products and information on how to interpret this data;
- Prevention at source (substitution) would help to avoid problems downstream;
- Policy makers should initiate the development of a knowledge base on the content of products on the market (e.g. through extended producer responsibility concepts);
- Information on the content of substances in articles is the basis of any further (risk management) activities and should be given the highest priority. Arguments that this information may be misinterpreted by (some) stakeholders should not prevent the development of such systems;
- Information systems should be based on data on the content and migration of substances and should be built step-by-step. Methods and tools for data interpretation should be sector-specific.

Systems may aim for full disclosure of content (challenges relate to confidentiality, resources and definition of full disclosure, in cases where new chemicals are formed in/by a product) or targeting specific substances (challenges relate to agreement and updating of substance lists and lack of data for 'old' products). Challenges for such an information system include levels of access, formats and standards, ensuring information quality and the legal status of the system.

3.5.5.2 National Ecolabel Schemes

Several Member States apply ecolabel schemes to different product groups, including articles, and specifically restrict the content of toxic substances. All of these ecolabels exclude the presence of CLS in products (with some exceptions). Award criteria may define product group specific requirements, e.g. an assessment of currently used substances, available substitutes and potential risks, as well as an agreement process with the relevant stakeholders. Ecolabel schemes exist in the Nordic Countries (Nordic Swan), Germany (Blue Angel) and Austria (Umweltzeichen)[103].

For several product groups, certification schemes exist that may include requirements on the substance content, including carpets (rug mark) and textiles (e.g. Oeco-Tex standard).

3.5.5.3 Databases on hazardous substances in articles

Several databases have been established by different organisations on the content of hazardous sub-

[103] Nordic Ecolabelling, *Home*; The Blue Angel, *Home*; Das Österreichische Umweltzeichen, *Home.*

stances in products. Most of these databases focus on mixtures (chemical products), with their data compiled from SDSs or manufacturers' declarations.

One example of an EU wide database is RAPEX, which provides information from market surveillance in which risks from products have been identified, including non-compliance with marketing and use restrictions (mixtures and articles). This provides information solely on the (illegal) content of restricted substances, thereby indicating where stronger enforcement or awareness raising of legal requirements is needed. It is not a tool for overall information collection and/or for consumer information in general.
The department of Ecology of the State of Washington runs a database and publishes the results from its product testing. As testing aims to control product compliance, it is limited to regulated substances/substance groups or those which are the focus of future regulation. The database could be useful for researchers or civil society organisations, but does not support communication to supply chain actors or the public about toxic substances in articles.

3.5.5.4 REACH Article 33 support

Stakeholder initiatives on the substitution of toxic substances in articles mostly focus on specific article groups. One initiative independent of specific article types is the development of Apps in Denmark and Germany to support consumers to request information on CLS in articles under REACH Article 33. The Danish App is connected to a database, which replies directly if it contains an answer from the producer/importer of the article. If the answer is not (yet) stored, it automatically generates a request to the article producer/importer. In Germany, a similar website exists, with an App in development[104].

3.5.6 Stakeholder initiatives and activities in the articles area

3.5.6.1 Textiles

Six textile brands started the so called 'Zero discharge of chemicals initiative' (ZDHC) which aims to phase-out the most hazardous substances. In 2015, the number of participating brands increased to 19. Their roadmap[105] documents the initiative, as well as outlining the goals and steps towards their achievement. The key objectives of the programme are to:

1. *'Eliminate or substitute priority hazardous chemicals in products and their manufacture;*
2. *Implement a transparent screening process to promote safer chemistry;*
3. *Implement common tools, best practices and training that advance chemical stewardship;*
4. *Partner with stakeholders to promote transparency of chemical use and discharge;*
5. *Promote scaling of best practices through engagement with key stakeholders.'*

The substances in question are prescribed on a commonly developed 'manufacturing restricted substances list'. The list contains substances that are legally restricted, as well as substances the initiative aims to voluntarily phase-out. The list has been criticised by NGOs because not all relevant toxic substances are included, and PFCs are not listed at sufficient level of detail.

ZDHC developed a framework to prioritise (further) chemicals for listing, identified research needs (e.g. to substitute these substances), and developed a chemicals management manual and related training for non-EU suppliers. ZDHC carried out a benchmarking project for non-EU suppliers to identify

[104] BUND Friends of the Earth, *Giftrage stellen*; REACH Informationsportal, *Verbraucheranfrage*, Scan4Chem *https://www.umweltbundesamt.de/en/topics/chemicals/reach-what-is-it/reach-for-consumers.*
[105] Zero discharge of hazardous chemicals programme, 2015.

current practices in taking inventory and measuring substance emissions via waste water. Non-EU suppliers are intended to be audited by the end-users, applying a standardised audit protocol, which is currently in development. The initiative established a foundation to oversee the implementation of the programme.

ChemSec has launched guidance[106] on identification of the hazardous substances present in textiles by following the entire production process. In addition, they provided ideas on phasing-out of these substances.

The NGO Greenpeace has run its so-called 'detox' campaign on textiles since 2011. The campaign requests committed textile producers to phase-out 11 groups of substances of high concern in their products by 2020. In total, 70 brands have signed the commitment, which represents 15% of global textile production, according to Greenpeace. The campaign includes awareness raising actions and the publication of several reports analysing the content of certain hazardous substances in clothing.

In several Member States, such as Germany and Denmark, roundtables exist to discuss problems within the textile industry and to identify possible solutions. This includes not only the use of toxic substances, but also sustainability issues, such as fair production conditions.

3.5.6.2 Furniture industries – use of flame retardants

The EU furniture industries, led by EFIC (the European Furniture Industries Confederation) identified a need for change in the current practice related to the use of flame retardants (FR) in furniture.
There is a high variety of flammability standards for furniture in the EU, some of which can only be met through the use of high amounts of FRs in furniture. Many FR pose serious threats to human health and the environment[107]. In addition, their use in furniture products prevents recyclability and responsible end-of-life treatment. The use of FR in furniture and the existence of many different flammability standards impose a costly burden on furniture producers.
A broad group of stakeholders stresses the need to change this situation, including the EFIC, environmental and health NGOs, and firefighters.
They describe the status quo as follows:

- The scientific community recognises many FRs as substances of concern due to several adverse effects, such as persistence, bioaccumulation, toxicity, mutagenicity, endocrine disruption, and carcinogenicity.
- Some FRs are banned at EU level and/or are restricted internationally. A particular concern is linked to the use of Brominated Flame Retardants (BFRs). Alternatives, however, are frequently of similarly high potential hazards and/or information is lacking to fully assess related risks.
- Several sources, including studies from the French authorities and the US, indicate that the benefits of FRs in furniture are not measurable[108], whereas other means of improving fire safety (e.g. smoke detectors) are efficient without potential hazardous consequences[109].
- Firefighters are concerned that FR increase the severity of fires, because materials containing FR produce toxic gases when inflamed and therefore endanger their health.
- The use of FRs changes the consistency of foams, decreasing the comfort and quality of the furni-

[106] ChemSec, *Textile guide.*
[107] San Antonio Statement on Brominated and Chlorinated Flame Retardants, 2010.
[108] The French agency ANSES (Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail) found in its report that the contribution of FRs in preventing fires cannot be measured. It recommends a series of other measures to reduce fires rather than exposing the whole population to flame retardant substances. For more info: https://www.anses.fr/fr/content/%C3%A9valuation-des-risques-li%C3%A9s-%C3%A0-l%E2%80%99exposition-aux-retardateurs-de-flamme-dans-les-meubles
[109] ARCADIS EBRS, 2011 demonstrates that 'Early detection by smoke detectors is a very effective measure to deal with fires in the initial stage of development and to reduce the number of fire deaths' while 'the stringency of non-flammability requirements for consumer products in a domestic environment does not have a statistically noticeable impact on the number of fatalities from fires in dwellings'.

ture for its user, while raising its price.

- Two major groups of testing methods exist in the EU to assess furniture flammability:
  - the 'open flame test', which simulates situations such as a candle coming into contact with the furniture;
  - a 'smouldering ignition test', which simulates situations such as a cigarette coming into contact with the furniture.
- High concentrations of FRs are needed to fulfill the requirements of the open flame test.
- Standards that require resistance to an open flame ignition source, such as the previous TB 117 in California or the current British fire safety standards, have therefore led to intensive use of flame retardant chemicals.
- Open flame tests are still requested in the public and contract market for furniture in many EU Member States.
- There is no harmonised standard for fire safety of upholstered furniture at EU level. Some Member States have drafted national fire safety regulations and standards for (upholstered) furniture, bedding, mattresses, etc., leading to different requirements for furniture sold to the public and for professional use (i.e. office furniture, furniture in public buildings, schools, etc.). For the latter, public procurement may also demand compliance with specific flammability standards and test methods.
- In California, the open flame test requirement for furniture was abandoned and replaced by less demanding standards, which can be fulfilled without the use of FRs[110].

The Stakeholders' Alliance calls for harmonised and legally binding legislation at EU level, to include an EU wide test method and enable marketing of furniture without the use of FRs. This would serve the environment (less use and emission of FRs), the consumers (fewer hazardous substances and lower costs) and the industries (less divergence in requirements, lower risk for workers, better products).

3.6 WASTE LEGISLATION

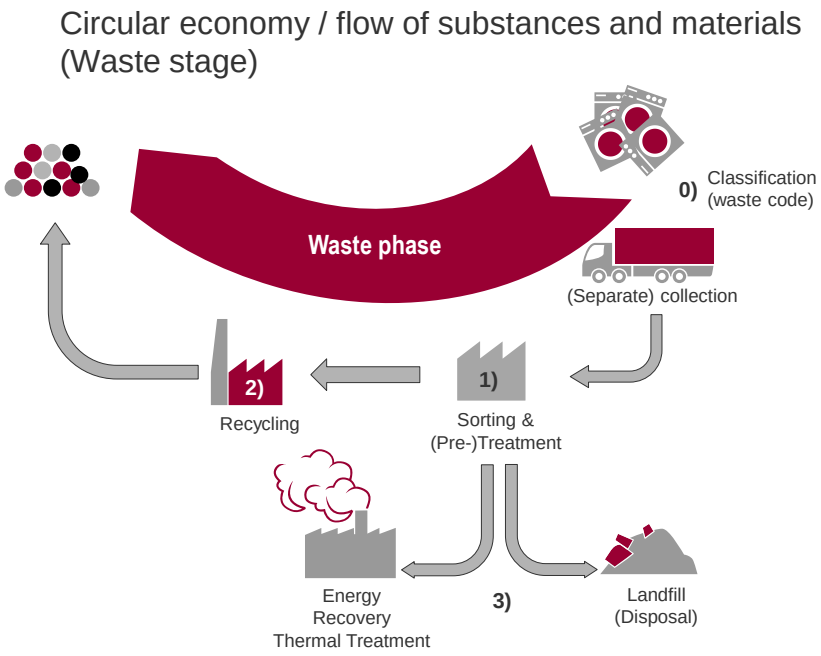
3.6.1 Overview

This section provides an overview of those provisions in waste legislation that relate to, or may have an influence on, closing material cycles and decontaminating materials streams. It focuses on treatment (pre-treatment, recovery, disposal) and collection requirements. It also considers preventative aspects (substance restrictions in products) and requirements on the composition of secondary raw materials.

Figure 5 indicates the overall options of waste management: preparation for reuse of articles and/or their components directly or after dismantling and/or refurbishing; separation and potential processing of waste fractions for recycling/recovery and/or disposal. The waste regime has interfaces with chemicals and product legislation at the stages where waste becomes a product and vice versa.

Figure 5: Possible flows of materials in the waste stage

[110] The State of California updated their furniture flammability standard. Introducing TB117 2013 enabled the sale of furniture without added flame retardant chemicals and has maintained fire safety.



With regard to material cycles, waste management has a filter or 'kidney' function[111] that aims to prepare material flows so as to separate out unwanted compounds, and fit the major materials to the needs of production processes or products, all while taking into account human health and environmental aspects. This requires an effective feedback mechanism from the production phase. This feedback mechanism can be material requirements regarding composition (e.g. maximum copper content in secondary steel), in properties (e.g. ductility) or the absence of a certain substance (e.g. because it is restricted in certain products). Feedback mechanisms which influence the activities in waste management can also be economically driven (e.g. higher prices for secondary metals with lower contaminations) or stem from legal requirements (e.g. restriction of marketing of certain substances).

Waste management also has a steering function for (waste) material flows that focuses on the reclamation of resources. The steering function is often influenced by collection and recycling requirements (e.g. collection and recycling rates, separation of printed circuit boards from electronic equipment, etc.). In such cases, the steering function does not rely solely on economic incentives for the output streams of waste management activities, e.g. plastic from packaging, resulting from national implementation of the Packaging Directive.

In order to generate the desired output, waste management needs information about the composition of input streams.

The various legal requirements, the availability of information and the feasibility of separate collection recovery and disposal paths, as well as economic aspects, determine the choices made in the waste sector. Focusing on the major intervention points, Table 4 lists the existing legislation relevant to the issue of toxic chemicals in articles and non-toxic material cycles.

Table 3: Specific legislation influencing the content and communication of substances in waste materials

#	Mechanism	Legislation	Comment
	Overall framework	WFD	Framework legislation for the waste sector, provides general waste management objectives (e.g. waste hierarchy), defini-

[111] See for example: Kral, U., Brunner P.H., Chen P-C., 2014; Kral U., Kellner, K., Bunner P.H., 2013.

#	Mechanism	Legislation	Comment
			tions, responsibilities and procedures
Fig.4; 1) & 2)	Prevention by use-restriction; communication of content	(ELVD	Use restrictions on specific substances (with exemptions) (waste driven but includes placing on the market); if exemptions are applied, communication is required (e.g. statement that lead can be expected in 'Bearing shells and bushes in engines, transmissions and air conditioning compressors' (exemption 4b of the ELVD))
		RoHS Directive	Use restrictions on specific substances (with exemptions) (waste driven but includes placing on the market); if exemptions are applied, communication of same is required
		Battery Directive	Use restrictions on specific substances (with exemptions) (waste driven but includes placing on the market); if exemptions are applied, communication of same is required
		Packaging Directive	General requirement regarding minimisation of hazardous substances in packaging
Fig.5, 0)	Classification, communication	WFD, LoW	Classification of wastes as hazardous or based on 'PROPERTIES OF WASTE WHICH RENDER IT HAZARDOUS' of the WFD and certain 'ASSESSMENT AND CLASSIFICATION' in the LoW. Waste code is to be communicated with the waste
Fig.5, 0)	Communication	WEEE Directive	General labelling of EEE, producer has to supply information on product composition (if relevant for treatment) to treatment facilities
		ELVD	Product producer has to supply information on product composition (where relevant for depollution) to the dismantling facilities
		Battery Directive	General labelling of batteries and accumulators, labelling of batteries and accumulators with elevated content of hazardous substances
1,2	Depollution requirements	WEEE Directive	Treatment requirements for depollution
		ELVD	
		Battery Directive	
1, 2, 3		IE Directive, BREF Waste Treatment	Generic requirements for proper waste management activities
1,2	Separate treatment requirement	WFD (Article 21 'waste oil')	General requirement to collect and treat waste oils of different characteristics separately[112]
1, 2	Collection and recycling targets	WEEE Directive	Quantitative collection and recycling requirements focussing on overall quantitative targets, not specifying specific materials and/or substances
		ELVD	
		Battery Directive	
1, 2	Delineation of waste and product	Council and Commission Regulations on end-of-waste criteria	Criteria developed in a stakeholder process, defining if a material can be placed on the market as a product or remains waste
	Restriction of shipments	Regulation on shipments of waste	Restriction of shipment of hazardous waste

Waste disposal legislation (e.g. the Landfill Directive) is not considered in detail because it has limited, if any, consequences for the content and communication of substances in waste materials.

3.6.2 Circular economy package

The circular economy package proposed by the EU Commission in December 2015 includes an action plan communication, a list of follow up activities and three legislative proposals. It combines waste management activities with related key aspects of the value chain, which are essential in order to 'close the loop' of the circular economy.

The Commission communication stresses the importance of the EU waste hierarchy and asks for further improvement of waste legislation by addressing existing implementation gaps and the develop-

[112] The former Waste Oil Directive included an explicit requirement to treat PCB containing oils separately. WFD Article 21 is more general and does not specify the criteria applied to identify if the characteristics require separate treatment.

ment of long-term visions and targets to guide investments[113]. The waste legislation sets quantitative targets for recycling and recovery for certain wastes, and maximum rates of wastes to be landfilled. At the same time, it aims to increase the use of secondary raw materials, the safe management of chemicals and to improve knowledge of material flows. It highlights, inter alia, quality standards for secondary raw materials and the analysis of the interface between chemicals, product, and waste legislation as key actions [114].

3.6.3 Stakeholder positions

Stakeholders point to the need for an effective strategy to ensure that waste management realises its full potential as a filter in material cycles and a circular economy. It requires avoiding 'hazardous legacies to be reinserted into the economy'[115] and at the same time addresses the conflict with the objective of achieving high recycling rates. The level of recycling is often used as an indicator for success in environmental efforts and to achieve a sustainable economy, e.g. by industry and public authorities and politicians[116]. This view is triggered by certain recycling targets of European waste legislation, which are based on the total mass of a material flow (e.g. ELVD, WEEE Directive, Packaging Directive, WFD). One option to improve the situation would be focused decontamination of material streams, in combination with a discharge of certain material streams (e.g. certain plastic wastes which contain BFRs). Such an approach would facilitate stakeholder groups requiring high quality input material for their production (e.g. plastic products without contaminations) and without risks for employees.

A similar but more technical development is proposed by parts of the waste industry. This puts forward a circular economy model where sinks and a 'decontamination process' [117] have dedicated places in the waste hierarchy and quantitative recycling targets are combined with qualitative criteria[118]. The 'sink' concept[119] combines the destruction of unwanted hazardous substances in waste streams and a final sink for non-recoverable and non-destructible hazardous components[120].

A similar but more comprehensive is the 'anthropogenic metabolism' approach, which concludes that 'final sinks' are a prerequisite for a recycling society[121].

In order to identify waste streams requiring specific treatment, stakeholders propose the establishment of information flows by labelling products for which a temporary exemption or an authorisation has been granted to allow the continued presence of hazardous substances due to re-manufacturing or use of recycled materials.

3.6.4 Material streams

In waste management, materials have different properties when it comes to recycling and the relevance of hazardous substances. Recycling of a broad range of metals comprises a purification step (either thermometallurgical or hydrometallurgical). Closing material cycles is not likely to be hindered by non-metallic hazardous substances because these are destroyed quantitatively in thermometallurgy

[113] Henry, P., 2016.
[114] loco citato.
[115] EEB, 2016.
[116] e.g. EAA 2006, EEA 2016, PlasticsEurope 2016.
[117] 'Decontamination' is defined in that context as an operation which removes or treats unwanted hazardous components or pollutants from a valuable waste material.
[118] Hazardous waste Europe (HWE), 2016.
[119] 'Sink' is defined as the antonym of 'source', i.e. a place on the planet where worthless materials are deposited after their use. Although this definition sounds like the description of a landfill, it goes beyond: Solid, liquid and gaseous emissions that are accumulated in the pedo-, atmo- or hydrosphere are also included. Brunner, 2014.
[120] EURITS, 2016.
[121] Kral, 2014.

recycling, other toxic contaminants (minerals, metals) are separated from the main material stream and eventually end up in the off-gas residues, in slags or in by-products[122].

Recycling of organic matrices and minerals usually does not comprise this purification step, due to their different material properties (e.g. the crystalline structure of minerals does not rebuild automatically after it has been split up for purification of the material). For this reason, the toxic substance content of the waste materials is transferred to the secondary materials.

3.6.5 Waste management approaches to toxic substances[123]

Currently, there are few (comprehensive) legal requirements on the content of toxic substances in wastes and related decontamination actions during waste treatment, in particular for recycling materials. In addition, the market for secondary raw materials is tight and it is challenging to provide recycling materials at a price that is both accepted by customers and covers the costs. To optimise margins, the recycled products frequently meet only the minimum technical standards (which do not necessarily include the content of toxic substances), unless customers define specific product quality requirements.

Toxic substances in waste may prevent the recycling of materials because:

- they may disturb the recycling process and/or risks to humans or the environment cannot be adequately controlled;
- they may not be separable from the material/end-of-life article (at a reasonable cost) and/or are not allowed in the resulting secondary materials/refurbished articles, or they may considerably reduce product quality, resulting in lower prices and profitability;
- legal provisions on material recovery and processing (e.g. due to the REACH authorisation regime[124]) may prevent certain waste from being and/or placed on the market as products.

Reducing the toxicity of waste is an aspect of waste prevention and is at the top of the waste hierarchy (Articles 4 and 12(c) of Directive 2008/98/EC). Few existing pieces of legislation trigger the prevention of toxic substances in articles at the waste stage by putting the general objective of the waste hierarchy in concrete terms. Waste legislation comprises concrete requirements for very few articles (e.g. EEE, vehicles) and substances (some heavy metals, FRs, potentially phthalates). There is no systematic regime enabling recycling by preventing (certain) toxic substances from entering waste streams.

In many cases, toxic substances are included in composite materials or mixed with other materials in such a way that their separation is very complicated and resource intensive. Product legislation could address the problem best through restrictions or implementation of design principles, but challenges from recycling might also trigger provisions. Where no specific obligations require it, mixed wastes are often finally disposed of and not recycled.

[122] By-products are not considered waste and their (re-)inclusion into material cycles would occur only at the end of their use phase in whichever product they are applied.

[123] The following assessment was generated before related activities were started on the chemicals-product-waste interface in relation to the circular economy.

[124] As recycling is considered a substance manufacture under chemicals legislation, the authorisation requirements would be applicable, if substances in REACH Annex XIV are included in the waste material. Consequently, an authorisation would have to be applied for, except where an authorisation already exists from an actor earlier in the chain that also covers the recycling process.
For the formulation and use of recycled PVC containing DEHP, authorisation applications were submitted and the RAC's and SEACs opinions concluded that authorisation should be granted for seven years. This is due to a lack of alternatives and despite the fact that in the application adequate control of risks to workers during formulation could not be demonstrated (c.f. ECHA/RAC/SEAC Opinion N°AFA-O-0000004151-87-16/D and ECHA/RAC/SEAC Opinion N° AFA-O-0000004151-87-17/D.)

There are three key issues in respect of information on toxic substances in waste:

- Lack of information in general: frequently, no information is available about toxic constituents of waste. For example, no information is available on whether a flat screen contains mercury in the backlight or if mercury-free technologies are applied. Often, the only way to identify this is to dismantle the item.
- Lack of access to economic information: even if information is available in principle, efforts to access it are often too onerous in relation to the comparatively small profit margins for recycled products. Time-consuming research, e.g. in SDSs or databases, or the separation of individual end-of-life products from the waste streams in order to identify their toxic substance contents are not carried out because it would be too expensive. In addition, waste management operations are often mass volume operations. This means that the whole content of large containers is treated, rather than individual end-of-life products.
- Lack of legal consequences for information: in some cases, information about the presence of toxic substances in wastes or end-of-life products is available but does not trigger actions in waste management operations. For example, if the presence of beryllium in electric products were known to the waste treatment operator, no separation of such contacts from the other waste materials would be triggered because it is not legally required and not considered economically profitable.

The following outlines the core instruments in waste legislation in respect of the content of hazardous substances in wastes and related information systems.

3.6.5.1 Preventative approaches

Some waste legislation restricts the use of certain substances in products to enhance recyclability, avoid contamination of secondary raw materials and reduce environmental emissions from waste treatment. This applies to products with specific treatment frameworks, like vehicles, electrical and electronic equipment or batteries and accumulators. Use restrictions are limited to selected substances with direct negative consequences in waste management and 'new' substances are added where necessary, i.e. where related issues are known to the legislator (in 2015, four new substances (phthalates) were added to Annex II of the RoHS Directive). For each substance, exemptions may be included in the legislation based on an individual assessment at EU level[125]. The exemptions are regularly reviewed in the light of new technical developments. One reason for such a small-step approach is that the evaluation of substance restrictions takes the specific situations of the individual treatment chains into consideration.

No waste legislation applies to a particular material, e.g. plastics or metals, similar to its absence in products or chemicals legislation.

3.6.5.2 Classification and communication based on the LoW

The LoW[126] categorises all wastes into more than 800 waste codes. More than 400 of these codes relate to hazardous wastes. Each waste code has six digits (XX YY ZZ).

- XX main section of the list of waste: 1 to 20, provides general information about the group of wastes (e.g. group with a same origin);
- YY subsection: provides more detailed information about the subgroup of wastes;

[125] For example, COMMISSION DIRECTIVE (EU) 2016/774 comprises electrical and electronic components which contain lead in a glass or ceramic, in a glass or ceramic matrix compound, in a glass-ceramic material, or in a glass-ceramic matrix compound.
[126] COMMISSION DECISION 2000/532/EC.

- ZZ consecutive number for each waste type.

The entries show a wide variety of ways to describe the wastes, and different descriptors are applied, including:

- Around 8% of the entries provide information solely on the origin (04 01 99 wastes from the leather, fur and textile industries not otherwise specified).
- Around 30% of the waste codes give information about the process where the waste has been generated (e.g. 01 04 07* wastes containing dangerous substances from physical and chemical processing of non-metalliferous minerals).
- Around 30% of the waste codes give information about the physical state of the waste (e.g. sludge or dust).
- Around 60% of the waste codes give information about the material or substance present in the waste as the main hazardous component (e.g. 16 01 09* components from ELVs containing Polychlorinated Biphenyls (PCBs)).

In determining the appropriate entry/waste code for a specific waste the following rules are applied[127]:

- *'Identify the source generating the waste in Chapters 01 to 12 or 17 to 20 and identify the appropriate six-digit code of the waste (excluding codes ending with 99 of these chapters);*
- *If no appropriate waste code can be found in Chapters 01 to 12 or 17 to 20, the Chapters 13, 14 and 15 must be examined to identify the waste;*
- *If none of these waste codes apply, the waste must be identified according to Chapter 16;*
- *If the waste is not in Chapter 16 either, the 99 code (wastes not otherwise specified) must be used in the section of the list corresponding to the activity identified in step one.'*

In several cases, only a rough indication is given for the constituents of the waste, because its composition differs widely even with the same origin or belonging to the same product type.
When assessing the hazardous properties of wastes, the criteria laid down in Annex III to the WFD shall apply. Certain specifics must be considered[127]:

- *'For the hazardous properties HP 4, HP 6 and HP 8, cut-off values for individual substances as indicated in Annex III to the WFD shall apply to the assessment;*
- *Where a substance is present in the waste below its cut-off value, it shall not be included in any calculation of a threshold;*
- *Where a hazardous property of a waste has been assessed by a test and by using the concentrations of hazardous substances as indicated in Annex III to Directive 2008/98/EC, the results of the test shall prevail.'*

For some wastes, only the codes for hazardous waste can be applied ('absolute' hazardous wastes) and for others, either hazardous or non-hazardous waste codes can be assigned ('mirror' hazardous wastes).

For a classification of a 'mirror waste' the following procedure is applied[127]:

- *'An entry in the harmonised list of wastes marked as hazardous, having a specific or general reference to 'hazardous substances', is only appropriate to a waste when that waste contains relevant hazardous substances that cause the waste to display one or more of the hazardous properties HP 1 to HP 8 and/or HP 10 to HP 15 as listed in Annex III to Directive 2008/98/EC;*
- *The assessment of the hazardous property HP 9 'infectious' shall be made according to relevant legislation or reference documents in the Member States;*

[127] COMMISSION DECISION of 18 December 2014 amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council (Text with EEA relevance) (2014/955/EU).

- *A hazardous property can be assessed by using the concentration of substances in the waste as specified in Annex III to Directive 2008/98/EC or, unless otherwise specified in Regulation (EC) No 1272/2008, by performing a test in accordance with Regulation (EC) No 440/2008 or other internationally recognised test methods and guidelines, taking into account Article 7 of Regulation (EC) No 1272/2008 as regards animal and human testing.'*

The characterisation as hazardous waste is not a 1:1 application of the CLP criteria and rules[128]. Waste classification is partly based on weaker rules than those of the CLP Regulation (e.g. M-factors are not applied). Additionally, the identification of hazardous wastes does not cover the substance categories PBT/ vPvB, nor does it correspond with the rules for identifying POPs.

The hazard criteria rendering a waste hazardous are not indicated in the waste codes or the related text. Instead, an asterisk at the end of the number code indicates the waste's hazardousness. This limits the suitability of the European LoW as a communication instrument on hazardous components in the waste. At Member State level, communication tools are required under WFD Articles 17 and 19, including information according to Annex IB of the Waste Shipment Regulation.

3.6.5.3 Mechanism to inform consumers about waste management requirements

In general, the WFD requires that consumers discard their wastes to the appropriate collection systems. Legal frameworks, like the WEEE Directive[129] include more specific requirements:

'2. Member States shall ensure that users of EEE in private households are given the necessary information about:
(a) the requirement not to dispose of WEEE as unsorted municipal waste and to collect such WEEE separately;
(b) the return and collection systems available to them, encouraging the coordination of information on the available collection points irrespective of the producers or other operators which have set them up'.

This is usually implemented through information campaigns. In addition, the WEEE Directive requires a mark on EEE when it is placed on the market, highlighting the need for separate collection[129]

Figure 6: Symbol for the marking of EEE according to Annex IX of the WEEE Directive

There is no further differentiation of the potential content of hazardous substances or additional information included on the product labels (e.g. about mercury in flat screens). The background to this is the desire that separate collection be as easy as possible for the consumer, removing potentially complex decisions in order to achieve the highest possible collection rates. Other specific collection and labelling requirements are part of the ELV and batteries legislation.

3.6.5.4 Information on substances in waste and extended producer responsibility

There are few legal and practical mechanisms in place to create an information flow on the composition of end-of-life products from article producers to the waste sector. These requirements are based

[128] This issue was addressed in a case study under the Fitness Check of CLP and chemicals legislation other than REACH.
[129] Article 14 'Information for users'.

on legal approaches in the context of the extended producer responsibility principle of the WEEE and ELV Directives:

- The WEEE Directive[130] requires producers to provide all necessary information to enable the preparation of end-of-life EEE for reuse, treatment and recycling in treatment facilities in compliance with the provisions of the Directive. This includes information on the different EEE components and materials, as well as the location of dangerous substances and mixtures in the EEE.
- The ELVD requires vehicle producers to provide sufficient information about the ELV composition to dismantling companies so that they can comply with its provisions. The automotive industry established a tool called IDIS (International Dismantling Information System), which highlights the presence of hazardous components in ELV.

Both approaches cover only those components, where dismantling/separation is obligatory and/or where information about the presence of certain hazardous substances is crucial for proper waste management. For example, the ELVD[131] requires the following treatment operations for depollution:

- Removal of batteries and liquefied gas tanks;
- Removal or neutralisation of potential explosive components, (e.g. air bags);
- Removal and separate collection and storage of fluids;
- Removal, as far as feasible, of all components identified as containing mercury.

For example, lead-containing components exempted from the use restriction under Annex II of the ELV Directive are not covered by treatment requirements and the information tool 'IDIS'.
Producers of EEE and vehicles use additional information systems, which describe the (chemical) composition of their complex products in more detail (e.g. IMDS and GADSL for car producers). Such information platforms are not available to the waste management sector, however.

Treatment of post-consumer wastes is usually performed by waste operators, with producers providing for the financing of waste sector activity, if at all. In practice, the current implementation of the extended producer responsibility principle (EPR) does not necessarily result in a situation where producers influence waste management operations beyond their financial obligations[132].

3.6.5.5 Management of hazardous waste

Steering of waste/materials to appropriate treatment and disposal routes and control of waste flows is a highly important element in the management of hazardous waste. Depollution requirements are set - where applicable - in many cases in order to get a 'clean' waste fraction which can be recycled, and another fraction that contains the hazardous substances in a concentrated form for final disposal. Recital 21 of the European Commissions 'Proposal for a Directive of the European Parliament and of the Council amending Directive 2008/98/EC on waste' (COM(2015) 595, 2015/0275 (COD)) states: '*Proper management of hazardous waste still presents a problem in the Union, and data on its treatment are partly missing*.' As a first step, the proposal recommends improvements in the monitoring of hazardous waste flows and management activities.

3.6.5.6 Depollution requirements

The WFD defines the general requirements on waste treatment operators for depollution of wastes that are not covered by specific legislation. It does not make the concept of depollution concrete or operational, i.e. it does not specify elements to be considered 'a pollution', means of depollution, or the

[130] Article 15(1) 'Information for treatment facilities'.
[131] Annex I of DIRECTIVE 2000/53/EC.
[132] Tasaki, T., Tojo, N., Lindhqvist, T., 2015.

characteristics of a 'depolluted waste fraction'.
The WEEE Directive and the ELVD define requirements for depollution (i.e. dismantling and separate treatment of parts containing hazardous substances) to ensure sound waste management operations in general, protect workers and enable the fulfilment of recycling targets. Depollution targets are hard to pinpoint because available data is insufficient to quantify the overall input of such hazardous substances contained in the waste used at a treatment site. Instead, non-quantifying obligations require, for example, the separation of mercury containing components 'in general'. The degree of the separation, such as a limit value for the output fraction of the treatment, is not usually specified.
The recycling targets usually apply to overall recycling quota by weight and do not focus on specific materials (see below). A focused approach for recovering critical raw materials is not established.
While waste management should be considered a global market activity, depollution and treatment requirements and infrastructures differ from country to country. Consequently, the implementation of strict depollution requirements might affect the EU waste sector's competitiveness.

3.6.5.7 Collection and recycling requirements

The collection and recycling targets of the current WFD[133] partly differentiate by type of material, e.g.:

'2. In order to comply with the objectives of this Directive, and move towards a European recycling society with a high level of resource efficiency, Member States shall take the necessary measures designed to achieve the following targets:

(a) by 2020, the preparing for reuse and the recycling of waste materials such as at least paper, metal, plastic and glass from households and possibly from other origins as far as these waste streams are similar to waste from households, shall be increased to a minimum of overall 50% by weight;

(b) by 2020, the preparing for reuse, recycling and other material recovery, including backfilling operations using waste to substitute other materials, of non-hazardous construction and demolition waste excluding naturally occurring material defined in category 17 05 04 in the list of waste shall be increased to a minimum of 70 % by weight.'[134]

The collection targets of the WEEE Directive differ by product type (e.g. large household equipment, IT equipment, consumer electronics, etc.). The recycling and recovery targets are not differentiated by material type (e.g. recycling of x% of plastics) but fall under overall recycling and recovery targets (e.g. for IT equipment: 75% recovery and 65% recycling).

In order to define qualitative targets for the maximum content of toxic substances in secondary raw materials, a comparison with the respective virgin materials would be useful and fair (i.e. the secondary raw material should have the same requirements). To derive these requirements, the content of (toxic) substances in primary raw materials must be known, which is not currently the case for most materials[135].

ECHA[136] initiated an approach to developing a database on the content of toxic substances in different materials, through stakeholder consultation and a stakeholder workshop. While the general approach was welcomed by many actors, including industry and Member States, concerns were raised about whether or not the approach could be implemented for complex materials (e.g. polymers) or materials

[133] The targets will be affected by the proposal of a legal package on the circular economy, currently being discussed by the European Council (see http://ec.europa.eu/environment/circular-economy/index_en.htm for the Commission's proposal).
[134] WFD Article 11(2).
[135] The lack of information is less of an issue for 'simple' materials, such as minerals, or for highly standardised ones, such as steel. These are usually materials less likely to contain toxic substances.
[136] Reihlen, A., 2016.

treated with many chemicals during processing (e.g. textiles). Due to a lack of willingness to cooperate, the project closed by concluding that a materials' information system was not feasible (at that time)[137].

In the context of the circular economy, the concept of 'traceability' is often discussed. One interpretation of the concept is the implementation of mechanisms to trace 'who uses a substance for what product' from production through to the waste stage. This type of tracing would include the second and consequent service lives, e.g. reporting the use of toxic substances along the supply chain. The result could be information based on the substance content of all products (mixtures, materials, articles, wastes) on the market, as well as providing the possibility to identify the actors responsible for risks and damage (if these occur) or who should bear the costs for disposal.
A 'traceability approach', as implemented for food, would require considerable efforts from all involved, even if limited to SVHC. However, if adapted to the specific needs of the non-toxic environment and circular economy, this might be an ideal approach to generate the required information. However, it is not clear if this is what is actually meant by the term traceability, or if it is simply a synonym for 'obtaining information on the chemical content of an article'.

While traceability is generally understood to enable the identification of actors responsible for a product or its components, the concept of a 'product passport' generally involves the characterisation of articles with regard to their material contents (and potentially toxic substances present). These passports, requested by the European Resource Efficiency Platform (EREP), should facilitate separation of waste streams and increase the opportunities to recycle materials with lower efforts for recycling companies, by making the product passports available through an EU-wide database. The product passport concept is not further specified by the EREP in terms of the information to be included, or how it may be obtained[138].

3.6.5.8 End-of-waste

The criteria for the end-of-waste, i.e. where a material or object ceases to be waste, are important from a legal perspective because they define the transition from waste legislation to chemicals legislation. This means that obligations for the treatment, monitoring and related documentation within chemicals legislation apply.

Gaps and deficits in this interface require particular attention because of the registration under REACH for 'end-of-waste materials'/products:

- Substances as such or in mixtures recovered from wastes have to be registered, unless an exemption can be claimed in accordance with REACH Article 7(2)d. The exemption from registration applies regardless of whether or not the use of the recovered substance (in a second life cycle) is covered by the original registration.
- If articles are produced in a recycling operation, only the communication obligations of REACH Articles 33 and 7 apply, i.e. for SVHC contained above 0.1% w/w.

The decision on the stage of a recycling process at which a material becomes a product (end-of-waste) determines which requirements apply. For example, a recovered polymer mixture is a non-waste, the monomers and (other) contained substances have to be registered. If window profiles extruded from the mixtures are the product (no waste), only REACH Articles 7 and 33 apply. If neither the polymer mixture nor the window profiles are declared a product (e.g. in case of faulty production of the profiles), waste legislation continues to apply.

[137] However, an initiative was started in the electronics sector (medical devices) to include a similar functionality as that implemented in the Materials Information Platform (c.f. Reihlen, 2016) into the tool 'BOMCheck'.
[138] Environmental Resource Efficiency Platform (ERPD), European Resource Efficiency Platform pushes for 'product passports', viewed November 2016.

Due to triggering information generation and communication under REACH, the criteria and processes for identifying when a waste becomes a product are important across the board.

The WFD sets a framework for determining the end-of-waste status (WFD Article 6). Concrete material related end-of-waste criteria are set for:

- Iron, steel and aluminium scrap (see Council Regulation (EU) No 333/2011).
- Glass cullet (see Commission Regulation (EU) N° 1179/2012).
- Copper scrap (see Commission Regulation (EU) N° 715/2013).

The criteria were defined in a longer process involving the EU Commission, Member States, industry and NGOs. According to WFD Article 6(4), for waste streams without end-of-waste criteria at community level, Member States may decide on a case-by-case basis if a certain waste has ceased to be waste, taking into account case law.

From the perspective of REACH, the existence of criteria or mechanisms defining the end-of-waste (and the beginning of a product) are necessary when registration obligations apply. In addition, the exemption in Article 2.7(d) implies that there are quality criteria for recycled materials, as they exempt substances from registration based on the assumption that sufficient information is already available. These quality criteria are included in the existing end-of-waste criteria.

Where Member States have to take decisions on the end-of-waste of a material, the applied criteria are likely to be heterogeneous and based on different considerations (e.g. with regard to installation permit requirements or technical material standards). This may lead to different levels of environmental protection and/or economic conditions in the Member States.

3.6.6 Discussions and conflicting policy goals

In the context of waste legislation, conflicts/diverging views often stem from responsibility for waste management activities and approaches to restricting the use of certain substances:

- There is a discussion about the extent to which waste legislation (in particular Directives on specific waste streams) should restrict the content of hazardous substances in articles, or whether REACH or some special article-related legislation would be more appropriate. This includes considering how the interface between waste, chemicals and article legislation shall be designed. In addition, the definition of the maximum content of restricted substances might have to be harmonised (e.g. the RoHS Directive bases the concentration levels on 'homogeneous materials, while REACH relates its threshold for CLS to the article)[139].
- The quality of recycled materials depends on the costs of the recycling process and the margin that can be realised on the market. High quality recycling is naturally chosen as the 'best' treatment option where it yields higher income or is related to lower costs than low quality recycling. This conflicts with the aim of securing (critical) resources and using them in (high quality) products, where producing low quality (contaminated) recycled materials are more profitable. One possibility could be the installation of collection systems that differentiate between 'new' articles in which toxic substances are excluded by design and 'old' articles, for which the content of toxic substances cannot be excluded. While the former material streams could be directly subject to recycling, the latter would have to be subject to testing and further analysis, where appropriate and economically justified.

[139] The differences in interpretation of Article 33 were clarified by a ruling of the European Court of Justice (CJEU), specifying that the threshold applies to an article. Where these are combined in a complex article, they do not cease to be an article and thus the substance content in this 'component' is not diluted in the entire (complex) article.

- The principle of EPR currently applies to certain end-of-life products like WEEE and ELV. The implementation of the principle might comprise shared responsibilities along the waste chain (e.g. the last product owner is required to provide the end-of-life product to the specific collection system, the collection systems at civic amenity sites have to provide the end-of-life products to the treatment sites). Waste collectors, separators and recyclers should optimise their cooperation, e.g. by designing waste collection systems that yield the best possible input stream to treatment installations rather than systems that are as cheap as possible[140].
- Reparability of articles might mean that the use or placing on the market of spare parts containing chemicals of concern (legacy contaminants) continues. Related exemptions from the REACH authorisation are under discussion, which would delay the removal of harmful substances from material cycles and imply continued production and use.
- Availability of information about the composition of end-of-life products is a challenging issue, even for those product groups where (some) information requirements exist, because its form must fit to the waste management processes. For example, a broad variety of WEEE products are collected in large containers, meaning that identification of each product and evaluation of its composition requires significant time and efforts, which are not financed by the revenues from material recycling. A system would be required that enables identification of products with very toxic components in an automated way, e.g. in form of a radio-frequency identification (RFID) tag read by a machine scanner.

3.7 SUMMARY OF POLICY ELEMENTS RELEVANT FOR A NON-TOXIC ENVIRONMENT

The following three chapters summarise the main principles and approaches in relation to non-toxic articles and material cycles within three policy areas'- chemicals, products (articles) and waste. In addition, they summarise the key policy instruments to converge the goals of non-toxic articles and material cycles, as well as a circular economy.

3.7.1 Chemicals policy

Chemicals policy ensures the availability of an information base for managing toxic substances in articles and material cycles, as it requires the identification of a substance's toxic properties and uses via registration, approval and notification procedures. These requirements apply to virgin substances as well as to substances recovered from waste (as such or in mixtures).

The primary mechanism of chemicals legislation to prevent the presence of toxic substances in articles that could cause unacceptable risks are CSAs and derived risk management measures. Hazard and risk management information should be communicated along the supply chain (including advising against unsafe use, such as in consumer products). Other chemicals legislation, such as the BPR, requires manufacturers, importers and those placing products on the market to identify and manage potential risks and measures.

Restrictions and authorisation procedures under REACH complement industry work on risk management and (may) result in the prevention or limitation of substance contents in mixtures and articles (Annex XVII and Annex XIV).

The information flow on chemicals is established (SDSs, REACH Article 32) and comprehensive. However, information about substances contained in mixtures below the concentration thresholds for identification in the SDS is lost, as no communication requirement exists. Some chemicals which are

[140] For example, municipal systems collect WEEE in big, 40-foot containers, as it is the cheapest option. Treatment sites prefer collection in small containers, where the end-of-life products are less damaged and would be better tailored for treatment.

not intended for inclusion in articles and are covered by other, more specific legislation, are exempted from the information requirements in REACH (e.g. pharmaceuticals, cosmetics).

Chemicals legislation forms the basis for any strategy to implement non-toxic articles and material cycles with regard to limiting the toxic substances content in products and providing related information.

While the overall principles and mechanisms in chemicals legislation generally appear appropriate, their implementation is not sufficient to ensure products and material cycles are free from toxic substances, for several reasons:

- The use of toxic substances cannot be avoided in all cases (yet) because suitable alternatives may not be available. Prevention of the presence of toxic substances in articles and materials is not always possible;
- Frequently, the data quality in REACH registration dossiers is not sufficient and information is not always up-to-date, i.e. hazard, use and exposure information as well as resulting safety assessments and risk management measures are not sufficiently detailed and reliable. This hinders industry from developing and communicating proper risk management measures, and authorities from identifying and regulating certain uses of concern, at EU level;
- Communication along the supply chain, in particular regarding substances in articles, does not work, with instances of non-compliance frequently observed;
- A risk-based regulatory approach may not always provide a sufficiently high level of protection and/or incentives for substitution and the implementation of risk management measures. Reasons for this include that an RCR under 1[141] is acceptable and normally implemented at a general level. This does not take combined and cumulative exposures into account and may fail to consider the specifics of sectors and products;
- Information on the content of toxic chemicals in articles is missing, because SVHCs are to be notified only where they exceed the threshold of 0.1% and the total amounts exceed 1t/a. The degree of compliance with this requirement appears to be low. Articles may enter the EU containing substances which require authorisation, as the authorisation does not cover the content of substances in articles.

3.7.2 Product policy

Product[142] policy focuses on ensuring that all products placed on the market are safe, with a strong focus on human health/consumer safety and mechanical or electrical risks. While taking into account sector and product-specific requirements and conditions, the legislation does not provide specific criteria for chemical safety or recyclability of products.

The main instruments of product policy relevant for a non-toxic environment and the circular economy are substance restrictions (e.g. based on hazard classes and/or specific CAS numbers, such as in toys legislation) and approval procedures (e.g. for FCMs). Further incentives for the use of less toxic substances are occasionally proposed by other means, e.g. ecolabelling and the possibility of their introduction into the Ecodesign Directive is currently under discussion[143].

There are few requirements in product legislation on the design of articles that relate to improving the possibility of separating materials and/or article parts into those containing toxic substances and those without. Ideas exist to include these aspects in the Ecodesign legislation in the future.

[141] With the exception of PBT/vPvB, for which no RCR is calculated.
[142] Although this study mainly refers to articles, the term 'product policy' is used here, as the more commonly used term.
[143] This might be different for the Ecodesign Directive if chemical requirements are included, following ongoing discussions.

Product policy includes instruments to direct the flow of toxic substances in articles and materials using industry self-responsibility and risk management implemented by authorities. However, certain elements are missing, some of which are regarded as essential for non-toxic articles and material cycles:

- There are no clear 'overarching' criteria in product policy in relation to the substances/substance properties to avoid. However, CMRs and sensitisers are usually considered.
- There are few requirements, instruments or methods to influence article design with regard to substance content and recyclability.
- Product legislation lacks specific requirements to communicate the content of toxic substances in articles[144] along the supply chain. There are no coherent and comprehensive provisions on gathering, documenting and providing information on (toxic) substances in articles.

3.7.3 Waste policy

Waste prevention, including the reduction of the toxicity of waste, is a primary objective of waste policy. However, there are few mechanisms to steer waste management practices towards this objective. Waste policy aims to turn waste into a resource, i.e. to reduce the amount of waste and to maximise reuse and recycling. This 'waste hierarchy' can be circumvented where concerns for the life cycle of materials justify doing so. Sustainability in a circular economy would integrate an increase in recycling with a decrease of toxic substances in material cycles, as well as an overall reduction of the use of resources and generation of waste.

Use restrictions triggered by waste legislation do exist (e.g. RoHS Directive) and should primarily prevent the contamination of material streams, thereby facilitating waste treatment at lower cost, as well as reducing waste-related concerns for the environment.

The EPR should create sufficient incentive for product design that takes account of recycling, including the avoidance of toxic substances, enabling separation of materials and articles, and ensuring materials and components can be reused. The incentive motivating producers to implement recycling-friendly product design is the requirement to contribute to waste sectors costs for the treatment of their articles. The EPR is implemented only very few products as yet and does not work as intended, as co-financing the costs of the waste sector is the main means of fulfilling the obligations.

While existing instruments on the communication on waste hazards are not sufficiently well adapted to facilitate waste treatment that considers the content of toxic substances in materials/wastes, no promising solutions to cover the information gap between articles and wastes were identified in this study.
Preventing toxic substances from being re-introduced into material cycles via a second service life from recycled waste is a new task, and one which the actors of the waste sector and the producing sector should tackle together. Current waste management and product policy instruments are not appropriately designed to facilitate cooperation from all parties on the identification, communication and treatment of wastes in light of their contents.
Further work may be needed to identify whether and how additional legislation and/or other policy measures might support the separation of waste, and guide decision-making on the treatment option that would best serve the goals of increased resource efficiency and a non-toxic environment. This includes appropriate mechanisms for information transfer. It is obvious that any move towards preventing the generation of toxic wastes would be less waste-related than product-related and would fall within the category of product design in the broadest sense.

[144] Exemptions are the Batteries Directive, the declaration of fragrances under the TSD and communication under the Biocides Directive. Apart from those, only REACH Article 33 requires information on toxic substances in articles.

3.7.4 Main instruments for policy integration

From the analysis of existing tools and instruments under the three policy areas, the following tools appear to be relevant for promoting the goals of a non-toxic environment and a circular economy.

- **Restriction and authorisation** procedures exist under chemicals, product and waste legislation and effectively reduce the use of toxic substances in articles and waste streams (steering the occurrence of chemicals). The 'initiative' for restrictions/authorisations could come from concerns identified in any of the three policy areas. Justifications for limiting/restricting the use of substances could thus be based on concerns related to:
  - the inherent hazardous properties of the substances (i.e. hazard based risk management);
  - particular risks for consumers, workers and the environment from the use of a substance in articles[145];
  - whether or not the waste can be processed, the technical fitness for purpose of the secondary materials and the profitability of waste treatment, including recycling, i.e. contamination that is difficult or costly to manage in the waste treatment operations.
- **Technical or organisational risk management** reducing or eliminating the release of substances relates to industrial processing and the waste stage, including emission capture and treatment, separation of material streams, and article service life, e.g. via particular article design, by preventing release, through providing use and disposal instructions, etc.
- **Measures to separate material streams** into those containing toxic substances and those without already exist but require further extension to promote a non-toxic environment and a circular economy. Among others, they relate to:
  - Article design criteria under product legislation, such as the substance content and recyclability of articles leading to a prevention of contamination;
  - Communication on substance contents in articles and waste, sufficient to enable separation and decision-making on treatment options;
  - Decision criteria or instruments for the waste sector for the identification of appropriate treatment options for particular wastes, taking into account the possible content of toxic substances and their potential re-introduction into material cycles;
  - Technical measures in the waste sector to separate and separately treat waste streams (infrastructure for separate collection, separation technologies and separate treatment of waste streams etc.).
- Most legislation at EU level is accompanied by **implementation guidance.** The respective documents should better address the prevention or reduction of emissions of toxic substances from articles and material cycles. This includes awareness raising of the life cycle of substances and products.
- Existing instruments on information provision in the supply chain and the waste sector need strengthening, with new complementary instruments necessary to fill information/communication gaps to ensure all actors have **sufficient information** to make informed decisions on their area of responsibility;
- Finally, all actors need **clear orientation and guidance** and, ideally, criteria for evaluating the most efficient decision on article design, waste treatment, etc. in contributing to a non-toxic environment AND an efficient use of resources.

3.8 DETAILED LISTING OF GAPS AND DEFICITS IDENTIFIED

The following list of gaps and deficits builds on the information provided in previous chapters and serves as an additional information resource.

[145] Restrictions or authorisations related to the manufacture, formulation and use of substances in articles, would naturally also affect the content in articles and waste streams.

3.8.1 Chemicals policy

Core gaps and deficits in EU chemicals legislation in relation to achieving the goal of non-toxic articles and material cycles are compiled from literature research and stakeholder inputs via the workshop held within the realm of this study. Many of these gaps and deficits are relevant for the current REFIT process of chemicals legislation and the REACH review.

3.8.1.1 Lack of information on hazards and uses

- There are no classification criteria and only limited data requirements for some hazards particularly relevant for exposures from articles (long-term, low-level) for human health and the environment, namely endocrine disrupters[146] and (developmental) neurotoxicants[147]. In addition, no requirements exist to generate specific data to identify these properties of substances.
  As a result, substance hazards may not be identified and are thus not communicated and managed under chemicals legislation, undermining the basis for risk management in relation to these properties.
- Insufficient hazard data is available to identify SVHC properties for substances registered under REACH in low tonnages (CMR, PBT/vPvB)[148].
  As a result, companies cannot identify SVHCs and the necessary risk management measures (RMM) to control risks from their use and/or communicate uses advised against. Authorities lack information to prioritise their work on specific substances, e.g. to identify a substance as SVHC and/or develop restriction proposals.
- Overview of information on the uses of (toxic) substances in articles is missing.
  As a result, authorities have difficulties in assessing risks and prioritising substances for risk management. The reasons for this lack of overview in chemicals legislation are:
  - Use information is systematically collected only for substances registered under REACH; however, the use descriptions are comparatively rough and do not allow much differentiation[149];
  - REACH Article 7(2), requires that the content of SVHC in imported articles are notified to ECHA under certain conditions. However, few notifications are received, partly because importers claim the exemption of an 'already registered use', which is difficult to prove[150];
  - Information communicated under REACH Article 33 is not stored in a central database and/or available to the authorities.
- Recycling operators recovering substances from waste may be exempt from the registration obligation under REACH Article 2(7)d, if they can demonstrate that the substance is already regis-

[146] The EU Commission published its approach to the definition of criteria for endocrine disruptors in its 'COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on endocrine disruptors […]'. Initial reactions show that NGOs and some Member States disagree with the proposed approach. When a decision may be expected on the criteria remains unclear.

[147] No definition of criteria for neurotoxic substances or related classification criteria exist. As presented by Prof. Grandjean at the workshop held within the realm of this study, this group of substances requires particular attention with regard to the protection of vulnerable groups. See also the sub-study on protection of vulnerable groups. For substances registered in high volumes, an extended one-generation reproductive toxicity study is required, which may trigger the obligation to include developmental neurotoxicity in the study design, based on a related concern.

[148] Molander, L., 2015; Brunn Poulsen et al., 2010; Ruden C. and Hansson, 2008.
Whether or not this is particularly relevant for substances used in articles or if this is a general problem cannot be ascertained, as insufficient information is available on the use of substances in articles.

[149] The guidance document was updated in 2015 and now contains a much more detailed list of article categories (AC). Whether this is sufficient to create a good overview of the substance content is unclear. However, the newly formed categories differentiate according to user groups (children) or legal coverage (vehicles covered by ELV and other vehicles), which is the most relevant information for prioritisation of risk management measures.

[150] Führ et.al., 2015.
At the stakeholder workshop, an ECHA representative stated, however, that claiming the exemption would be difficult to prove. In addition, the guidance document on information requirements and CSA was updated with regard to the use descriptors (Chapter R12), and is now much more detailed than it was before.

tered and if they have an SDS[151].

- Substances from wastes may enter a second life cycle in products which are not safety assessed by the registrant. If recyclers are exempted from registration, the safety of the second life cycle is not assessed;
- It is unclear whether and how the concept of a 'substance' can be implemented by the recycling industries, in particular for UVCBs or multi-constituent substances. These substances are recovered in a different composition than the registered substance, meaning that a considerable amount of 'impurities' or 'contaminants' might be accepted in a recycled substance, which are not present in the originally registered substance.

3.8.1.2 Deficits in risk assessment for articles and the waste stage

- Sufficiently well-developed guidance and tools to assess chemical safety of articles are missing[152]. This may result in incomplete or incorrect communication on safe use[153].
- Aggregated and cumulated exposures from articles, as well as combination effects, are generally not sufficiently well considered under REACH, or in regulatory CSAs in general.
  This may lead to underestimation of risks and placing on the market of articles which, in combination with other emission sources, may cause risks to humans and the environment[154].
- Risk assessment tools do not exist for the waste stage and the ECHA guidance document seems to be rarely applied in REACH CSAs in practice. This may be due to different reasons, such as:
  - Waste stage is not regarded as relevant under the cut-off criteria in REACH Article 14;
  - Lack of information on substances in waste and how the waste should be treated;
  - Lack of enforcement of the respective REACH provision.
- As the waste sector is organised according to material streams rather than individual toxic substances, communication, information collection and development of models and assumptions remains a challenge[155].
  As a result, it is unclear if waste treatment processes could pose risks due to toxic substances contained in waste.
- Risks from the waste stage do not have to be assessed under the Biocidal Product Regulation. As a result, products may be placed on the market, from which risks occur during waste treatment[156].

3.8.1.3 Deficits in preventing risks from unsafe uses in chemicals legislation

- REACH does not prevent the occurrence of toxic substances in articles and wastes with sufficient speed:
  - The number of substances subject to authorisation is low and in practice the inclusion of SVHC in Annex XIV partly depends on ECHA's and the Committees capacities to handle authorisation applications;
  - NGOs criticise authorisation decisions as too 'industry friendly'[157], enabling the use of toxic substances in articles too often and thereby preventing substitution[158];

[151] Chemtrust, 2015.
[152] For example, industry developed only one specific environmental release category addressing substance emissions from articles (Eurometaux on the industrial use of articles).
[153] Führ et al., 2015.
[154] KemI, 2011, Brunn Poulsen et al., 2010.
[155] Experience from several projects, including the development of background information for the ECHA guidance document on Chemical Safety Assessment of the Waste Stage (R18), the related PEG meeting, several BAT processes and work on waste prevention programmes in Germany.
[156] As biocidal products are mixtures, no waste may occur in many cases. However, whether or not there are any specific waste treatment processes of articles treated with biocides and/or if any risks could arise, is unclear.
[157] See for example the discussion on the authorisation of the use of DEHP in PVC.
[158] These concerns were reiterated at the stakeholder workshop in June.

- Authorisation does not cover the use of (the substance in) (imported) articles[159];
- NGOs and national/Member States authorities criticise the restriction process as too slow resulting in (too) few substances being restricted since REACH entered into force[160].

- REACH Article 33 requires communication on SVHC in articles but does not influence the actual content of SVHC in articles directly.
- Annex XVII of REACH includes generic (top-down, hazard-based) restrictions only for CMR in mixtures for consumer use. There are no similar provisions on substances in articles; however, a relevant mechanism is already included under REACH (Article 68(2)).
- Industry criticises the fact that due to the complexity of chemicals and product legislation, it is difficult to identify the obligations applying to each substance.

3.8.1.4 Communication on substances in articles

- Little (or no) information is generated in the REACH (CSA) on risk management measures related to article service life and the waste stage (c.f. risk assessment methods). As a result, little or no relevant information - including uses advised against - is communicated via the SDS.
- Where chemicals are included in articles, no communication requirements exist, other than REACH Article 33 on SVHC. Therefore, communication on chemicals in articles stops at the point of their inclusion in articles. Consequently, article suppliers lack information on the content of (toxic) substances that are not included on the CLS[161].
- Communication on CLS in articles is mostly limited to providing the substance name[162], i.e. no information is provided on safe handling and disposal, nor is it legally required to positively state/reply on the absence of CLS in articles. Consequences of these gaps are a lack of clarity about the presence of CLS in articles, whether that presence causes a risk, and how humans and the environment could be protected.
- The delay in answering consumer requests on CLS in articles prevents this information from being taken into account in purchasing decisions; i.e. the market demand for products without CLS could be increased if that information was directly available[161].
- Even though information on safety during waste treatment may be generated during registration or provided for SVHC according to REACH Article 33, it does not reach the actors in the waste sector. Decision-making and implementation of recycling or safe disposal therefore cannot consider the content of, or potentially identified risks from, particular substances.

3.8.1.5 Other issues in relation to articles/waste

- Several stakeholders are of the opinion that enforcement of chemicals legislation is too weak (too few controls, too few resources) and lacks harmonisation, despite the efforts of the FORUM and the common REACH- EN-FORCE projects. In addition, national legislation on sanctions differs and is viewed as insufficiently strict. This creates an uneven playing field for market actors and insufficient incentives to implement the requirements.
- Awareness of companies of their legal obligations and those of supply chain actors outside the EU on REACH are low and hinder the running of the entire system[163].
- Consumer awareness on the issue of SVHC in articles is regarded as low. As a result, too little market pressure is exerted on companies to substitute SVHC in articles[164].

[159] Molander L., 2015; Führ et al., 2015; KemI 2011; this was also discussed in the break-out group at the stakeholder workshop.
[160] Brunn Poulsen et al., 2010.
[161] Führ et al., 2015.
[162] Führ et al., 2015; KemI, 2011.
[163] The lack of awareness among companies was discussed as an important gap in the implementation of legislation at the stakeholder workshop held within the realm of this study in June 2016.
[164] KemI, 2011.

3.8.2 Product legislation

The following gaps and deficits in EU articles-related legislation are regarded as relevant for this sub-study and for the achievement of non-toxic articles and material cycles. They relate to the occurrence of toxic substances in articles, the assessment and potential reduction of related risks, and approaches to make sufficient and relevant information available.

- There is no systematic and comprehensive approach at EU level to regulate 'substances in articles'. This concerns:
  - The **content** of toxic substances in articles: existing restrictions (in chemicals and product legislation) are narrow, relating to specific article types and particular, individual substances. Therefore, they neither cover all potentially relevant substances nor all article types, and the sum of these provisions is regarded as insufficiently protective and inconsistent (Brunn Poulsen P., Strandesen M. and Schmidt A., 2010).
  - The lack of obligation of article producers to **identify** the toxic substances included in their articles, apart from identified SVHC in concentrations above 0.1%[165].
  - The **provision of information** on substances other than identified SVHC in concentrations above 0.1% w/w in articles **in the supply chain.** Due to a lack of legal provisions, industry actors using articles (components) to produce complex articles have no information basis to take the content of toxic substances in input materials into account in their product design/purchasing decisions[165,166].
  - The provision of information on substances in **consumer** articles: with a few exceptions (toys, batteries), there are no legal requirements to communicate the content of (toxic) substances in articles to consumers. Some information may be communicated via voluntary schemes, such as ecolabels or industry-based certificates, but this is patchy and frequently not available/comparable for different articles.
- The existing requirements on chemical product safety are frequently vaguely phrased, using terms like 'products must be safe', which is difficult to implement for market actors and authorities without further specification (GPSD). Furthermore, the requirements usually relate only to consumer safety (e.g. TSD and FCM);
- An overall, life cycle based (regulatory) approach on product design that would give guidance on the use of non-toxic substances and improved recyclability of articles does not exist[167]. Such a framework could cover both limitations and positive guidance on the substance content of articles in relation to their function and uses, as well as the choice of and separable nature of materials and/or the possibility to dismantle articles.
- EU product legislation includes few limit values for substances or substance groups in articles. There are little or no procedures integrated into product legislation to quickly impose new restrictions or revise existing ones, e.g. through a committee procedure[168].
- For many products, specific methods and tools (risk assessment standards, IT tools, emission factors from article matrices, etc.) to assess chemical product safety are missing[169]. Aggregated and cumulated exposures from substance in articles are rarely taken into account, e.g. in setting limit values/concentration thresholds in legislation[168].
- The existing product-related instruments to set requirements for the identification and communi-

[165] The identification of SVHC above 0.1% w/w in an article is required under REACH. However, there may be substances not yet identified on the CLS or substances with other properties of concern that could cause risks and the 0.1% threshold may be too high for certain substances.
[166] Market forces may solve this problem in the long run, as chemical quality or absence of toxic substances may be an increasing factor for business relationships.
[167] While the Ecodesign Directive includes systematic approaches to product design, it is currently limited to energy-using products and aspects related to energy efficiency rather than resource efficiency and toxicity.
[168] Brunn Poulsen P., Strandesen M. and Schmidt A., 2010; ANEC, 2014.
[169] Exemptions are FCMs for which migration models exist (plastic FCMs). In addition, national approaches may be available, e.g. the General Scheme to Evaluate Construction Products (AgBB) in Germany to evaluate VOC emissions via chamber tests, for comparison with emission thresholds defined by an expert group.

cation of the content of toxic substances contents in products (in particular the Ecodesign Directive and the CPR standards) are currently little assessed or used, resulting in a lack of implementation at product design stage.

- Overview and specific information (e.g. through a database) on the content of toxic substances in articles is lacking.
  As a result, authorities lack data to prioritise risk management and enforcement, while the waste sector is missing the data needed to manage waste streams and processing. The reasons for this lack of an overview in product legislation are:
  - There is no centralised information collection and related notification requirement for the use of toxic substances in articles;
  - Information from enforcement actions are not compiled and evaluated in a central system, apart from the RAPEX system, which only includes cases of incompliance.

The lack of communication requirements on toxic substances in articles (with the exception of CLS and biocide active substances) poses challenges to the actors producing, importing or disposing of articles to comply with marketing and use restrictions, to carry out risk or safety assessments for their products and/or any voluntary phase-out or risk assessment initiatives. For the waste sector, uncertainties in adequate treatment and risk management measures arise, as well as difficulties related to manufacturing (potential authorisation requirements) and placing on the market of compliant secondary raw materials (use restrictions, SDSs etc.).

3.8.3 Waste legislation

The following gaps and deficits are identified as relevant in EU waste legislation.

- There is no overall life cycle approach to the decontamination of waste streams from legacy chemicals. Resource efficiency through recycling is promoted by increasing quantitative recycling targets, while but no qualitative approaches or targets exist, which would limit the content of toxic chemicals.
- Monitoring of decontamination or separation activities requires significant effort; separation requirements on an operational level are fixed for few waste streams (ELV, WEEE). Effective control and monitoring of decontamination and separation activities is rarely implemented as a self-steering process; i.e. current market incentives for 'clean' recycled materials are too low.
- Comprehensive and systematic information management of toxic chemicals in materials, which would inform decision making on how particular wastes (consisting of particular objects) should be treated or decontamination or discharge, is largely non-existent.
- The European LoW shows limited suitability as a comprehensive tool to communicate the content of hazardous substances in waste or hazardous properties of wastes, and only limited information on the content of toxic substances is communicated along the waste chain under existing legal requirements.
- The system to characterise waste as hazardous differs from the classification of chemicals in its limit values and calculation methods (e.g. the consideration of M-factors) or for hazardous substances (e.g. the categories of substances highly hazardous to the environment identified under REACH and included in the concept of SVHC is missing).
- Waste codes form part of permits for installations that recycle/use waste. In many cases such waste input permits are combined with limit values on the content of hazardous substances. Due to the fact that the LoW codes are often not combined with limit values, waste codes are not a sufficient communication tool for that interface between waste management and such installations.
- Financing of additional efforts for decontamination or separation activities are often not related to the 'polluter pays principle' but, rather, covered – if at all – by general waste fees.

The quantitative recycling targets may conflict with the interest of keeping toxic substances out of material cycles. Recycling targets are linked to requirements for separation and destruction/final dis-

posal of hazardous substances and contaminated materials (e.g. treatment requirements of the WEEE Directive) but do not take the (chemical) quality of recovered materials into account.

There is little information providing an overview of the substances in material streams which could create problems for waste treatment, either by preventing the proper and efficient processing or by contaminating secondary raw materials, making it more difficult to obtain recycled materials of a high technical quality, if indeed it is possible at all. The mixing of material from different sources is progressively increased during the course of recycling. This may involve the use of emulsifiers or other agents that link materials, which are not initially compatible or miscible. This is not a regular procedure but could be an increasingly used method to meet recycling targets or recycle materials, such as normally incompatible materials which are merged using emulsifiers or agents linking materials covalently (particularly relevant for plastics).

4 AVAILABLE TOOLS TO RESPOND TO GAPS AND DEFICITS

The gaps and deficits identified in current policy are not new, with Member States and stakeholders developing, to a greater or lesser extent, measures to address these gaps. The catalogue of available tools listed below comprises the existing measures practiced in Member States and/or by other stakeholders, as well as those described in the literature reviewed.

A number of ongoing initiatives within the Commission are assessing the performance of chemicals legislation. These include the fitness check of all chemicals legislation except REACH, and the standalone REACH review, which are both due in 2017. The results of this study also provide useful input to those initiatives.

The catalogue of tools to respond to gaps and deficits is a comprehensive inventory of all possible measures identified during the work of this study. The potential impacts of these tools have not, however, been assessed in this study. This requires a further step, taking into account the tools identified in the better regulation agenda.

4.1 POSSIBLE INTERVENTION POINTS AND STRATEGIES

Due to the varied size and scope of gaps and deficits identified, a considerable number of policy responses could be considered. The different options have different scales with regard to changing the regulatory environment – from implementing small-scale voluntary initiatives to developing new legislation. They are grouped into:

- Short-term actions, which aim to improve the implementation of existing legislation, awareness raising and supporting ongoing stakeholder activities.
- Medium-term actions, which aim to improve existing legislation by amending it with specific provisions related to the content of, and information on, toxic substances in articles and material streams.
- Long-term actions, which include development of new, comprehensive legislation with an improved approach to reducing and managing the flow and emissions of toxic substances and related information availability.

4.2 POSSIBLE RESPONSE – OVERARCHING MATERIALS-RELATED LEGISLATION

The most fundamental approach identified to achieve non-toxic articles and material cycles, including an increase in resource efficiency through recycling, relates to the development of a comprehensive, overarching and life cycle based legislation on toxic substances at the level of materials.
Such a materials-based approach should consider safety requirements for materials according to their uses (e.g. restrictions for FCMs), information availability and information needs of all actors handling materials as such, whether mixtures, articles or waste. It could include:

- Restrictions on the content of toxic substances in materials that are applicable throughout the entire life cycle of a material.
- A system to categorise the uses of materials in articles and waste according to their exposure potentials, including possibly exposed vulnerable groups and environmental compartments.
- A definition of quality for each material in a use with a particular exposure potential, including limitations of toxic substances.
- Mechanisms ensuring collection and recycling of materials at the same quality level as the material used in an article, allowing a recycled material to be used in the same ‘use category’ that it has been recovered from. In addition, lower quality uses may be necessary in cases where con-

tamination with toxic substances cannot be avoided during the service life or recycling. Here, a distinct decision may be necessary to enable the highest use quality possible, i.e. an 'intended downcycling' to ensure optimal materials use.

- A requirement that material producers identify the toxic content of their materials in terms of the technical performance of the materials.
- Partial standardisation of (the toxic composition of) materials based on (voluntary) industry agreements for materials intended for circulation, including consideration of the materials' technical performance after continued recycling and the complexity of the materials themselves.
- Research and development on non-toxic materials with high technical performance and good recyclability.
- Article design standards considering the exposure classes and material standards, as well as implementing criteria for the reuse and recyclability of articles, including easy separation (and potential decontamination).
- Public access to information on the toxic contents of (standardised) materials via
  - a central database (composition with concentration cut-off), and
  - supply chain communication mechanisms (only relevant data).
- Implementation of a marking system applied to materials intended for recycling that can be easily identified by waste management operators.
- An obligation on all actors in the supply chain and waste sector to comply with the requirements on the maximum content of toxic substances.
- A right to know for consumers about the content of toxic substances in articles, including the appropriate means of obtaining this information.

Currently, requirements relate to substances, articles or wastes. All life cycle stages are connected by the material level: Substances are included into or onto materials, articles consist of materials and recycling aims to recover materials. Therefore, one option to improve the consistency of legislation on chemicals, articles and wastes could be to implement all requirements at the material level. If communication requirements or restrictions applied to materials, all actors would have to comply, irrespective of their role or activities. Substance manufacturers might include material-specific safety assessments and/or risk management measures in their registrations. Article producers might use more standardised materials, and restrictions would apply to all articles consisting of the same material. Finally, the waste streams might be more homogenous, facilitating sorting and separate treatment. In addition, communication requirements would stretch from the material production stage until the waste stage, as information would follow the material regardless of the life cycle stage. The result of a regulatory approach targeting the materials level could be:

- Establishment of a knowledge base on the composition of materials, with particular focus on the content of toxic substances.
- Supply chain actors better able to derive the content of substances in their products and use that information for prevention (e.g. article design), legal compliance (e.g. Article 33, product safety) and further activities towards a non-toxic environment.
- Better information for actors in the waste sector to plan their waste management, including classification of waste, (separate) collection and treatment of waste streams, as well as the need to comply with legal obligations and standards related to their products (e.g. REACH, product quality requirements).
- Better information for authorities to prioritise risk management, enforcement and support actions for R&D on substitution of particular substances in materials.

This kind of regulatory approach could establish a legal obligation for material producers to reduce the toxic content of, and to provide related information on, their materials. In the ECHA feasibility study on a materials information platform[170] some aspects of such an approach were discussed, based on the

[170] Reihlen, A. 2016.

assumption that any data provision would be voluntary, i.e. without considering the possibility of implementing new, horizontal legislation.

A second, long-term approach identified from the literature review and stakeholder consultations consists of horizontal legislation on the content of toxic substances, covering the policy area of articles and wastes either individually or together. Legislation on articles would aim to prevent or reduce the content of toxic substances in articles and communicate it (better), whereas waste legislation would focus on separating and decontaminating waste streams, where toxic substances are not yet excluded (legacy). Legislation improving the overall article design could cover the following aspects:

- Integration of requirements enabling reuse and recycling and a safe second service life into article design provisions.
- General restrictions on toxic substances in (specific) article types and guidance on preferable alternatives to toxic substances, taking into account:
  - the potential article uses and exposures at a generic level;
  - safety factors or other mechanisms to take account of aggregated and multiple exposures;
  - existing (and potential future) legislation on specific product groups, e.g. relating to vulnerable groups or sector specific conditions (e.g. possibilities for closed loop recycling).
- Reporting requirements on the content of (certain) toxic substance to a central database, which might/should be accessible to the waste treatment actors.
- Provisions to communicate relevant information on toxic substances in articles to consumers.
- Training all actors on the life cycle approach and the aim of non-toxic articles and material cycles.
- Enhanced enforcement by Member States.
- Quality criteria for the use of recycled materials in article production to ensure that no toxic substances are included in (specific) articles.

The management of material cycles becomes very difficult - if not impossible - when secondary raw materials leave the EU and its legislation and enforcement. Therefore, a precautionary approach ensuring that no toxic substances can contaminate secondary raw materials and articles is more far-reaching than limiting the types of raw materials that could be recycled.

In waste legislation, new approaches to controlling chemical risks during waste treatment could be considered. This could be complemented by incentives and routines for separate waste treatment of contaminated and non-contaminated wastes. Changes or enhancement of waste legislation could be implemented in combination with the approaches above, or as an isolated effort. Such legislation could include:

- Clear guidance and decision rules to identify the optimal waste treatment option for any material stream, considering the content of toxic substances, the resource gains from recovery and recycling, and the product that could/should be produced from recycled materials, including approaches to deal with a lack of information.
- Inclusion of CSA principles into waste management practices to derive safe processing conditions for workers and the environment, including development of emission models for different treatment options of waste, including final disposal.
- Instruments and tools to obtain and interpret information on toxic substances in end-of-life articles and/or waste materials.
- Qualitative AND quantitative recycling targets, including targets for the content of toxic substances in secondary raw materials.

4.3 POSSIBLE MEDIUM-TERM AND SHORT-TERM RESPONSES

Table 4: Overview of identified responses

Gap / Deficit	Reason for Gap / Deficit	#	Identified responses	Qualification	Discussion
Relevant hazardous properties of substances are not identified and/or communicated due to gaps in chemicals legislation	Lack of classification criteria (EDC, (developmental) neurotoxicants Lack of data requirements (REACH, low volume, CMR and PBT/vPvB, as well as nano)	1	Inclusion of new hazard categories in the CLP regulation for EDCs, (developmental) neurotoxicants and PBT/vPvB. This would require work at international level in order to ensure harmonisation with the GHS	Long-term, regulatory; address under CLP and GHS	New hazard categories would improve information availability (hazards identified and communicated)
		2	Extend information requirements for registration volumes < 100 t/a	Medium-term, regulatory and implementation; address under REACH	This would increase information availability for classification and hazard assessment for lower volume substances
		3	Increase of activities to include SVHC on the REACH candidate list	Short-term, implementation; address under REACH	This would increase knowledge on the content of toxic substances in articles and might push substitution
		4	Initiation of a discussion on whether and which additional hazards (such as developmental neurotoxicants) could be included as reasons of very high concern under REACH Article 57(f)	Short-term, implementation; address under REACH	Discussions of further hazards potentially resulting in candidate listing would increase awareness and potentially broaden the scope of the CLS
	Hazard assessment and prediction methods are not well used	5	Exploration of possibilities to enhance the use of intelligent testing strategies and/or waiving	Short-term, implementation; address under various chemicals legislation	This might ensure a more comprehensive use of existing information and at a higher confidence level
		6	Increase the use of non-standard data and weight of evidence approaches	Short-term, implementation; address under various chemicals legislation	Use of (existing) non-standard data would increase the number of hazards identified (via classification)
		7	Develop hazard prediction tools to generate additional data (short-term to medium-term action, non-regulatory)	Short-term / medium-term, support action	This could lead to more high quality data and methods to support prevention of regrettable substitution
Overview information on the functionalities and uses of (toxic) sub-	Lack of reporting requirements for information on the toxic content of substances in	8	Implement a requirement to 'cc' ECHA in Article 33 communication and implement a publicly accessible register of substances in articles (general)	Medium-term, regulatory, address under REACH	This would increase information availability on CLS in articles for all actors. It might enhance substitution (transparency on future markets) and support authorities in targeting enforcement. Interfaces between legislation could be improved by more knowledge on toxic substances in

Gap / Deficit	Reason for Gap / Deficit	#	Identified responses	Qualification	Discussion
stances in materials and in articles is missing	materials and articles to authorities and in the supply chains, information on functionalities of substances (in materials) is (regarded) as confidential Lack of structured and accessible information on toxic substances in materials and articles				articles and resulting waste/material streams
		9	Develop legislation on reporting the content of certain) toxic substances in (certain) materials in articles; collect and publish the information, including to the waste sector	Medium-term, regulatory; address under product or chemicals legislation	The response would increase information availability to all actors, including the waste sector. This allows for better risk management and future planning of waste management and decontamination
		10	Develop a publicly available information database with general information on toxic substances in materials and in relation to technical properties of materials and substances	Medium-term, regulatory or implementation; address under chemicals or product legislation	Such an information platform would increase overall knowledge of the (potential) toxic inventory of materials and would generally support supply chain actors to focus activities to identify and communicate on SVHC. Waste actors could use information to inform their decisions on recycling or disposal
		11	Compile all information available on the possible content of toxic substances in materials or article from published information and make it available to the public	Medium-term, support action	A general information database on toxic substances would support targeting company and authority actions
		12	Develop more specific use descriptors[171]	Medium-term, implementation, address under REACH	More specific use descriptors would result in better information on substances in articles from REACH registrations
Risks from toxic substances might occur due to aggregated and multiple exposures to toxic substances in articles (and from other sources)	Regulatory risk assessment insufficiently addresses aggregated and multiple exposures from articles, as this is complex and requires detailed information and additional resources	13	Identify and introduce a safety factor (e.g. 10 as proposed in discussions on mixture toxicity) in methods for regulatory chemicals risk assessment for articles	Short-/medium-term, regulatory; address under various chemicals legislation	This identified response would increase the level of protection from toxic substances in general, thus making risk conclusions more likely and triggering substitution or risk management measures, where necessary
		14	Consider multiple and aggregated exposures in restriction proposals to establish methodology and identify impacts on risk management measures	Short-term, implementation; address under REACH and product legislation	The response could increase the number of risk conclusions, potentially resulting in more restrictions and promoting substitution and would support method development
		15	Conduct research to collect further information on the (synergistic) health and environmental effects of continuous, low-level chemical stress	Long-term, support activities	This response would increase information availability on effects from multiple exposures to toxic substances and support priority setting and justification for regulatory action, if needed
Guidance and tools for chemical safety	Top down assessment is challenging, requires	16	Identify and evaluate available approaches and tools for the chemical safety assessment of articles. Promotion of useful tools and initiation of	Short-term, implementation	Improved tools might increase the number of actors conducting risk assessments and the quality of results, including recommendations for risk management. This could

[171] The current version of the respective REACH guidance document is comparatively new and no experience exists on whether or not this improves the level of information detail.

Gap / Deficit	Reason for Gap / Deficit	#	Identified responses	Qualification	Discussion
assessment of articles and of the waste stage are insufficiently well-developed; REACH CSAs frequently do not cover these stages. Assessment of the waste stage is not required under BPR at all	detailed information on use conditions; no detailed requirement for safety assessment in product legislation; lack of data on specific substances in waste treatment (missing data to develop emission models)		the development of tools, where these are missing		increase substitution activities
		17	Clarify obligations for the assessment of the waste stage in REACH CSAs in guidance and specific communication, promote and enforce use of related guidance documents (R18)	Short term, implementation; address under REACH	Clarification of registration requirements regarding waste would support overall compliance and improve the information availability on toxic substances in wastes; interfaces between REACH and waste may be positively affected
		18	Motivate industry or do with Commission / ECHA resources: relate waste stages to article categories and link to risk assessment tools, such as spERCs, SWEDs etc.	Short term, support action; address under REACH	The response would improve interfaces between legislation and assessment methods. This could relate to activities under the circular economy work
		19	Check and enforce the quality of CSAs with view to articles and wastes (dossier and substance evaluations); send 'quality observation letters' and initiate follow-up	Short term, implementation; address under REACH	Quality checking of CSAs would inform tool development and create incentives for related activities in industry. It may lead to better CSAs and increased levels of protection, if risks were initially overlooked
		20	Include obligations under the BPR to assess potential risks and deduce related risk management recommendations in the substance approval and product authorisation procedures, with particular focus on treated articles	Medium-term, regulatory; address under BPR	Including risk assessment of (treated) article wastes would increase information availability and potentially the level of protection through either use restrictions (limiting due to waste risks) or conditions for waste treatment (work environment)
		21	Enforce communication on safe use of substances in articles and safe disposal in SDSs and under Article 33 in the Member States	Short-term, implementation	Increased enforcement should increase compliance and thus information availability in the supply chain. The option would also improve interfaces between legislation through information availability. Increased transparency could lead to more and better substitution activities
The (implementation) of the authorisation procedure does not sufficiently take (imported) articles (and their waste stage) into account	Authorisation focuses on production steps rather than the products produced	22	Increase ECHA's and the Committees' capacities to handle authorisation applications and accelerate including substances in Annex XIV	Short-/medium-term, implementation; address under REACH	Response would increase substitution needs and related actions and prevent the production of hazardous wastes indirectly via the products
		23	Develop / review overall principles for granting authorisations	Short-term, implementation; address under REACH	The response might improve consistency in granting or denying authorisations, sending clear signals to the market
		24	Extend the scope of authorisations to (imported) articles	Medium-term, regulatory; address under REACH	Avoids toxic substances in imported articles, ensures level playing field and consistent regulatory approach, supports substitution
Restrictions	Restrictions re-	25	Develop common understanding on which sub-	Medium-term, sup-	The response could create a better basis for systematic

Gap / Deficit	Reason for Gap / Deficit	#	Identified responses	Qualification	Discussion
procedures are slow and cumbersome, lack a consistent, overarching (generic) approach and cover a limited number of substances in (specific) articles	quire demonstration of (specific) risks by authorities. They developed over time rather than as a systematic approach to risk reduction, legislation does not always include mechanisms to integrate restrictions easily, i.e. as 'adaptation to technical progress'		stances in materials or articles are of priority concern (hazards, mobility, exposure patters)	port action	restriction approaches and (potentially) risk management approaches
		26	Develop restriction proposals for articles including substances on Annex XIV according to REACH Art. 69(2)(ECHA and Member States)	Short-term, implementation; address under REACH	This response would increase the level of protection and accelerate phase-out
		27	Decrease requirements to demonstrate risks / increase opportunities to restrict substances based on hazard/precautionary approach under REACH	Short-term, regulatory or implementation; address under REACH	Lowering barriers for restrictions (and increasing the use of the precautionary principle) would enable more dossiers in a shorter time
		28	Extend the scope of Article 68(2) to PBT/vPvB and/or EDCs in order to enable general restrictions for this type of hazard and to develop related general use restrictions for these substances in (consumer) articles	Medium-term, regulatory and implementation; address under REACH	This option would broaden the ability to develop general use restrictions for (groups of) substances, facilitating and easing restriction proposal development and allowing broader restrictions
		29	Develop (the possibility for) restrictions of toxic substances in articles based on classification in articles legislation	Medium-term, regulatory; address under relevant product legislation	This response could support implementation of a consistent, regulatory approach to limiting chemical risks from articles and would increase substance phase-out
		30	Define a concentration limit of e.g. 0.1% for SVHC in articles as a general requirement of chemical product safety; allow higher limits based on information on actual migration and lower limits for substances/articles of particular concern	Medium-term, regulatory; address under relevant (product) legislation	The response would increase the phase-out of SVHC and support the interface between REACH, product and waste legislation. It would increase consistency of restrictions across (product) legislation
		31	Introduce stricter/new/more product specific restrictions in existing articles legislation, such as toys, construction products, RoHS etc.	Medium-term, regulatory; address under relevant product legislation	This response would increase the level of protection and support phase-out through regulatory pressure
		32	Expand the scope of the Ecodesign Directive to any article. Develop and implement guidance and methods to define substance related eco-design criteria. Define chemical eco-design requirements for specific product groups	Medium-term, implementation; address under Ecodesign Directive	The response would make use of the existing framework to increase product safety and trigger safer article design. This might result in substitution pressure. The response should be combined with response 61
		33	Introduce options for quick inclusion or revision of substance restrictions upon new evidence in product legislation	Medium-term, regulatory; address under relevant product legislation.	This would allow easier and quicker responses to new scientific findings or societal values, potentially accelerating the phase-out of toxic substances

Gap / Deficit	Reason for Gap / Deficit	#	Identified responses	Qualification	Discussion
		34	Define minimum requirements regarding the content of toxic substances in secondary raw materials; assess how this could relate to the implementation of end-of-waste criteria	Medium-term, regulatory; address under waste and product legislation	This response could achieve better links between articles and waste legislation and improve the information availability on toxic substances in articles
Companies receive (too) little support in substitution	Lack of competence and resources in Commission and Member States	35	Support substitution activities, e.g. by implementing help desks or providing research funding, in particular to SMEs	Short term, implementation	Substitution support should facilitate the implementation of restrictions, the topic is further elaborated in the dedicated sub-study a
Supply chains: Communication on toxic substances in articles is required almost only by REACH (CLS); it is not obligatory to assert the absence of CLS in articles and, in practice, no information on safe handling and disposal is communicated	(Product) Legislation lacks communication obligations, communication on SiA has low priority for industry and enforcement[172], understanding of communication on safe use is unclear, resources and information for implementing Article 33 are lacking	36	Develop material declaration requirements on toxic substances in materials along the supply chain	Medium-term, regulatory; address under products or waste legislation	This option should ensure that specific information on the content of toxic substances in articles flows along the supply chain and reaches the waste sector (risk management and future waste management and decontamination planning)
		37	Extend REACH Article 33 from only CLS to ▪ All substances fulfilling the SVHC criteria, and/or ▪ Substances with particular hazards (additionally to those in Article 57), and/or ▪ Substances included in an additional list	Medium-term, regulatory; address under REACH	The response would broaden the scope of substances for which communication is required (and authorisation possible). It could improve information availability to all actors and substitution may be increased for additional substances
		38	Support article suppliers with tools and information to identify and store information on SVHC in their articles	Short-term, support action	The response might increase compliance with Article 33, resulting in an overall higher response rate to consumer requests
		39	Motivate more enforcement of the implementation of Article 33 in the Member States	Short-term, implementation; address under REACH	The response should increase compliance and information availability in the supply chain and to consumers
		40	Support the development of internationally agreed communication formats on (toxic) substances in articles, e.g. in the context of the UN CiP	Medium-term, support action	Harmonised and centralised information on SiA considers the global supply chain and trade and would decrease communication efforts considerably
Consumers: Consumers do	REACH Article 33 includes a (max-	41	Delete/reduce the option to answer with a 45-day delay from Article 33(2)	Medium-term, regulatory; address under	This would enable consumers to take SVHC content into account and potentially increase market pressure to

[172] A pilot enforcement project on REACH Article 33 implementation will start in 2017, suggesting that the focus of enforcement is changing.

Gap / Deficit	Reason for Gap / Deficit	#	Identified responses	Qualification	Discussion
not have information on toxic substances in articles at the point where they make their purchasing decisions. Hence, they cannot take this information into account	imum) 45 days delay in responding to consumer requests, requirements to declare toxic substances in articles are missing, voluntary instruments are mostly non-specific			REACH	move towards less- hazardous products
		42	Support stakeholder activities to develop Apps to facilitate Article 33(2) implementation	Short-term, support action	
		43	Establish an obligation to declare the content (in concentration ranges/intervals) of all classified substances if exceeding 100 ppm for all consumer products	Medium-term, regulatory; address under product legislation	This would increase information availability for consumers and enable changes in consumption behaviour, creating market pressure for substitution
		44	Support the development of a voluntary label 'hazardous substance free article'	Short-term, support action	Labels aggregate information on toxic substances in articles and support consumers to choose non-toxic products while protecting confidential business information
Enforcement of legislation is not sufficiently harmonised across the EU, too weak	Enforcement is the task of the Member States with different systems; insufficient harmonisation instruments, lack of resources, lack of information for strategic campaigns	45	(Provide continued support for the) Further harmonisation work and enforcement projects – Member States	Short-/ medium-term, implementation; address under any relevant legislation	Increased enforcement should increase compliance rates, including increased substitution actions and information provision
		46	Develop overview of national sanctions for REACH non-compliance to enable comparison and harmonisation	Short-term, support action; address under REACH	This option would increase harmonisation thus creating a more level playing field and enhancing compliance
		47	Make the market surveillance system more efficient, including random tests and control measures - Member States	Short-term, implementation; address at Member State level	The identified response is likely to increase compliance rates
		48	Allocate adequate funding to inspections - Member States	Short-term, implementation; address at Member State level	More enforcement is likely to increase compliance rates
		49	Collect and evaluate information from enforcement across the EU and draw conclusions on possible regulatory needs (stricter limit values, risk management)	Short-term, implementation; address under product legislation	The response would increase information availability on substances in articles and make it useful for policy development and enforcement
		50	Enable enforcement ensuring secondary raw materials containing restricted substances are finally disposed of or decontaminated within the EU	Medium-term, regulatory; address under waste legislation	The response should prevent the risks posed by toxic SiA in countries with less developed waste treatment and production legislation and infrastructures, i.e. re-introduction into articles via secondary material stream is prevented

Gap / Deficit	Reason for Gap / Deficit	#	Identified responses	Qualification	Discussion
		51	Ensure a system that controls depollution activities and the marketing of waste fractions with toxic contaminants, independently and without association	Medium-term, implementation; address under waste legislation	Strengthening Member States' enforcement should increase overall compliance with legislation
Awareness of companies and consumers of hazardous chemicals is low, consequently, there is only little market pressure for substitution and the use of less toxic substances	Hazardous substances have less attention than other environmental and economic challenges, adverse impacts from chemicals are difficult to allocate to exposures, understanding chemical risks is complex	52	(Motivate stakeholders to) Increase/continue awareness raising and capacity-building measures, including partnering with industry organisations (target groups: actors in the article supply chain and consumers)	Short-term, support action; address under any relevant policy	Overall increased awareness should trigger substitution by companies and increase market pressure for safer products
		53	Initiate and support dialogues with sectors on substitution and non-toxic articles and on experience with related tools and approaches	Short-term, support action	The response should increase awareness and knowledge, triggering substitution and better legal compliance, as well as reduced emissions of toxic substances from articles
		54	Develop good manufacturing practices for articles (potentially with sector focus), to limit toxic substances in articles as contaminations, e.g. carry over from machinery	Medium-term, support action	The response could raise awareness of process contaminations and increase the level of protection
		55	Awards for innovative, non-toxic articles (incentives for non-toxic articles)	Short-term, support action	The response would raise awareness of substitution and increase/reward substitution activities
Recovered substances may be wrongly identified and not registered (REACH Article 2(7)d) leading to unassessed uses	Support recycling by reducing regulatory burdens	56	Change REACH Article 2(7)d so that recyclers placing the substance on the market must register and assess uses not covered by the main registration	Medium-term, regulatory; address under REACH	This response would improve the interface between REACH and waste legislation (no unassessed risks, including in and after the waste stage)
		57	Develop guidance on the identification of substances recovered from wastes, including clarification on dealing with 'impurities'	Short-term, implementation; address under REACH or waste legislation	This response should result in overall increased awareness of and compliance with registration of recovered substances
The definition of chemical product safety is vague and difficult to implement and does not in-	Framework legislation is not specific, chemical assessment methods are not a 'traditional instrument',	58	Define chemical product safety, e.g. in accordance with REACH, including the environment	Medium-term, regulatory; address under GPSD	The response should clarify how chemical safety is defined and how it can be demonstrated
		59	Develop guidance and tools on how 'chemical product safety' can be demonstrated, including risk assessment and/or testing methods for materials and/or articles	Short-term, implementation; address under GPSD	The response should improve the quality of risk assessments for SiA, potentially resulting in the identification of substitution needs and related substitution activities

Gap / Deficit	Reason for Gap / Deficit	#	Identified responses	Qualification	Discussion
clude the environment	product safety focuses on humans	60	Develop and publish best practice examples for the assessment of chemical product safety	Short-term, implementation; address under relevant product legislation	The response should improve the quality of risk assessments for SiA
There is no comprehensive approach / overarching product legislation requiring (improved) recyclability / design for the waste stage of articles	Circularity and recovery and ruse of resources have not been a priority issue in the past, related legal instruments were not yet developed	61	Integration of article design principles for reuse and recycling in legislation (including toxin content), e.g. under the Ecodesign Directive. This should include 'design for dismantling' and 'design for depollution'	Medium-term, support action / implementation; address under relevant product legislation	This response would better interlink chemicals, articles and waste legislation and ensure consistency at material level. It would facilitate waste treatment that favours recycling due to easier decontamination and sorting possibilities. C.f. response 32
		62	Support market actor's activities in article design, e.g. via awards or research funding	Short-term, support action	The response should stimulated improved recyclability of articles.
		63	Integrate article design principles for recyclability / non-toxic substances in eco-label awards	Short-term, implementation	The response should stimulate improved recyclability of articles
		64	Define quality standards for materials (virgin and recycled) for use in specific articles	Medium-term, regulatory; address in product legislation	The option would provide support for article producers in deciding whether a particular recycled material can be used in the production of articles
		65	Develop guidance documents on potential contaminations of secondary raw materials	Medium-term, implementation; address under product or waste legislation	The response should increase decontamination and the use of recycled materials by providing information on potential contaminations of (waste) material streams
Lack of overall management approach to decontaminate and manage waste streams and related guidance	Toxic substances in waste streams and recycled products has not been a priority in the past	66	Develop an overall approach for the management of waste decontamination based on life cycle thinking	Long-term, regulatory	An overall approach to waste decontamination would guide decision-making on further aspects of waste policies and ensure integration with chemicals and articles policy
		67	Clarify the relation between waste treatment hierarchy and decontamination of material cycles	Short-term, implementation	The response is essential to systematically identify and implement policy principles in waste management
		68	Develop guidance and criteria for decision-making on treatment of waste (recycling or disposal), including approaches to overcome the (current) information gaps	Short-term, implementation; address under waste legislation	The response should support waste managers in selecting which materials can be recycled and which should not, resulting in cleaner material cycles and higher compliance rates
There is a lack of economic incentives to recycle waste materials con-	Profit margins are low, information collection and separate treatment are costly	69	Develop a regulatory system with incentives to create minimised dismantling and depollution efforts for the waste sector, e.g. by extending producer responsibility until after waste enters a second product life	Medium-term, implementation (regulatory); address under waste legislation	By allocating responsibility/costs for waste management to article producers, efforts for preventing toxic substances in waste and/or separating contaminated materials should be increased

Gap / Deficit	Reason for Gap / Deficit	#	Identified responses	Qualification	Discussion
taining toxic substances		70	Establish recycling fees for products requiring specific end-of-life treatment, including decontamination of toxic substances; parts of the fees should be allocated to setting up related enforcement activities	Medium-term, regulatory; address under waste legislation	Fees should create an incentive for changes in article design towards less toxic substances content and better separation/recyclability; controlled allocation should ensure implementation of depollution activities
A comprehensive and systematic information management on toxic chemicals in materials, should be treated regarding decontamination or discharge, is largely lacking	Toxic substances have not been a priority in the past, information from articles does not reach the waste sector, testing approaches are missing	71	Develop approaches for a better application of information about end-of-life product composition in waste management (e.g. automatic readable/sensor coding, which can be detected in daily practice of waste treatment)	Medium-term, implementation; address under waste and articles legislation	This response should overcome the information gap between consumer articles and wastes and save efforts in information collection
		72	Develop standardised test methods suitable for recycling materials	Medium-term, implementation	Methods to test the substance contents in recycling materials are missing in many cases, hindering quality control and compliance testing
		73	Revise the EU LoW and include more information on the content of toxic substances (contained in materials) in waste; consider revising the rules for classification of waste as hazardous to harmonise with the CLP	Medium-term, regulatory; address under waste legislation	The response should enrich waste codes with specific information supporting decision-making on waste treatment options
		74	Collect information from REACH CSAs on risks for the waste stage and identify potential priority areas, exchange information with the waste sector on (specific, article related) information needs and identify options to satisfy them	Medium-term, support action/implementation	This response would improve the interface between REACH and waste legislation by identifying potential risks and making available information useful under both legislations. Better assessment tools under REACH - based on information from the waste sector - would increase information availability from CSRs
Missing depollution requirements for waste management	Low priority and awareness of the issue, high effort for depollution	75	Enact depollution requirements on a legal basis for additional waste streams as 'guard railing' for waste management companies	Medium-term, regulatory; address under waste legislation	This response should increase depollution activities and ensure cleaner material cycles
		76	Integrate qualitative (i.e. restricting the content of specific substances or substances with specific properties) in addition to quantitative (recycling and recovery) targets	Medium-term, regulatory; address under waste legislation	This response should ensure a high quality of recycling materials regarding the content of toxic substances and ensure that no risks occur from second service lives
		77	Enact separate collection requirements for relevant waste streams to facilitate sorting and reduce costs	Medium-term, regulatory; address under waste legislation	Separate collection is a pre-condition for efficient, high quality recycling
Second and further life	Only the first loop of material is	78	Require risk assessments of recycling materials (e.g. for recycling exemptions) to extend beyond	Medium-term, regulatory; address under	These responses should support assessment and steering of flows further than the second service life of materials

Gap / Deficit	Reason for Gap / Deficit	#	Identified responses	Qualification	Discussion
cycles are not (risk) assessed	considered when recycling options are assessed		the second service life and trigger necessary risk management measures, (e.g. obligatory separate collection and specific treatment); if safe management of wastes from the 'second loop' cannot be ensured, no exemption should be issued	waste legislation	
		79	Establish a management system for articles which are produced from secondary raw materials that contain hazardous contaminants (e.g. DEHP containing recycled PVC in beacon bases or tubes, or heavy metal containing plastics) as a specific material-oriented form of an EPR approach	Medium-term, regulatory; to be addressed under waste legislation	These responses should support assessment and steering of flows further than the second service life of materials
Lack of recycling technologies	High costs are not covered by income from secondary raw materials	80	Invest in technology development to recover materials and decontaminate waste streams at the same time, e.g. innovation programmes	Short-term, implementation	These responses should support the development of technologies and infrastructure to decontaminate wastes and produce non-toxic secondary raw materials
		81	Review existing technologies, e.g. molecular recycling of polymers, and identify best practices	Short-term, implementation	

5 CONCLUSIONS

Large volumes of toxic substances are included in articles. They may emit during the articles' entire lifecycle and may cause exposures and risk to human health and the environment, including from waste treatment and the use in products made from recycled materials. Due to the complexity of global article supply chains, the heterogeneous composition of articles, including a large variety of toxic substances with different functionalities, as well as the large article and waste flows around the globe, controlling the content of toxic substances in articles is very challenging. Possibilities for prioritising risk management measures for toxic substances in articles (and materials) by authorities as well as possibilities to (re-)consider the article design with regard to the chemicals content by enterprises is hindered by a lack of respective information in the supply chains and at a general level.

The content of toxic substances in articles and the lack of information thereon is a particular challenge for the implementation of the EU policy goal of increasing resource efficiency by closing material cycles, if a high quality of secondary raw materials should be achieved. While it is hardly possible to identify materials containing toxic substances due to a lack of respective information, also the separation of the diverse end-of-life articles that is necessary to prevent a potential distribution of toxic substances in the materials may be challenging, in particular for complex articles, such as end-of-life vehicles or electrical and electronic equipment.

Chemicals, product and waste policies aim to regulate the content of, and information on, toxic substances in articles and material cycles. However, a number of gaps and deficits are identified, which prevent - or at least considerably slow down - progress in reducing the content of toxic substances in articles and removing them from material streams.

From a structural perspective, an overarching, life cycle and materials-based approach regulating the content of and communication on toxic substances in articles and material streams is missing. Therefore, the current regulatory system is partly inconsistent, appears not to cover all potential risks from substances in articles and partly fails to prevent the occurrence of toxic substances in recycled materials sufficiently. Furthermore, all actors lack information for informed decision making on the use and disposal of articles containing toxic substances.

Information

Chemicals policy determines the availability of substance property information through various mechanisms, including registration, approval and substance evaluations. The extent of available data also determines the amount of substances that could be identified as SVHC and would thereby fall under the articles-related communication requirements under REACH.

In addition, chemicals legislation requires generating and providing information on uses, exposures, potential risks and risk management measures for the use of toxic chemicals along the supply chain via the safety data sheet. This information is the basis for article producers to identify, if they incorporate a toxic substance/SVHC into an article, if this could cause risks to humans and the environment and if communication is required.

Article producers need information on the composition of functionalised technical materials and their use in articles in order to select less hazardous and at least compliant materials to produce less or non-toxic articles. However, this information if frequently not available from suppliers or centralised information sources. Particular challenges exist if recycled materials are used.

Waste management operators need to have information on the content of toxic substances in wastes at the material level, to be able to identify, sort and separately treat or recycle materials with and without toxic substances. While that information is the very basis of such activities, further conditions need to be implemented, such as the separability of materials in articles, the availability of detection and sorting installations and economic incentives to implement additional waste treatment steps.

Any communication approach on toxic substances in articles is based on the information generated in the chemicals supply chain. Communication gaps to the waste sector could be closed by including composition information into the material it concerns. Labelling of the toxic substances content in articles may be an option to improve the information situation for consumers.

The following types of information on toxic substances should be available in general, while this depends for specific articles/supply chains on the needs and capability of the information receivers:

- Information on hazardous properties, in order to identify substances of concern;
- Information on mobility, technical stability and environmental fate in order to identify how substances might behave in articles (exposure and risks during service life) and during waste treatment, and to identify potential use restrictions and waste treatment approaches at the substance level;
- Transparency on the content and quantities of toxic substances included in different types of technical materials and the functionalities (intended to be) achieved by their use;
- Differentiated information on the functional needs within complex articles that lead to the use of technical materials including toxic substances;
- Detailed information on alternatives to create the same material function and/or the same product use without toxic substances;
- Content of materials including toxic substances that are present in end-of-life articles in waste streams, in order to enable risk assessment and to direct substance and material flows towards safe uses and waste treatment and recycling options, ensuring non-toxic multiple service lives.

Content of toxic substances in articles

In a non-toxic environment, all risks from substance in articles should be controlled, including from combined, low-level long-term exposures. This requires a comprehensive assessment and identification of risks from substances in articles and risk management instruments to reduce an identified risk to an acceptable level, e.g. via use restrictions.

Instruments to steer or influence the content of toxic substances in materials and articles range from hard measures, i.e. substance bans or restrictions and authorisation procedures, to setting economic incentives or imposing taxes, enhancing the use of voluntary labels and raising awareness on chemical risks.

Many of the instruments influencing the content of toxic substances in materials and articles, or information relating to such content, are already in use for particular articles or article wastes. However, they are patchy, inconsistent and - at least from the perspective of non-toxic articles and material cycles - insufficiently stringent, and overly broad in coverage.

A wide range of these and additional instruments are proposed by different stakeholders working within chemicals, product and waste policy, as well as across these policies to respond to the existing shortcomings in the legal framework and its implementation.

The most far-reaching proposal is to develop overarching, consistent and life-cycle based legislation on the use (reduction) of hazardous chemicals at the level of materials. This legislation would overcome challenges posed by legal interfaces between chemicals, articles and wastes and could include more comprehensive communication requirements on hazardous substances in articles. This would increase transparency on the article composition for market actors, consumers and authorities.

This framework could include 'generic restrictions' based on hazardous properties and generic exposure and risk considerations of materials, complemented by specific, product-based restrictions that target individual articles and substances based on specific risk assessments.

At a less fundamental level, the following main improvement options were named in relation to the individual policy areas.

The information requirements under chemicals legislation should be amended to ensure that sufficient information is available on substances that are used in articles. This concerns (up to date) information on a substance's hazardous properties, emission behaviour, mobilisation and transfer during waste processing, and the fate in the environment. Furthermore, risk identification by substance manufacturers and importers in relation to materials and/or articles should be detailed enough to develop top-down risk management measures, such as restrictions based on hazard and generic risk considerations. Related changes would mean partial amendments to existing legislation, as well as a better implementation and enforcement of existing provisions. Some of these issues are expected to be discussed as part of the ongoing policy reviews (REFIT of chemicals legislation).

Also under product legislation, the lack of information on the content of toxic substances in articles could be addressed as well as use restrictions be implemented. This would require respective legal provisions be integrated in existing legislation as well as risk assessment methods be developed and made available. This would also enable market actors to assess chemical safety of products falling under those directives that require 'products placed on the market to be safe' but failing to provide ways to check this.

Aspects regarding the circular economy

The implementation of safe waste treatment would first and foremost be improved, if the content of hazardous substances in articles and article wastes were prevented. However, legacy chemicals in waste streams must be managed, as long as this in not yet fully the case.

Principally, two types of materials can be distinguished with regard to the content of toxic substances and circularity: basic materials versus technical materials.

- Basic materials, such as paper, glass or basic metals, are generally homogenous and consist of a low number of different substances. Collection and treatment systems are already in place and appear to be functioning on the level of pure materials as well as on the level of simple products composed of these basic materials (e.g. packaging waste); however, their efficiency could be improved.
- Technical materials, such as functionalised plastics or specially treated textiles, generally include a higher number of different (toxic) substances, which provide particular functions to the material. Due to the lack of knowledge of the material composition (and its functionalisation) efficient recycling - in terms of merging similar waste streams or explicitly keeping them separate – is almost impossible. Instead, technical materials are either incinerated, disposed of, or downcycled by diluting toxic substances in virgin material.

Most attempts to recycle waste streams of complex articles (which are generally non-homogeneous and include a very high number of different technical materials) currently lead to recycling at the level of basic materials and not at the level of technical materials. The main reasons are the lack of knowledge on the material composition of the complex articles and the failure to separate waste at the level of the different technical materials (with different functionalisation) for very non-homogeneous materials. Efforts for separation and treatment of complex article wastes are currently not justified by the quality of secondary materials achieved, which include diverse (diluted) toxic substances.

Policies aiming at increasing material recycling, while reducing the dilution of toxic substances in secondary materials, might identify different strategies to deal with the two different types of materials. New approaches could focus on the functionalised materials, which appear to provide the highest improvement related potential, while refinement of the existing instruments could be considered for basic materials.

The aim of circulating functionalised materials would be to increase the recycling amounts and to ensure a high quality of these materials so they can be introduced into high quality uses. Complementary approaches could include industry agreements to standardise the content of groups of the necessary materials, categorisation of exposure levels related to groups of uses of materials, and mechanisms to

ensure that recycled materials are re-applied in uses, in the same group of exposure, to ensure high-level recycling.

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Appendix 1:
Case study Plastics

APPENDIX 1: CASE STUDY PLASTICS

1 INTRODUCTION

This case study aims to illustrate and further analyse the assessment of gaps and deficits, together with the responses identified for achieving non-toxic products and material cycles for the sample material 'plastics'. The case study also includes some discussion on recycling of plastics containing toxic substances, in order to show different views on the topic.

The case study describes the regulatory situation of 'toxic substances in plastics' and the specific challenges for recycling in three applications:

- FCM - specific materials-related product legislation exists.
- Construction products - specific legislation exists but without plastics-specific provisions.
- Packaging material – specific waste legislation exists.

Aspects of consumer safety are not the focus of the case study, although these are addressed in relation to product quality requirements.

2 REGULATION OF SUBSTANCES IN PLASTICS

2.1 CHEMICALS LEGISLATION - REACH

Chemicals policy aims to ensure the safe use of substances in isolation, in mixtures and in articles, while improving competitiveness and innovation within EU industries. CSA is the basis for decision-making on substance uses, including the uses to be supported by the registrants and/or the risk management measures to be implemented. As CSA requires knowledge of chemical hazards and exposures, chemicals legislation includes extensive provisions on data collection, generation and evaluation.

While REACH requires the registration of monomers, polymers are exempted from registration[173]. Consequently, potential risks from polymers are neither assessed nor communicated under REACH, while risks from unreacted monomers are addressed in CSAs.

Plastic materials normally consist of polymers (which may be composed of different compounds) and additives, which provide technical or aesthetic functions. These additives may belong to different chemical groups, have different hazards properties and can be included in the polymer matrix in different ways, e.g. dissolved or integrated by chemical bonds. The most common example of a plastic additive is DEHP, which is used to soften polyvinyl chloride (PVC).

Plastic additives must be registered under REACH and their uses (in plastics) must be assessed in a CSA if the individual registration volumes exceed 10 t/a. Information on properties and uses must be provided along the supply chain, through the SDS.

Several plastic additives are included on the Candidate List for Authorisation (CLA) under REACH, some of which are already subject to authorisation, such as some phthalates. Information on plastic additives included on the CLA must be provided with the articles if the content exceeds 0.1% w/w. The use of the additives in REACH Annex XIV, including those in recycled plastics and for the production of articles, requires an authorisation. Exemptions from authorisation exist, where the concentrations of the substances remain under the specified limits, as well as for particular applications. The use of phthalates in immediate packaging of medical applications is exempted from authorisation.

2.1.1 Specific provisions for recycled plastics

Recyclers of plastics who place a recycled material on the market must register the substances contained in these plastics under REACH, unless an exemption is granted under Article 2(7)d. In order to claim the exemption, the recycler must demonstrate that the substances recovered with the polymers are identical with a substance are already registered.

Although recyclers may claim an exemption from registration, they do have to provide SDSs for their recycled plastics, where these are required under REACH Article 31. The plastics industry group Polymer Comply Europe[174] have developed generic SDSs for the most common polymers to support their members to comply with this requirement.

To develop these so-called R-SDS, the group compiled information from statistics and expert knowledge on the 'worst case composition' of the most common polymers. Based on that assumption,

[173] The EU Commission may propose to change the current exemption and require registration of specific/all polymers.
[174] Polymer Comply Europe consists of three partners: Plastic Recyclers Europe, PlasticsEurope and VinylPlus. The group presented their SDSs for recycled polymers to the workshop held within the realm of this study in June 2016.

they developed 'worst case safety data sheets' that polymer recyclers can use in cases where they have no information on the actual composition, apart from the main constituent polymer. If some information on the absence of certain additives is available, or is determined through measurements, the recycler can adapt the SDS accordingly. In specific situations, such as when additives are identified in the recycled plastics which are not included in the worst-case scenario, or when the content of hazardous substances is lower than implemented in standard refinements, customised SDSs could/should be developed.

2.1.2 Provisions related to the exempted uses

Substances in **FCM**s are exempted from certain provisions under REACH, namely:

- Risks to human health do not have to be considered in the CSA for substances used in plastics intended to come into contact with food (REACH Article 14(5)a),
- Uses in FCMs of substances that are included on the authorisation list only because of their human health properties are exempted from authorisation under REACH Article 56(5)b[175].

No specific provisions are included in REACH on the use of recycled plastics in **construction products or packaging materials** (except those that are intended to come into contact with food, as described above). No separate chemicals legislation exists on polymer mixtures or the material 'polymer/plastic'.

2.2 PRODUCT LEGISLATION

Product legislation aims to ensure that consumer articles are safe for humans during normal and reasonably foreseeable use, including the assurance that toxic substances contained in these articles do not pose risks to human health. The GPSD includes the relevant general provisions and defines a 'safe' product[176]. For particular products, such as toys or electrical and electronic equipment, specific legislation exists, which includes restrictions of the use of specific substances and/or substances with particular hazardous properties. In addition, restrictions in REACH Annex XVII may also relate to articles.

Use restrictions on substances in product legislation, such as the limitations for the use of cadmium or BFRs under the RoHS Directive, are independent of the materials in which they are found. This means that they may apply to plastic articles or plastic parts in an article, but the restrictions are not specific to plastics and may also address the content of substances in metals or textiles.

Restrictions in product legislation normally relate to the additives in plastics, which may be addressed via their specific properties (e.g. CMRs in toys) or by their specific name/chemical group (e.g. FRs (PBDE) or softeners (phthalates)).

No horizontal legislation exists regulating the content of hazardous substances in either 'plastic articles' or 'plastic parts' in articles.

2.2.1 Provisions for recycling and the use of recycled plastics

Product legislation does not specifically address the use of recycled plastics, which are neither required nor proscribed. While there are no individual product quality requirements for the content of substances in recycled plastics, the requirements on the absence, or maximum concentrations, of toxic

[175] The use of specific additives in FCMs may, however, be regulated through restrictions, where no exemptions exist.
[176] The definition of a safe product only concerns human health.

substances in products apply to virgin and recycled materials alike.

There may be voluntary instruments, such as ecolabels, specific product certification systems or declaration schemes that include incentives to use recycled plastics, in order to increase demand and include resource efficiency in the evaluation of products. These may include requirements for the substances contained in the recycled materials.

The use of **recycled plastics in FCMs** is controlled by a separate regulation[177]. It applies to all recycled plastics or plastics containing recycled plastics, except where the recycled plastics are recovered via depolymerisation, stems from production off-cuts or if the intended use includes a barrier between the recycled plastics and food.

The regulation requires that recycled plastics may only be used in FCM if the recycling process is authorised by the Commission via an implementing decision. Authorisation may be granted only if the following criteria are met for the recycling process:

- The input materials only stem from uses in FCMs and are continuously characterised and controlled;
- The process is able to reduce any contamination in these materials;
- The output material must be continuously characterised and controlled, and must comply with the requirements of the FCMR;
- A quality management system is in place.

The use of **recycled plastics in construction products and packaging material** is not regulated specifically. However, the Directive on Packaging and Packaging Wastes (PPWD)[178] specifies that the recycling targets for plastics should relate to the use in plastic products (e.g. no thermal recovery) and that Member States should promote the use of recycling materials in general.

Indications that toxic substances in plastic articles stem from the use of recycled plastics are reported by Samsoneka, J., Puypea, F., 2013 and IPEN, 2015, among others. Another report[179] concludes that of all POP-BDE included in WEEE, around 22% are destined for recycling, with that figure at 14% in ELV. They also identify POP-BDE in consumer articles, including childrens toys, which are expected to have come from recycled plastics. An analysis of imported articles intended to come into contact with food shows that substances normally used in EEE may be contained in these articles, including BFRs[180].

2.2.2 Requirements for plastics in the exempted uses

The regulation on plastic materials and articles **intended for food contact**[181] requires that no constituents are released to a degree that could pose a human health risk via the food contact. The plastic FCM should comply with the labelling and traceability requirements of the FCMR[182] and be produced according to good manufacturing practice. Only those substances included on the Union List of substances for FCM may be used. Substances can be included on the list once the EU Food Safety Authority (EFSA) concludes its safety assessment - which is based on an application dossier – and reaches a favourable decision. The list includes additives and oligomers, as well as processing aids for the

[177] COMMISSION REGULATION (EC) No 282/2008 on recycled plastic materials and articles intended to come into contact with foods.
[178] PARLIAMENT AND COUNCIL DIRECTIVE 94/62/EC on packaging and packaging waste.
[179] Leslie, H. et al., 2016.
[180] Puype, F. et al., 2015.
[181] COMMISSION REGULATION (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.
[182] REGULATION (EC) No 1935/2004 on materials and articles intended to come into contact with food.

manufacture of plastics.

In addition, the regulation on plastic FCM defines a general migration limit for substances in plastic FCM, which may be overwritten by specific values derived during the safety assessment, or from other sources.

If FCMs are produced from recycled plastics, the above-listed requirements must be fulfilled.

There is considerable criticism of the FCMR, particularly with respect to the non-regulated materials constituting a large share of FCM, such as paper. With regard to the use of toxic substances in plastics and/or the use of recycled plastics in FCM, the challenges are identified but are insufficiently addressed, as e.g. toxic substances occur in FCM.

Chemtrust[183] quotes a scientific paper specifying that substances with endocrine disrupting properties identified as SVHC on the REACH CLA, or which are included on the REACH authorisation list, are also authorised as constituent in FCMs. This is regarded as inconsistent and indicative of potential risks.

Another issue highlighted by several stakeholders relates to substances not intentionally added to, but nevertheless contained in (plastic) FCMs, such as impurities in the starting materials or reaction and breakdown products generated during the manufacture of these materials. The identity and hazards of these so-called non-intentionally added substances (NIAS) is not normally known, although the regulation specifies that none of the constituents in FCM, whether added intentionally or not, should migrate to the food to an extent that could endanger human health. In light of the numerous potential NIAS[184], this provision appears to present significant implementation challenges.

The CPR does not include any provisions on the content of toxic substances specific to plastics.

However, Annex I, Section 3 requires that 'The construction works must be designed and built in such a way that they will, throughout their life cycle, not be a threat to the hygiene or health and safety of workers, occupants or neighbours, nor have an exceedingly high impact, over their entire life cycle, on the environmental quality or on the climate during their construction, use and demolition […]'. The regulation further specifies that construction works should not release any toxic substances to indoor or outdoor air, water or soil.

The release of toxic substances is identified via testing, according to standards specified by the CEN/TC 351 for emissions to air (chamber tests) and leaching (percolation testing or surface leaching test). Construction products with a CE marking, including those made from recycled plastics, should meet the pass levels of these tests. There are no general requirements on the content of substances in construction products, i.e. toxic substances that are not released during the service life of construction products could be present.

There are no particular provisions on the substance contents, or their emissions from packaging materials.

2.3 WASTE LEGISLATION

According to the EU waste hierarchy (WFD Article 4), waste should be prevented (reducing the amount and/or hazardousness of waste) and if this is not possible, it should be reused and recycled to

[183] Chemtrust, 2016.
[184] Bradley E. and Coulier, L., 2007.

the maximum extent possible. Recycling and closing material cycles should improve overall resource efficiency and ensure the supply of strategic raw materials and reduce resource dependency[185]. Incineration should be limited to non-recyclable materials.

It is possible to depart from the waste hierarchy (WFD Article 1) where this is justified by life cycle-thinking on the overall impacts of the generation and management of such waste (WFD Article 4(2)), such as the presence of toxic substances in materials.

In addition, the WFD establishes the concept of EPR as a key principle in waste management.

Different general approaches are implemented in waste policies to reduce the potential negative impacts of hazardous substances in material cycles:

- Use restrictions, which can be seen as a preventative approach from the point of view of waste management (qualitative waste prevention, e.g. RoHS Directive);
- Separation and destruction/final disposal of hazardous substances and contaminated materials (e.g. treatment requirements of the WEEE Directive);
- Closed loop recycling of wastes with elevated levels of hazardous compounds (e.g. limited allowance for recycling of plastic with DEHP).

Some of these broad-based approaches are implemented at regulatory level via producer responsibility schemes that should be developed as separate legal acts (Article 8 WFD) for selected product groups/waste streams.

With regard to plastic materials, the general provisions of the WFD apply, i.e. to prevent (toxicity of) waste as a primary objective and to recycle plastics from waste materials as much as possible. The WFD does not include any specific provisions on plastics.

The PPWD defines quantitative recovery and recycling targets (as a percentage of packaging waste). In its Annex II it requires ensuring that the content of 'noxious and other hazardous substances and materials […] is minimised with regard to their presence in emissions, ash or leachate when packaging or residues from management operations or packaging waste are incinerated or landfilled.' This requirement should be implemented through standards. The PPWD does not refer to the content of these substances in the packaging materials as such, or to the related risks that could arise from the packaging material or the recycled materials entering further use.
The identification system for packaging materials[186] under the PPWD requires labelling of packaging material in a harmonised way[187]. For plastics, it requires the labelling of the main polymers polyethylene terephthalate (PETE), high density polyethylene (HDPE), polyvinyl chloride (PVC or vinyl); low density polyethylene (LDPE), polypropylene (PP), or polystyrene (PS), with the numbers 1 to 6. It does not differentiate between primary and recycled material or between different components (e.g. heavy metals, plasticisers).

2.4 SUMMARY OF LEGISLATION AND GAPS AND DEFICITS

Plastics are used in a multitude of applications. They may contain hazardous substances, which may be intentionally added (additives), impurities (residual monomers and oligomers) or breakdown prod-

[185] European raw material initiative (European Commission 2008, also: Commission Staff Working Document on the implementation of the Raw Materials Initiative (European Commission 2014a)), EU 2020 strategy (European Commission 2010).
[186] European Commission 1997.
[187] The implementation has been performed in conjunction with the SPI Resin Identification Code resp. the standard ISO 14021.

ucts, or contamination from processing. The content of toxic substances may be directly related to the technical function of a plastic material, as this is provided by the additives in the plastics, as well as the nature of the monomers/polymers.

Recycled plastics may consist of different polymers and contain a multitude of different additives, except where closed material loops are established, which keep material streams comparatively free from contamination. An example is food packaging materials, where the recycling process requires authorisation and demands rigorous control of the input and output materials.

There is no legislation regulating the composition and use of the material 'plastics', without any relation to a particular product or product group. There are thus no general requirements for the composition of plastics, regardless of whether it is virgin or secondary material.

Limited communication requirements exist for plastics, e.g. those defined for SVHC in articles under REACH and the labelling provisions set out for packaging materials. The latter only address the main polymer but not components, which might have consequences for non-toxic material cycles. The association of the European Plastic Converters (EUPC) proposes that additional labelling should be placed on the product, e.g. for PVC containing elevated amounts of Cd the pictogram 03 for PVC and the wording 'Contains recycled PVC' in national languages[188]. Currently, however, knowledge of hazardous compounds is lost when recycled plastic leaves the waste regime and is used as a product[189].

Under product and waste legislation, restrictions on the composition of plastics exist, either defined based on substance properties (CMR) or relating to specific substance (group) names (e.g. phthalates, PBDE). Two types of provisions can be differentiated: those limiting the actual content of substances, such as under RoHS Directive or the TSD, while others limit the release of substances, such as the three sample pieces of legislation described above.

The main gaps and deficits resulting from the legal situation can be summarised as follows:

- Requirements on the content of toxic substances in plastics differ across product legislation.
- No information is provided with products on the composition of plastics. This limits the possibility for recyclers to identify 'problematic' materials, sort plastics and direct material flows in a way that minimises contamination, separates and finally disposes of toxic substances of material streams with toxic substances or, vice versa, prevents dilution of toxic substances in material streams.
- Labelling of different polymer types is rudimentary and limited to certain materials.
- Release-related requirements on toxic substances in products do not necessarily prevent their presence; this approach may overlook potential releases and risks from recycling, as well as contamination of secondary materials.
- Analyses of products indicate the likelihood of toxic substances reaching sensitive applications via products made from recycled materials, such as FCMs.

2.5 DISCUSSION ON PLASTIC RECYCLING AND TOXIC SUBSTANCES

2.5.1 Authorisation of the use of DEHP in recycled PVC

The use of recycled materials containing substances listed in REACH Annex XIV is subject to authorisation. With regard to recycled plastics, this obligation may become relevant for all plastic additives

[188] EUPC, 2011.
[189] An example is the recycling of DEHP containing plastic in beacon bases. The bases labelling does not show the DEHP content.

included on the authorisation list.

In 2016, three companies submitted an authorisation application for the use of DEHP containing PVC in formulations and in industrial processes to produce PVC articles[190]. In view of the opinions of ECHA's Risk Assessment Committee (RAC) and its Committee for Socio-Economic Analysis (SEAC) the EU Commission granted the authorisation[191]. The authorisation is valid until February 2019 and includes obligations to monitor the process and make information available to the authorities on request.

The RAC identified a risk for workers during formulation and use of recycled PVC and stated that alternatives with lower risks to the use of DEHP were not available. The SEAC concluded that the qualitative assessment of risks and benefits demonstrates that the formulation and use of DEHP containing recycled PVC are proportionate[192].

The EU Parliament passed a resolution on the authorisation applications, having expressed its concern that the Commission exceeds its implementing powers under REACH when granting the authorisation and therefore requested that it be rejected. The Parliament called on the Commission to end all uses of DEHP because it feels that safer alternatives are in fact available, and it stated that recycling in itself is no justification for the continued use of legacy hazardous substances[193].

NGOs demand that recycling materials (secondary raw materials) should fulfill the same requirements as virgin material unless a closed loop can be ensured[194].

In their statement, 55 civil society organisations called on the Commission to reject the authorisation of DEHP containing recycled PVC because they regard such authorisation as undermining the REACH protection goals and the aim of enhancing the phase-out of SVHC. They believe an authorisation would contradict the call for a ban of phthalates under the RoHS Directive, and claim that suitable alternatives are available. They held that the authorisation applications for the formulation and use of recycled, DEHP containing PVC does not sufficiently meet the conditions for an authorisation, including demonstration that the socioeconomic benefits outweigh the risks. Consequently, the NGOs regard granting of an authorisation to fail to conform with the legal requirements of REACH[195] [196].

Chemical Watch quotes the European Council of Plasticisers and Intermediates (ECPI), welcoming the decisions of RAC and SEAC as representing great value for the PVC supply chain and making legislation consistent and more predictable[195].

ECHA reacted to criticism on the opinions of its scientific committees[197], defending the opinions and stating that:

- the committees based their opinion on collected evidence;
- the committees identified shortcomings in the application but nevertheless found that the information content fulfilled the legal requirements;
- some wording in the opinions could be misunderstood, in particular that SEAC could judge whether or not the socioeconomic benefits outweigh the risks;
- some of the information criticised as missing from the application was removed because of its

[190] Vinyloop Ferrara S.p.A., Stena Recycling AB, Plastic Planet srl.
[191] COMMISSION IMPLEMENTING DECISION granting an authorisation for uses of DEHP.
[192] Opinion of RAC and SEAC, 2014a and 2014b.
[193] EU Parliament, 2015.
[194] For example Wacholz, 2016.
[195] Buxton, Luke, 2016.
[196] EEB, 2015.
[197] Roberts, G., 2016.

confidential nature.

The discussion about recycling of DEHP containing PVC illustrates different interests among the stakeholders. In general, civil society organisations and the European parliament have asked that authorisations not be granted to recycle DEHP-containing PVC because a) contaminated recycled products could pose risks, in particular if used in products with high exposure potential, b) alternatives (with lower risks) are believed to be available, and c) the phase-out goal would be undermined. The phase-out of toxic substances is thus prioritised over resource efficiency.

Industry values the recycling of materials higher than the separation of legacy chemicals from the material cycles, in particular as risks are (mostly) regarded as limited. They consider related requirements on toxic substances as endangering the circular economy, and are in favour of differentiating requirements for recycled materials, if supporting recycling.

RAC and SEAC evaluated the authorisation application with regard to its completeness and plausibility and concluded that while there are risks to workers health, there are also benefits to society from the use of recycled PVC. The EU Commission decided that these benefits outweigh the risks and granted an authorisation with a fairly short review period, probably taking into account that alternatives are available but not yet considered suitable.

The authorisation of the use of recycled PVC was a highly political issue because PVC has long been a cornerstone of the discussion on 'non-toxic' products, and because the authorisation was one of the first of these kinds of decisions and therefore believed to set a precedent for future applications. Relating the discussion to the circular economy and the non-toxic environment strategy, the decision points to the need to determine clearer criteria for decisions on when the risks from toxic substances outweigh the benefits from material recycling.

2.5.2 End-of-waste criteria

According to the WFD, end-of-waste criteria may be defined to identify when a given waste stream ceases to be waste and legally becomes a product. End-of-waste criteria may be applied only to waste streams for which a recovery operation is implemented. The development of the criteria was technically performed by the Commission's Joint Research Centre (JRC)[198].

The development of end-of-waste criteria for plastics started in 2011 and was undertaken by an expert group composed of representatives from the Member States, industry, academia and NGOs. Although the JRC published a technical proposal for end-of-waste in 2014, the Commission did not finalise a regulatory procedure on their implementation. Currently, therefore, no harmonised end-of-waste criteria exist and all Member States implement their own criteria and procedures to determine the end-of-waste of plastics.

The JRC's proposal covers waste plastics that should be used as input materials to conversion processes, i.e. not covering the use of plastics for energy recovery or for reuse as plastic articles. The proposal includes criteria on:

- The quality of the plastics recovered from waste, including:
  - meeting customer requirements and/or related standards;
  - not classified as dangerous;
  - fulfilling the requirements for authorisation under REACH or under the POPs Regulation.
- The types of input materials, excluding:
  - certain wastes, such as from the health care sector;

[198] JRC, 2014.

- hazardous wastes, except where the recycling process is proven to destroy any hazardous components;
- The treatment processes as such, including:
  - keeping waste streams separate;
  - decontaminating wastes from WEEE;
  - decontaminating hazardous wastes.
- Information provision
  - stating the intended use of the recycled materials;
  - statement of conformity with the end-of-waste.
- The management system of waste treatment operators producing end-of-waste plastics.

These end-of-waste criteria for plastics could be regarded as a quality standard for recycled plastics, including mechanisms to control the material flows (requirements on input materials), their processing (requirements for treatment processes) and related communication. Recycled plastics fulfilling the end-of-waste criteria are likely to meet many of the product-related restrictions, potentially even those for FCM. Consequently, they could ensure that mixing of virgin materials with secondary materials would not lead to a deterioration of product quality in respect of the presence of toxic substances.

The plastics recycling industries did not support these criteria because they considered the requirements for the sector and for authorities to impose significant, unnecessary costs. In addition, not all currently recycled plastics would meet the criteria and would hence lose their product status, which they regard as a step backwards in recycling policies[199]. They criticised the requirements for contaminants which should, the held, be derived from the intended use of a product rather than being defined generally. In addition, they criticised the requirement for quantitative analyses and obligations related to the purity of polymers, preventing the use of commonly used blends and mixtures.

2.6 PLASTICS IN A CIRCULAR ECONOMY

The circular economy package proposed by the European Commission in December 2015[200], combines an action plan communication, a list of follow up activities and four legislative proposals. It combines activities in the waste management area with related key aspects of the value chain, which are essential to 'close the loop' in a circular economy.
For waste management, it stresses the importance of the EU waste hierarchy, while, when waste management is further improved, it will move to address implementation gaps and provide long-term visions and targets to guide investments. It sets quantitative targets for recycling and recovery for certain wastes, as well as maximum rates of wastes to be landfilled. At the same time, it aims to increase the use of secondary raw materials, the safe management of chemicals and to improve knowledge of material flows and highlights, including quality standards for secondary raw materials and analysis of the interface between chemicals, products, and waste legislation.

EEB and Green Alliance published their concerns about the lower recycling targets and absent resource efficiency targets of the revised Communication[201].

In an article on the circular economy, PlastEurope.com quotes a representative of the recycling industries, stating that limiting POPs and SVHC in recycled plastics in order to achieve a non-toxic environment would endanger efficient material recycling and thus the achievement of a circular economy. Particular concerns relate to the growing candidate list for authorisation. He also states that toxic sub-

[199] For example EUWID, Recycling und Entsorgung, 2013 or recycling news, 2012.
[200] European Commission 2015, European Commission 2015b, The communication of 2015 was a revised version of the communication of 2014 (European Commission 2014b).
[201] EurActiv 2015.

stances such as BFRs could be safely managed and would not need to be eliminated from the material cycles, e.g. via incineration[202.]

A study by the RIVM[203] investigates the recycling of PVC containing cadmium, lead and DEHP, and the recycling of Expanded Polystyrene (EPS) containing Hexabromocyclododecane (HBCDD) from insulation waste materials. The following legal situation is presented:

- The cadmium concentration in recycled PVC was raised from 0.01 to 0.1 enabling the use of recycled PVC in particular applications which have been assessed as safe
  → recycling is possible in closed loops.
- Lead is currently on the candidate list for authorisation, with any such authorisation expected to define a concentration limit of 0.1%. The report quotes an industry position specifying that a threshold of 1% would be necessary to allow PVC recycling without an authorisation
  → recycling is currently possible but may be limited by potential future authorisation requirements, if there are no specific provisions regarding the concentrations of lead in PVC.
- DEHP recycling is allowed without authorisation if the content remains <0.3% under authorisation. As no technologies exist on an industrial scale to remove DEHP from PVC during recycling, wastes need to be incinerated or treated via high temperature decomposition to produce raw materials for the chemicals industry. This process is deemed far less favourable than direct recycling, due to the high energy input needed
  → recycling only possible with authorisation.
- Under the POPs convention, a concentration limit for HBBCC between 0.1 and 0.01% is discussed for wastes that must be treated in such a way that HBCDD is destroyed. The concentration limit of 0.001% for unintended impurities in new products was rejected and a limit of 0.01% is under discussion. The content in insulation materials is 0.7%. An experimental technology called Solvolyse exists, that reduces the HBCDD concentration in the recyclate to 1% of its original concentration.

The current vision of the EU authorities on the principles of uniting the goals of the circular economy and a non-toxic environment were reflected in an article in Chemical Watch, summarising speeches by Joanna Drake, Deputy Director General of DG ENV and Geert Dancet, Executive Director of ECHA. Accordingly, it is expected that REACH will, in the long-term, prevent inclusion of substances of high concern in materials and articles.

Toxic substances that are already included in products and will be entering waste streams eventually and those which are identified as hazardous or priority for phase-out that are currently included in new products must either be removed from the recycling streams or the materials containing them should be destroyed.

The identification of waste streams containing toxic substances for destruction poses significant challenges to legislation, including the provisions of REACH Article 33. Mr Dancet therefore called for a revision of the provisions[204].

The report 'The New Plastics Economy'[205] outlines a global vision for improving the efficient use of plastics, including aspects related to the composition of plastics and their decontamination during recycling. Core elements of the vision relating to the ideas of a non-toxic environment and a circular economy include:

[202] PlastEurope.com, 2016.
[203] Janssen, M.P.M. et al., 2016.
[204] Stringer, Leigh, 2016.
[205] Ellen MacArthur Foundation, 2016.

- Collective action by all stakeholders, including businesses, governments, academia and civil society organisations to implement fundamental changes and overcome fragmented improvement approaches.
- Development of a global approach, including standardising materials for different applications, such as packaging materials, and directing material flows providing '*guidance on design, labelling, marking, infrastructure and secondary markets, allowing for regional differences and innovation, in order to overcome the existing fragmentation and to fundamentally shift after-use collection and reprocessing economics and market effectiveness*.'
- Research on toxic substances in plastics, impact assessment and prioritisation for phase-out, followed by the actual phasing out of the use of these substances.
- Research and development on 'biologically benign plastics', including:
  - plastics that are degradable under natural conditions, in particular in the aquatic (marine) environment;
  - plastics which do not include any hazardous substances.
- Increased transparency on the composition of plastics, including potentially standardising and minimising the number of material/additive combinations.
- Boosting demand for recycled plastics, thereby potentially increasing their market value.
- Improving collection and recycling infrastructure, including strengthening of plastics reuse, in particular in countries with developing economies.

The report includes examples of current technology developments that could support the circular economy. Examples are the development of 'mono-materials' instead of 'multi-materials', to reduce the complexity of polymer compositions and improve (separation potential and) recyclability of materials, chemical markers to enable efficient sorting of plastics, e.g. for particular closed loop recycling and recycling technologies that are economically viable and would increase decontamination of plastic wastes, such as depolymerisation processes.

Potential recycling technologies that could separate, remove or destroy toxic substances in or from plastics are understood to fail market entry for economic reasons. The demand for recycled plastics is low, a supply of (cheap) virgin materials exists and there are no quantitative and qualitative recycling targets that would drive the development of the waste sector. For example, the CreaSolv® process has shown to be able to separate different components from different polymers using Solvolyse. Upscaling to industrial scale has not been possible due to the costs of the resulting secondary plastics and the uncertainty of whether sufficient input with an acceptable price and appropriate purity will be available in the future to secure investment in an industrial scale plant.

3 IDENTIFIED RESPONSES

When considering the responses in relation to non-toxic plastics and plastic waste recycling, it is useful to differentiate between:

- Materials, products and wastes originating from the current systems of manufacturing and information provision, resulting in the inclusion of SVHC and other toxic substances in materials and products without related communication on their content and without an overview of the overall uses of such substances in different applications;
- A plastics economy that would prevent the presence of toxic substances in plastic materials as much as possible, enable detection of materials with toxic substances included, and separate these from other material streams.

The current method of managing plastics and plastic waste appears to be inefficient, leading to considerable economic loss as well as loss of materials. As for all materials, responses could be implemented from the perspective of chemicals policy, articles policy and waste policies.

However, an overarching approach targeting the management of the 'material plastics' presents the most efficient opportunity to tackle issues related to toxicity and the efficient use of resources. A potential 'plastics regulation' could include several elements such as:

- Design principles and quality requirements that apply throughout all potential primary and secondary life cycles of plastics, such as:
  - Restrictions of use of toxic substances and/or positive list of substances that can be used o ensure safe products. These could be differentiated according to broader groups of applications (e.g. packaging materials, plastics in contact with food, and/or vulnerable groups, plastics for outdoor use, etc.);
  - Increased knowledge of the composition/groups of 'standard' plastic polymers in order to reduce the number mixtures/compounds that would have to be kept separate in order to allow efficient and high quality recycling.
- A system to mark plastic materials that allows sorting of waste plastics for reuse or recycling, as well as for separating materials containing legacy substances for final disposal; this could be a system that is integrated into the polymer, e.g. via chemical markers.
- Support (the development of) recycling technologies that can remove toxic substances (legacy substances or contaminations acquired during use, including from printing) from plastic materials, e.g. via binding recycling targets and/or product requirements to include particular shares of recycled materials. These recycling technologies could be based on:
  - Decontamination of materials;
  - Decomposition of polymers and reuse of monomers as chemical feedstock.
- Implementation of closed loop systems for plastics applications with either very high or very low standards of product quality (including the content of toxic substances), including authorisation procedures for recycling processes (as implemented for FCM).

A Dutch report[206] outlines a less far-reaching opportunity to decide on the recycling of (plastic) materials containing toxic substances. It suggests the following:

- Exemptions to the concentration limits of particular substances in recyclates for use in particular applications should be possible where these are assessed to be safe and where closed loops can be established and controlled. This would widen the possibilities for use of waste as raw materials (e.g. cadmium in PVC recyclates).

[206] Janssen M.P.M. et al., 2016.

- Stakeholders could identify safe uses of recyclates at a general level and derive generic exemptions for toxic substances in these materials. This would require cooperation of all actors from the areas of chemicals, products and waste to ensure a comprehensive of potential exposures (construction waste in the Netherlands)[207].
- Legislation should encourage the implementation of innovative recycling technologies by considering their capacity to eliminate toxic substances from waste in the setting of concentration limits of toxic substances in recyclates.

They propose a general model to optimise recycling/circular economy, comprising five elements:

1) Clear policy goals for recycling and the management of toxic substances.
2) Translation of policy goals into requirements for recyclates (products).
3) Risk assessment to identify 'safe applications' of products meeting the requirements for recyclates.
4) Societal acceptance of this risk assessment.
5) Economic feasibility of recycling and the relevant market demand for the recyclates.

Apart from these overarching approaches, many of the detailed identified responses highlighted in the main report are relevant and are not repeated here.

[207] Leaching limit values for stony demolition wastes were derived from the Dutch Decree on Soil Quality.

4 CONCLUSIONS ON TOXIC SUBSTANCES IN PLASTIC WASTE FOR RECYCLING

The content of toxic substances in waste and the consequences for the recyclability and safety of the resulting materials and products is a matter of intensive debate, with different opinions voiced by stakeholders. The core questions discussed are:

- Overall, is it 'better' to recycle a material/waste which includes a toxic substance, or should the toxic substance be removed from material cycles and the material 'lost' for further use?
- Should the same standards be applied to virgin materials and recycled materials with regard to their contents of toxic substances, or should it be possible to define exemptions, e.g. based on the technically achievable concentrations?
  Can substances in recycled materials be 'reused' in the second service life, e.g. BFRs and phthalates, thus preventing the use of additional amounts of these substances[208]?

Reaching the end-of-life phase, all articles and their potential content of hazardous substances become waste. Well-functioning and effective material cycles are a high priority from an environmental and economic point of view and a core element of the European raw materials initiative and the EU 2020 strategy. However, toxic substances in these materials may pose risks in their second service life or could prevent high quality recycling (contamination of the recycled product), thus yielding less valuable products.

Very often, toxic and non-toxic components are combined in one article. Separating such components to ensure proper recycling often results – where possible at all – in considerable cost and effort for the stakeholders in waste management. In fact, very few legal requirements exist for obligatory separation of hazardous components. Such an approach is realised in the WEEE Directive, which requires separation of plastics with BFRs. Inadequate labelling of such plastics often makes identification problematic. Even if enforcement of such separation requirements would be very effective – which is difficult in daily practice – the risk from such plastic streams is not eliminated because they can re-enter the product cycle by recycling in open loops[209]. Ensuring closed loops in a global (secondary) raw materials market is related to high effort, if it is indeed possible at all.

Keeping non-toxic and toxic waste streams separate is an additional cost factor in logistics and waste treatment activities. Mixing hazardous and non-hazardous wastes is not a legal option. The European waste legislation prohibits mixing of hazardous waste in general (WFD Article 18) and the achievement of reclassification of hazardous to non-hazardous waste by diluting or mixing is similarly banned (WFD Article 7.2).

The analysis of approaches to non-toxic material cycles is therefore a logical consequence.

Where it is intended to strengthen the circular economy, to increase the recycling of materials and to substitute primary raw materials for secondary raw materials, the management of hazardous substances plays an important role and might comprise a broad variety of approaches. In addition to the prevention of the use of hazardous substances, other examples could be:

- Minimising the carryover of hazardous substances in the production phase in articles (e.g. toxic catalysts which remain in articles);

[208] This question chiefly relates to situations where no alternatives are available to a toxic substance or where the substance that should be recovered/recycled is particularly valuable, e.g. due to the efforts to produce it, or its scarcity. In these cases, specific conditions may have to be implemented, such as closing (and enforcing) loops and prevention of dilution of the respective material streams.

[209] As for example shown for plastics from waste electrical and electronic equipment, which re-entered the European market in non-WEEE-articles (Puype 2015).

- Keeping materials with hazardous substances separate from other materials;
- Enabling closed loops for hazardous materials and ensuring enforcement to prevent leaking of material from the loops. This includes the need for discussions as to whether such material with an elevated content of hazardous substances (e.g. plastic waste with BFR) should be kept in a geographical area where enforcement can be ensured.
- Where derogations from substance bans are discussed (e.g. recycling of DEHP containing PVC) the 'next loop' of the resulting products shall be included in the assessment. In order to prevent contamination of material streams from wastes resulting from those products (e.g. beacon bases made from DEHP PVC), information flows and waste management obligations shall be in place.
- Applying technologies and approaches to separate hazardous from non-hazardous materials.
- Applying technologies which separate hazardous substances from polymer matrices (e.g. by depolymerisation).

5 DECISION-MAKING ON WASTE TREATMENT

Even if a system of product design was established and waste separation and decontamination of material streams were working sufficiently well, decision-making on how to deal with existing, contaminated material streams still remains relevant. It could be useful to establish a systematic approach to decide whether or not materials should be recycled or destroyed in order to remove toxic substances from the material cycles.

One approach could consider different aspects of waste and the recycled products. The issues and questions outlined below are regarded as the core aspects that should be taken into account to determine whether a waste should be subjected to recycling or finally disposed of. For many aspects of this discussion, there may be a lack of information. In addition, waste treatment operations that are able to actually separate and recover substances or materials and/or to eliminate toxic substances might not be established (yet).

Finally, in current waste management practices, economic issues play an important role, e.g. whether or not the income that can be generated from the treatment of a particular waste (be it the service of disposing or the potential income through sales of recycled materials) exceeds the costs of the waste treatment option.

5.1 TYPE OF WASTE

The types of articles/post-consumer waste influence the waste treatment decision, in particular the composition of the waste stream (number of different materials and articles in the waste and their separability), the content of valuable/critical substances and/or materials, and the content of articles/components that could be reused without further processing, but having been dismantled and refurbished.
In order to identify waste treatment options and their limitations, the following questions should be considered:

- Are there articles (parts) which can be separated and reused?
- Can the different materials (and articles (part) be easily separated?
- Do any of the materials in the waste stream contain raw materials/substances which are of particular importance because:
  - They are valuable as such (e.g. noble metals);
  - Their production requires high resource input, which makes it valuable;
  - They are characterised as critical raw material, e.g. based on the 'Communication on the review of the list of critical raw materials for the EU'[210], critical because resources are scarce or the material is obtained from areas with political conflicts.

5.2 TYPE OF CONTAINED TOXIC SUBSTANCE

Toxic substances in waste could cause risks to workers or the environment during waste treatment, might contaminate secondary raw materials resulting in low material quality, and/or technically disturb the recycling process. There are indications that it is difficult to 'reuse' a toxic substance as a functional component in a material. For example, as the concentration of BFRs in recycled plastics is normally not known, their content cannot be considered in the production of the material for a new use and the related additives content, thus they do not save any resources. However, whether this holds

[210] European Commission, 2014.

true for all materials and toxic substances, and whether or not cheaper technologies to measure substance concentrations in homogenous materials could change this situation, remains unclear.
In order to identify waste treatment options and their limitations, the following questions should be considered:

- Which toxic substances are included in the waste streams to be treated?
- What risks for workers and which environmental emissions of the toxic substance could occur during the recycling process and/or disposal process?
- Would the substance be destroyed during the recycling process or would it remain in the recovered material?
- If the substances are still included in the secondary materials, are they to be regarded as contaminants or could they provide a useful function during the second service life of the material/article?
  - If the substance is a contaminant, would it be contained in the secondary raw material in higher concentrations than in virgin materials?
  - If, in principle, the substance has a useful function, can this function be used in practice with respect to the possible uncertainties about its exact concentration and the way it is bound to the matrix of the secondary materials? Furthermore, is the use of this function desirable? Would the recovered toxic substance in the material lead to a replacement of the same substance in the secondary raw materials, or are there safer alternatives which could be applied to obtain the same function?

5.3 TYPES OF SUBSEQUENT USES

The use of a recycling material requires information on the (exact) composition of the secondary raw material. In other cases, the actual destination of recycled materials and their use in particular products is unknown. In order to identify waste treatment options and their limitations, the following questions should be considered:

- In the case of reuse of articles or article parts: are there any legal requirements on composition that would differ for virgin and for recovered articles/article parts, e.g. because the requirements have changed[211]?
- Is the use and the potentially related requirements on the composition of a recovered material known?
- What legal requirements apply to mixtures and substances obtained from a recycling process from chemicals legislation and/or from product legislation?
- Is it likely that the content of toxic substances may cause relevant emissions and/or exposures of humans and the environment that differ from those of products produced from virgin materials?

In order to answer the above questions, different types of information are needed, which are currently not available. The establishment of relevant information flows are crucial to establish any knowledge-based and rational approach to decision-making on the adequate and most environmentally friendly option to treat waste.

[211] For example, if an article is placed on the market and a new legal requirement on the content of a particular substance is decided on during its service life, the recovered article for reuse would face a different legal situation than the virgin article.

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Appendix 2:
Case study EEE

APPENDIX 2: CASE STUDY EEE

1 ELECTRICAL AND ELECTRONIC EQUIPMENT (EEE)

The case study on EEE illustrates the legislation applicable, the tools that are in place to implement it, and the gaps and deficits identified with regard to toxic substances in materials and material cycles, as well as related information. Specific responses are identified which could cause both a reduction of use and emissions of toxic substances in/from EEE, as well as improved options for reuse and recycling. In this case study, cathode ray tube television sets/PC monitors (CRT TVs/PCs) and washing machines serve as examples to illustrate the specific challenges.

1.1 CRT TELEVISIONS AND PCS

Over many decades, cathode ray tube television sets and PC monitors (CRT TVs/PCs) were the state-of-the-art TV/PC technology. CRT are the main components of CRT televisions and PC monitors, creating the visible image on the screen. In recent years the technique was increasingly replaced by flat screens with LCD or LED technology, resulting in rising numbers of end-of-life (EoL) CRT TVs/PCs accompanied by a declining number of new devices sold on the market.

Table 5 shows the development of sold CRT TVs/PCs in Germany from 1997 until 2011.

Table 5: Sales of new CRT TVs and PCs in Germany from 1997 until 2011 (Source: Sander et al. 2016)

CRT TVs/PCs – Total market Germany (1,000 units)									
	1997	2000	2003	2006	2007	2008	2009	2010	2011
CRT TVs	10,000	7,875	5,172	2,730	1,435	639	150	30	0
CRT PCs	4,600	2,965	1,330	50	50	50	50	0	0

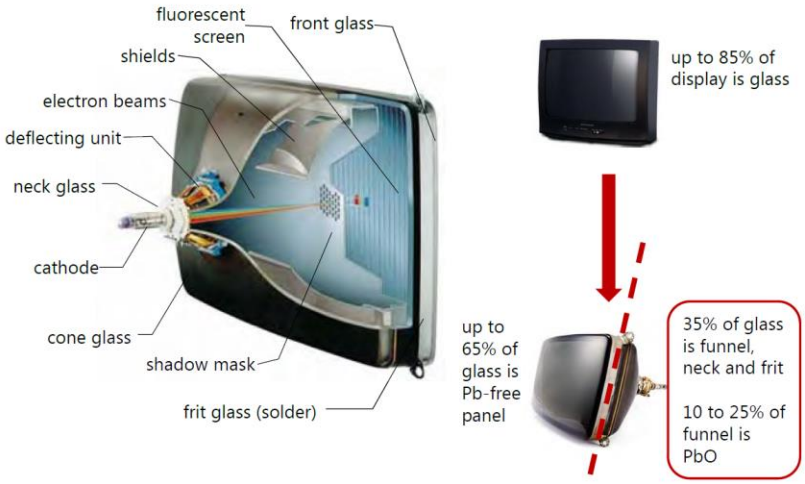
This is in line with the finding that the production of new CRT TVs/PCs in Europe ended[212]. Today, only a few companies in Asia are producing CRT TVs/PCs[213]. Although the number of new CRT TVs/PCs declined rapidly, it is to be expected that EoL CRT TVs/PCs will arrive at recycling facilities for some years to come, resulting in the need to establish adequate recycling/disposal solutions for these devices. According to Rocchetti and Beolchini[214], about 50,000-150,000 tonnes/year of EoL CRTs are currently collected within Europe.

CRT TVs/PCs contain a number of hazardous substances that require special treatment before/during recycling/disposal, the most important being lead, cadmium and BFRs.
CRTs constitute around 65% of the weight of a television or a computer monitor and are composed of 85% glass[215], mainly funnel glass and screen or panel glass (see Figure 7). CRTs are listed as one of the WEEE components with the highest content of hazardous substances[216]. The funnel glass contains a large percentage of lead oxide (up to 25%)[217] to shield against X-Rays produced inside the CRT[218]. According to ICER[217], the amount of lead oxide in CRT varies between 0.5 kg for a 12" CRT to 3 kg

[212] Vieitez et al., 2011; UBA, 2016.
[213] Bleher, 2014; Widmer, 2016.
[214] Rocchetti and Beolchini, 2014.
[215] Herat, 2008.
[216] Pizzol et al., 2012.
[217] ICER, 2004; UBA, 2016.
[218] Rocchetti and Beolchini, 2014.

for a 32" CRT.
The screen consists of homogenous barium-strontium glass (up to 12% barium oxide and up to 12% strontium oxide)[219]. On the inside, it is coated with a fluorescent coating composed of several compounds, which may also contain lead oxide, yttrium, cadmium and other heavy metals[220]. Diederich and Daniel[221] specify the average amount of this fluorescent coating in a CRT to approx. 2 mg/cm^3, subsuming between 7 and 15 g, depending on the particular device.

Figure 7: Composition of CRT (Source: Widmer 2016)



CRT TVs/PCs have a plastic casing; the share of plastic of a CRT TV/PC can vary between 10% and 40%, thus representing a major source of WEEE plastics[222]. Most plastic casings contain BFRs in order to reduce the flammability of polymer materials in electric and electronic equipment (EEE), such as polybrominated diphenyl ethers (PBDEs).

Acrylonitrile-Butadiene-Styrenes (ABS) are the most frequently used polymers for CRT TV/PC casings, followed by High Impact Polystyrene (HIPS) polymers[223]. The main PBDE used in plastic casings for CRT TVs/PCs was c-OctaBDE[224] and decaBDE[225]. The EU stopped the use and production of c-OctaBDE in the 1990s, so that substantial amounts of this BFR are mainly found in devices produced in the 1980s[226]. DecaBDE is still being produced and applied to plastics as a flame retardant[225].

PBDEs were detected in plastic casings of CRT TVs/PCs in 20% of the analysed samples for a study by Sindiku et al.[225,] and in 40% for a study by Schlummer et al.[227].

Analyses of European WEEE by Waeger et al.[228] detected a value of 0.087% w/w for c-OctaBDE, whereas the level of c-OctaBDE in CRT TVs/PCms exported to Nigeria were 0.27% w/w and 0.86% w/w for decaBDE[229].

[219] Herat, 2008.
[220] ICER, 2004; Rocchetti and Beolchini, 2014.
[221] Diederich and Daniel, 2007.
[222] Stockholm Convention 2015.
[223] Waeger et al., 2010; Babayemi et al., 2015; Stockholm Convention 2015.
[224] Babayemi et al., 2015; Stockholm Convention 2015.
[225] Sindiku et al., 2015.
[226] Sindiku et al., 2015; Stockholm Convention 2015
[227] Schlummer et al., 2007.
[228] Waeger et al., 2010.
[229] Sindiku et al., 2015.

1.2 WHITE GOODS – WASHING MACHINES

Capacitors are electrical components used to store electrical charge or electrical energy. They are also used in white goods, such as washing machines. In the past, polychlorinated biphenyls (PCBs) were used in capacitors of white goods as cooling agents and insulants. PCBs are organic chlorine compounds. Between 1930 and 1980 they were produced on an industrial scale (in total 1,325,810 t[230]). Due to their chemical and physical properties, they were deployed in the electrical industry but also in a broad range of further applications as softener or flame retardants. There is no database available to quantify either the amount or the share of washing machines with PCB containing capacitors.

In the 1970s, PCBs were widespread in the environment as the disposal of equipment and PCB containing wastes were not regulated[230]. Since the identification of their adverse properties, their application - and later their disposal - was regulated by a number of international regulations, among others the Stockholm Convention on Persistent Organic Pollutants (POPs)[231].

1.3 OVERVIEW OF LEGISLATION

1.3.1 Chemicals legislation

In 2009, c-PentaBDE and certain congeners of c-OctaBDE were added to Annex A (elimination) of the Stockholm Convention, prohibiting their production and use in new articles[232]. Annex A, Part V exempts PBDE containing materials from recycling and the use of PBDE-containing recycled materials in articles under certain conditions. The reason for this exemption was the large volumes of these materials in the global recycling flow and the already existing reuse and recycling of materials and wastes containing POP-PBDEs[233]. This exemption generated significant discussions, with concerns raised that recycling of POPs would inevitably increase the possibilities of generating new environmental and health risks[234]. Exposures could occur during the recycling process and future life cycles, thereby conflicting strongly with the principal objective of the Stockholm Convention to protect human health and the environment from POPs[235].

DecaBDE, which is a major BFR in CRT TV/PC casings, is not yet listed under the Stockholm Convention. It has, however, been proposed for listing as a POP by Norway in 2013[236]. The POPs Review Committee (POPRC) decided in 2014 that it meets the criteria of Annex D and recommended it for listing in Annex A under the Convention[237]. A decision on its inclusion is still pending.
In 2012, decaBDE was identified as SVHC and included in the candidate list for authorisation as PBT/vPvB in accordance with Annex XIII of REACH[238].

Regulation (EC) 850/2004 on persistent organic pollutants (POPs Regulation) and amending Directive 79/117/EEC implements the specifications of the Stockholm Convention in European law. Following the addition of some PBDEs to the Stockholm Convention, the EU updated the POPs Regulation and defined limit values for the sum of tetra-, penta, hexa- and hepta-BDE of 1000 mg/kg. DecaBDE was not listed. The listed PBDEs have to be treated according to Article 7 in order to destroy or convert the hazardous substances irreversibly if the defined threshold limits are exceeded.

[230] Weber et al., 2013.
[231] COM, 2001.
[232] UNEP, 2009.
[233] Stockholm Convention 2015.
[234] Weber et al., 2010; Waeger et al., 2010.
[235] Sindiku et al., 2015.
[236] Stockholm Convention 2013.
[237] UNEP, 2014.
[238] ECHA, 2012.

Lead and its compounds are identified as SVHC under REACH. There are some restrictions on their use in articles and chemical mixtures listed in REACH Annex XVII. None of the restrictions is directly relevant to EEE.

Cadmium is classified as carcinogenic and is included in the candidate list for authorisation. There are no restrictions on the use of cadmium in EEE in Annex XVII of REACH.

In 1976, the EEC adopted a Directive on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (76/403/EEC), prohibiting 'the uncontrolled discharge, dumping and tipping of PCBs and of objects and equipment containing such substances' (Article 2). In view of technical progress, the need for further regulation and the complexity of the topic, this Directive was replaced in 1996 by Directive 96/59/EC on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT), requiring a final phasing out of equipment containing liquids with PCB >500 mg/kg until 2010. Equipment with PCBs between 50 and 500 ppm have to be included in inventories but may stay in use until their lifetime expires and they have to be decontaminated or disposed of.

PCBs are listed in the Stockholm Convention under Annex A (elimination), i.e. production and use (in new articles) is prohibited. Parties to the convention have to 'make determined efforts designed to lead to environmentally sound waste management of liquids containing polychlorinated biphenyls and equipment contaminated with polychlorinated biphenyls having a polychlorinated biphenyls content above 0.005 per cent' (Annex A, Part II (e)).

In the POPs Regulation, PCBs are listed in Annex III as group of substances subject to release reduction provisions.

1.3.2 Articles legislation

Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) specifies in Article 4(1) the restrictions on the use of six substances listed in Annex II. Among these are lead and PBDE, with a maximum concentration value tolerated by weight in homogeneous materials of 0.1% w/w and cadmium with a maximum concentration value tolerated by weight in homogeneous materials of 0.01% w/w.

Annex III presents exemptions from the restrictions in Article 4(1) for particular applications, including for example for lead in CRT (exemption 5a). As a result of this and other exemptions, the regulated toxic substances may still be used and may thus be present in the EoL articles during waste treatment.

The restrictions on PBDE in RoHS account for all PBDEs, consequently also for c-OctaBDE and decaBDE. Waste plastics intended to be recycled and subsequently used for electronic equipment have to comply with the RoHS Directive, which means that the sum of all PBDE congeners must not exceed a 0.1% w/w threshold in homogenous material.

1.3.3 Waste legislation

The list of waste (Commission Decision 2000/532/EC)[239] categorises 'Transformers and capacitors containing PCBs or PCTs' (16 02 09*), 'Insulating or heat transmission oils and other liquids containing PCBs or PCTs' (13 03 01*) and 'Waste glass in small particles and glass powder containing heavy metals (for example from cathode ray tubes)' (10 11 11*) as hazardous waste.

[239] Recently amended by Commission Decision (EU) No 2014/955/EU.

Whole WEEE items containing CRTs are classified as hazardous waste under 16 02 13*, the bare CRT is classified as hazardous waste under 16 02 15*.
According to Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) PCs and TVs are EEE of the categories 3 - 'IT and telecommunications equipment' - and 4 - 'consumer equipment and photovoltaic panels'. Washing machines are grouped in category 1 'Large household appliances'.

Capacitors containing PCBs, plastics containing BFRs and CRTs must be separated from other equipment, treated separately from any WEEE (Annex VII WEEE Directive) and be disposed of or recovered in compliance with Directive 2008/98/EC. The fluorescent coatings of separately collected CRTs must be removed from the glass (Annex VII).

The WEEE Directive sets weight-based recovery and recycling targets for all equipment within its scope. Since 15 August 2015, of all of the separately collected equipment of equipment 1, 85% by weight shall be recovered and 80% by weight shall be prepared for reuse and recycled. Of all of the separately collected equipment of equipment 3 and 4, 80% by weight shall be recovered and 70% by weight shall be prepared for reuse and recycling. As plastic casings and CRT make significant contributions to the weight of a TV/PC monitor, this requires the recycling of at least some part of these components. The Directive thereby acts as a driver for recycling.

The WFD bans the mixing of hazardous waste, either with other categories of hazardous waste or with other waste, substances or materials (Article 18(1)). Consequently, the dilution of hazardous substances in waste is not allowed. Member States are, however, allowed to permit the mixing of hazardous wastes when the requirements of Article 18(2) are fulfilled, meaning that:

a) the mixing operation is carried out by an establishment or undertaking which has obtained a permit in accordance with Article 23 (´Issue of permits´);
b) the provisions of Article 13 (´Protection of human health and the environment´) are complied with and the adverse impact of the waste management on human health and the environment is not increased; and
c) the mixing operation conforms to best available techniques (BAT).

According to Directive 96/59/EC, PCB containing wastes have to be disposed of in operations D8, D9, D10, D12 and D15, as provided for in Annex I of Directive 2008/98/EC[240].

The requirements of the POPs Convention, to which Article 7(2) of the POPs Regulation corresponds, specify that 'waste consisting of, containing or contaminated by any substance listed in Annex IV shall be disposed of or recovered, without undue delay […] in such a way as to ensure that the persistent organic pollutant content is destroyed or irreversibly transformed so that the remaining waste and releases do not exhibit the characteristics of persistent organic pollutants'.

Annex V, part 1 specifies the disposal and recovery operations. For PCBs, it only allows operation D9 and operation D10[240], thereby differing from Directive 96/59/EC. In practice, the most applied method for disposal of PCB containing waste in the EU is high-temperature incineration.

However, the POPs Regulation allows the isolation of PCBs from waste, provided that the PCBs are

[240] D8: Biological treatment not specified elsewhere in this Annex which results in final compounds or mixtures which are discarded by means of any of the operations numbered D1 to D12; D9: Physico-chemical treatment not specified elsewhere in this Annex which results in final compounds or mixtures which are discarded by means of any of the operations numbered D1 to D12 (e.g. evaporation, drying, calcination, etc.); D10: Incineration on land; D12: Permanent storage (e.g. placement of containers in a mine, etc.); D15: Storage pending any of the operations numbered D1 to D14 (excluding temporary storage, pending collection, on the site where the waste is produced).

subsequently disposed of in accordance with the first subparagraph of its Article 7(2). Waste containing PCBs below the concentration limit of 50 mg/kg, as specified in Annex IV, may be otherwise disposed of or recovered in accordance with the relevant Community legislation. Thus, according to legislation, PCB containing components of WEEE cannot be disposed of in urban landfill sites.

1.4 INFORMATION AND MATERIAL FLOWS

Article 7 of the RoHS Directive states that 'manufacturers draw up the required technical documentation and carry out the internal production control procedure in line with module A of Annex II to Decision No 768/2008/EC'. This decision sets out the requirement for manufacturers to provide the following information:

- A general description of the product;
- Conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- A list of the harmonised standards and/or other relevant technical specifications […];
- Results of design calculations made, examinations carried out, etc.;
- Test reports.

The RoHS Directive does not oblige the suppliers or producers of EEE to provide information on the content of substances in their products or components therein, thus making it impossible for the recycler to integrate this knowledge into his recycling practices[241].

The RoHS Directive is restricted to only six substances. Gross et al.[242] recommended the inclusion of five additional organic substances in RoHS and labelling of four inorganic substances. They also regarded PVC used in wires and cables and organochlorine and organobromine compounds used as FRs as substances of concern, because of the risk that can potentially occur during their end-of-life treatment (e.g. dioxins and furans may form in the combustion of BFRs and PVC in open fires or at low temperatures in improperly functioning incinerators[243]). However, the scope of the RoHS has not (yet) been extended to include more toxic substances.

The WEEE Directive recognises the problematic role of hazardous substances such as mercury, cadmium, lead, hexavalent chromium, polychlorinated biphenyls (PCBs) and ozone-depleting substances in WEEE during the waste management phase (recital 5). In Article 15, it regulates the provision of information in order to facilitate reuse, maintenance, upgrade, refurbishment and recycling, and requires that producers provide information about the location of dangerous substances and mixtures in EEE. It shall be made available by producers of EEE in the form of manuals or by means of electronic media. Article 14 sets out that Member States shall also ensure that users of EEE in private households are given the necessary information about 'the potential effects on the environment and human health as a result of the presence of hazardous substances in EEE'.

Information made available by producers, e.g. on their company website, can be requested by authorised institutions like WEEE treatment plants. Some obstacles in the current situation have been observed:

- Recyclers are often not aware that such information exists, or where it can be accessed;
- The WEEE Directive does not specify the level of detail or any data format, i.e. similar information could be obtained in totally different forms from different producers;
- The information is not always sufficient (e.g. missing the amount of hazardous substances);
- Data inquiries are difficult (e.g. missing contact points, information not easily identified on the

[241] Pizzoll et al., 2012.
[242] Gross et al., 2008.
[243] Pizzol et al., 2012.

website, time-consuming process, etc.);

- The information is available in a form which does not match the daily procedures in the WEEE treatment plants and which requires considerable effort. Technically, it is possible to check each individual appliance at the WEEE treatment site; however, the reality at WEEE treatment sites, where appliances are delivered as mixed material and emptied from the container on site (see Figure 8 and Figure 9 below), means that a high degree of effort is necessary (identification of the serial number of the individual appliance and checking databases for the serial number). Usually, the revenues from selling waste fractions from treated WEEE do not cover such efforts[244].

Article 33 of REACH obliges EU article suppliers to inform the article's recipients of the content of substances on the REACH CLS if they are present in concentrations > 0.1% w/w. This provision is applicable to decaBDE, lead and cadmium and their compounds, as these are listed on the REACH CLS. No such communication is required for pentaBDE or PCBs. The POP Convention and the EU POP Directive 850/2004 do not contain specific communication requirements.

In summary, the following legal obligations apply to some of the substances in CRT TVs/PCs (lead, cadmium, PBDE) and washing machines (PCBs) according to the POPs Regulation, the RoHS, the WEEE Directive and REACH:

Table 6: Summary of legal obligations applying to some of the substances in CRT TVs/PCs (lead, cadmium, PBDE) and washing machines (PCBs)

Substance	Use restrictions	Waste decontamination	Communication requirements
Lead	Use in new EEE is restricted to 0.1%	Decontamination if included in WEEE	Communication of content if exceeding 0.1%
Cadmium	Use in new EEE is restricted to 0.1%	Decontamination if included in WEEE	Communication of content if exceeding 0.1%
PBDE	Use in new EEE for sum of components is restricted to 0.1%	Decontamination if included in WEEE	Communication of content for PBDEs on CLS
PCB	Ban on production and use in new articles	Separation of PCBs in waste and subsequent destruction of PCBs or destruction of complete wastes containing PCBs	-

The actual application of the legal obligations and the current recycling practices are described below for the specific WEEE components.

1.4.1 Lead-containing glass

1.4.1.1 Information flow

As there are no CRT TVs/PCs with lead-free funnel glass, it is not difficult for recyclers to identify lead-containing glass from CRT TVs/PCs. Thus, once there was an awareness of the problem and regulations for treatment requirements came into force, it became 'common knowledge' that CRT TVs/PCs must be treated differently to other wastes.

1.4.1.2 Waste treatment options

A prerequisite for the recycling of single components is the systematic disassembling and sorting according to the needs of the recipients of the recyclates. Due to new techniques (e.g. laser), the funnel

[244] Fulvio and Mathieu, 2012; Sander et.al., 2016.

and the front glass of a CRT device can be easily separated – even if the glass is already broken - thus enabling sorting, dismantling and further treatment options.

Use of CRT front glass

Due to the low lead concentration, panel glass can be used – after the phosphorous coating is vacuumed or washed off - in container glass production, and this seems to be the most common recycling option for panel glass[245]. Further options are use in glass wool, cement bricks or housing tiles. The phosphorous coating can be separated from the fountain solution and be recycled or disposed of[246].

Use of CRT funnel glass

Glass-to-glass

Until a few years ago, the lead containing funnel glass was used in the production of new CRTs, thus establishing a closed-loop recycling process. However, as no new CRTs are produced, the amount of EoL CRT glass far exceeds the demand in the CRT TV/PC production, meaning that this option is no longer viable. Bleher[245] estimates the drop in prices from EUR/t 120-150 in the mid-2000s to EUR/t 20-30 in 2014.

Glass-to-landfill

Glass-to-landfill is not a method of recycling but of disposal. As lead containing CRT glass is classified as hazardous waste, it has to be disposed of in a hazardous waste landfill if landfilling is intended. Backfilling of old mines is another feasible option for lead containing glass. All landfilling scenarios have to keep in mind the recycling targets specified by the WEEE Directive, as disposal is not regarded as a method of recycling or recovery in the WFD. In Germany, the recycling targets in 2013 and previous years for equipment categories 3 and 4 were fulfilled[247].

Glass-to-further-applications

The Packaging Waste Directive (Directive 94/62/EC) limits the amount of lead allowed in container glass to 100 ppm[248] — leaded glass from CRTs is therefore unsuitable for recycling into applications in contact with food and drink, such as container glass[249], but other open-loop recycling options are allowed. In his literature review, Widmer[250] identified various possible and currently applied recycling options as alternatives to glass-to-glass recycling and landfilling. CRT glass may be and is currently used:

- In the production of construction materials such as clay bodies, foam glass or concrete, lowering the melting point and substituting the input of primary resources such as sand;
- In ceramic glazes, such as for tiles or in crystal glass;
- As smelting flux, e.g. for copper or lead smelting, meaning that less primary lead remains in the slag. The remaining slag contains lead from the CRT glass and has to be land- or backfilled[251];
- For waste vitrification to insulate from the rays of radioactive waste material and thereby take advantage of the shielding effect of lead. According to Widmer[250] this is a promising but as yet largely untested procedure.

In recent years, some companies (e.g. Nulife Glass; Sweeep Kuusakoski) declared that they had de-

[245] Bleher, 2014.
[246] Diederich and Daniel, 2007.
[247] UBA, 2015; no specific data are available for the recycling quota of CRT devices.
[248] However, the German Packaging Regulation permits a concentration limit of 250 ppm for lead in container glass if the substance is not added on purpose but derives from secondary resources.
[249] Vieitez et al., 2011; ICER, 2004.
[250] Widmer, 2016.
[251] Behler, 2014.

veloped a technique that allows the separation of lead from the glass by chemical treatment and melting it in specially designed furnaces. The British company Nulife Glass claims to produce lead-free glass from CRTs and lead with a purity of up to 99.7%[252].
The lead can be used, for example in car batteries, substituting lead from primary resources. According to the company, the de-leaded glass can be used in construction products such as floor screeds, worktops and glass tiles, or in applications as road surfacing, grit blasting and production of higher value decorative glass products[253]. A company official advised against the use in the glass container industry, thereby indicating that the glass is not completely lead-free[254].

No studies were identified that evaluated this specific approach, thus no information is available on the remaining content of lead in the glass or the economic feasibility of the process. However, Compagno et al.[255] conducted a Life Cycle Assessment analysis (LCA) for a presumably similar chemical and electrolytic treatment technique of leaded glass[256], demonstrating that it is (at least in the pilot stage) more environmentally friendly compared to the commonly practiced landfill disposal. They attribute great potential to this approach to become the BAT in the foreseeable future. The success of this technology could also have an impact on the discussion on the end-of-waste criteria for CRT glass and the question of whether CRT glass should be allowed as input in container glass and flat glass manufacturing if it could be freed from hazardous substances[257].

1.4.2 PCB-containing capacitors

1.4.2.1 Information flow

Legislation did not stipulate the labelling of PCB-containing capacitors until the ban on the use of PCBs. Nevertheless, recyclers can identify PCB-containing devices on the basis of letter combinations applied to the capacitors[258]. Lists with this information can be obtained from industry associations[259].

1.4.2.2 Use of PCBs in capacitors

The restrictions on the use of PCBs in EEE is a good example of how regulations can contribute to the successful elimination of hazardous substances in devices by setting requirements for their design (absence of specific substances). In new washing machines, the use of PCB-containing capacitors is prohibited. Due to the phase-out, washing machines containing capacitators with PCB are seldom found at recycling centres.

1.4.2.3 Waste treatment of PCB capacitors

If PCB containing capacitors are separated from washing machines, the specific provisions on the treatment of PCB containing waste, i.e. the final disposal via incineration and/or hazardous waste landfilling, ensured and continues to ensure that PCBs are continuously removed from the technosphere, at least in the EU. However, a requirement for disposal is the separation of capacitors at recycling facilities. This requirement might not always be fulfilled as no control mechanisms are in place to observe the proper removal of PCBs from washing machines or other WEEE. Although PCB con-

[252] WMW, 2012.
[253] Sweeep Kuusakoski n. d. a; Rocchetti and Beolchini, 2014.
[254] Sweeep Kuusakoski n. d. b.
[255] Compagno et al., 2014.
[256] Specific details were not described in the study due to a 'patent pending' process.
[257] Vieitez et al., 2011.
[258] Small PCB containing capacitors in washing machines could be labelled with the one of the following letter combination: A30, A40, C, CD, 3CD, 4CD, CD, C2, CP, Cp, CPA40, CPA50, C100, C125, C180, 76C 6D, 9D, 3LP, Chlordiphenyl, Clophen (Hamburg 2002).
[259] In Germany for example at www.zvei.org; Bonk et al., 2011.

taining capacitors are usually labelled, the separation and identification is too labour-intensive, and thus too expensive for recycling facilities, resulting in the shredding of whole devices[260].

1.4.3 BFRs in plastic casings

1.4.3.1 Use of BFRs

Results of several studies suggested that in a substantial share of plastic casings from CRT TVs/PCs and other WEEE, BFRs are applied. The analysed content of PBDE partially exceeds the allowed threshold of 0.1% w/w set by the RoHS Directive. Waeger et al.[261] reported average values of 0.087% w/w for c-OctaBDE in European CRT TVs/PCs, whereas Sindiku et al.[262] measured average quantities of 0.27% w/w for c-OctaBDE and 0.86% w/w for decaBDE in CRT TVs/PCs exported to Nigeria. Waeger et al.[261] therefore consider plastic casings from CRT TVs/PCs to be a critical fraction, with one or more RoHS substances well above the corresponding threshold.

1.4.3.2 Waste treatment of plastic casings

According to the WEEE Directive and the Stockholm Convention (and the POPs Regulation), BFR contaminated plastics have to be separated and treated separately in order to avoid dilution of POPs and contamination of other waste streams, and to prevent broader exposure in sensitive uses[262]. Plastics from TV/PC casings with BFR values above the RoHS threshold must thus be treated before they can be used in the production of new EEE.

The implementation of such requirements is challenging because the identification of BFR containing plastics is hardly realistic in day-to-day practice of waste management companies. Identifying a device – for example by screening technologies[263] - which contains hazardous substances would be very time consuming and costly, if possible at all. Thus, recyclers usually do not identify WEEE plastics with and without hazardous substances on the basis of individual appliances, nor do they separate contaminated plastics from non-contaminated plastics. Consequently, BFR containing plastics from WEEE are being recycled in mixed plastics, enter the global plastic market and are used for production of new products in Europe or elsewhere in the world.

Even if the existing requirements were fully implemented, it is unlikely that waste treatment companies would be able to sort and separate to the extent required or make use of that information in their treatments. This mainly results from the fact that in the daily routine of waste treatment companies, WEEE is delivered in 40-foot containers and dumped on the premises of the operators (see Figure 8 and Figure 9).

[260] Sander, 2016.
[261] Waeger et al., 2010.
[262] Sindiku et al., 2015.
[263] Stockholm Convention 2015.

Figure 8: Collected WEEE at a recycling facility (Source: own picture)

Figure 9: Collected WEEE in a recycling facility (Source: own picture)

Even if the enforcement of separation requirements was effective, the risk from such plastic streams would not be eliminated because they can re-enter the product cycle by recycling in open loops, e.g. when sold on the global plastic market[264].

Ensuring closed loops in a global (secondary) raw materials market requires significant international efforts, if it is possible at all. In several studies, POP-PBDEs and other BFRs were identified in products with high exposure potential, although no BFRs were required for production of those products, such as children´s toys, video tapes and household goods[265]. The use of recycled plastics can therefore cause higher risks to human health and the environment than their original use in EEE.

Additionally, there are still large knowledge gaps, even in industrial countries, on material and substance flows of hazardous substances, creating a situation where those flows are badly controlled and there is no dedicated strategy for recycling of BFR containing WEEE plastics[266].

A relatively new approach to separate BFRs and recover the polymer is the CreaSolv® process. A proprietary CreaSolv® solvent is used to extract PBDE/BFRs from the polymer materials, thus removing dissolved contaminants. In addition, non-dissolved compounds (e.g. non-target polymers or other interfering materials) can be separated from the target polymer[267]. The process is capable of treating BFR-rich plastic fractions from WEEE and generating plastics compliant with the RoHS threshold levels. The high levels of BFR in the by-product can be used for bromine recovery, chemically treated or incinerated[268].

According to the Fraunhofer Institut IVV, where the process was developed, it is able to compete economically with feedstock recycling[269]. In a comparison with other recycling and recovery technologies, it receives good ratings by the 'Guidance on best available techniques and best environmental practices for the recycling and disposal of wastes containing polybrominated diphenyl ethers (PBDEs) listed under the Stockholm Convention on Persistent Organic Pollutants'[270]. According to Schlummer

[264] As for example shown for plastics from waste electrical and electronic equipment which re-entered the European market in non-WEEE-articles (Puype et al. 2015).
[265] Stapleton et al., 2011; Sindiku et al., 2015; Stockholm Convention 2015.
[266] Babayemi et al., 2015; Stockholm Convention 2015.
[267] Schlummer et al., 2006.
[268] Schlummer and Mäurer, 2012.
[269] Fraunhofer Institut, 2016.
[270] Stockholm Convention 2015.

and Mäurer[268], the process is ready for commercialisation[271]. However, a prerequisite for the application of such techniques is, again, the upstream sorting and separation of BFR-containing plastics, which is expensive and time-consuming and therefore not common practice in recycling facilities.

1.5 TREATMENT COSTS

The economic feasibility of WEEE recycling depends on the ratio of the fractions with a positive or negative value, i.e. if the products can be sold with sufficient profit margin to recover costs from recycling and potential disposal of non-recyclable fractions.

For CRT recycling, currently the fractions with a negative value (e.g. lead glass) outweigh the fractions with a positive value (e.g. printed circuit boards and copper wire), resulting in negative treatment costs for CRT recycling if recycling occurs under proper conditions. The main reason is the cost-intensive treatment of lead containing funnel glass that amounts to approximately 30% of the total product weight. Although different studies vary widely in their estimation of costs for lead glass downstream treatment options, they agree none of the current options are profitable for recyclers, thus increasing the need for better financing instruments[272].

PCBs are not subject to any recycling but are to be disposed of. Here, the legal requirements are a sufficient incentive to ensure correct treatment, provided the separation of PCB containing wastes is carried out (see Chapter 1.4.2.3).

The recycling of BFR containing plastic casings from TVs/PCs is not profitable at the moment and has to be cross-financed. Also, BFRs in the recycled plastic cannot be used for BFR plastics again, due to the unknown amount of BFRs in the recyclates.

1.6 SPECIFIC RESPONSES IDENTIFIED FOR CRT TVS AND PCS

The best way to eliminate hazardous substances from waste streams is substitution with non-hazardous or less hazardous substances, where possible. This would also ensure that hazardous substances do not harm people and the environment in countries that do not implement BAT in waste treatment.

Substitution can be initiated via legal restrictions on the content or use of substances in particular applications. In the case of PCBs these restrictions were implemented globally (POP Convention) and implemented effectively. The phasing out of PCB containing capacitors was achieved successfully and it is to be expected that the numbers of PCB containing EoL washing machines and other EEE devices will continuously decline and run off[273].

Lead in CRTs is not restricted but substitution took place in the context of a larger technology change from CRTs to LED/LCDs, meaning that there will be a declining number of EoL devices in the future and a total run off once the devices sold in the past few years have been discarded (in approximately 15-20 years).
The RoHS restricts the content of PBDE in EEE to 0.1%, thus limiting the amount of these substances in products and waste streams, but not totally eliminating them.

If substances cannot be substituted, possibilities for cost recovery of various recycling steps and/or effective legal obligation to separate and dispose them are necessary.

[271] See also Sindiku et al., 2015.
[272] Magalini, 2016; Bleher, 2014.
[273] Sander, 2016.

For lead in glass, product requirements limit the possibilities to use recycled glass (no container glass) and promotes open loop recycling in lower quality applications. The high costs of new technologies allowing separation of lead and resulting in the possibility to reuse the recycled glass and lead in high quality applications currently prevent their implementation. Legal options to support their implementation could be to restrict the content of lead in glass in any application (i.e. prevent uses where no separation is necessary) or to develop specific recycling targets for leaded glass, e.g. with quantitative and qualitative (lead-related) requirements. Economic instruments could include investment support in new technologies or taxes on the content of lead in (any) glass. In view of the declining amounts of CRT waste, no new investments can be expected for costly technologies.

Legal options to support the separation of BFRs from plastics or the separation of BFR containing plastics from BFR-free materials could include the definition of quality requirements for recycled plastics or a broadening of the EPR fom articles/products to materials (e.g. material responsibility), such as WEEE plastics. This would create incentives for prevention of the use of BFRs, communication on the content to ensure proper treatment and, potentially, financial contributions to recycling of plastics.

The implementation of an advanced recycling fee paid by the consumers might be difficult to realise in this specific case (but could be possible for other products) since CRT TVs and PCs vanished from shops and almost entirely old CRT from existing stockpiles end up in recycling facilities. Another financing possibility consists of the inclusion of BFRs or plastic producers to a higher degree in financing the recycling. In the case of plastics from TVs/PCs this would require a 'pension' approach where the financial contribution from new appliances (e.g. flat screens) contributes to the recycling of 'historical' WEEE. It is expected that the additional costs for an improved separation would not lead to a significant rise in product prices since only 0.75% of the total price of a laptop originates from plastic materials.
It is also sensible to support further development and marketability of technologies such as the separation of BFRs from WEEE plastics and further use of the decontaminated plastics recyclates (see below), e.g. via research projects or (greener) technology investment support.

Technologies for the analytical detection of PBDE in WEEE plastics – which is a prerequisite for separating POP-PBDE from materials in recycling processes – exist and are described in the 'Draft Guidance on Sampling, Screening and Analysis of Persistent Organic Pollutants in Product and Articles'[274]. However, some methods are not practical for the separation of POP-PBDEs in commercial recycling operations due to time or money constraints[275].

Currently, the introduction of recycled materials containing POP-PBDEs into further use is insufficiently controlled. This can lead to increased releases of hazardous substances and further contamination of waste and articles once those articles themselves become waste[276]. During the Stockholm Convention COP5 in May 2011, the contracting parties recommended phasing out the recycling of materials containing POP-PBDEs if no environmentally sound management is possible[277]. The 'revised draft guidance on best available techniques and best environmental practices for the recycling and waste disposal of articles containing polybrominated diphenyl ethers listed under the Stockholm Convention' recommends the elimination of any remaining stockpiles of BFR containing plastics, or ensuring they become subject to environmentally sound management, such as separation from other waste streams and prevention of exposure to consumers[278].

[274] Stockholm Convention 2013.
[275] Stockholm Convention 2015.
[276] Hale et al., 2006.
[277] Stockholm Convention 2011.
[278] Stockholm Convention 2015.

One possible approach to better control of waste streams and to meet the obligations of the EPR could involve a change of business model. Instead of selling hardware, producers could sell the benefits of a product and take back the device after use, placing them in control of further recycling activities and establishing a 'safe closed loop'. In the case of CRT TVs/PCs, this approach is no longer applicable because of its disappearance from the market, but it could be applied for other EEE devices. An example for this business model can be found in the PV producer First Solar.
Several studies remarked that the exemptions made for PBDEs under the Stockholm Convention allowing the recycling of POP-PBDE containing polymers (see above) would make labelling of such products necessary in a way that is not the case right now. Only the labelling and control of articles including POP-BDEs can ensure that these products can be treated in an environmentally sound manner at the end of their product life and do not enter the regular waste stream again, contaminating other wastes and products with sensitive uses[279]. Alternatively, the exemptions for recycling of PBDE containing materials could be withdrawn or restricted to specific uses. Regardless of this, the labelling of components with hazardous substances is reasonable if the contamination of waste streams and products should be avoided. An obligation for labelling of BFR containing plastics in EEE is established in Japan, for example, in order to optimise recycling of plastics in electrical home appliances, thereby linking the information flow with the mass flow (Japanese Industrial Standard C9912)[280].

1.7 CONCLUSIONS

- Substitution is the most effective means of eliminating hazardous substances from material streams. Incentives can be created through bans and restrictions, as well as qualitative and quantitative recycling targets, in combination with producer responsibility.
- Global approaches to restricting substances in products/materials are efficient, as they provide clear signals, ensure a level playing field and common efforts to identify alternatives at global level, while also preventing the contamination of regional markets - such as that of the EU – with imported products.
- Substitution may be enhanced if it is combined with broader technology changes.
- Waste separation and sound disposal require identification of toxic substances and/or the components or materials in which they are present, in particular in (heterogeneous) waste streams. Analytical methods and practical approaches (e.g. material-integrated labelling via chemical markers or labelling with RFID) are necessary. Separation is easier if the substance content can be clearly allocated to article components (PCBs and CRTs).
- Clear treatment requirements ensure that separation and sound disposal are implemented, even if this is not economically viable (PBTs).
- Economic incentives and financing of waste treatment that separates toxic substances from material streams are essential to create an operational market.
- The implementation of material stream based producer responsibilities appears to be an efficient option to control toxic substances, as it applies along the entire supply chain. However, new approaches may be needed for its practical implementation.
- Knowledge of the content of substances in materials and articles by all actors is crucial to ensure safe products (content in recycled materials) and safe disposal (content in waste); communication should be physically linked to a material, i.e. by easily readable, material-integrated markers, if possible.
- Development and particularly the establishment of new technologies in waste treatment need substantial support; environmental soundness is not sufficient for market penetration.
- General communication requirements, as implemented in the WEEE, are not effective and require concrete implementation tools, both for information providers and users, if they are to be useful.

[279] Sindiku et al., 2015; Stockholm Convention 2015.
[280] Aizawa et al., 2010 in Stockholm Convention 2015.

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Study for the strategy for a non-toxic environment of the 7th EAP

Sub-study c: Protection of children and vulnerable groups from harmful exposure to chemicals

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August 2017

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Sub-study c - Protection of children and vulnerable groups from harmful exposure to chemicals

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ABBREVIATIONS USED

ADHD	Attention Deficit Hyperactivity Disorder
ANSM	French National Agency for Medicines and Health Products Safety
ATSDR	Agency for Toxic Substances and Disease Registry
BBP	Benzyl butyl phthalate
BBzP	Butyl benzyl phthalate
BM	Biomarkers
BPA	Bisphenol A
CEHAP	UK Children's Environment and Health Action Plan
CHMS	Canadian Health Measures Survey
CLP	Classification, Labelling and Packaging
CNS	Central Nervous System
CO	Carbon monoxide
CONTAMED	Contaminant mixtures and human reproductive health – novel strategies for health impact and risk assessment of endocrine disruptors
COPD	Chronic obstructive pulmonary disease
COPHES	Consortium to Perform Human Biomonitoring on a European Scale
CRCE	Centre for Radiation, Chemical and Environmental Hazards (UK)
CZ-HBM	Human Biomonitoring Project (Czech Republic)
DBP	Dibutyl phthalate
DDE	Dichlorodiphenyldichloroethylene
DDT	Dichlorodiphenyltrichloroethane
DEER	Developmental effects of environment on reproductive health
DEHP	Di 2-ethylhexyl phthalate
DEMOCOPHES	Demonstration of a study to Coordinate and Perform Human biomonitoring on a European Scale
DES	Diethylstilbestrol
DiDP	Diisodecyl phthalate
DiNP	Diisononyl phthalate
DnHP	di-n-hexyl phthalate
DNP	Dinitrophenol
EAP	Environment Action Programme
EC	European Commission
ECHA	European Chemicals Agency
ED	Endocrine-disrupting
EDC	Endocrine-disrupting chemical
EEA	European Environment Agency

EEC	European Economic Community
EHC	Environmental Health Criteria
ENNS	French National Survey on Nutrition and Health
EPA	Danish Environmental Protection Agency
EU	European Union
EU-OSHA	European Agency for Safety and Health at Work
FACET	Flavourings, Additives, and food Contact materials Exposure Tool
FLEHS	Flemish Environment and Health Study
GerES	German Environmental Survey
HBM	Human biomonitoring
HELIX	Human Early-Life Exposome - novel tools for integrating early-life environmental exposures and child health across Europe
HERMOSA	Health and Environmental Research in Make-up Of Salinas Adolescents project
HPA	Health Protection Agency (UK)
ILO	International Labour Organisation
IPCS	International Programme on Chemical Safety
IQ	Intelligence Quotient
JRC	Joint Research Centre
KorSEP	Korea National Survey for Environmental Pollutants in the Human Body
MoBa	Norwegian Mother and Child Cohort Study
MOCEH	Mothers and Children's Environmental Health study (South Korea)
NECTAR	Network for Environment Chemical Toxicants Affecting Reproduction
NEWGENERIS	Newborns and genotoxic exposure risks project
NHANES	National Health and Nutrition Examination Survey (US)
NIOSH	National Institute for Occupational Safety and Health (US)
NO_2	Nitrogen dioxide
NTE	Non-toxic environment
O_3	Ozone
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational exposure limits
OSH	Occupational Safety and Health
PAH	Polycyclic aromatic hydrocarbon
PBB	Polybrominated biphenyl
PBDE	Polybrominated diphenyl ethers
PCB	Polychlorinated biphenyl
PCE	Perchloroethylene
PCOS	Polycystic ovary syndrome

PCT	Polycyclohexylenedimethylene terephthalate
PFAS	Per- and polyfluoroalkyl substances
PFC	Perfluorinated compound
PFOS	Perfluorooctane sulfonate
PHIME	Public Health Impact of long-term, low-level Mixed Element Exposure in Susceptible Population Strata
$PM_{2.5}$	Particulate matter (diameter of 2.5 µm or less)
PM_{10}	Particulate matter (diameter of 10 µm or less)
POF	Premature Ovarian Failure
POP	Persistent organic pollutant
PROBE	Programme for Biomonitoring the Italian Population Exposure
PVC	Polyvinyl chloride
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RFR	Replacement flame retardants
RIVM	Dutch National Institute for Public Health and the Environment
ROS	Reactive oxygen species
SERM	Selective oestrogen receptor modulator
SMEs	Small and medium-sized enterprises
SO_2	Sulphur dioxide
TBBPA	Tetrabromobisphenol A
TCE	Trichloroethylene
TTR	Transthyretin
UNEP	United Nations Environment Programme
UK	United Kingdom
US	United States
VOC	Volatile organic compound
US EPA	United States Environmental Protection Agency
WHO	World Health Organization

ABSTRACT

This sub-study report focuses on the population groups that are particularly vulnerable to the negative effects of exposure to chemicals, and how these groups can be (better) protected. The study describes the main vulnerable groups in society, showing how these groups can be exposed to harmful chemicals and setting out the main adverse health effects that may arise from chemical exposure. Examples of groups with higher susceptibility are children (from the developing foetus to adolescence), pregnant women and the elderly, as well as certain occupational groups and people with lower socioeconomic status. The analysis of the EU legislative framework relevant to the scope of the sub-study shows that provisions referring to vulnerable groups are often lacking or inconsistent between similar types of legislation. In particular, where relevant, EU legislation should include provisions defining any vulnerable population groups where special protection should be ensured. This would include specific windows of vulnerability, which would be particularly useful for the protection of children. In addition, certain EU legislation, such as the Drinking Water Directive and Food Contact Materials Framework Regulation, are not updated with the most relevant scientific evidence and lack specific measures which can strengthen the protection of vulnerable groups. This study also highlights how current risk assessments typically focus on single substances and do not consider the risks to children and other vulnerable groups from combined exposure to toxic chemicals. Therefore, as humans are usually exposed to numerous chemicals simultaneously, a regulatory approach for cumulative risk assessment needs to be developed.

While a wealth of information and evidence on the impacts of chemicals on specific vulnerable populations has been collected in recent decades, significant knowledge gaps remain. Some areas of considerable concern include the lack of knowledge on non-intentionally added substances, nanomaterials, as well as on the potentially harmful effects of certain neurotoxic chemicals on brain development. During sensitive early life stages, exposure to EDCs and neurotoxins - such as lead, arsenic, mercury, PCBs, pesticides, and solvents - can cause lifelong damages, and further research on the impact of chemicals on the brain is therefore of paramount importance. The potential effects of new substances such as nanomaterials also need to be further investigated, as does the 'early exposure – late effect' pattern, particularly in relation to chemicals with endocrine-disrupting properties. Finally, the study shows the need to develop communication strategies among the general public and specific vulnerable groups on how to reduce exposure from certain toxic compounds (i.e. household dust) and classes of chemicals (EDCs and neurotoxicants), as well as on how to avoid certain harmful behaviors (i.e. hand to mouth). Improving labelling and packaging of consumer products would also help to increase knowledge on the potential harmful effects of exposure to certain ingredients or compounds.

EXECUTIVE SUMMARY

Certain groups of the population – such as children, pregnant women, the elderly, and workers – are particularly vulnerable to the risks stemming from chemical exposure, and, as such, have a higher probability of developing adverse health effects throughout their life. This increased vulnerability depends on a variety of reasons, spanning from specific behaviours, increased sensitivity to chemicals, specific biophysical characteristics, health status, constant exposure to highly hazardous chemicals, reduced ability to protect from exposure, and social factors (e.g. where a person lives or works or spends the majority of his/her time). In light of their higher vulnerability, these categories of the population need special protection from the hazardous effects that chemical exposure can cause on their health.

Chemicals can enter the human body in various ways and can cause different kinds of health effects. A chemical can produce a health effect directly at the site of contact (local) or elsewhere in the body (systemic) and the effect can be either immediate or delayed. Organ systems that can be affected by exposure to hazardous chemicals include the nervous system, the reproductive system, the endocrine system, the thyroid system and the immune system. Recent reports have also suggested that when chemical substances are combined, they might cause adverse effects to human health even if they are harmless individually. These chemicals, even at low dose levels, can give rise to subtle but long-term health effects such as reduced fertility, lower birth weights and neurodevelopmental diseases. Pathways of exposure to chemicals in products involve indoor air as well as household dust. Another area of concern is that of environmentally induced epigenetic changes, which may have far-reaching consequences, particularly for foetuses and young children.

The human foetus is considered to be particularly vulnerable to chemical exposure because of its rapid cell reproduction rates, sensitive developmental periods of different organ systems, greater surface areas in skin, lungs, and intestinal mucosa per unit of body weight (so that more toxins are absorbed per unit of body weight), immature liver and kidney enzyme systems to metabolise, conjugate, and eliminate toxicants, and an undeveloped blood-brain barrier that allows transport into the brain. While the placenta was initially believed to protect the foetus from harmful chemicals, evidence now demonstrates that the placenta does not block the passage of many environmental toxicants from maternal to foetal circulatory systems. Over 200 foreign chemicals have been detected in umbilical cord blood, including pesticides, ingredients in consumer products, food packaging, and chemical by-products from burning coal and flame retardants.

The developing human brain is particularly vulnerable to chemical exposures, with major windows of developmental vulnerability occurring in utero, during infancy and early childhood. During these sensitive life stages, exposure to neurotoxins such as lead, arsenic, mercury, PCBs, pesticides, and solvents – of which more than 200 have been identified, with many more suspected to exist - can cause functional deficits and life-long adverse health effects at low levels of exposure that would have little or no adverse effect in an adult. Early-life epigenetic changes are also known to affect subsequent gene expression in the brain.
In addition to impacts on the cognitive development of the foetus, prenatal exposure to environmental toxicants has also been linked to negative reproductive effects, severe congenital malformations, premature birth and growth retardation. Studies also show links to early puberty in girls, feminisation of male children, and decreased fertility in both men and women later in life, as well as breast and testicular cancer. There is a growing body of evidence to suggest that in utero exposure to harmful chemicals can impact the metabolic system and influence the onset of adult diseases such as atherosclerotic cardiovascular disease, hypertension, type 2 diabetes, stroke and cancer.

After birth, children remain uniquely vulnerable and can be exposed to harmful chemicals in a number of ways. Firstly, research has shown that a large number of chemicals, such as polychlorinated biphenyls, dioxins, dibenzofurans, polybrominated diphenyl ethers, and heavy metals, are transferred

to the infant through human breastmilk. Some of the highest levels of contaminants are found among women in agricultural areas and those in remote areas whose diet is heavily based on the marine food chain that accumulates heavy burdens of persistent organic pollutants. Another source of exposure for neonates are nurseries and hospital settings, where they can be exposed to chemicals such as polyvinyl chloride (PVC), di 2-ethylhexyl phthalate (DEHP), Bisphenol A (BPA), and parabens, which have been shown to impact fertility in later life, as well as causing neurological defects, obesity, and cancer. Health implications can also evolve due to environmental chemicals found in water, food, and body care and consumer products.

As children grow up, they begin exploring, touching and testing, which exposes them to chemicals through various pathways. Given their specific exploring and hand-to-mouth behaviour, together with their inability to read warning labels, the main danger for toddlers is the ingestion of toxic chemicals that may cause permanent damage to their health. Toddlers also spend a large part of their time at home, making them particularly vulnerable to indoor pollution and exposure to household dust, which has been shown to contain chemicals linked to reproductive toxicity, endocrine disruption, and cognitive and behavioural impairment. Such chemicals can cause diseases such as cancer, asthma, immune dysfunction and various chronic illnesses. Recent studies in the U.S. have shown that, indoors, phthalates and phenols are found at the highest levels, phthalates and replacement flame retardants (RFRs) have the highest estimated intakes, and phthalates and PFASs are associated with the most hazardous traits in terms of human health.

In addition to indoor air pollution, when children start to move around, they are more likely to go outside, where their exposure to outdoor air pollution is a special concern in light of their breathing in higher volumes of air relative to their body weight, together with their continuing tissue growth and organ development. Air pollution, particularly traffic-related pollution, is associated with infant mortality and the development of asthma and atopy, as well as acute bronchitis. Air pollutants may also adversely affect infant lung development, cause coughing, and aggravate asthma. A growing body of evidence suggests that air pollution can affect mental and cognitive health in children, even at low levels of pollution, resulting in mental illnesses (including autism) or impacting their overall learning and development.

Puberty and adolescence are also periods of increased risk of exposure to chemicals. During this time, endocrine, neurological, and other systems undergo development and growth, making the developing tissues and organs particularly sensitive to the effects of carcinogenic and endocrine-disrupting chemicals. Changes in behaviour, such as the use of toxic substances such as tobacco and alcohol, may expose them to greater risks. Adolescents are more likely to increase their use of personal care products containing toxic chemicals such as parabens and phenols. Studies show that when teenage girls stop using personal care products, even briefly, the levels of hormone-disrupting chemicals drop significantly. Another area of concern is the impact of endocrine-disrupting chemicals (EDCs) on the reproductive health of adolescent girls. Most information on the effects of endocrine disruption on female reproductive health comes from molecular, cellular and animal studies, which have shown that exposure to EDCs during both prenatal and adult life can play a role in the pathogenesis of several female reproductive disorders.

Environmental chemicals not only harm people's ability to reproduce, but can also negatively affect pregnancy. As explained above, many chemicals absorbed or ingested by pregnant women can cross the placenta to the foetus and can cause an array of adverse health effects. However, women are also particularly vulnerable during pregnancy as physiological changes such as weight gain and increases in blood and plasma volume occur, which can alter concentrations of chemicals and result in a greater absorption of toxic substances. Studies have shown that BPA and high levels of flame-retarding chemicals (polybrominated diphenyl ethers) can alter pregnant women's thyroid hormones, which are essential for normal foetal growth and brain development.

As a part of the ageing process, people experience a gradual deterioration in body function and their

capacity to respond to chemical exposure, including the metabolism and elimination of chemical substances. This development, as well as people's life-long, chronic exposure to environmental chemicals which have been accumulating within the body, and the high prevalence of various age-related diseases, make that elderly susceptible to the harmful effects of environmental chemicals. Research shows that chemicals, such as solvents and lead, can contribute to cognitive impairment and have adverse effects on immune and respiratory function. They can also increase blood pressure and insulin levels, possibly resulting in cardiovascular effects or the onset of metabolic syndromes, including diabetes mellitus.

Another area of concern is the potential for drug-toxicant interactions, as the elderly, in general, use more medication than the rest of the population. This includes polypharmacy (the use of more medications than may be medically necessary), as well as pharmaceutical-to-environmental chemical reactions. Pharmaceuticals in drinking water present an additional environmental challenge as they may, even at very low concentrations, impact the health of elderly adults whose metabolic capability is already compromised and who are taking a variety of pharmaceutical medications. Finally, the elderly, like young children, typically spend a significant portion of each day indoors at home or in care facilities, which makes them more susceptible to indoor air pollution.

In addition to the different life phases, particular vulnerability to chemical exposure can arise from living and working environments or overall socioeconomic situation. Types of work that carry a higher risk include agriculture, construction and painting, cleaning and maintenance services, and hairdressers and beauty salons. For example, a growing number of studies have identified cleaners as a group at risk for adverse health effects to the skin (e.g. dermatitis) and the respiratory tract (e.g. asthma). The emission of volatile organic compounds (VOCs) and particulates which can be easily inhaled have been associated with asthma. Hairsprays, permanent waves, acrylic nail application and numerous other salon products have been linked to higher incidences of cancers, neurological diseases such as dementia and depression, immune diseases, birth defects, reproductive disorders, skin diseases, asthma and other breathing problems. The waste management and recycling industry is another particular sector of concern; large numbers of substances are emitted during work activities that could give rise to a significant burden of ill health. Few studies have examined the potential impacts on the health of people working in this sector, but the most significant issues appear to be presence of dust, bioaerosol and hazardous metals.

Evidence exists that people from lower socioeconomic groups are at higher risk of adverse health outcomes after chemical exposure compared to wealthier social groups. Factors such as living environment, level of education, ethnicity, type of employment and lifestyle can have a significant effect on the burden of environmental toxicants, their accumulation in the body and the prevalence of diseases and health problems. Recent studies have shown that food habits and lifestyle can have a profound impact on the types and level of intake of harmful chemicals by disadvantaged communities.

The EU is equipped with a comprehensive regulatory framework to protect human health and the environment from the risks associated with chemical exposure. Since 2006, the EU has achieved substantial progress in the area of chemicals management by adopting its flagship regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Its chemicals regulatory framework is, however, fragmented as far as the protection of vulnerable groups from chemical hazards is concerned. In certain key acts, references to vulnerable groups are lacking, despite the subject of the legislation being directly relevant. While a reference alone would not provide protection, it would nonetheless be useful for such legislation to describe the particular vulnerable groups requiring special protection and to clarify how such protection might be provided. For example, in certain cases, protection might mean requiring a greater margin of safety in risk assessment and management measures, while in other cases protection might involve restrictions on chemicals such as not allowing use of endocrine disrupting chemicals in products aimed at young populations.

Chemicals regulation depends on a hazard identification and a risk assessment procedure to estimate the extent of the exposure and on that basis the probability of harm as well as its possible severity. On the basis of such assessments, measures can be set in place to manage the known risks so that they are at levels considered acceptable (safe) to humans and the environment. But controlling the risk of harm is a moving target, given that quantities of chemicals and subsequent exposures are likely to increase dramatically. Moreover, risk assessments, usually carried out by a chemical's proponents (e.g., the producer), often underestimate the risk of harm. Additional scientific research into the possible hazards posed by chemicals almost always leads to increased (and seldom to lessened) concern over risks to human health and the environment.

Moreover, recent studies have pinpointed the detrimental effects caused by combined exposure to certain chemicals on the foetus, which can ultimately lead to persistent pathological diseases later in life. As such, these studies stressed that risk assessment based on single substances alone is not to sufficient to interpret the effects that combined exposure may cause on human health and thus urged policymakers to develop a cumulative risk assessment which could take into account all chemicals, spanning from pesticides, to industrial chemicals, and environmental contaminants (e.g. food, cosmetics, dust, and other sources).

This report sets out some of the most important knowledge gaps on the protection of children and vulnerable groups, provides examples of policy measures and other activities in the field, and describes improvement opportunities in the short, medium and long term.

Key Findings

The problem

- Children, pregnant women, workers, and the elderly are particularly vulnerable to risks arising from chemical exposure, and have higher probabilities of adverse health symptoms or diseases throughout their lives.

- The developing human brain is particularly vulnerable to chemical exposures, with major windows of developmental vulnerability occurring in utero, during infancy and early childhood. During these sensitive life stages, exposure to EDCs and neurotoxins such as lead, arsenic, mercury, PCBs, pesticides, and solvents can cause lifelong neurological damage.

- Chemicals can enter the body through ingestion, inhalation, skin contact, and injection. Everyday sources of exposure include consumer products, household dust and drinking water. Toddlers, who often play or crawl on floors and carpets, are especially vulnerable because of hand to mouth behaviour.

- Lack of attention to the vulnerabilities of specific populations has led to only sporadic protective measures in the relevant pieces of legislation.

Gaps and inconsistencies

- Lack of provisions in EU legislation defining which vulnerable groups should be ensured special protection, especially for those pieces of legislation that are of particular relevance to the protection of certain groups in society from chemical exposure.

- Although the EU Toys Directive provides standards to protect children as a vulnerable group, other consumer products aimed at children such as clothing and bedding are not covered.

- Chemicals having developmental neurotoxic (DNT) properties should be further regulated in order to ensure an adequate level of protection for the foetus and children.

Key Findings

- Certain EU legislation, e.g. the Drinking Water Directive and Food Contact Materials Framework Regulation, are not updated with the most relevant scientific evidence and lack specific measures which could strengthen the protection of vulnerable groups.

- EU risk assessments focus on single substances and do not protect children and other vulnerable groups from combined or cumulative exposures to toxic chemicals.

- Knowledge is lacking on the toxic effects that certain categories of chemicals (e.g. Non-intentionally added substances [NIASs] and nanomaterials) can have on vulnerable groups. More research is also needed on how chemicals interfere with brain development.

1 INTRODUCTION

Sub-study c focuses on those groups in the population that are particularly vulnerable to the negative effects arising from exposure to chemicals. Groups with higher susceptibility are children (from the developing foetus to adolescence), pregnant women and the elderly, as well as certain occupational groups and people with lower socioeconomic status.

More specifically, the sub-study aims to:

- Provide an overview of the current state in respect of issues of protection of children and vulnerable groups from harmful exposure to chemicals, highlighting current legislation and policy measures at the EU level, activities in international and regional organisations as well as Member States and other countries, and the activities of industry and civil society organisations.
- Identify and describe the most important health issues relating to children and vulnerable groups and the main causes of these issues (e.g. source of and/or route of chemical exposure) according to current knowledge. Where possible, the study describes or exemplifies the magnitude of the issues based on available studies.
- Provide a general analysis of current policy measures and other activities in terms of their impact on, and effectiveness at, improving the protection of children and vulnerable groups.
- Identify and describe the most important knowledge gaps on the protection of children and vulnerable groups, assessing if and how these hinder action.
- Identify and describe opportunities to close the gaps identified, from a short, medium and long-term perspective, including legislative and other policy measures, improvements to the knowledge base, and provision of support to research and development.

The study considers the following problem:

Box 1: Problem definition of sub-study c

Problem Definition
The increased use of chemicals stemming from economic development in various sectors exposes humans to a continuous cocktail of chemical substances present in sources such as food, water, medicines, air, cosmetics, health care and consumer products. Some of these chemicals can be harmful to human health, with immediate, acute effects or chronic effects, often resulting from long-term exposures. Chronic, low-level exposure to various chemicals may result in a number of adverse outcomes, including damage to the nervous and immune systems, impairment of reproductive development and function, cancer, and organ-specific damage. Several groups in the population are particularly vulnerable to the risks arising from chemical exposure. This increased vulnerability depends on various factors, from specific behaviours, intrinsic biophysical characteristics and health status, as well as social factors, such as living or working environment. The developing foetus is considered to be one of the most vulnerable groups in the population for chemical exposure, largely because of its developmental mechanisms: at certain early stages of development, exposure to environmental toxicants can lead to irreversible damage. Also, after birth, children remain a group of particular concern, as they have some specific vulnerabilities to the toxic effects of chemicals. For example, they have greater exposures to toxic chemicals than adults in proportion to their bodyweight as they breath in more air, consume more food and drink more water. Their behavioural tendencies (e.g. hand-to-mouth contact, crawling, chewing toys) also lends itself to contact with toxic chemicals unsafely used or stored. Other vulnerable groups include: rural workers; industrial workers, who are often not properly equipped to work with large volumes of chemicals; pregnant women, who may expose themselves and the developing foetus to the effects of chemicals in their environments at crucial development periods; the elderly may be more susceptible to the toxic effects of some chemicals due to physiological changes; people with pre-existing medical conditions; illiterate people, who are unable to follow written instructions; and inappropriately trained people, who tend to use chemicals unsafely. A wealth of scientific literature exists, showing the hazardous health impacts of chemicals. However, research tends to focus on single compounds or the impacts of chemicals on specific health or organ systems. By contrast, knowledge of the effects of mixtures of chemicals, as well as environmentally induced epigenetic toxicity, is limited. Further investigation is also needed into the impacts of chemicals on vulnerable groups, particularly the foetus and its

Problem Definition

specific sensitive windows of development, adult onset effects resulting from early life exposures, and potential health impacts of new technologies, such as nanomaterials.

The EU's 7th Environment Action Programme (EAP) recognises the need to ensure a high level of protection for vulnerable groups from chemical hazards. Numerous pieces of EU legislation incorporate measures to protect children and other vulnerable groups from toxic exposure. Yet, the overall EU chemical legal and policy framework is fragmented, with various opportunities identified to strengthen EU protection of vulnerable groups from harmful chemical exposure. Numerous gaps in relation to risk assessment methodologies, awareness raising and information distribution also need to be closed.

This sub-study aims to provide an analysis of the current state of the protection of vulnerable groups from harmful exposure to chemicals in terms of scientific evidence, policy measures and EU legislation. It highlights the current knowledge and regulatory gaps, as well as the opportunities to improve such protections in the framework of the EU strategy for a non-toxic environment.

The following chapter introduces the sub-study in general, describing the main vulnerable groups, outlining the ways in which these groups can be exposed to harmful chemicals and, finally, setting out the main adverse health effects that result from chemical exposure.

Subsequent chapters set out the legislative framework relevant to the scope of this sub-study, and describe in further detail the evidence, literature and information on vulnerable groups in relation to the negative effects arising from exposure to chemicals. They also provide an overview of current gaps and deficits, together with opportunities for improvement.

1.1 WHO ARE THE VULNERABLE GROUPS IN SOCIETY?

Vulnerability is the degree of susceptibility of a given population to cope with, resist or recover from the impact of harmful effects caused by exposure to hazardous events[1].. In the framework of chemical exposure, certain groups in society may have an increased vulnerability because of their[2]:

- Lower exposure thresholds for health effects;
- constant exposure to highly hazardous chemicals;
- Reduced ability to protect from exposure;
- Particular health status.
- Specific behaviours,

The concept of vulnerability is deeply linked with that of risk, which - in the context of chemicals - is defined as the likelihood that a person will experience an adverse health effect if exposed to a hazard under specific conditions[3]. Among the factors that might influence the degree of risk are: length of exposure to the chemical substance; route of the exposure (e.g., breathing in a vapour, skin contact); and severity of the effects stemming from the exposure.

When assessing risks, other factors which might lead to a greater vulnerability on the part of some populations should also be taken into account. For instance, individual factors, such as biophysical characteristics, can make certain individuals more vulnerable. Behavioural factors, such as certain activities, hobbies and occupational exposures, may increase the level of vulnerability. Social factors, such as where a person lives, works or spends the majority of the time, may also intensify the degree of vulnerability[4].

[1] WHO, 2003
[2] WHO, 2009.
[3] For a guide to terminology in the field of hazard and risk assessment in chemicals, see David J, 1992.
[4] ANHE, official website.

Individual, behavioural and social factors can lead to an increased risk of chemical exposure, and, consequently, to a higher vulnerability across the population. Therefore, in this context, vulnerability can be defined as "a series of threshold factors that increase or amplify risk and lead to poorer health outcomes"[5]. This explains why the concept of vulnerability is linked to that of risk, as well as why certain categories of the population deserve special attention and protection from the risks of chemical exposure.

1.2 HOW ARE VULNERABLE GROUPS EXPOSED TO HARMFUL CHEMICALS?

Exposure is defined as the contact of an individual with a chemical substance for a given time. Exposure can be classified in terms of intensity, frequency, and duration[6]. A chemical can make contact with or enter the body and become hazardous to a person's health through four major routes: ingestion, inhalation (breathing), skin contact and injection. As the first three routes of exposure are most relevant to the scope of the study, these are discussed below. Exposure through the placenta and breastfeeding, as well as workplace exposure are discussed separately. The route of exposure is an important consideration, as it often predicts the organ system or part of the body that will be affected directly or in later years.

1.2.1 Ingestion

Chemicals can enter the human body through swallowing of contaminated mucus expelled from the lungs, or by eating or drinking contaminated food or drinks. Food and drink can be contaminated through contact with unwashed hands, gloves or clothing, or via contact with hazardous chemicals at the workplace. Nail-biting, smoking, as well as cosmetic products and medicines are also routes through which chemicals may be ingested[7]. Once ingested, chemicals travel down into the stomach. From there, the majority of chemicals end in the small intestine, where they eventually enter into the blood stream. It is important to notice that some acids and caustics can damage the digestive system if ingested in high concentrations[8].

Children and the elderly are more susceptible to the ingestion of chemicals products because of their behaviours and differences in some physiological parameters, as further explained in Chapters 2 and 4.

1.2.2 Inhalation

Inhalation of contaminated air is one of the most common means of chemicals entering the body. Chemical vapours, gases and mists, if not trapped into the mucus, can reach the alveoli in the lungs, eventually enter into the blood stream and ultimately circulate in the body. . Certain solid particles in dusts, fumes and smoke which escape the filtering mechanisms of the nose may also be trapped by the mucus. However, the mucus can be either expelled through the mouth or ingested and travel down the stomach. In this latter case, the contaminating chemicals will enter the body via the same mechanisms explained in the ingestion section[9].

It is also worth noting that some of the solid particles mentioned above can cause permanent damage to the alveolar walls, which can eventually interfere with the lung's ability to transfer oxygen into the blood stream. Furthermore, certain organic chemicals, acids, or caustics, when inhaled in ample amounts, can critically damage the mouth, nose, trachea, bronchi and lungs[10]. With inhalation exposure, it is important to differentiate between indoor and outdoor pollutants.

[5] ANHE, official website.*Contra*: Clark HF & Driever MJ, 1983; Speirs J, 2000.
[6] WHO, 2011a.
[7] Canadian OSH website, 2016.
[8] Canadian OSH website, 2016.
[9] Canadian OSH website, 2016; see also para 1.2.1
[10] Canadian OSH website, 2016.

Indoor air pollution

Indoor air pollution is responsible for two million deaths per year globally[11]. People who are particularly susceptible to indoor air pollution include infants, children, pregnant women, elderly persons over 65 years of age, and those suffering from asthma, respiratory diseases, or cardiovascular diseases[12]. For some pollutants (e.g. microbes), other health compromises (immunodeficiency) may render people more vulnerable. Genetic traits, nutritional status and lifestyle factors may also contribute[13]. Furthermore, susceptibility of vulnerable groups to pollutants vary due to existing diseases and genetic factors[14].

In the framework of indoor pollution, a particular area of concern is indoor dust, which can harbour a cocktail of toxic chemicals linked to increased risk of a range of adverse health hazards, including endocrine disruption, cognitive and behavioural impairment, cancer, asthma, and immune dysfunction[15]. A recently published study which conducted a comprehensive analysis of consumer product chemicals in U.S. indoor dust, concluded that a wide array of chemicals used in everyday products – including those associated with reproductive and developmental toxicity, endocrine disruption, cancer and other health effects - are present in indoor environments to which people are continuously exposed[16]. As a consequence, toxic chemicals such as phthalates, phenols, flame retardants, and polyfluorinated alkyl substances (PFASs), which are responsible for various negative effects on human health, are extensively present in the general population and especially among vulnerable groups such as children and pregnant women[17]. Children, who often play or crawl on the floor, are particularly vulnerable to inhaling or ingesting toxic chemicals in household dust.

Outdoor air pollution

Outdoor air pollution results from human activities, such as inefficient combustions of fuels for transport, home heating and cooking[18]. In particular, combustion processes produce a mix of air pollutants, consisting of both primary emissions (e.g. diesel soot particles and lead), as well as the products of atmospheric transformation (e.g. ozone and sulphate particles)[19]. Outdoor pollutants vary according to density of traffic, degree of industrialisation, time and climate[20]. According to the WHO, the six main outdoor pollutants are: ozone (O3), particulate matter (PM10 and PM2.5), lead, sulphur dioxide (SO2), carbon monoxide (CO) and nitrogen oxide (NO2)[21].

Urban air pollution causes significant health problems throughout Europe, reducing the life expectancy of residents of more polluted areas by more than one year[22]. Air pollution is a global health crisis that has long been linked to lung disease, heart disease and stroke. Children and the elderly are most vulnerable to the effects of outdoor pollution[23].

A recent study identified the abundant presence of magnetite nanoparticles in the human brain, which match the high-temperature magnetite nanospheres prolific in urban, airborne particulate matter[24]. As many of the airborne magnetite pollution particles are <200 nm in diameter, they can enter the brain directly, with toxic effects, e.g. the production of reactive oxygen species (ROS), which has been

[11] WHO, official website, 'air pollution', available at: www.who.int/topics/air_pollution/en/.
[12] SCHER, 2007.
[13] TNO & RIVM, 2006.
[14] Balk S *et al.*, 2004.
[15] Mitro SD *et al*., 2016.
[16] WHO, official webpage, Air pollution.
[17] Mitro SD *et al*., 2016.
[18] WHO, official webpage, Air pollution.
[19] WHO, official webpage, Air pollution.
[20] WHO, 2011b.
[21] WHO, 2011b.
[22] WHO/EURO, 2013.
[23] Almeida SM *et al*., 2016.
[24] Maher BA *et al.*, 2016.

linked to neurodegenerative diseases such as Alzheimer's disease. One study showed that magnetite was directly associated with the damage seen in Alzheimer's brains[25]..

Moreover, a 2015 large cohort study in Taiwan suggested that long-term exposure to O3 and PM2.5 above the current U.S. EPA standards is associated with increased risk of Alzheimer's disease[26]. Other research showed a role for air pollution in damage of the central nervous system (CNS) among children and young adults, and its impact on the developing brain and the potential aetiology of Alzheimer's disease and mood disorders[27]. Air pollution has also been linked to cognitive decline in older men and women[28,29].

Children's exposure to air pollution is a special concern because they breathe higher volumes of air relative to their body weight and their tissue and organs are growing[30]. In addition, children spend more time outside, where the concentrations of pollution from traffic, power plants, and other combustion sources are generally higher. Scientific evidence has suggested that air pollution, particularly traffic-related pollution, is associated with infant mortality and the development of asthma and atopy, as well as acute bronchitis[31].

A recent study has linked outdoor air pollution to increased mental illness in children, even at low levels of pollution[32]. New research found that relatively small increases in air pollution were associated with a significant increase in treated psychiatric problems. While this is the first study that establishes a link of this kind, it must be noted that the latter is consistent with a growing body of evidence that air pollution can affect mental and cognitive health and that children are particularly vulnerable to poor air quality. The research in question examined the pollution exposure of more than 500,000 under-18s in Sweden and compared this with records of medicines prescribed for mental illnesses, ranging from sedatives to anti-psychotics. There have also been several earlier studies that found associations between air pollution and autism spectrum disorders and learning and development in children[33]. However, this study adds to evidence that air pollution may have detrimental effects on the brains of children and adolescents.

1.2.3 Skin contact

Chemicals can also enter the body through skin contact. For instance, organic and caustic chemicals can soften the skin, and through this layer reach the dermis; from there they can enter the veins and eventually access the blood stream. Chemicals can also enter the body through cuts, punctures or scrapes of the skin, where the protective layer of the skin is weakened. Moreover, contact with detergents or solvents are of particular concern as they can penetrate the skin and thus = circulate directly into body[34].

It is worth noting that chemicals can penetrate the skin with various degrees. For instance, some solvents such as trichloroethylene, naphtha and toluene may soften the keratin layer of the skin, but are not capable of going further unless the contact is delayed. Chemicals such as benzene, carbon tetrachloride, carbon disulphide and methyl alcohol, instead, can quickly damage the epidermis and hence enter the blood stream. Corrosive chemicals can burn the skin immediately, allowing infection or other chemicals to enter. In given circumstances, certain chemicals may enter the body by injection. This can occur in hospital settings. Once chemicals are in the blood stream, chemicals circulate into

[25] Plascencia-Villa G *et al*, 2016.
[26] Jung CR *et al.*, 2015.
[27] Calderón-Garcidueñas L *et al*., 2012.
[28] Power MC *et al.*, 2011.
[29] Weuve J *et al.*, 2012.
[30] Canha N *et al*., 2011.
[31] Schwartz J, 2004.
[32] Oudin A *et al*., 2016.
[33] Wang S *et al*., 2009.
[34] Canadian OSH website, 2016.

the body and can spread their effects[35]. After absorption, chemicals are also capable of causing poisoning or diseases such as cancer[36].

Adolescents, pregnant women, children and workers are particularly vulnerable to chemical absorption through the skin.

1.2.4 Other routes of exposure

The placenta

The placenta is a semi-permeable barrier which regulates the exchange of nutrients, gases, waste and molecules between the mother and the foetus. It is an essential organ as it allows the foetus to grow and develop[37]. While originally the placenta was thought to shield the cord blood and the developing foetus from most chemicals and pollutants in the environment, this has now proved to be untrue[38]. The thalidomide crisis demonstrated the vulnerability of the foetus and the permeability of the placenta to toxic exposures[39] (see box 2). Another example of a crisis, before which the placenta was thought to protect the foetus against toxicants, is the 'Minamata disaster' (see box 3).

Box 2: The thalidomide crisis

In 1953, the anti-morning sickness drug 'thalidomide' was developed in Germany. In 1956, it was licensed for over-the-counter sale in Germany and most European countries. Doctors prescribed the drug for several years, before determining in 1961 that it caused many babies to be born with malformed limbs. Over 10,000 children were born with thalidomide-related disabilities worldwide.

Afterwards, doctors discovered that other chemicals, such as instance, lead, mercury, polychlorinated biphenyls (PCBs), and nicotine could also cross the placenta and cause adverse health effects on the foetus.

Sources: *Almond D & Currie J, 2011, and The Guardian, 2012.*

Box 3: The Minamata diseaster

The Minamata disaster, which affected thousands of individuals, was the first large-scale incident of methylmercury poisoning. Between 1932 and 1968, large amounts of this highly toxic chemical were released in the industrial wastewater from the Chisso Corporation's chemical factory, and bioaccumulated in shellfish and fish in Minamata Bay. When eaten by the local population, it resulted in mercury poisoning: a condition later referred to as the 'Minamata disease' or the 'Chisso-Minamata disease'.

Minamata disease is a neurological syndrome, and symptoms including ataxia, tremor, memory loss, loss of peripheral vision, and vision and hearing problems. In certain cases, death can follow the previously mentioned symptoms. Minamata showed the neurotoxic effects that mercury can have on the general population, and especially on foetuses, infants, and young children. Before Minamata, the placenta was thought to shield the foetus against toxic chemicals.

Sources: *Spheres of Influence, 2013.*

It is worth noting that since the foetus has an immature metabolism and is thus unable to detoxify substances efficiently, the role played by the placenta is crucial insofar it determines the substance exchanged between the mother and the foetus. In fact, any toxic substances that the mother is exposed to might be transferred to the foetus. Carbon-dioxide, lead, ethanol, and cigarette smoke, are substances likely to be transferred through the placenta[40].

[35] Canadian OSH website, 2016.
[36] EU-OSHA, 2008.
[37] Prouillac C & Lecoeur S, 2010.
[38] Grandjean P, 2013.
[39] Konkel L, 2016.
[40] ATSDR, official webpage.

Breast milk

Human breast milk provides wide benefits for the growth, immunity, and development of the foetus[41]. Breast milk in fact help infants to fight infection, contribute to brain development, and strengthen resistance to certain diseases such as asthma, allergies, and diabetes[42]. However, breast milk can be also a source of chemical exposure. Since the 1950s, scientists are aware of the widespread contamination of human breast milk, as a consequence of decades of inadequately controlled pollution of the environment by toxic chemicals[43]. Polychlorinated biphenyls, dioxins, dibenzofurans, polybrominated diphenyl ethers, and heavy metals are among the toxic chemicals frequently found in breast milk[44]. These compounds are encountered among women in both developed and developing countries[45].

Some of the higher level of contamination is found among women in agricultural settings exposed to pesticides, as well as among women whose diet is heavily based on fish and marine food, as this accumulates persistent organic pollutants[46]. The level of risk for infants and children of being exposed to chemicals in human milk can vary and ultimately depends on the diet of the mother, the class and amount of chemicals present in the milk, as well as on the toxicological potency of the chemicals[47].

Occupational exposure

Many occupations involve the exposure to hazardous chemicals. Health effects can span from eye irritation to serious diseases, such as cancer[48]. Adverse health effects can occur both as a result of a single episode of persistent exposure or from a constant, long-lasting exposure. Workers can be exposed to toxic chemicals for long period and showing no pathological symptoms for years. Yet, in some cases, symptoms appear only when irreversible harm has already occurred. While certain chemicals can be easily recognised as dangerous substances (e.g. lead, arsenic), others may not appear harmful on a first check. For instance, exposure to flour dust may result in various adverse health outcomes from conjunctivitis to baker's asthma[49].

The types of industry where the risk to chemical exposure is highest include[50]:

- mining, quarrying, oil and gas drilling, where there is high risk of exposure to respirable crystalline silica, as well as lubricants and drilling muds;
- manufacturing industries, where there is a risk of being exposed to solvents, as well as paints and lubricants);
- farming, as the chance to be exposed to toxic pesticides is high;
- service industries, where the risk of exposure to cleaning products, asbestos, and bioaerosols is relevant;
- healthcare sector, there is risk of exposure to pharmaceuticals and disinfectants;
- hairdressing sector and beauty salon industry, where there is a constant exposure to a wide range of hazardous chemicals used in products such as sprays and paints;
- recycling industry, where there is the risk of exposure to dusts and biohazards.

[41] U.S. Institute of Medicine, 1991.
[42] Oddy WH, 2001.
[43] Laug EP, *et al*., 1951.
[44] Hooper K & McDonald TA, 2000.
[45] Landrigan PJ, *et al*., 2002.
[46] Landrigan PJ, *et al*., 2002.
[47] Landrigan PJ, *et al*., 2002.
[48] Ekenga CC, *et al*., 2015.
[49] Stobnicka A & Górny RL, 2015.
[50] Keen C, 2016a.

1.3 WHAT ARE THE MAIN ADVERSE HEALTH EFFECTS IN VULNERABLE POPULATIONS?

As described above, chemicals can enter the human body through a variety of routes, and can have different health effects on certain population groups depending on their susceptibility. A chemical exposure can produce a health effect directly at the site of contact (local) or elsewhere in the body (systemic), and that effect can be either immediate or delayed. The specific health effects and main routes of exposure most relevant to different vulnerable groups are described in Chapters 2 to 6. The purpose of this section is to set out an overview of the main adverse health effects of chemical exposure among vulnerable populations.

Different organ systems can be affected by chemical exposure, resulting in a range of health effects. This table is not a comprehensive overview but, rather, provides illustrative examples of the adverse health effects which may be caused by some of the chemicals listed.

Table 1: Examples of health effects of chemicals on different organ systems

Nervous system
Possible health effects: Adverse health effects caused by neurotoxicants include narcosis, nausea, dizziness, vertigo, irritability, euphoria, movement coordination problems, impaired memory and behaviour, as well as autism, Attention Deficit Hyperactivity Disorder (ADHD), cerebral palsy, and mental retardation. Exposure has also been associated with neurodegenerative diseases like Alzheimer's disease and Parkinson's disease. Other health effects include decreased speech, sight and muscle strength, ataxia, and seizures. Damage to the developing nervous system of the foetus may result in neural tube defects, decreased intelligence and increased likelihood of behavioural problems. **Examples of possible contaminants**: Many chemicals cause mild CNS depression that may be misdiagnosed as inebriation and, if undetected, can progress to psychosis or dementia, such as: Retinoic acid, arsenic, valproic acid, lead, cadmium, carbon monoxide, cyanide, methanol, mercury, PVC, PCBs, toluene.
Reproductive system
Possible health effects: Early or delayed puberty, early pregnancy loss, premature birth, foetal death, impaired foetal growth, decreased fertility/subfertility, increased foetal mortality, increased birth defects (structural, e.g. cardiac defect, or functional, e.g. learning disability), infertility, low birth weight, menstrual irregularities. The impact of exposure to a reproductive toxicant may not be immediately evident but instead emerge at key life transitions (e.g. adult fertility, pregnancy, embryonic development, puberty, etc.). **Examples of possible contaminants**: Examples include methylmercury, carbon monoxide, lead, polybrominated biphenyl (PBB), ethanol. An elevated risk of prostate cancer has been linked to unspecified agricultural pesticides, PCBs, cadmium and arsenic, while dioxins, PCBs and solvents have been associated with breast cancer.
Endocrine system
Possible health effects: Maternal smoking causes decreased birth weight and increased risk for the baby of diabetes and osteoporosis later in life, Lead poisoning causes abnormal bone structure and poor growth. EDCs have also been associated with the onset of conditions such as diabetes and obesity, as well as cardiovascular disease and hypertension. Certain EDCs have been described as affecting the function of beta cells in the pancreas, which are responsible for insulin production and, therefore, crucial for maintenance of glucose levels. **Examples of possible contaminants**: An increased risk of Type 2 diabetes has also been reported after exposure to persistent organic pollutants (POPs) (including PCBs, DDE, dioxin, organochlorine pesticides, and hexachlorobenzene), arsenic and some flame retardants.
Respiratory system
Possible health effects: Asbestosis, lung cancer, chronic bronchitis, fibrosis, emphysema, and decreased oxygen supply in the blood. In the foetus, it can alter airway growth with increased collagen deposition in airway walls as a result of exposure to maternal smoking, and neonates may experience an increased incidence of respiratory mortality following exposure to particulates in the air. Children may exacerbate pre-existing asthma from exposure to particulates in the air and workers may develop work-aggravated and work-related asthma. More than 100 toxicants have been shown to cause asthma, and many more can exacerbate it. **Examples of possible contaminants**: Asbestos, radon, cadmium, benzene, carbon monoxide, soot, aluminium, ammonia, arsenic.
Renal system
Possible health effects: Decreased formation of urine, decreased blood flow to kidneys, decreased ability to filter the blood, prevented urine flow, kidney tissue damage, and kidney cancer. The environment, the workplace and, especially, taking medicines, represent potential sources of nephrotoxicity. **Examples of possible contaminants**: Organic solvents and heavy metals known to adversely affect renal function. Cadmium, lead, mercury, uranium, chlorinated hydrocarbon solvents (TCE, PCE, PCT).
Cardiovascular system

Possible health effects: The cardiovascular and haematological systems are frequent targets of toxicants, producing adverse effects in the cardiovascular system by acting on the myocardial cells or the autonomic nervous system (ANS). This can result in various issues, including problems with heart rate, blood pressure or cardiac contractility, heart failure, aplastic anaemia, acute leukaemia and chronic myelogenous leukaemia. **Examples of possible contaminants**: Carbon monoxide, carbon disulphide, nitrates, methylene chloride, methylmercury, lead, arsenic, cadmium, ozone, vinyl chloride, benzene.
Thyroid system
Possible health effects: Hypothyroidism or hyperthyroidism, thyroid autoimmune disease, neurodevelopmental effects with changes in circulating levels of thyroid hormones. **Possible contaminants**: PCBs, BPA, perchlorate, dioxins, pentachlorophenol, triclosan and the PBDE flame retardants. Animal evidence of thyroid disruption exists for the phthalates DEHP, DIDP, DnHP, DBP, resorcinol and the flame retardant TBBPA.
Immune system
Possible health effects: Allergies, immune system inhibition or failure, auto-immunity. Early-life exposure to chemicals commonly found in households has been associated with the occurrence of allergic airway diseases, asthma and rhinitis (hay fever). Positive relations have been found between phthalates in dust or phthalate-related products, such as PVC flooring, and asthma or allergic symptoms. Associations between BBzP and DEHP concentrations in dust and selected allergies and asthma have also been found. Also of concern is the finding that exposure to perfluorinated compounds can suppress antibody response to routine childhood immunisations. **Examples of possible contaminants**: Mercury, lead, pesticides, polychlorinated biphenyls (PCBs), polycyclic aromatic hydrocarbons (PAHs).

Sources: WHO, 2011a; ATSDR, webpage.

In recent years, there has been an increased focus on the effects of exposure to chemicals on both human health and the environment. Humans are simultaneously exposed to numerous chemical substances present in food, water, medicines, air, cosmetics, health care and consumer products. The effects of such chemical mixtures are referred to as combination effects, mixture effects or cocktail effects.

Studies focusing on the health effects of mixtures of chemicals have, however, been limited, for a variety of reasons. Firstly, it is easier to study a single compound in an animal study and to obtain traditional dose–response information. Secondly, an almost infinite number of combinations of contaminants is possible, and it is often difficult to know which is the most important, which dose ranges should be investigated, or which biological end point should be studied. Thirdly, many factors must be taken into account: the amount of chemical the person was in contact with; the duration of the contact; the frequency of exposure; pathway of the chemical through the body of the person; and his/her prior general health. In addition, susceptibility of an individual to the toxic and carcinogenic effects of a chemical mixture is believed to have a significant genetic component.

In the EU, current risk assessments (RA) of chemicals focus on exposure to individual chemicals and do not provide a comprehensive and integrated assessment of cumulative effects of different chemicals, taking into account different routes of exposure[51]. The 2012 Commission Communication on Combination effects of Chemicals (Chemical mixtures) recognised the disadvantage of the EU current RA, which only assess chemicals one by one and launched a new process to develop an effective way to assess exposure stemming from combination effects of chemicals[52]. The new Commission approach arises from the 2012 opinion on "Toxicity and Assessment of Chemical Mixtures", issued by the scientific committees SCHER, SCENIHR and SCCS[53]. The report notes that the number of possible combinations of toxic substances is enormous and suggests risk assessors focus only on circumstances of a particular concern. The report also highlights that although data gaps limit the assessment of chemical mixtures, the information collected via the REACH Regulation can contribute to reducing some of the challenges risk assessors are facing.

International bodies have also developed other frameworks for the assessment of chemical mixtures in recent years. For instance, a WHO/IPCS workshop resulted in framework for risk assessment of combined exposure to multiple chemicals that could be adapted to the needs of specific users.

[51] Kienzler *et al*., 2016.
[52] Communication from the Commission to the Council, 2012.
[53] SCHER, SCENIHR, SCCS, 2011.

However, its use is often limited by large data gaps on exposure as well as hazard information[54].

Even though new frameworks for assessing cumulative effects are thus being developed and applied[55], an overarching, comprehensive approach across different EU acts is still lacking. While frameworks such as the ones described above may provide reference for further development, their concrete application is limited due to lack of exposure data[56].

Yet, recent studies have pinpointed the detrimental effects caused by combined exposure to certain chemicals on the foetus which can ultimately lead to persistent pathological diseases later in life[57]. As such, these studies stressed that risk assessment based on single substances alone is not to sufficient to interpret the effects that combined exposure may cause on human health and thus urged policymakers to develop a cumulative risk assessment which could take into account all chemicals, spanning from pesticides, to industrial chemicals, and environmental contaminants (e.g. food, cosmetics, dust, and other sources)[58].

In addition to combination effects from chemical mixtures, another area of concern is the issue of environmentally induced epigenetic toxicity. An epigenetic trait has been described as: '*a stably heritable phenotype resulting from changes in a chromosome without alterations in the DNA sequence*'[59]. Epigenetic programming is fundamental for normal mammalian development, and provides a more subtle mechanism by which the environment can rapidly alter gene expression within single or multiple generations. It is the complex interaction between our genome, epigenome and environment that shapes development into unique individuals, and thus influences human health and potentially the health of future offspring[60].

While regulatory bodies have developed comprehensive testing procedures and safety guidelines to protect human health against the adverse effects of environmentally induced genetic mutations causing, for example, cancer, there are few established regulatory procedures in chemical safety programmes for determining environmentally induced epigenetic toxicity[61]. Such changes can influence people's health, with numerous adult onset diseases associated with abnormal epigenetic changes, including cancer, diabetes, and neurological, renal, cardiac and respiratory conditions[62]. Epigenetic processes also play a key role in initiating the onset of puberty, changes to which can also increase the risk of some of these adult onset diseases[63].

Certain stages in development and cell types can be thought of as particularly sensitive to epigenetic change due to the severity of the outcome for the individual, or the potential to affect multiple generations[64]. For example, in utero exposure could result in environmentally induced epigenetic changes during early embryo and germ line development. Such changes could have far-reaching consequences on embryo viability and development, and thus subsequent future health and fertility. It is also important to consider ex utero exposures, as early childhood and adolescence are also periods of significant growth and development. Environmentally induced epigenetic changes during these stages could also have detrimental effects on future health and fertility[65].

[54] Kienzler *et al*., 2016
[55] Price, 2012.
[56] Kienzler *et al*., 2016.
[57] Govarts E., *et al*., 2016.
[58] Hass U., *et al*, 2017.
[59] Berger SL *et al.*, 2009.
[60] Marczylo EL *et al.*, 2016.
[61] Reproductive generation studies (such as EOGRTS) are partly design to address some of these conditions, such as sexual maturation and neurological developmental aspects. See for more info: Saghir SA & Dorato MA, 2016.
[62] Hamm CA & Costa FF, 2015.
[63] Rzeczkowska PA *et al.*, 2014.
[64] Marczylo EL *et al.*, 2016.
[65] Ibid.

A recent study[66] concluded that research in the area of epigenetic toxicity is largely in its infancy, and is incomplete with respect to the specific mechanisms of epigenetically mediated environmentally induced toxicity in humans at doses relevant to human exposures. There is, however, sufficient information to perform retrospective epigenetic analysis of existing regulatory studies and to identify future research needs. Collaboration between scientists from academia, industry, and governmental and regulatory bodies will promote further research within a regulatory context, and drive the development and implementation of epigenetically relevant integrated testing strategies or policies for the continued protection of public health.

In order to bridge the gap between science, the general public and policy makers, in 2010 the EU launched the FP7 European Community-funded Network of Excellence: EpiGeneSys[67]. The goal of this initiative, which ended in March 2016, was to address fundamental epigenetic mechanisms, both spatially and temporally, in quantitative terms, using systems biology approaches. It helped to build a bridge between the fields of epigenetics and systems biology, facilitated communication of the underlying science in an accessible and interesting manner, and built public support for scientific research, changing the public's perception of science through education.

[66] Ibid.
[67] EpiGeneSys, project website, available at: www.epigenesys.eu/en/.

2 CHILDREN: FROM THE DEVELOPING FOETUS TO LATE ADOLESCENCE

Foetuses, infants, children and adolescents are especially susceptible to chemical exposures, owing to developmental stage-specific exposure patterns and physiological and toxicodynamic factors[68,69]. They possess distinct characteristics and/or behavioural tendencies that contribute to a particular susceptibility to chemical exposures. A report published in 1993 by the American National Research Council entitled *Pesticides in the Diets of Infants and Children*[70] was the first publication to highlight the unique risk of chemical exposure faced by children. Prior to this, little attention was paid to the impact of chemicals on children.

The following sections further analyse the vulnerability of children according to their developmental stages and outlines the reasons for their increased vulnerability compared to the general population.

2.1 FOETUS

As explained in paragraph 1.2.4, scientific studies demonstrated that the placenta does not shield the foetus from the exposure to certain toxic chemicals[71]. In particular, research has shown that chemicals in pregnant women can cross the placenta; in addition, chemicals such as with lead, mercury, polychlorinated biphenyls (PCBs) and nicotine, can accumulate inside the foetus, resulting in higher exposure doses for the latter compared to the mother[72].

The developing foetus is considered to be one of the most vulnerable groups in the population for chemical exposure[73]. Their increased exposure and risk is mainly due to factors such as[74]:

- Fast cell reproduction rates, which make the developing organs of the foetus particularly susceptible to toxic aggression;
- Different development stages of sensitive organs, which make the foetus highly sensitive to harmful chemicals;
- Immature ability of the foetus' body to expel toxicants;
- The undeveloped blood-brain barrier, which does not shield the developing brain from transport of toxic chemicals.
-
- The vulnerability of the foetus, linked to increased exposure and absorption, can be further increased by socioeconomic conditions such as poverty and poor nutrition. If, for instance, the foetus does not receive the adequate intake of protein, calcium, and iron, the absorption of toxic substances such as lead is likely to increase[75].

Given the above, the exposure to neurotoxicants such as lead, arsenic, mercury, PCBs, pesticides and solvents during this unique sensitive life stage can cause lifelong damages[76,77]. For these reasons, research has developed the concept of 'windows of vulnerability', which describes the critical periods in early development when exposures to even minimal doses of toxic chemicals - which would not have any adverse effects on adults - are able to cause long-lasting hazardous health effects on the

[68] WHO, 2011a.
[69] KEMI, 2012.
[70] US National Research Council, 1993.
[71] Kim H & Cizmadia P, 2010.
[72] Grandjean P, 2013; Rollin HB *et al*., 2009.
[73] Ondeck M & Focareta J, 2009.
[74] Bruckner JV, 2000.
[75] Landrigan PJ & Goldman LR, 2011.
[76] Diamanti-Kandarakis E *et al*.,2009; Grandjean P, 2013
[77] Diamanti-Kandarakis E *et al*., 2009.

foetus and, more in general, children[78].

- In fact, prenatal exposure to environmental chemicals is linked to adverse health consequences, including: pre-term birth; low birth weight (due to intrauterine growth retardation); congenital abnormalities (birth defects); pregnancy loss (miscarriage); childhood morbidity; and neurodevelopmental defects[79].

A focus of recent studies has been the developing human brain, which is uniquely vulnerable to toxic chemical exposures, with critical windows of developmental vulnerability occurring in utero, as well as during infancy, childhood and early adolescence[80]. Toxic substances can contribute to neuropsychiatric disorders in children, with disorders of neurobehavioral development affecting 10–15% of all births, and prevalence rates of autism spectrum disorder and ADHD appeared to have spread worldwide[81]. It is worth noting that all of these clinical conditions have profound consequences for the society in its entirety, as they lead to reduced academic performance and behavioural disorders, thus strongly reducing overall quality of life.[82].

According to a 2006 study, among the chemicals which can be more harmful for the developing brains there are the following neurotoxicants: lead, methylmercury, arsenic, polychlorinated biphenyls (PCBs), and toluene[83].

For instance, studies have demonstrated that exposure to *lead* – which can be found in the paint of old houses and water pipes[84] - may cause neurological effects, strain development, behavioural difficulties and learning problems, as well as loss of IQ, hyperactivity and inattention[85].. In addition, exposure to lead during early childhood can decrease school performance and lead to antisocial behaviour later in life[86].

Methylmercury is formed from inorganic mercury and is common contaminant of fish. It is a strong neurotoxin which is formed primarily from mercury emitted by coal-fired power plants, waste incineration, and other industrial processes. Exposure to methylmercury can reduce cognitive performance and attention, as well as causa psychomotor deficiencies in children[87]. Even post-birth exposure can cause negative health effects; in fact, children which consumed contaminated seafood have experienced deficits in attention, motor function, language, and memory impairments[88]. It is also important to notice that developmental neurotoxicity in the foetus occurs at much lower exposures than the one that would affect adults[89].

As far as *PCBs* are concerned, despite being banned, they can still be found in certain products such as electrical transformers. They are pollutants with endocrine disrupting properties. Evidence strongly suggest that exposure to PCBs can negatively affect brain development[90].

With regard to *arsenic*, prenatal and early postnatal exposures to this chemical are associated with neurological disease appearing in adult life[91].

[78] Barker DJ, 2004.
[79] Kim H & Cizmadia P, 2010; Gluckman PD & Hanson MA, 2004; Stillerman KP *et al*., 2008.
[80] Grandjean P & Landringan PJ, 2014; Rice D & Barone S Jr, 2000.
[81] Landrigan PJ *et al*., 2012.
[82] Gould E, 2009.
[83] Grandjean P & Landringan PJ, 2006.
[84] CHEM Trust, 2017.
[85] Goodlad JK, Marcus DK, Fulton JJ, 2013.
[86] Fergusson DM, *et al*., 2008.
[87] CHEM Trust, 2017.
[88] Grandjean P *et al*. 1997.
[89] Grandjean P & Landringan PJ, 2014.
[90] WHO, Regional Office for Europe, 2014
[91]Hamadani, JD, et al., 2011.

Finally, concerning *toluene*, maternal consumption of alcohol during pregnancy, even in very small quantities, has been linked to several neurobehavioural diseases in children, spanning from reduced IQ, antisocial behaviour, and sensory problems[92].

In addition to the above five chemicals, recent epidemiological studies have documented six additional developmental neurotoxicants, i.e. manganese, fluoride, chlorpyrifos, dichlorodiphenyl-trichloroethane, tetrachloroethylene, and the polybrominated diphenyl ethers[93]. In particular, recent studies showed that exposure to *manganese* is associated with reduced performance at school, hyperactivity, and impaired functions of the motor system[94]

Furthermore, scientific research demonstrated that exposure *fluoride* in drinking water, lead to a decrease of IQ[95]. As far as *solvents* are concerned, exposure to these chemicals during pregnancy has been linked to hyperactivity and anti-social behaviour, as well as psychiatric disorders[96].

In addition to these chemicals, other 200 chemicals are known to cause neurotoxic effects; moreover, many additional chemicals have shown neurotoxic properties in laboratory[97]. The entire picture of neurotoxicity is thus not yet known, and further research is required to fully understand the impact of chemicals on the developing human brain.

Other than neurotoxicants, a large variety of pervasive chemicals, such as dioxin-like compounds, certain flame retardants, PCBs, bisphenol A (BPA), perchlorate, pentachlorophenol and several other common contaminants have been shown to have thyroid-disrupting properties[98]. Thyroid hormones play a significant role in the development of the CNS, pulmonary system, cardiovascular system, and other organs. Small modifications in thyroid serum levels during pregnancy – particularly during the first trimester - have been associated with cognitive deficits and other damaging effects on neurological outcome. Various studies have shown that hypothyroidism in the mother can result in impaired intellectual development in her children, as well as hearing loss. Perinatal exposure to thyroid-disrupting chemicals such as PCBs has also been associated with poorer neurodevelopment in neonates, toddlers and school-aged children[99].

Endocrine-disrupting chemicals (EDCs) are exogenous substances or compounds that cause adverse health effects in the organism by disrupting the endocrine functions. Compared to adults, infants and children are not only exposed to chemical toxins in the environment but may also be exposed indirectly during their intrauterine life[100]. The foetus can also be exposed to toxic chemicals through the placental cord[101]. In particular, exposure to endocrine toxic chemical components can impair the hormonal, neurological and immunological development of the foetus[102]. Studies have demonstrated that foetuses, exposed to EDCs are not only born with congenital abnormalities, but may also experience a wide range of neurological diseases later in life[103]. This explains why certain adult diseases are the results of prenatal exposure[104].

Few studies exist on human exposure to chemical carcinogens during early life, with most concerning animal studies. One such study showed that acute exposure of juvenile animals to several carcinogens

[92] Grandjean P & Landringan PJ, 2014.
[93] Grandjean P & Landringan PJ, 2014.
[94] Bouchard, M, *et al*., 2007; Khan, K, *et al*., 2012; Lucchini, RG, *et al*., 2012.
[95] Choi, AL, *et al*., 2012.
[96] Janulewicz, PA, 2012.
[97] Grandjean P & Landringan PJ, 2006.
[98] CHEM Trust, 2017.
[99] Grandjean P, *et al*., 2011.
[100] Ünüvar, T., & Büyükgebiz, A., 2012.
[101] Ünüvar, T., & Büyükgebiz, A., 2012.
[102] Ünüvar, T., & Büyükgebiz, A., 2012.
[103] Crinnion WJ, 2009.
[104] Barker DJ, 2003.

with the same intensity, showed a greater sensitivity compared to adult animals[105].. Moreover, certain chemicals, such as benzo[a]pyrene, showed a nine-fold increase in risk for liver cancer when administered to neonatal animals compared to adult animals[106].

Bioaccumulation is another important factor to consider. It refers to the accumulation of (possibly toxic) substances at a faster rate than the rate at which the substances are expelled from the body. Children are at particular risk to this process, as they have more years, compared to adults, to accumulate environmental chemicals, such as persistent organic pollutants (POPs), pesticides, and flame retardants. Exposure to these toxic chemicals early in life can lead towards the development of cancer during adult life[107].

Maternal exposure to atmospheric contaminants, in particular, can have several negative health consequences on the foetal development, as the risk of low birth weight increases. The timing of maternal exposure is also important, as a developing foetus is more susceptible to exposure during the first trimester. Maternal exposure to pesticide exposure has also shown to contribute to growth retardation[108].

The following table provides a non-exhaustive overview of the commonly identified environmental chemical exposures and birth defects.

Table 2: Commonly identified environmental chemical exposures and birth defects in the developing foetus.

Exposure	Birth Defect
Arsenic	■ Cardiac defects
Bisphenol A (BPA)	■ Reproductive system anomalies
Dioxin	■ Neural tube defects ■ Neurobehavioral problems ■ Hypospadias ■ Oral clefts
Lead	■ Neural tube defects ■ Neurobehavioral problems ■ Hypospadias ■ Oral clefts
Methylmercury	■ Neural tube defects ■ Neurobehavioral problems
Particulate matter in air	■ Vascular defects
PCBs	■ Impaired hearing
Sulphur dioxide	■ Musculoskeletal defects ■ Cardiac defects
Environmental tobacco smoke	■ Low birth weight ■ ADHD
Air pollution	■ Low birth weight
Pesticides	■ Low birth weight ■ Congenital anomalies

Source: Kim H & Cizmadia P, 2010

HELIX is a collaborative project funded through the European Commission 7th Framework Programme. It is intended to exploit new tools and methods for characterisation of early-life exposure to environmental hazards. The 'exposome' concept was coined to map the totality of human environmental exposures. The objectives of Project HELIX include measurement of a range of chemical and physical environmental hazards in food, consumer products, water, air, noise and the built environment, pre- and postnatal early-life periods, definition of multiple exposure patterns and individual exposure variability, and quantification of uncertainty in exposure estimates. Six prospective birth cohort studies contribute to HELIX as 'the only realistic and feasible way to obtain

[105] Ginsberg, GL, 2003.
[106] Carpenter DO & Bushkin-Bedient S, 2013.
[107] Carpenter DO & Bushkin-Bedient S, 2013.
[108] Kim H. & Cizmadia P., 2010

the comprehensive, longitudinal, human data needed to build this early-life exposome'. The project is intended to lead to major improvements in health risk and impact assessments and thus to improved prevention strategies for vulnerable populations[109].

2.2 CHILDREN

Children have an increased susceptibility to chemicals in the environment for various reasons. Firstly, children have greater exposure to toxic chemicals in proportion to their bodyweight[110]. They are constantly growing, breathing in more air, consuming more food, and drinking more water than adults.[111].
Moreover, children have larger respiratory ventilation rate compared to adults. Consequently, they absorb more air pollutants and/or toxic air compounds per body weight[112].

Secondly, children's behaviour is different than adults, resulting in different routes of exposure. For instance, children crawl on the ground where they can be exposed to chemicals present on floors, soils, and household dust. Their hand-to-mouth behaviour also magnifies their exposure[113]. Furthermore, children's immature behaviour may lead them to take poor choices regarding their health and safety (e.g. touching caustic chemicals). In addition, they are often not able read warning labels on products thus being exposed to higher risks compared to adults[114].

The following table shows the behavioural factors that are likely to affect children's exposures and the associated developmental windows.

Table 3: Behavioural factors by age group that can affect children's exposure to chemicals

Age group	Characteristics relevant to oral and dermal exposure	Characteristics relevant to inhalation exposure
Birth to <3 months	Breastfeeding and bottle feeding. Hand-to-mouth activities	Time spent sleeping/sedentary
3 to <6 months	Solid food may be introduced. Contact with surfaces increases. Object/hand-to-mouth activities increase	Breathing zone close to the floor
6 to <12 months	Food consumption expands. Floor mobility increases (surface contact). Children are increasingly likely to mouth non-food items	Development of personal dust clouds
12 to <24 months	Children consume full range of foods. They participate in increased play activities, are extremely curious and exercise poor judgement. Breastfeeding and bottle feeding cease	Children walk upright, run and climb. They occupy a wider variety of breathing zones and engage in more vigorous activities
2 to <6 years	Children begin wearing adult-style clothing. Hand-to-mouth activities begin to moderate	Occupancy of outdoor spaces increases
6 to <11 years	There is decreased oral contact with hands and objects as well as decreased dermal contact with surfaces	Children spend time in school environments and begin playing sports
11 to <16 years	Smoking may begin. There is an increased rate of food consumption	Increased independence (more time out of home). Workplace exposure can begin
16 to <21 years	Alcohol or drugs consumption may begin. High rate of food consumption begins	Independent driving begins. Expanded work opportunities

Source: EPA, 2001.

Thirdly, children's central nervous, immune, reproductive, and digestive systems are still developing and are thus immature. The developing organs are particularly susceptible to toxic aggression, given

[109] HELIX project, official webpage: http://www.projecthelix.eu/index.php/en
[110] U.S. National Research Council, 1993.
[111] Ershow AB & Cantor KP, 1989.
[112] Bennett WD *et al.*, 1996.
[113] WHO, 'environmental risks', available at: http://www.who.int/ceh/risks/en.
[114] WHO, 'environmental risks', available at: http://www.who.int/ceh/risks/en.

the increased rate of cell division and immaturity of some functional excretion systems. Another consequence of their immature organs and systems is that children's ability to metabolise and expel toxic chemicals from their body is weaker than adults[115]. Given the above, exposure to toxicants during this sensitive life stage can lead to lifelong irreversible damage[116].

Finally, children have more time than adults to develop chronic diseases. In fact, research has demonstrated that cancer and many neurological diseases appearing during adult life are the results of early childhood exposure[117].

These observations are summarised in the following table.

Table 4: Characteristics, exposure and vulnerability to environmental health hazards by developmental stage

Developmental stage	Developmental characteristics	Exposure	Vulnerability
Preconception	Lack of awareness of gonadal exposure	All environmental exposures	Potential for genotoxicity
Pregnancy	High calorie intake Permeable placenta	All environmental exposures Ad-hoc diagnostic investigations	Potential for teratogenicity due to embryonic development of various organs and apparatuses
First three years	Oral exploration Beginning to walk Stereotyped diet	Food (milk and baby foods) Air (indoor) Water Mattress/ carpets/ floor	Potential for damage to brain (synapses) and lungs (developing alveoli) Allergic sensitisation Injuries
Preschool and school-age child	Growing independence Playground activities	Food (milk, fruit, vegetables) Air (indoor and outdoor) Water	Potential for damage to brain (specific synapse formation, dendritic trimming) and lungs (volume expansion) Injuries
Adolescence	Puberty Growth spurt Risk-taking behaviour Youth employment	Food (any) Air (indoor and outdoor) Water Occupational exposure	Potential for damage to brain (continued synapse formation), lungs (volume expansion) and pubertal development Injuries

Source: WHO & EEA, 2002.

The table above introduces the concept of. 'windows of susceptibility', and shows which health effects can be triggered by chemical exposure during a particular period of time. Windows of susceptibility in children are broad, as they span from the preconception period until to the end of adolescence[118].

The European Environment and Health Strategy[119], adopted in 2003, includes a strong focus on children as a section of the population with particular susceptibility to environmental agents. Covering the first cycle of the Strategy, the European Environment & Health Action Plan 2004-2010[120] maintains a focus on concerns related to children. The first cycle aims at understanding the link between environmental factors and (1) childhood respiratory diseases, asthma, allergies; (2) neurodevelopmental disorders; (3) childhood cancer; (4) endocrine-disrupting effects. It also aims at identifying and preventing new health diseases caused by environmental factors.

The items selected for the first cycle include the following:

- European Integrated Environment & Health Monitoring and Response system, which includes:

[115] Cohen Hubal EA, 2000.
[116] Diamanti-Kandarakis E *et al*.,2009.
[117] Landrigan PJ, *et al*., 2005.
[118] WHO, 2011a.
[119] COM(2003) 338.
[120] COM(2004) 416.

(a) Establishing an EU Biomonitoring Framework, which aims to assess environmental and health linkages insofar as they relate to children;
(b) Pilot projects on dioxins, heavy metals and endocrine disruptors (the choice of the specific pollutants was made on the basis of significant health effects in children)
(c) Developing harmonised environment and health indicators.

- Research on environment and health issues, including:
  (a) Application of research results arising from activities funded under the EU research Framework Programmes and other sources, such as progress in genomics research by the Joint Research Centre (JRC) and the research by the European Science Foundation networks on genetic susceptibility to environmental toxicants and their impacts on human health, with particular attention to the interaction between nutritional, environmental and genetic factors in early human development;
  (b) Annual research meetings and reports organised by the Commission, and research supported by the Policy Interpretation Network on Children's Health and the Environment which operates in the context of the European Health Forum;
  (c) Development of methodologies to identify exposures and to perform combined exposure analysis of environmental factors connected to particular diseases, and risk assessment which takes account of individual susceptibilities and genetic predisposition;
  (d) Strengthening the research base for the economic valuation of the health impact of policies, measures and technologies, with a particular focus on the environment and children's health.

- Reducing exposure, including:
  (a) Improvement of air quality (indoors and outdoors), linked to the evidence showing that exposure to environmental smoke causes increased risks of several illnesses in children and reduced foetal growth;
  (b) Adoption of a strategy and measures on heavy metals;
  (c) Studying possible health effects of exposure to electro-magnetic fields;
  (d) Adoption of a thematic strategy on the urban environment, including biomonitoring of children in an urban environment.

The Third WHO International Conference on Children's Health and the Environment in Busan, Republic of Korea (June 2009), resulted in the Busan Pledge, asking the WHO to facilitate the development of a global plan of action to improve children's environmental health[121] and to regularly monitor and report on its progress. The Pledge recognised that the activities of the plan should be implemented in close interactive partnerships with all sectors. Five target areas of work are included in the Global Plan of Action, including: (1) data collection and analysis; (2) collaborative research; (3) advocacy; (4) clinical service delivery; and (5) awareness raising and education. Among the more detailed actions listed in the Plan, those related to chemicals include 'promotion of human biomonitoring and human tissue measurements in order to enable better measurement of children's exposure to chemicals, as well as urging national and global efforts to clean the air, water and soil of contaminants and to properly manage chemicals in the environment'[122].

The Danish Chemicals Action Plan for 2010-2013[123] aims to ensure that no products which can be harmful for human or the environment should be available on the market. The plan consists of two parts: general initiatives, and challenges relating to specific target groups or specific substances and groups of substances. Vulnerable groups are explicitly considered in the context of a number of the listed initiatives. For example, continued efforts in the consumer field will focus more studies on consumer products, including product groups such as toys, cosmetics, hobby products and textiles, as

[121] WHO, 2010.
[122] WHO, 2010.
[123] Danish Government, 2010.

well as examining the overall exposure of specific population groups, such as children. The plan also mentions targeted information campaigns for particularly vulnerable or at-risk groups, as well as institutions and parents. It specifically targets endocrine disruptors and combination effects through knowledge acquisition and information sharing, as well as a voluntary phasing-out of EDCs in medical equipment.

The previous Swedish Action Plan for a Non-toxic Everyday Environment (2011-2014) focused on safeguarding the reproduction of human beings and child health, and this remains the focus for the current plan (2015-2020). The national level measures in the plan include information campaigns on sustainable consumption targeted at pre-school and school pupils. The impact of chemicals on children and young people is listed as one of the main challenges, with the Swedish Chemicals Agency placing considerable importance on a national action plan for endocrine disruptors and a national action plan for allergenic substances during 2015-2020[124]. The plan includes activities to influence chemicals policy at EU and international level.

The French strategy on endocrine disruptors[125] targets the prevention of health risks and the exposure of vulnerable populations, pregnant women and young children. The strategy makes reference to several research projects, with a goal to increase expertise and improve measures to evaluate the dangers and risks of EDCs through a programme of expertise carried out by Anses and ANSM. Based on their conclusions, EDCs are subject to appropriate regulatory measures prioritised at EU level in order to reduce exposure. France strongly promotes the adaptation of EU regulations to the specificities of EDCs. The strategy also envisages educational and information-sharing activities.

Adopted in 2010, the UK Children's Environment and Health Action Plan (CEHAP) aims to identify a set of indicators that appropriately describes the burden and distribution of hazards and risks of childhood disease and injury due to environmental factors at a sub-national level. One of the indicators is the potential exposure to chemical incidents, defined as 'an acute event in which there is, or could be, exposure of the public to chemical substances which cause, or have the potential to cause ill health'. It is noted that the impact of such exposure will likely be acute and short-term rather than chronic. The numerator for the indicator is the number of uncontained chemical incidents occurring within the West Midlands between January and December 2007. The source of the information is the Chemical Incident Surveillance System hosted and managed by the CRCE of the HPA. Another indicator is exposure to air pollutants, measured as the annual mean levels of nitrogen oxide (NO_2) and particles (PM_{10}) at background locations. It is noted that children living in the more urban/industrial areas experience poorer air quality, and that ambient air pollution is associated with a range of health impacts in children.

2.2.1 Neonates and infants

Neonates, i.e. children of less than four weeks old, are especially vulnerable to toxic chemical exposures because of the immaturity of their anatomy and physiology[126]. In fact, after delivery, all newborns' systems and organs are immature – a circumstance that exposes them to higher risks stemming from chemical exposure. In particular, their gastrointestinal tract is more permeable and thus absorbs more toxins compared to older children or adults[127].Moreover, having a larger respiratory rate, infants are exposed to higher intake of chemical compounds per body weight compared to adults. Infants also need more water and food per body weight than adults. This circumstance increases their exposure to toxic compounds (e.g. pesticides) which are present in food and water. In addition, newborns spend the majority of their time in the same environment (e.g. hospital or home), and are thus constantly exposed to indoor contaminants[128]. It is worth noting that vulnerability to chemical

[124] KEMI, 2014.
[125] French Ministry of the Environment, Energy and the Sea, 2014.
[126] Sattler B *et al*., 2012.
[127] Wigle DT, 2003.
[128] Bearer CF, 1995.

exposure through inhalation may be highest during the first six months after birth[129]. Air pollutants may in fact cause a wide range of clinical conditions spanning from asthma to bronchitis, as well as infant mortality due to respiratory diseases[130]. Infants are also extremely sensitive to to lead and environmental tobacco smoke[131].

The research project FACET, originally designed to create a food chemical exposure surveillance system, is intended as a tool for post-market monitoring. The concept for the project originated in an attempt to harmonise monitoring methods and to provide a scientific standardised approach to food chemical exposure assessment in Europe – an area where efforts tended to be orientated towards specific groups of chemicals in isolation. The FACET project draws on scientific expertise in the areas of food additives, flavourings and FCMs, together with expertise in food intake, exposure assessment methodologies and software development. A number of the food categories chosen for the study are relevant to children's health, e.g. baby foods and fennel tea. Limitations in the amount of available data in certain countries were observed during the project, such as the lack of food consumption data on children under five years, younger adults between 18-25 years and older adults over 65 years[132].

In a study carried out in the U.S., over 200 toxic chemicals were detected in the umbilical cord blood, including pesticides, chemicals found in food packaging, chemical by-products from burning coal and flame retardants[133]. It is worth taking into account that as infants are delivered in hospitals, they are exposed to chemicals used in nursery and hospital settings, such as polyvinyl chloride (PVC), di 2-ethylhexyl phthalate (DEHP), BPA, phthalates, and parabens. The sections below analyse the chemicals of special concerns for infants.

Bis (2ethylhexyl phthalate) (DEHP)

Bis (2-thylhexyl phthalate) (DEHP) is a common plasticiser. Its aim is to make plastics more flexible. Medical products used in hospitals which contain DEHP include IV tubing and bags, respiratory equipment, and haemodialysis equipment[134]. Research suggests that exposure of ill infants to DEHP may negatively affect male reproductive tract development and function[135]. As a consequence of these concerns – not specifically limited to medical products - the European Chemicals Agency (ECHA) has recently proposed a restriction on DEHP and other phthalates[136].

Bisphenol A (BPA)

BPA is an organic compound used to make polycarbonate plastic, food can linings and epoxy resins. Exposures to this chemical occur when consuming liquids and canned foods stored in BPA-containing vessels. BPA is an EDC[137]. Additionally, recent evidence shows that BPA has developmental neurotoxic (DNT) properties[138].

A number of animal studies have associated BPA exposure to neurological risks in infants[139]. Moreover, perinatal exposure to low doses of BPA may increase the risk of developing breast

[129] Ginsberg G *et al*., 2004.
[130] WHO, 2005.
[131] Grandjean P & Landrigan PL, 2006.
[132] FACET, executive summary, webpage: http://cordis.europa.eu/result/rcn/45323_it.html.
[133] EWG, 2005.
[134] Sattler B, *et al*., 2012.
[135] SCENIHR, 2015
[136] ECHA, official webpage: https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/13919/term?_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=204-211-0&_viewsubstances_WAR_echarevsubstanceportlet_DISS=true (accessed March 2017).
[137] Sattler B, *et al*., 2012.
[138] CHEM Trust, 2017.
[139] EFSA, 2015;

cancer[140]. According to recent scientific evidence, newborn rats which have been exposed to low doses of BPA, have developed prostate cancer in adulthood[141]. Several recent studies also link obesity with BPA exposure[142]. Currently, the European Food Safety Authority (EFSA) is re-evaluating the potential toxicity of BPA on the immune system in light of new evidence highlighted in a recent publication issued by the Dutch National Institute for Public Health and the Environment (RIVM) which raised concerns about the effects of BPA on the immune system of foetuses and young children[143].

Body care products containing fragrances and parabens

Body care products such as baby soap, shampoo and lotion usually contain several synthetic chemical compounds. While some of the ingredients such as surfactants and fragrances may have some positive features, they may also cause hazardous health effects to humans.

For instance, fragranced products may contain parabens which have shown to have hormone disrupting properties by mimicking and binding to oestrogen receptors on cells. Exposure to these compounds early in life is linked to an increased risk of breast cancer and reproductive toxicity[144].

2.2.2 Toddlers and school-aged children

The term 'toddler' refers to children who are learning to walk; it is often used for children aged one to two years, but sometimes also up to three years[145]. During this life stage, children start moving, crawling, touching and testing, and, as such, they have higher chances of being exposed to toxic chemicals present at home such as pesticides, cleaners or chemical which accumulate in carpet or household dust[146]. It is worth considering that given their specific exploring and hand-to-mouth behaviour, together with their incapacity to read warning labels, the main danger to which toddlers are exposed is the ingestion of toxic chemicals that may cause permanent damage to their health[147].

A recent study reported that a two-year old girl who accidentally ingested endosulphan - a polychlorinated hydrocarbon pesticide used in agriculture – presented with clinic-status epilepticus[148]. This study also highlighted the importance of considering the relevant framework of the poisoning, as in the case in question it happened in a rural agricultural environment. It is also worth noting that often the socioeconomic status is an indicator of possible unsafe childcare practices which may be the cause of hazardous episodes of poisoning.

Another study reported the case of a male child, aged one year and nine months, who swallowed a computer lithium battery cell. The lithium battery cell is potentially dangerous due to its ability to cause chemical damage to the mucosa and cause early inflammation and oedema, leading to dysphagia and respiratory obstruction[149]. This study also shows that insufficient supervision of children may increase their risk of exposure and subsequent accidental poisoning[150].

In addition to this, toddlers spend a large part of their time at home, making them particularly vulnerable to indoor pollution and increasing the likelihood of exposure to household dust. In particular, house dust is an important route of exposure for many chemical contaminants, with various

[140] Brisken C, 2008.
[141] Jenkins S *et al*., 2009.
[142] Vom Saal FS *et al*., 2007.
[143] EFSA, Bisphenol A immune system safety to be reviewed, official webpage, available at: https://www.efsa.europa.eu/en/press/news/160426a (accessed April 2017).
[144] Gray J *et al*., 2010.
[145] Berk LE, 2009.
[146] SCCS, 2011.
[147] Riffat F & Cheng A, 2009.
[148] Kamate M. & Jain A, 2011.
[149] Majumdar AB *et al*., 2011.
[150] WHO & UNICEF, 2008.

levels of pesticides, PCBs, PAHs, plasticisers (phthalates, phenols), flame retardants, other organic xenobiotics, and inorganic constituents[151][152]. Among the toxic substances that a toddler is likely to inhale are cleaning products, home improvement supplies, gas stoves and heaters. In addition, as young children breathe rapidly and are smaller, they are more likely to absorb large doses of any chemicals present in the air. Furthermore, at home, toddlers can come into contact with several dangerous household products, such as pesticides, ammonia, chlorine bleach, glue, shoe polish, and gasoline[153].

2.3 ADOLESCENCE

Puberty and adolescence are vulnerable life stages as far the exposure to chemicals is concerned. Although adolescents are able to take more independent choices compared to children, their immature behaviour may increase their exposure to toxic substances such as tobacco and alcohol, substances likely to be abused, and chemicals in some personal care products[154].

Moreover, during adolescence, all organs and systems are subject to changes and development, a circumstance which make them particularly vulnerable to the exposure of toxic chemicals and especially to carcinogens and EDCs[155].

Another factor which contributes to higher risks during adolescence is their life expectancy. In fact, adolescents have more time to absorb environmental chemicals, and especially air contaminants[156].. An example is dioxin, a known human carcinogen, which has a half-life of about seven years[157].

For instance, persistent organic pollutants (POPs), including polychlorinated biphenyls (PCBs), chlorinated pesticides, and brominated flame retardants – which are able to accumulate in the adipose tissue – may explicate their negative effects on human health several years. after the initial exposure. Hence, exposures occurring during vulnerable phases such as adolescence may lead towards the development of a wide range of hazardous diseases (e.g. cancer) later in life[158].

In addition, adolescents tend to increase the consumption of personal care products thus intensifying their exposure to toxic chemicals, such as phthalates, parabens, and phenols[159]. For instance, one study found that the average adult woman uses approximately 12 individual personal care products each day, while the average teenage girl uses 17[160]. In particular, cosmetics, fragrances, and other personal care products are a possible source of human exposure to potential EDCs[161].

Furthermore, according to a recent study, '*Reducing Phthalate, Paraben and Phenol Exposure from Personal Care Products in Adolescent Girls: Findings from the HERMOSA Intervention Study'*, when teens stop using personal care products, even briefly, levels of these EDCs drop significantly[162]. Scientists took urine samples from 100 teenage participants before and after they used products with lower levels of pthalates, parabens, triclosan and oxybenzone for three days. Even after a brief lapse in exposure to these EDCs, there were substantial differences. Cosmetic preservatives methyl and propyl parabens dropped 44% and 45% respectively. Triclosan, found in soaps and toothpastes, and

[151] Mitro SD *et al.*, 2016.
[152] EPA, 2004.
[153] SCCS, 2011.
[154] Mills KL *et al*., 2014.
[155] Anderson LM *et al*., 2000; Soto AM & Sonnenschein C, 2010.
[156] Carpenter DO & Bushkin-Bedient S, 2013.
[157] Flesch-Janys D *et al*., 1996.
[158] Carpenter DO & Bushkin-Bedient S, 2013.
[159] Braun JM *et al*., 2014; Meeker JD *et al*., 2013.
[160] EWG, 2008.
[161] Braun JM *et al*., 2014
[162] Harley KG *et al*., 2016.

benzophenone-3, used in sunscreen, dropped 33%. Levels of metabolites of diethyl phthalate commonly used in fragrances fell 27%[163].

During this phase, adolescents are also likely to be employed – a situation that increases their risks to be exposed to workplace chemicals. It should also be borne in mind that adolescents can also work as entrepreneurs, thus creating their own working environments which do not always comply with health and safety rules. In addition, adolescents may be unaware of hazardous materials to which they might exposed, such as tobacco smoke, solvents, and other cleaning agents[164]. It has also been noted that more than two million young people are exposed to farm-related chemicals, such as fertilisers and pesticides, some of which are known to be carcinogenic, neurotoxicants and hormone disruptors[165].

[163] Ibid.
[164] Ibid.
[165] ANHE, available at: www.envirn.org.

3 REPRODUCTIVE HEALTH AND PREGNANT WOMEN

Since the mid-20th century, numerous studies have reported an increasing incidence of human reproductive diseases and a consequent decline in reproductive function worldwide[166]. The following trends, related to changes of the reproductive system, have been described in the literature[167]:

- Data from the U.S. show that the percentage of women who have difficulty in achieving and maintaining pregnancy has increased between 1982 to 2002, and is slightly lower in 2006-2010 (though still higher than in 1995 and earlier). While some of this increase is likely due to people starting families later in life (fertility decreases with age and miscarriage rates increase with age), this does not explain why the sharpest increase in reported infertility between 1982 and 2002 was among younger women.
- In the U.S., UK and Scandinavia, the preterm birth rate has increased by more than 30% since 1981. Since 1990, the percentage of infants born in the U.S. with low birth weight also rose by 16% to 8.1% of births in 2004.
- There is a trend toward earlier onset puberty among American and European girls. Premature puberty can lead to reduced adult height and is also associated with a higher risk of breast cancer and polycystic ovary syndrome. It can also have psychological consequences, such as greater likelihood of engaging in risky behaviours (smoking, unprotected sex, alcohol and drugs.

Given the short time frame, the above described developments cannot be explained by genetic changes alone. Environmental and other non-genetic factors, including nutrition, age of mother and viral diseases are also at play, and the exposure to environmental substances may play a part in the trends observed.

A large body of research exists on the adverse effects of EDCs on the reproductive system. This, together with the consistent detection of endocrine-disrupting residues in human serum, seminal plasma and follicular fluid, has raised concern that environmental exposure to EDCs is affecting human fertility[168]. EDCs may affect the development and functioning of the reproductive system in both sexes, causing infertility, as well as developmental and reproductive disorders in foetuses. As male sexual differentiation is androgen-dependent (and potentially oestrogen-dependent) and female differentiation occurs largely independently of oestrogens and androgens, it is expected that different disorders are seen in males and females as a result of EDC effects[169].

Many EDCs are known to act as agonists (triggers) of oestrogen receptors, e.g. bisphenol A and alkylphenols, with several antagonising androgen receptors, such as the dicarboximide fungicides. Progesterone receptors are also a potential target for many chlorinated EDCs, such as DDT and derivatives[170]. Other examples of EDCs that have shown to have an effect on the reproductive system are: diethylstilbestrol (DES), tributyltin, phytestrogens, alkylphenolethoxylates, phthalate esters (DEHP, BBP, DiNP, DBP), dioxins, polychlorinated biphenyls, herbicides, lead, cadmium, and manganese[171].

Experimental studies with rodents have widely studied the adverse effects of EDCs on the reproductive system. These animal studies, which enable the investigator to measure hormone action at various times during development and thus to accurately interpret the relationship between exposure and each of the effects on the endocrine system, indicate that early prenatal and/or perinatal exposure to EDCs can lead to long-term effects on reproduction and development which become evident later,

[166] Woodruff TJ, 2011.
[167] Balabanic D *et al*., 2011; UNEP & WHO, 2013.
[168] Younglai EV *et al*., 2002.
[169] Diamanti-Kandarakis E *et al.*, 2009.
[170] Caserta D, 2008.
[171] UNEP & WHO, 2013.

even at sexual maturity and/or at adulthood. The identification and characterisation of this 'early exposure—late effect' pattern of EDCs represents a challenge for scientists and risk assessors[172]. Additionally, EDCs can have varying effects throughout development because of variations in tissue hormone receptor isoforms and concentrations at different developmental stages[173].

With regard to the EU legislative framework, the Commission adopted its first Strategy on Endocrine Disruptors in 1999[174]. The EU legislation in force already takes account of endocrine disruptors and, as such, consumers are protected from endocrine disruptors via the authorisation of chemical substances to be used in plant protection products, biocidal products, chemicals falling within the scope of REACH, and cosmetics. However, no formal criteria have been established, internationally or at EU level, to identify substances with endocrine-disrupting properties. For this reason, on 15 June 2016, the EC issued two draft legal acts – one under the Biocidal Products legislation, the other under the Plant Protection Products legislation – which set out the criteria to identify endocrine disruptors[175]. The two draft legal acts containing the criteria now need to be adopted by the Parliament and the Council under the relevant procedures.

The acts were also subject to the feedback mechanism procedure which closed on 28 July 2016. The Commission received 260 public responses to the draft act for plant protection products and 126 responses to the draft act for biocidal products. In particular, the chemical industry denounced the lack of inclusion of potency – the capacity of a substance to induce adverse effects depending on its concentration – as part of these criteria[176]. Nevertheless, if adopted, the EU regulatory system will be a global first in defining scientific criteria for endocrine disruptors in legislation.

The use of certain chemicals such as alkylphenols, some of the phthalate plasticisers, PCBs and the pesticide DDT, in addition to DES, are now prohibited in many countries, as they are considered to have hormone-disrupting properties. In the EU, paragraph 50 of the 7th EAP notes the potential of EDCs to cause adverse effects on health, including children's development. Efforts must be stepped up to ensure that, by 2020, all relevant substances of very high concern, including those with EDC properties, are placed on the REACH candidate list. According to paragraph 54, the 7th EAP must also ensure that, by 2020, the combination effects of chemicals and safety concerns related to endocrine disruptors are effectively addressed in all relevant EU legislation, and risks to the environment and health associated with the use of hazardous substances, including chemicals in products, are assessed and minimised.

In 1999, the Commission adopted the Communication 'Community strategy for endocrine disruptors – A range of substances suspected of interfering with the hormone systems of humans and wildlife'[177]. As a short-term action the document indicated that the Commission intended to establish a priority list of substances for further evaluation of their role in endocrine disruption – the so-called 'ED priority list'. The priority list was meant to be used, inter alia, to identify specific cases of consumer use (e.g. more vulnerable groups of consumers, such as children) for special consideration from a consumer policy point of view. In such cases, insofar as the substances are not covered by the methodology agreed under existing legislation, the Commission would consult the relevant scientific committees for independent scientific advice and consider potential restrictions on use through Community legislative instruments. The possibility of using existing instruments such as Directive 92/59/EEC for short-term emergency action was also mentioned.

It is intended that the priority list of chemicals developed within the EU-Strategy for Endocrine

[172] Caserta D, 2008
[173] Crain DA *et al*., 2008.
[174] European Commission, DG ENV, 'Endocrine disruptors', available at: www.ec.europa.eu/environment/chemicals/endocrine/index_en.htm.
[175] European Commission, 2016, Communication on endocrine disruptors.
[176] EurActiv, 2016.
[177] European Commission, 1999, Community Strategy for Endocrine Disruptors.

Disruptors will be used to prioritise further detailed review of the information. However, it is important that the listings produced are not regarded as final and unchangeable: addition and removal of chemicals may be required in response to either developments in scientific knowledge or changes in chemical usage patterns.

A Communication on the implementation of the Community strategy was adopted in 2001, with a number of Staff Working Documents subsequently produced, the most recent in August 2011[178]. This last Staff Working Document mentions ongoing large-scale projects in the field of endocrine disruption and food, relevant to vulnerable groups: NEWGENERIS[179] focusing on the role of exposure to genotoxic substances (including endocrine disruptors) in the development of childhood cancer and immune disorders; PHIME[180] focusing on public health impact of long-term, low level mixed element exposure in susceptible population strata; NECTAR cluster[181] (Network for Environment Chemical Toxicants Affecting Reproduction) comprising four projects (and receiving over EUR 10m in EU funding)focusing on the impact of early life exposures to endocrine disrupting substances on foetal testes development and male reproductive disorders in newborns and young adults (DEER[182]); the impact of foetal exposure to mixtures of endocrine disrupting substances on human reproductive health (CONTAMED[183]); and the impact of endocrine disrupting substances on female reproductive tissue and consequent effects on conception, maintenance of pregnancy, and hormonal processes that regulate reproduction (REEF).

3.1 REPRODUCTIVE HEALTH

The female reproductive tract depends on specific biological processes that, if altered during critical development periods, can have critical negative effects on women's health and reproductive system[184]. Worldwide, women today are mainly affected by the following three reproductive disorders, as causes of infertility or sub-fertility[185]:

- *Polycystic ovary syndrome* (PCOS) can affect between 3% and 15% of women of reproductive age. It is the leading cause of sub-fecundity and anovulatory infertility, and women with this disorder are more likely to have gestational diabetes, endometrial cancer, preterm labour, and pre-eclampsia.
- *Uterine fibroids* (also termed leiomyomata) are the most common tumour of the female reproductive tract, affecting up to 25-50% of pre-menopausal women. They are a significant cause of pelvic pain, abnormal uterine bleeding, menorrhagia, infertility and complications of pregnancy, including preterm labour.
- *Endometriosis* occurs in 10-15% of women of reproductive age (15-49 years) and a minimum of 176 million women worldwide, and in up to 50% of women with infertility and/or chronic pelvic pain. The prevalence of endometriosis is higher in infertile or sub-fertile women than in the general population, and the pelvic pain associated with endometriosis is a major cause of disability and compromised quality of life.

In Europe, uterine fibroids and endometriosis are the two most common conditions, affecting an estimated 70% of women and are the leading causes of female infertility[186]. While most female reproductive disorders are well described in terms of clinical presentation, histological evaluation of

[178] Commission Staff Working Paper SEC(2011) 1001 final.
[179] NEWGENERIS, project summary.
[180] PHIME, 2011.
[181] NECTAR, project abstract.
[182] DEER, webpage, available at: http://www.eu-deer.net/.
[183] CONTAMED, project summary.
[184] Diamanti-Kandarakis E *et al.*, 2009.
[185] UNEP & WHO, 2013.
[186] Diamanti-Kandarakis E *et al.*, 2009.

the involved tissue and diagnostic classification, their causes and the factors influencing them are often not well understood. Environmental factors, including diet, age, exercise habits, sexually transmitted infections, and access to good health care, play a role in a woman's overall reproductive health and thus could contribute to the abovementioned disorders[187].

Research shows that EDCs play a role in the pathogenesis of several female reproductive disorders, including PCOS, aneuploidy, Premature Ovarian Failure (POF), reproductive tract anomalies, uterine fibroids, endometriosis, and ectopic gestation[188]. In a recent study, researchers determined that 56,700 cases of fibroids among women in Europe were probably due to DDE exposure, and 145,000 cases of endometriosis were probably caused by phthalates[189]. The researchers arrived at these estimates through studies that looked at typical DDE exposures in women of reproductive age in Europe and the association between DDE levels in the blood and fibroid diagnoses.

The most well-known case, showing the ability of synthetic chemicals to alter reproductive function and health in females, is the case of diethylstilbestrol (DES) (see box below).

Box 4: DES case

In the adult female, the first evidence of endocrine disruption was provided through observations of uncommon vaginal adenocarcinoma in daughters born to women treated with Diethylstilbestrol (DES) during pregnancy. DES is an oestrogenic compound that was prescribed to prevent miscarriages in women until 1971. It was initially given to women with at-risk pregnancies, but ultimately it was also prescribed to women with normal pregnancies to make babies 'healthier'.

Apart from the link between women exposure to DES and genital tract cancers in their babies, other abnormalities have been observed as the daughters have also experienced decreased fertility and increased rates of ectopic pregnancy, increased breast cancer and early menopause.

The DES case shown that the female foetus is susceptible to environmentally induced reproductive abnormalities that certain diseases may occur even decades after the first exposure, and that exposure to DES may lead to several female reproductive disorders.

Sources: Crain et al., 2008; Diamanti-Kandarakis E et al., 2009;Giusti et al, 1995.

Research also shows that endocrine disruptors could cause an increasing variety of reproductive health problems in women, including altered mammary gland development, irregular or longer fertility cycles, and accelerated puberty. These changes indicate a higher risk of later health problems such as breast cancer, changes in lactation, or reduced fertility. EDCs can also have an effect on the development of female reproductive disorders, particularly those occurring during critical windows of susceptibility (in utero, neonatally, in childhood, during puberty, and during adulthood)[190].

Most of the information on the effects of endocrine disruption on female reproductive health comes from molecular, cellular and animal studies. In addition to DES, these studies have shown that the following EDCs could be linked to female reproductive health problems: BPA, PCBs, dioxins, DDT, DDE and phthalates[191]. The table below sets out an overview of some of the EDCs that have been shown capable of interfering with the female reproductive system and which are possibly implicated in the development of some gynaecological pathologies.

[187] Ibid.
[188] Diamanti-Kandarakis E *et al.*, 2009.
[189] Hunt PA *et al.*, 2016.
[190] UNEP & WHO, 2013.
[191] Bredhult C *et al.*, 2008; Buck Louis GM *et al.*, 2013; UNEP & WHO, 2013; Upson K *et al.*, 2014.

Table 5: Overview of EDCs, their pathways of exposures, mechanisms of action and observed health impacts in relation to female reproductive health

Chemical(s)	Pathways of exposure	Mechanisms of action	Observations
Persistent Organic Pollutants (POPs)			
Polychlorobiphenyls (PCB)	Food chain (fat-rich food, e.g. milk and derivatives, fatty fish, etc.), living environment	Alteration steroid hormone metabolism/ transport, ability to bind with the thyroxin transport protein, transthyretin (TTR), interaction with thyroid hormone receptors, neuroendocrine effects	■ *Animal models*: Vaginal thread; mild hypospadias; delayed the timing of vaginal opening ■ *Human puberty*: Slowed breast development
Dioxins and 'dioxin-like' PCBs	Food chain (fat-rich food, e.g. milk and derivatives, fatty fish, etc.), living environment	Aril hydrocarbon receptor interaction leading to altered steroid hormone metabolism and neuroendocrine effects, including on the thyroid	■ *Animal models*: Delayed puberty; cleft phallus; vaginal thread; reduced ovarian weight; enhanced incidences of constant oestrus; cystic endometrial hyperplasia; decreased fertility rate; reduced fecundity ■ *Human puberty*: Later onset of breast development; lower stage of breast development
DDT and metabolites	Food chain (fat-rich food, e.g. milk and derivatives, fatty fish, etc.), living environment and workplaces (in developing countries)	Mainly oestrogenic activity	
Substances used in agricultural and farm animal production			
Organochlorine insecticides (e.g. Lindane)	Food chain (fat-rich food, e.g. milk and derivatives, fatty fish, etc.), living environment, workplaces (mainly in developing countries)	Homeostasis of steroid hormones (oestrogenic and/or anti-androgenic effects, interaction with progesterone receptor)	
Triazoles, Imidazoles	Food chain (agricultural and zootechnical fungicides), living environment and workplaces (agricultural areas)	Inhibition of steroid hormone biosynthesis	
Triazines	Food chain (herbicides), living environment and workplaces (agricultural areas)	Effects on hypothalamo-hypophysis-gonadal axis	
ETU (metabolite of ethylene bisdithiocarbamates, e.g. maneb), benzimidazoles	Food chain (agricultural and zootechnical fungicides), living environment and workplaces (agricultural areas)	Thyreostatic effects	
Industrial products and daily-use products			
Nonyl-phenols and octyl-phenols	Detergent by-products: food chain (seafood) and consumer products	Oestrogen agonists—oestrogen receptor alpha	
BPA	Food chain (e.g. plastics in contact with food), consumer products (e.g. dental sealant, plastic additive, etc.)	Oestrogen agonist—oestrogen receptor alpha	
Several phthalates (di-2-hexyl-ethyl-, di-n-butyl-, etc.)	Food chain (e.g. plastics in contact with food), consumer products (e.g. PVC, deodorants, adhesives, etc.)	Agonists of pregnane X receptor, effects on steroid hormone biosynthesis	*Animal models*: Uterine abnormalities; reduced fertility
Polybrominated flame retardants	Food chain (fat-rich food, e.g. milk and derivatives, fatty fish,	Interaction with pregnane X receptor	

Chemical(s)	Pathways of exposure	Mechanisms of action	Observations
	etc.), living environment, workplaces, consumer products (e.g. electronic devices, etc.)	leading to altered steroid and thyroid hormone homeostasis	
Organotins	Food chain (seafood), consumer products (e.g. anti-fouling agents)	Aromatase inhibition	
Perfluorooctane sulphonate	Food chain (bioconcentration in animal tissues), consumer products (e.g. plastics, carpets, materials, etc.)	Alteration hypothalamo-hypophysis-gonadal axis	
Parabens	Main cosmetic, toiletries and pharmaceutical preservatives	Oestrogen agonist—oestrogen receptor alpha and beta	
UV-screen (benzophenone 2, 4-methylbenzylidene camphor, etc.)	Mixture for protection against UV radiation	Oestrogen agonist—oestrogen receptor alpha	
Cadmium	Food chain (e.g. refined food as flour, rice, sugar; seafood), cigarette smoking	Oestrogen agonist—oestrogen receptor alpha	*Animal models*: Perturbed oestrous cycles; Reduced number of differentiating germ cells and the size of the ovary in 16.5-day embryos; Tendency towards delayed timing of vaginal opening; Earlier onset of vaginal opening; Increased the epithelial area and the number of terminal end buds in the mammary glands and decreased the number of alveolar buds
Phytoestrogens			
Isoflavones, lignans, etc.	Food chain (e.g. vegetables, soy-based food), consumer products (e.g. cosmetics)	SERMs, high affinity for oestrogen receptor beta	*Animal models*: Decreased pituitary responsiveness to GnRH; increased the size of sexually dimorphic nucleus of the preoptic area; increased/decreased the weight of uterus; decreased the weight of ovaries; reduced serum oestradiol levels; reduced serum progesterone levels; irregular oestrous cycle; histopathological changes in the ovaries and uterus; induced permanent oestrous; decreased the age of vaginal opening

Source: Adapted from Caserta, D., 2008, and UNEP & WHO, 2013

In 2016, Hunt et al estimated the cost of female reproductive disorders and diseases as a result of exposure to ECDs. The study was based on epidemiological evidence, which, in Europe, is mostly available for diphenyldichloroethene (DDE)-attributable fibroids and phthalate-attributable endometriosis in Europe. Across the EU, attributable cases were estimated to be 56,700 and 145,000 women, respectively. The authors concluded that EDCs (DDE and phthalates) contribute substantially to the almost EUR 1.5 billion annual cost of these reproductive diseases. The estimated cost for fibroids was EUR 163 million, while the costs related to endometriosis accounted for EUR 1.25 billion. Cost estimation was carried out from a societal perspective and included direct costs (e.g., treatment costs) and indirect costs, such as productivity loss[192]. Other health problems that could be caused by the conditions, such as infertility, cancer and autoimmune disorders, were not factored in,

[192] Hunt PA, *et al*., 2016.

leading researchers to conclude that the costs are probably even greater.

3.2 PREGNANCY

During pregnancy women are particularly vulnerable to chemical exposure[193]. This is due to the numerous physiological changes occurring during this unique stage, such as weight gain and increases in blood and plasma volume, both of which can influence chemicals absorption and thus lead to a greater exposure to toxins[194]. Behavioural changes, such as diet modification (e.g., quantity and food type), may also influence the degree of chemical exposure during pregnancy[195]. For instance, according to scientific evidence there is an inverse relationship between weight gain during pregnancy and levels of POPs in pregnant women[196]. Certain behaviours, such as smoking, may also influence chemicals body burden in pregnant women thus triggering adverse health effects for the foetus[197]. In particular, a recent study demonstrated that drinking alcohol or smoking during pregnancy can lead to the development of the attention deficit hyperactivity disorder (ADHD) in children[198].

Avoiding toxic exposure during this vulnerable stage is particularly difficult for women, as chemicals are found in everyday products. Food, for instance, can contain DDT and PVC, which can accumulate in adipose tissues of pregnant women. They are also exposed to the chemicals contained in cosmetics/personal care products, such as sunscreens, cosmetics, fragrances, shower gels and hairsprays[199], as well as to some medicines, that are linked to adverse health outcomes. A recent Spanish birth cohort study found that mothers using acetaminophen (an over-the-counter medication widely used by pregnant women as an antipyretic and analgesic) were more likely to give birth to boys with autism[200].

It is also worth noting that, according to scientific research, pregnant women can be exposed to multiple chemicals at one time. These chemicals may lead to severe health outcomes for both the mother and the child. In particular, exposure to perchlorate, PCBs, polybrominated diphenyl ethers (PBDEs), and triclosan can lead to maternal thyroid hormone disruption, while exposure to mercury, lead and PCBs can damage the developing brain[201].

Significant evidence exists to consider EDC exposure as a risk factor for women's fertility and fecundity, as well as for the trans-generational transfer of undesirable, potentially toxic compounds[202]. The disorders stemming from EDC exposure include disorders of the ovary: aneuploidy[203], PCOS[204], endometriosis[205] and altered cyclicity[206]; disorders of the uterus: uterine fibroids[207]; disorders of placental function and adverse pregnancy outcome: early pregnancy loss, recurring abortion, foetal growth restriction[208]; disorders of the breast: breast cancer, reduced duration of lactation[209] and, finally, the timing of puberty[210].

[193] Woodruff TJ *et al*., 2011.
[194] Pirani BBK & Campbell DM, 1973.
[195] Mirel LB *et al*., 2009.
[196] Bradman A *et al*., 2006.
[197] Takahashi O & Oishi S, 2000.
[198] NHS choices, webpage, 2016.
[199] Witorsch RJ & Thomas JA, 2010.
[200] Avella-Garcia BC *et al*., 2016.
[201] National Research Council, 2008.
[202] Caserta D *et al*., 2011.
[203] Crain DA *et al*., 2008.
[204] Takeuchi T *et al*., 2004.
[205] Cobellis L *et al*., 2003.
[206] Lu LJ *et al*., 2000.
[207] McLachlan JA *et al*., 2006.
[208] Chiaffarino F *et al*., 2006.
[209] Crain DA *et al*., 2008.
[210] Krstevka-Kostantinove M *et al*., 2001.

Pregnant women can be particularly vulnerable to toxicants absorbed through the skin due to the increased vascularity and vasodilatation associated with pregnancy[211]. In fact, chemicals used in cosmetics and personal-care products have been shown to have endocrine-disrupting properties. Ethanolamine compounds, commonly found in shampoos, soaps and facial cleaners, have been demonstrated to be carcinogenic; exposure to synthetic 'fragrances' has been shown to affect the CNS; heavy metals like lead, arsenic and mercury that can be found in personal care products including lipstick, whitening toothpaste and nail polish can also cause various adverse health effects[212]. Note that the risk assessments carried out in the context of the Cosmetics Regulation concerning the use of substances classified as CMR 1A and 1B are supposed to take into account the exposure to those substances of vulnerable population groups, such as pregnant and breast-feeding women, as well as children.

An analysis of National Health and Nutrition Examination Survey data from 2003–2004 found that virtually every pregnant woman in the U.S. is exposed to at least 43 different chemicals[213]. As recalled in paragraph 2.1, prenatal exposure is linked to a range of adverse health effects which can affect the neurological and reproductive system of the child later in life. For instance, prenatal exposure to certain pesticides can increase the risks of developing cancer during childhood[214]. It was also observed from the French ELFE study that pregnant women are particularly exposed to phthalates[215], and findings from the South Korean MOCEH study suggested that prenatal exposure to phthalates may cause neurologic diseases on infants[216].

The FLEHS study demonstrated that lead, arsenic, and thallium are transported to the foetus from the mother. Moreover, prenatal exposure to these chemicals can cause serious adverse health effects on newborns[217].. The MOCEH study shown that the higher the exposure to lead and cadmium s during pregnancy and the lower the children scored on neurodevelopment[218]. The Norwegian MoBa cohort study reported a negative association between maternal exposure to mercury and birth weight[219]. The Japanese Tohoku HBM study also demonstrated the existence of link between maternal exposure to mercury, and motor deficits in infants[220].

All these studies showed the importance of monitoring chemical levels in pregnant women in order to reduce risks of developing hazardous health disorders in newborns.

[211] ATSDR, 2014.
[212] EWG, 2007.
[213] Woodruff TJ *et al*., 2011.
[214] Sutton P *et al*., 2011.
[215] Zeman FA *et al*., 2013.
[216] Kim Y *et al*., 2011.
[217] Baeyens W *et al*., 2014.
[218] Kim Y *et al*., 2013.
[219] Vejrup K *et al*., 2014.
[220] Suzuki K *et al*., 2010.

4 THE ELDERLY AND AN AGEING SOCIETY

The elderly are vulnerable to chemical exposure due to the ageing process, which imposes both physiological and metabolic limitations[221]. Their weakened nervous system limits their ability to absorb or eliminate toxic substances from their bodies. Furthermore, decreased liver and kidney function increases the likelihood of absorbing toxic substances and thus triggering psychiatric and neurological disorders.

As the life expectancy has drastically raised in Europe, a higher percentage of the population is expected to face higher risks stemming from chemical exposure

It is also worth considering that, if concurred to certain medical conditions, chemical exposure can have particular negative effects on the elderly's health[222]. Human biomonitoring programmes have shown that certain metals appear to accumulate in the elderly throughout their lives. For instance, the FLEHS study showed that the highest levels of mercury were found in elderly's blood[223]; the PROBE study also demonstrated that lead and palladium concentrations in blood intensified with age[224]. The Slovenian HBM study found that the blood cadmium, blood lead, and hair mercury levels were highest among older women compared to other adults. Apart from metals, urinary levels of phthalates also appeared to be higher among the elderly population[225].Furthermore, a scientific HBM study from Australia observed that PFOS concentration was higher in the portion of the population aged 60 or older[226]. These findings suggest that the elderly population is highly vulnerable to chemicals as they have more time to absorb toxic compounds during their life which are known to cause a wide range of negative effects on human health. It is therefore paramount to monitor chemical levels within this sub-group of the population through human biomonitoring programmes.

A significant problem among this category of the population is accidental poisoning, either through medication or toxic chemicals. The following factors are likely to increase the risks of swallowing hazardous compounds[227]:

- The elderly's olfactory and gustatory perception is impaired. This problem is particularly relevant among the elderly over 80 years old[228].
- The elderly's impaired vision makes it difficult for them to read warnings and ultimately enhance the risks of ingesting hazardous chemicals[229].
- A study taking into account 45 older adults showed that 55% of respondents reported motor difficulties in handling products, 42% reported memory difficulties, 40% perceptual difficulties, and 29% difficulties with symbol comprehension and text comprehension. All these circumstances may increase the risks for elderly of being exposed to toxic chemicals.[230].
- Unlike young children, the elderly are often alone and under no supervision for prolonged period of times, which makes difficult to intervene promptly in case of accidental ingestion[231].
- In case of accidental ingestion of toxic chemicals, the elderly may not seek for help immediately, for reasons of shame or uncertainty[232].
- When disoriented - due to illnesses or medications - elderly often lack the ability to distinguish

[221] Wagner W *et al*., 2008.
[222] Ibid.
[223] Croes K *et al*., 2014.
[224] Alimonti A *et al*., 2011.
[225] Lee KM *et al*., 2011.
[226] Toms LML *et al*., 2009.
[227] SCCS, 2011.
[228] Doty RL *et al*.1984.
[229] Parsons SO *et al*. 1999.
[230] Mayhorn CB *et al*., 2004.
[231] SCCS, 2011.
[232] SCCS, 2011.

between hazardous and not hazardous products,[233].

In addition, the elderly often spend the majority of their time indoors, which is the main site contributing to exposure to air pollutants[234]. Furthermore, inadequate ventilation in elderly care centres further increases the degree of absorption of toxic substances[235].

[233] Klein-Schwartz W & Oderda GM, 1991.
[234] Shusterman D *et al*., 2003.
[235] Almeida-Silva M *et al*., 2014.

5 OCCUPATIONAL GROUPS

Several substances used at the workplace can have toxic properties and are thus capable of causing lifelong damages to workers. Moreover, these substances may not always be easy to identify. Toxic compounds can be found in paints and glues, cleaning fluids, as well as in food being left exposed at the workplace. For instance, according to recent scientific evidence, exposure to flour dust may cause adverse health outcomes ranging from conjunctivitis to baker's asthma[236].

In order to protect workers from these risks, the European legislation sets out health and safety measures, and especially rules to limit the exposure to hazardous chemicals at the workplace[237].

Moreover, in the EU, supplied chemicals must have accompanying safety data sheets, which include information about the properties of the substance, its hazards, instructions for handling, as well as exposure control measures[238]. However, many harmful substances are process-generated materials, and as such can't require safety data sheets. For example, stone dust contains respirable crystalline silica, which can cause irreversible effects on workers' lungs, while wood dust can cause asthma. Both of these types of dust can also cause cancer[239].

It is worth noting that certain categories of workers are intrinsically more vulnerable than others, such as migrant workers, young workers and those with certain medical conditions. Other workers, instead, can be vulnerable only during specific period of time, for instance when conducting work activities (e.g. maintenance work) which expose them to particularly hazardous chemicals)[240].

Among the reasons which make certain workers more vulnerable to the risks of chemical exposure there are[241]:

- constant exposure to hazardous chemicals in certain occupation;
- language barriers which may hamper access to health and safety information;
- Poor working conditions which increase the likelihood to be exposed to toxic chemicals;
- conduction of high-risk, non-routine activities involving chemical exposure;
- exposure to multiple lower level exposures;
- Lack of training or experience on safety standards;
- Lack of access to preventative services;
- Working at client premises with unregulated conditions.

The most significant route of exposure is inhalation, i.e. breathing air contaminated with dangerous substances. Dangerous substances can become airborne through several ways. For instance, liquid can become easily vapour if the temperature at the workplace is high. Moreover, solvents can quickly contaminate the working environment, if the latter is not sufficiently ventilated. Others examples according to which indoor air might be contaminated include: spray applications or fusion of metals at elevated temperatures[242].

Dermal (skin) exposure to hazardous chemicals is another common route of exposure at the workplace, either as a result of direct effects on the skin, or through the absorption of chemicals into the body. Dermal exposure often happens via direct contact to contaminated items, surfaces or objects. Jobs where the risks of dermal exposure are higher including degreasers, painters, hairdressers, and

[236] Stobnicka A & Górny RL, 2015.
[237] Council Directive 98/24/EC.
[238] For more information, see: REACH Regulation (EC) No 1907/2006.
[239] IARC, 1995.
[240] EU-OSHA, oshwiki.
[241] EU-OSHA, oshwiki.
[242] Keen C, 2016a.

fruit pickers. The degree of exposure may vary according to the circumstances. Well known chemicals that are capable of being absorbed through the skin are mercury, isocyanates, polychlorinated biphenyls (PCBs), acrylates, and nicotine[243].

Work-related ingestion of hazardous substances usually occurs in one of the following ways:

- ingestion of contaminated food or beverages;
- (contamination via hand-to-mouth or object-to-mouth contact;
- contaminants which accumulate around the mouth and into the oral cavity.

Substance groups which are of particular concern as far as ingestion at the workplace is concerned are metals, pesticides, pharmaceuticals, infectious agents, radionuclides, as well as certain molecular weight materials which can cause allergenic reactions. Some of the substances are also suspected to be carcinogens[244].

Secondary Exposure

Secondary exposure refers to situations where work activities may cause exposure to toxic compounds to people which are not directly employed. For instance, secondary exposure happens when workers inadvertently transfer toxic compounds outside of their workplace. Secondary exposure is of a particular concern insofar it can increase hazardous exposure for the general population, and especially for certain groups which are already intrinsically vulnerable[245].

One of the most common cases of secondary exposure happen when workers bring contaminated clothing home. This situation has the potential to extent exposure to toxic compounds to vulnerable groups such as young children, elderly and pregnant women[246].

Scientific findings demonstrate that workers who were in contact with asbestos and brought contaminated clothing at home, increased the risks for their families of contracting asbestos related cancer. The same situation, but with different health effects, has been registered in the case of workers exposed to lead who brought contaminated food or objects into their homes[247]. Farmers exposed to pesticides created secondary exposure and thus triggering a wide range of negative health effects for their families through overspray or spray drift[248].

The sections below analyse the categories of workers that need special attention and protection.

Migrant workers

According to the International Labour Organisation (ILO) migrant workers are particularly vulnerable to chemicals for a variety of reasons[249]:

- Higher risks: migrant workers usually work in poorer conditions than local workers. For instance, migrant workers are often employed in higher risk sectors, such as farming and construction. These jobs involve working with dangerous substances, such as pesticides or silica dust, that further increase the risk of toxic exposure[250].
- Language barriers: migrant workers usually work in environments where the language employed is not their native one; this circumstance creates language barriers which can significantly hamper

[243] Grandjean P, 1990.
[244] Cherrie JW *et al.*, 2006.
[245] Keen C, 2016b.
[246] Keen C, 2016b.
[247] Thompson B *et al*., 2003.
[248] Keen C, 2016b.
[249] ILO, 2004.
[250] Eurofound, 2007.

communication of written and verbal occupational safety and health (OSH) information. If migrant workers are not in the position to understand safety regulations, they will likely receive higher exposure to toxic chemicals[251].

- Cultural issues: workers moving to more developed countries may not be used to different health and safety standards. This may result in a different culturally based risk perception which may ultimately increase their exposure to dangerous substances[252].
- Longer working hours and a tendency to regularly work overtime: the longer the time workers spend with dangerous substances, the higher their chances of being exposed to toxic substances[253].

Young workers

According to the ILO, young workers are those within the age group of 15 to 24 years[254]. This subgroup thus includes adolescents. All of the categories included in this subgroup have one thing in common: they are all relatively immature and lack experience in the workplace, which means they may not always be fully aware of OSH regulations and the risks around them. As a result, young workers are 50% more likely to experience accidents at work[255]. In order to protect this category, which is uniquely vulnerable to chemical exposure, specific EU legislation was adopted[256].

The reasons for the increased risk among young people when working with dangerous substances are given below:

- Unique vulnerability: during this particular stage young people are still developing their mental and physical conditions[257].
- Increased susceptibility: data indicate that allergic reactions (such as asthma) and work-related skin disorders are higher among young workers. Moreover, lead exposure may be especially harmful to young people, given its effects on the development of the nervous system[258].
- Employment in high-risk sectors: young workers are often employed in temporary or precarious jobs and in industries that are acknowledged to be more hazardous than others, such as agriculture, construction, transport, and hairdressing. For instance, young workers tend to be employed on farms, where they could be exposed to toxic substances such as pesticides. Young workers are also employed in low-skilled manufacturing jobs or the construction sector, with the potential for exposure to a range of dangerous substances[259].
- Lack of awareness of health and safety issues: young people lack experience in the workplace and are often unfamiliar with safety standards. This leads them to take greater risks than older people, magnifying their exposure to chemical substances. The risks stemming from toxic exposure are also exacerbated in situations where young workers receive little or no appropriate supervision or training[260].

Maintenance workers

Maintenance is defined as a 'combination of all technical, administrative and managerial actions during the life cycle of an item intended to retain it in, or restore it to, a state in which it can perform the required function'[261]. Since maintenance operations take place in various sectors, from the chemical industry to manufacturing and agriculture, maintenance workers may come into contact with

[251] Guldenmund FW *et al*., 2010.
[252] Renn O & Rohrmann B, 2000.
[253] ILO, 2004.
[254] ILO, 2012.
[255] EU-OSHA, webpage 'young workers'.
[256] Council Directive 94/33/EC.
[257] See Chapter 3.
[258] EU-OSHA, 2016.
[259] EU-OSHA, 2007.
[260] EU-OSHA, 2016.
[261] EU-OSHA, 'young workers', available at: https://osha.europa.eu/en/themes/young-workers.

wide range of dangerous substances. Generally, the following three major sources of exposure can be identified:

- Exposure through products that need to be used in certain operations (e.g. detergents, solvents, acids, etc.)[262];
- Exposure via contact with substances that are generated by the products during the maintenance operations, such as welding fumes, diesel exhaust, and dust[263];
- Exposure through compounds that may be encountered during the maintenance process, such as lubricants and hydraulic fluids, dusts, ammonia, poisonous gases, etc.[264].

As a consequence, maintenance workers may be exposed to all of the substances that have been identified as 'emerging chemical risks' by EU-OSHA: ultrafine particles, diesel exhaust, nanoparticles, man-made mineral fibers, isocyanates, epoxy resins silica and wood dust[265]. Among the maintenance activities which involve exposure to hazardous substances are[266]:

- Cleaning activities (exposure to detergents and acids);
- Metal degreasing (exposure to solvents);
- Painting (exposure to dust, ammonia, solvents and detergents);
- Welding (exposure to gases);
- Vehicle repair activities (exposure to solvents, isocyanates, and polyester resin);
- Maintenance of façades of buildings (exposure to acids, solvents, lyes);
- Maintenance of refrigeration and cooling systems (exposure to ammonia, propane/butane);
- Maintenance of swimming pools (exposure to toxic chlorine gas);
- Road maintenance (exposure to asphalt fumes, and traffic exhaust);
- Maintenance of diesel motor exhaust (exposure of gases and particles).

As the toxic substances to which a maintenance worker may be exposed are various, so too are the health effects associated with such exposures. For instance, skin contact with acids or dyes may lead to acute irritation or burns; detergents, epoxy resins, isocyanates, cement, oils and greases may cause irritant contact dermatitis (eczema).

Inhalation of chlorine or ammonia may result in acute irritation of the airways. Wood dust exposure may also lead to bronchitis[267]; exposure to isocyanates may cause asthma[268]. Exposure to silica and diesel motor exhaust may contribute to the development of lung cancer[269]. Additionally, the inhalation of hazardous substances in maintenance activities might lead other additional health effects. For instance, exposure to solvents may lead to neurological diseases, such as chronic toxic encephalopathy[270].

Given the several routes of exposure, as well as the multiple substances that they may encounter, maintenance workers are a subcategory of the population which is particularly vulnerable to chemicals.

New workers

New workers are also particularly sensitive to chemical exposure. The reasons of their highly vulnerability is explained below:

[262] EU-OSHA, 2012.
[263] EU-OSHA, 2012.
[264] EU-OSHA, 2012.
[265] EU-OSHA, 2009.
[266] EU-OSHA, 2012.
[267] EU-OSHA, 2009.
[268] Pronk A, 2007.
[269] Tjoe Nij E, 2003.
[270] Meyer-Baron M, 2008.

- Lack of training: new workers are often not sufficiently equipped with the necessary information about the possible routes of exposure trough which toxic for the substances may enter in their body, as well as the associated negative health consequences. New workers also lack of the adequate level of supervision; this circumstance further increases their risks of being exposed to hazardous compounds[271].
- Increased susceptibility: new workers may experience symptoms at levels of exposure which do not cause any effects to more established workers[272].

[271] EU-OSHA, oshwiki.
[272] EU-OSHA, oshwiki.

6 OTHER VULNERABLE GROUPS

The following chapter sets out some of the other vulnerable groups that should be considered when putting in place protection measures against chemical exposure.

Lower socioeconomic groups

According to research in the U.S., some communities (e.g., low income, minority, indigenous groups) bear multiple sources of chemical exposure associated with where they live, work, or play which can increase their risk of adverse health outcomes. For instance, some studies have found that low-income or indigenous populations often live in areas where the concentration of pollution is higher (e.g., near high-traffic roadways, industrial site, hazardous waste site) than the average population, which increases their risk of being exposed to hazardous chemicals. Hence, factors such as level of income, and/or occupation) together with lifestyle may have indirect effects on the degree of exposure to toxic compounds and consequently on health status. It is also worth noting that people with low incomes may not have the same level of education or access to health care as those in higher socioeconomic groups [273].

These results are also confirmed by the findings of the Environmental Justice Movement, according to which chemical concentrations in the body are higher where people face hazards in their social environments[274]. The Environmental Justice Movement emerged in the 1980s and believes that all citizens, regardless of their socioeconomic status, should equally share burdens of environmental hazardous chemicals[275]. The major focus of the Environmental Justice Movement is individuals in lower socioeconomic groups, as, according to research, they are the category of the population which are particularly vulnerable to environmental toxicants. In fact, certain diseases – such as cancer, asthma and diabetes - appear more within the population having a low socioeconomic status[276]. Evidence also suggests that there is social disparity concerning certain chemicals, with higher exposure to lead[277], pesticides[278] and polychlorinated biphenyls[279] identified in specific sub-groups of the population.

A recent study has further investigated the link between socioeconomic status and chemical concentrations in the body, finding that chemicals concentration affects the whole population across the poverty spectrum, and not just those from economically deprived backgrounds as previously thought[280].These findings also contradict the environmental justice hypothesis, which states that the lower is the socioeconomic status, the higher is the concentration of chemicals in the body. Instead, this study shows that lifestyle and diet are the factors which play a major role as far the accumulation of chemicals in the body is concerned[281].

While this study should be taken into account, recent research also shows link between two chemicals and socioeconomic status. Poor people are in fact more likely to accumulate higher levels of BPA, while wealthier people are more likely to show concentration of perfluorinated compounds (PFCs). BPA exposure is particularly harmful for the human body, as it may lead to behavioural impacts, developmental changes that increase the risk of mammary and prostate tumours, decreased sperm count and increased risk of Type 2 diabetes and obesity[282]. These results also reflect the findings

[273] EPA, 2000.
[274] Brown P, 1995.
[275] Pijawka DK *et al*., 1998.
[276] Zheng H & Land KC, 2012.
[277] Iqbal S *et al*., 2008.
[278] Cox S *et al*., 2007.
[279] Vrijheid M *et al*., 2012.
[280] Tyrrell J *et al*., 2013.
[281] Ibid.
[282] Nelson JW *et al*., 2012.

published in a study issued in 2007[283].

People with medical conditions and/or disabilities

People with medical conditions, or those with a disability, may also have particular susceptibilities to chemical exposure. In fact, certain medical conditions can make people more vulnerable to hazardous chemical exposure.

For instance, atopic people have higher risks of developing respiratory diseases after inhaling irritant materials[284]. People suffering from cardiovascular diseases are more vulnerable to particles[285], and people having respiratory diseases are more susceptible to several air pollutants[286]..

Furthermore, medical conditions may result from occupational exposure. For example, certain substances can cause sensitisation if individuals are constant exposed to them. The skin or respiratory system are often affected by such substances which can trigger dermatitis, asthma and allergic alveolitis. respiratory sensitization, in few cases, can also cause death[287].

Lastly, transient medical conditions, which are medical conditions that are not permanent and are not necessarily caused by work, can make affected workers more vulnerable. For instance, workers with damaged skin are more susceptible to dermal exposure. Through the damaged skin chemicals can easily enter into the body and circulate into the blood stream thus causing adverse health effects on human health[288].

[283] Calafat AM *et al*., 2008.
[284] Droste J *et al*., 2003.
[285] WHO, 2003b.
[286] WHO, 2005.
[287] EU-OSHA, oshwiki.
[288] EU-OSHA, oshwiki.

7 REGULATING AND ASSESSING CHEMICAL EXPOSURE OF VULNERABLE POPULATIONS

The protection of vulnerable groups from the health risks of chemical exposure has been addressed at the EU and global level through a variety of initiatives and actions. The following sections set out the state of play with regard to the current legislative framework and assessment methods, such as risk assessment and biomonitoring.

7.1 LEGISLATIVE FRAMEWORK

7.1.1 Regulation of chemicals and the exposure of vulnerable groups

Chemicals are regulated through a dense network of legislation at a number of levels. At the international level, chemicals are primarily addressed by the Strategic Approach to International Chemicals Management, which defines a policy framework to foster sound global management of chemicals[289]; the Globally Harmonised System of Classification and Labelling of Chemicals, which provides for uniform physical, environmental, and health and safety information on hazardous chemical substances[290]; the Stockholm Convention, a global treaty to protect human health and the environment from persistent organic pollutants (POPs)[291]; the Rotterdam Convention, a multilateral treaty promoting shared responsibility and cooperative efforts among parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm[292]; the Basel Convention, an international treaty to reduce the movements of hazardous waste between nations, and specifically to prevent transfer of hazardous waste from developed to less developed countries[293]; and the Montreal Protocol, which was designed to reduce the production and consumption of ozone-depleting substances[294].

The EU has compiled a comprehensive legal and regulatory framework to ensure a high level of protection for human health and the environment, while preventing barriers to trade. EU chemicals legislation applies to all industry sectors dealing with chemicals and along the entire supply chain, making companies responsible for the safety of chemicals they place on the market. The legislation put in place consists of rules governing the marketing and use of chemical products, major accidents and exports of dangerous substances, as well as restrictions on marketing of specific hazardous substances[295].

Substantial progress has been achieved in the management of chemical substances in Europe since 2006, when the EU adopted its flagship regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[296]. The Classification, Labelling and Packaging Regulation (CLP)[297] also ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the EU through classification and labelling of chemicals. EU chemicals legislation is spearheaded by REACH and CLP, which address chemicals horizontally. Particular groups of chemicals, such as biocides, pesticides, pharmaceuticals or cosmetics, are regulated through

[289] Strategic Approach to International Chemicals Management, 2006.
[290] United Nations, Globally Harmonised System of Classification and Labelling of Chemicals, 2011.
[291] Stockholm Convention on Persistent Organic Pollutants, 2001.
[292] Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, 2004.
[293] Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, 1992.
[294] Montreal Protocol on Substances that Deplete the Ozone Layer, 1989.
[295] European Parliament, webpage, EU Fact Sheets, Chemicals.
[296] REACH Regulation (EC) N0 1907/2006.
[297] CLP Regulation (EC) N0 1272/2008.

specific pieces of legislation[298].
No single comprehensive legal framework exists that specifically addresses the protection of vulnerable groups from the risks of chemical exposure. Instead, a range of provisions, spread across different legal sources, refer to the importance of protecting vulnerable people from chemical exposure. Most of these provisions stress the need to protect vulnerable groups in a general way, such as recital 12 of the REACH Regulation, or recital 8 of the Plant Protection Products Regulation[299]. Other provisions are more specific, and require concrete actions to be taken, such as Article 33 of the CLP Regulation which establishes that '*packaging containing a hazardous substance or a mixture supplied to the general public shall not have either a shape or design likely to attract or arouse the active curiosity of children*'[300], or article 6 of Council Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding, which prevents pregnant and breastfeeding workers to be obliged to perform duties for which the assessment has revealed a risk of exposure of toxic chemicals[301].

Other than these, often vague, references to vulnerable groups included in chemicals legislation, there is no clear definition of the groups in society that require specific attention and/or protection. At international level, the WHO uses the following definition for vulnerable groups in relation to chemicals[302]:

Box 5: WHO Definition of 'vulnerable groups' in relation to chemical exposure

'Susceptible subpopulations exist in all groups of individuals. Such susceptible subpopulations may have a greater inherent risk of suffering adverse health effects from a chemical incident, for example, because:

- *- their exposure thresholds for health effects are lower;*
- *- they receive a relatively high exposure;*
- *- their mobility is reduced or their ability to protect themselves from exposure is reduced.*

Some common examples of populations that must be considered when evaluating population susceptibility are children, pregnant women, elderly persons, hospital patients and people with low socioeconomic status. The actual list will vary by location and by toxic end-point to be considered.'

While this definition offers a strong basis for describing those population groups that are particularly vulnerable to chemical exposure, it does not encompass all groups identified in this study. For example, women of childbearing age are not covered by the WHO definition. Secondly, the definition does not refer to specific windows of vulnerability, which are especially important when considering the vulnerability of the foetus and children.

At EU level, specific definitions of vulnerable groups in relation to chemical exposure have been defined in two regulations: The Plant Protection Products Regulation[303] and the Biocidal Products Regulation[304]. Again, while these definitions offer a good basis, they do not cover all vulnerable groups identified by the literature review conducted as part of sub-study c.

Box 6: EU legislation definition of 'vulnerable groups' in relation to chemical exposure

Article 3 of the Plant Protection Products Regulation:

[298] For more information, see Table 2 below.
[299]. More information is available in Table 2 below.
[300] CLP Regulation (EC) N0 1272/2008.
[301] Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding.
[302] WHO, 2009.
[303] Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market.
[304] Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

'…Persons needing specific consideration when assessing the acute and chronic health effects of plant protection products. These include pregnant and nursing women, the unborn, infants and children, the elderly and workers and residents subject to high pesticide exposure over the long term- their exposure thresholds for health effects are lower.'

Article 3 of the Biocidal Products Regulation:

'…Persons needing specific consideration when assessing the acute and chronic health effects of biocidal products. These include pregnant and nursing women, the unborn, infants and children, the elderly and, when subject to high exposure to biocidal products over the long term, workers and residents.'

A review of the relevant international and EU chemicals legislation was conducted for the current study, which analysed which pieces of legislation refer to the importance of protecting or considering vulnerable groups. The results of this review are described in the following two sections. In the first instance, the regulations and other legislative documents that refer to vulnerable groups are described and set out, followed by an overview of the chemicals legislation that does not consider vulnerable groups even though it would be relevant to do so.

7.1.2 Chemical legislation containing reference to vulnerable groups

The following table lists the chemical legislation – both international and European – which makes specific reference to vulnerable groups. It sets out the general legal framework, as well as specific pieces of legislation that are relevant to certain types of vulnerable groups: children, pregnant and breastfeeding women, the elderly, workers, people with medical conditions and/or disabilities, and lower socioeconomic groups. The table shows for each of the pieces of legislation described, the category of vulnerable groups addressed. More specifically, those provisions that refer to vulnerable groups directly, or that include a reference relevant to the protection of vulnerable groups, have been listed in the right-hand column.

Table 6: Overview of relevant EU and international chemicals legislation and their provisions concerning vulnerable groups

Chemicals legislation [305]	G	C	PB	E	W	O	Comments/Remarks
General chemicals framework, international level							
2001, Stockholm Convention on Persistent Organic Pollutants (POPs)		x	x		x	x	▪ Non-binding provision recognising the health concerns stemming from the impact of women's exposure to POPs (**recital**). ▪ Provision on the development of educational and public awareness programmes and training - especially for children, women, workers and the least educated - on POPS, their health and environmental effects and the alternatives (**Art. 10(c)**).
2004, Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade					x		▪ General non-binding provision on the need to protect human health of consumers and workers (**preamble**); ▪ Provision on the requirements for notifications of the procedures for banned or restricted chemicals. The notification shall include a summary of the hazards and risks presented by the chemical to the health of consumers and workers (**Annex I, point 2**)
2006, Strategic Approach to International Chemicals Management (SAICM)		x	x	x	x	x	▪ General provisions on the need to protect vulnerable groups by reducing the risks from hazardous chemicals and making scientific information available for appropriate risk assessments (**point 9 and 23 Dubai Declaration**; **point 7 and 15 of the Overarching Policy Strategy**).
2013, Minamata Convention on Mercury		x	x				Provisions on: ▪ Adopting science-based health guidelines relating to exposure to mercury (**Art. 16**); ▪ Setting targets and developing strategies to reduce mercury exposure (**Art. 16 + Annex C**); ▪ Promoting education, training and public awareness of the effects of exposure to mercury (**Art. 16**); ▪ Monitoring the levels of mercury in vulnerable populations (**Art. 19**).
General framework, EU level							
Regulation (EC) 1907/2006 (REACH)	x	x	x		x		▪ General non-binding provisions on the need to protect vulnerable groups (**recital 12, 69**); ▪ Provisions on identifying different DNELs for certain vulnerable groups (**Annex I, point 1.4.1**); ▪ Provisions on the restriction of marketing substances that might be harmful for children or workers (**Annex XVII, point 30, 31, 52, 59**); ▪ Provisions on the standard information requirements for certain substances that might be harmful for the foetus (**Annex VIII, point 8.7.**)
Regulation (EC) No 1272/2008 (CLP)		x	x				▪ Provision stressing that packaging containing a hazardous substance or a mixture supplied to the general public shall not have either a shape or design likely to attract or arouse the active curiosity of children (**Art. 33**); ▪ Special rules for labelling and packaging of mixtures or substances that can harm children, such as lead, cyanoacrylates, (**Annex II, 2.1, 2.2**); ▪ Provision on precautionary statements to be used in labelling of hazardous substances in order to protect children (**Annex IV**); ▪ Classification and labelling requirements for hazardous substances and mixtures and the need to protect pregnant women (**Annex I, point 3.7.1.4.**)
Regulation (EC) 1107/2009 on plant protection products (PPP)		x	x	x	x	x	▪ General non-binding provisions on the need to protect vulnerable groups (**recital 8, 24**); ▪ Provision on the definition of vulnerable groups (**Art. 3, point 14**); ▪ Binding provision specifying that the residues of PPP shall not have any harmful effects on vulnerable groups (**Art.3(2)** and **(3)**); ▪ Provisions on the advertising of PPP and the need to protect children (**Art. 66**); ▪ Provisions on the requirements of the authorisation of the PPP and the need to protect workers (**Art. 31**); ▪ Provision on different risk assessments for workers (**Annex IV, point 2**).
Regulation (EU) 528/2012 on biocidal products		x	x	x	x	x	▪ General provisions on the need to protect vulnerable groups (**recital 3, Art. 1, Annex VI, point 24, 32, 59**); ▪ Provision on the definition of vulnerable groups (**Art. 3**); ▪ Provision on conditions for granting an authorisation and the need to protect vulnerable groups (**Art. 19**); ▪ Provision on the possibility for a Member State to derogate from mutual recognition to protect vulnerable groups (**Art. 37**); ▪ Provision on the obligation for notification of new data on adverse effects for vulnerable groups (**Art. 47**); ▪ Provision on the possibility for a competent authority to derogate from Art. 19 – while always preventing harmful effects for vulnerable groups (**Art. 55(3)**).

[305] **G:** Reference to vulnerable groups in General; **C**: Reference to Children (and/or the foetus) as a vulnerable group; **PB**: Reference to Pregnant or Breastfeeding women as a vulnerable group; **E:** Reference to the Elderly as a vulnerable group; **W**: Reference to Workers as a vulnerable group; **O**: Reference to Other types of vulnerable groups.

Chemicals legislation [305]	G	C	PB	E	W	O	Comments/Remarks
							▪ Provision on the obligation for a Member State to report to the EC any occupational diseases in respect of vulnerable groups (**Art. 65**); ▪ Provision on labelling biocidial products and the appropriate warnings for vulnerable groups, which shall not be attractive for children (**Art. 68, Art.69**); ▪ Provision according to which a Member State, when it has justifiable grounds to consider that a biocidal product constitutes a serious risk to vulnerable groups, may take appropriate prevention measures (**Art. 88**).
Directive 2001/83/EC on the Community code relating to medicinal products for human use		x	x	x		x	▪ Provision on the obligation to review safety data taking into account guidelines published by the Commission, with particular attention to events resulting in changes of dose or need for concomitant medication, serious adverse events, events resulting in withdrawal, and deaths. In these cases, particular attention shall be given to vulnerable groups (**Annex I, point 5.2.5.1**); ▪ Provision on the labelling, packaging and advertising of medicinal products and the need to protect vulnerable groups (**Art. 54, 59, Art.90**).
Directive 2008/50/EC on ambient air quality and cleaner air for Europe		x					▪ Provision on the need to include specific measures as well as drawing up short-term action plans to protect vulnerable groups (**Art. 23, 24, Annex XV, letter B, point 3(h)**).
Regulation (EC) 850/2004 on Persistent Organic Pollutants (POPs)					x		▪ Provisions on developing awareness programmes and training on POPs for vulnerable groups (**recital 19, Art. 10**).
Regulation (EC) 1223/2009 on cosmetic products		x	x	x		x	▪ Provisions on substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) should also take into account the exposure to those substances of vulnerable groups (**recital 34, Art. 15**); ▪ Provision on the information contained in the cosmetic product safety report and the need to protect vulnerable groups (**Annex I**); ▪ Provision on substances prohibited in cosmetic products in order to protect children (**Annex II** and **Annex III**).
Directive 2001/95/EC on general product safety		x		x			▪ Provisions which specify that the safety of products should be assessed, taking into account the categories of consumers which can be particularly vulnerable to the risks posed by the products, such as children and the elderly (**recital 8, Art. 2(b)**).
Regulation (EU) 1169/2011 on the provision of food information to consumers		x	x				▪ Specific provision for foods with certain chemicals that may not be nutritionally appropriate for breastfeeding women and children under the age of 5 years (**Annex III**).
Directive 93/42/EEC on medical devices		x	x				▪ Specific provision on the requirements for the design and construction of the medical device, and the need to reduce to a minimum the risks posed by toxic substances leaking from the device for children or pregnant women (**Annex I, point 7.5**)
Regulation (EC) 1333/2008 on food additives		x					▪ Binding provision specifying that food additives shall not be used in foods for infants and young children except where specifically provided for in Annex II to this Regulation (**Art. 16**); ▪ Binding provision in the Annex specifying the list of food colours for which the labelling of foods shall include additional information (**Annex V**).
Regulation (EC) 1881/2006 setting maximum levels for certain contaminants in foodstuffs	x	x					▪ Non-binding provision on setting lower maximum level for certain food contaminants to which vulnerable groups are exposed in order to protect them (**recital 4, 23, 45, 56**); ▪ Non-binding provision which suggests that targeted consumer advice is an appropriate approach in the case of methylmercury for protecting vulnerable groups of the population (**recital 43**); ▪ Specific provision on setting maximum levels for cetin contaminants in foodstuffs to which children are exposed (**Annex**).
Regulation (EC) 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin	x	x					▪ Non-binding provision which specifies that maximum residue levels should be set at the lowest achievable level consistent with good agricultural practice for each pesticide, with a view to protecting vulnerable groups such as children and the unborn (**recital 5**); ▪ Specific provision defining maximum residue level' (MRL) which is the upper legal level of a concentration for a pesticide residue in or on food or feed set in accordance with this Regulation, based on good agricultural practice and the lowest consumer exposure necessary to protect vulnerable consumers (**Art. 3(d)**).
Specific legal framework for children, international and EU level							
1990, UN Convention on the rights of the child	x						▪ General provision on the right of the child to enjoy the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. Since States Parties shall pursue full implementation of this right, this provisions can be considered a legal basis to protect children from the harmful effects of chemicals (**Art. 24**).

Chemicals legislation [305]	G	C	PB	E	W	O	Comments/Remarks
Directive 2009/48/EC on the safety of toys		x					▪ Non-binding provision on the need to adopt specific safety requirements to protect children against risks caused by carcinogenic, mutagenic and repro-toxic (CMR) substances in toys (**recital 21, 25**); ▪ Provision which obliges manufacturers to carry out assessment procedures before placing a toy on the market (**Art. 18 + recital 35, 47**); ▪ Provision specifying that the Commission may adopt specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth (**Art. 46(2) + recital 22, 24 + Appendix C**); ▪ Provisions setting out particular safety requirements for the chemical properties of toys intended for use by children (**Annex II, point II and III**); ▪ Provisions on warning and indications of precautions to be taken when using certain categories of toys (**Annex V, part B, point 4**).
Regulation 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control	x	x					▪ Non-binding provision on setting the MRL of pesticides in food for infants at the lowest achievable level to protect vulnerable population groups (**recital 21**); ▪ Non-binding provision stressing the need to take into account the restriction and prohibitions of certain pesticides classified in accordance with Regulation (EC) No 1272/2008 in the delegated acts adopted pursuant to this Regulation (**recital 22**); ▪ Non-binding provision stressing that, in the interest of protecting vulnerable consumers, labelling requirements should ensure accurate product identification for consumers (**recital 26**).
Specific legal framework for pregnant women, international and EU level							
//							▪ No specific international legislation was identified. However, pregnant women are mentioned in the general international framework.
Directive 92/85/EEC pregnant workers		x	x		x		▪ Provision preventing pregnant and breastfeeding workers to be obliged to perform duties for which the assessment has revealed a risk of exposure of toxic chemicals (**Art. 6**); ▪ Provision obliging the employer to assess the nature, degree and duration of exposure for all activities likely to involve a specific risk of exposure to the agents, processes or working conditions for which a non-exhaustive list is given in Annex I (**Art. 4 + Annex I, point 3**).
Specific legal framework for the elderly, international and EU level							
//							▪ No specific international or EU legislation could be found. However, the elderly are mentioned in the general international framework and specific provisions are available in the EU general legal framework.
Specific legal framework for workers, international and EU level							
1990, ILO Chemicals Convention No. 170, concerning Safety in the use of Chemicals at Works					x		▪ Provision on labelling hazardous chemicals in a manner that is easily understandable to workers (**Art. 7**); ▪ Provisions on the responsibilities of employers, notably in respect of identification (**Art. 10**), transfer of chemicals (**Art. 11**), exposure (**Art. 12**), operational control (**Art. 13**), information and training (**Art. 15**); ▪ Provisions on the duties and rights of workers concerning chemicals (**Art. 17 and 18**).
Directive 98/24/EC on risks related to chemical agents at work					x		Directive lays down minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents present at the workplace or as a result of any work activity involving chemical agents. Specific provisions include: ▪ Occupational exposure limit values and biological limit values (**Art. 3**); ▪ Employers' obligations, e.g. determination, assessment, prevention of risk associated with hazardous chemical agents, as well as specific protection and prevention measures and information and training that the employer shall carry out (**Art. 4, 5, 6, 7, 8**); ▪ Prohibition of certain chemical agents at work (**Art. 9 and Annex III**); ▪ Health surveillance (**Art. 10 and Annex II**).
Directive 2004/37/EC carcinogens or mutagens at work					x		Directive laying down the minimum requirements for the protection of workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens or mutagens at work. Specific provisions include: ▪ Employers' obligations (**Art. 4, 5, 6, 7, 8, 9, 10, 11, 12, 13**); ▪ Health surveillance (**Art. 14 and Annex II**); ▪ Limit values for occupational exposures (**Art. 16 and Annex III**).
Directive 94/33/EC on young people at work		x			x		▪ Provisions on the general obligations on employers to adopt the measures necessary to protect the safety and health of young people, also taking into account the nature, degree and duration of exposure to physical, biological and chemical agents (**Art. 6**); ▪ Provision prohibiting Member States from employing young people for work involving harmful exposure to chemicals (**Art. 7 and Annex**).

Chemicals legislation [305]	G	C	PB	E	W	O	Comments/Remarks
Directive 2009/148/EC protection of workers from the risks related to exposure to asbestos at work					x		Directive laying down the minimum requirements for the protection of workers against risks to their health, including the prevention of such risks, arising or likely to arise from exposure to asbestos at work.

The table shows that, currently, only two pieces of EU legislation provide a definition of the term 'vulnerable groups'. These are the Plant Protection Products Regulation and the Biocidal Products Regulation. It could be worth considering adding provisions defining which particular 'vulnerable groups' may need special protection to relevant EU legislation. For instance, while the CLP Regulation refers to children and pregnant women as vulnerable categories, other relevant categories such as the elderly and workers are not mentioned and therefore arguably not given adequate attention in the Regulation.

Another area that could be considered in EU legislation are the specific windows of vulnerability that exist for certain vulnerable groups. For instance, the different EU Regulations and Directives analysed only refer to children as a general category, without distinguishing between neonates, infants, toddlers and adolescents. Referring to these different windows of vulnerability in the legislation seems an option worthy of consideration, given the particular vulnerability of foetuses, neonates and infants. At the very least it would seem important to provide sufficient safety margins to foetuses and neonates, the most vulnerable among the vulnerable categories, particularly for those chemicals suspected of being neurotoxins or endocrine disrupters. As shown by the scientific evidence described in this report, there is a need to protect children from hazardous chemical exposure from the very early stages of their development. Particular exposure of the foetus can result in significant health impacts that affect their entire life[306].

The types of protection from chemical exposure that can be offered to vulnerable groups by EU legislation can be grouped into four different categories: (1) legislation related to work, (2) legislation related to food, (3) legislation related to products; and (4) legislation related to the environment (air). This grouping is not incidental but, rather, reflects the routes through which vulnerable groups are exposed[307]. In each of these groups there is EU legislations that considers vulnerable groups, as well as other EU legislation that, while sharing the same objectives, does not include vulnerable groups in its provisions. For instance, in the 'food' group, there are pieces of EU legislation which refer to vulnerable groups (e.g. Food Additives Regulation) and other EU legislation that - despite being directly related to specific circumstances or environments in which the protection of vulnerable groups is a consideration - do not provide any references to vulnerable populations (e.g. Novel Food Regulation, and Food Contact Materials Regulation). For the sake of consistency, therefore, it would be worth reviewing these groupings of legislation in order to identify if references to vulnerable groups should be included in all legislation belonging to the four categories mentioned above.

This study identified the following types of provisions to protect vulnerable groups:

- Lowering the level of exposure or setting maximum levels of exposure;
- Marketing restrictions and general prohibitions;
- Authorisation procedures;
- Risk assessment rules;
- Information requirements (labelling/packaging/advertising);
- Manufacturing obligations and safety requirements (design and construction);
- Obligations for employers (training and awareness raising programmes);
- Member States' obligations and rights (e.g. notifications procedures, possibility to enact provisional measures, etc.).

This list could be used by the Commission to add provisions belonging to these areas to both the EU legislation which refers to vulnerable groups, as well as those that do not.

[306] Grandjean P, 2013.
[307] See paragraph 1.2 above.

7.1.3 Chemical legislation that could contain references to vulnerable groups

Numerous pieces of legislation were identified that, despite dealing with chemicals and having the protection of human health as a general objective, nonetheless do not contain any direct references to vulnerable groups. As demonstrated by the literature review, the scope of these regulations and legislative documents is directly related to specific circumstances or environments in which the protection of vulnerable groups should be an important consideration. An overview of the most relevant pieces of legislation that could include provisions to protect vulnerable groups from the risks of chemical exposure are listed below. An exhaustive list of all legislation considered can be found in the list of references (Chapter 10).

- Regulation (EC) No 648/2004 on detergents;
- Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (Drinking Water Directive);
- Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food (Food Contact Materials);
- Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food;
- Directive 98/79/EC on in vitro diagnostic medical devices;
- Directive 2008/98 on waste;
- Directive 2006/66/EC on batteries & accumulators;
- Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Regulation (EC) No 2232/96;
- Directive 2004/107/EC relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air;
- Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast).

Three of the above-mentioned pieces of legislation offer, in particular, significant opportunities to improve the protection of vulnerable groups, as indicated by EU institutions and civil society organisations[308]. They are described in further detail below, together with an argument for the inclusion of the protection of vulnerable groups in these contexts.

Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (Drinking Water Directive)

The main aim of the Drinking Water Directive (DWD) is to protect the health of EU consumers as well as ensuring the water is healthy. The Directive obliges Member States to regularly monitor the quality of drinking water and to provide consumers with adequate information on the quality of the water. In order to ensure that drinking water everywhere in the EU is healthy, clean and tasty, the DWD sets standards for the most common substances (parameters) that are found in drinking water. A total of 48 microbiological and chemical parameters must be monitored and tested regularly.

The parameters and parametric values are included in Annex I of the DWD. Part A of this Annex refers to microbiological parameters, while part B refers to chemical parameters. With regard to the latter, only 25 chemicals have been listed in part B of the Annex. While the list contains chemicals of concerns for both general and vulnerable populations - such as arsenic, cadmium, chromium, lead and mercury - there are other chemicals of concern, such as the perfluorooctanoic acid (PFOA), that are not included in the list[309]. In particular, foetuses and newborns are highly vulnerable to exposure of PFOA through umbilical cord blood or via breast milk after birth.

[308] For example, see: European Parliament, 2016, "Food Contact Materials', available at: http://www.europarl.europa.eu/RegData/etudes/ATAG/2016/589786/EPRS_ATA(2016)589786_EN.pdf (accessed December 2016).

[309] For more information about the main concerns regarding PFOA see Vierke, L. et al., 2012.

In line with the general scope of the Directive, i.e. the protection of human health from the adverse effects of any contamination of water intended for human consumption, it seems relevant to study the number of chemicals listed in Annex I, part B, and to update the list based on the latest scientific evidence available, in order to protect the general population and, especially, certain vulnerable categories, such as foetuses, pregnant women and children.

Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food (Food Contact Materials)

Food contact materials (FCMs) encompass all materials and articles intended to come into contact with food, such as packaging and containers, processing machinery, kitchen equipment, cutlery and dishes[310]. 15,000 different substances are estimated to be present in FCMs. These substances can migrate into food thus triggering hazardous health effects on human health. Hence, the safety of FCMs should be assessed; they also have to be manufactured in compliance with EU Regulations[311].

General requirements for all FCMs are laid down in Framework Regulation EC 1935/2004. The principles set out in the Regulation require that FCMs do not release their harmful constituents into food or change food composition, taste and odour in an unacceptable way. The Regulation also allows the European Commission to adopt specific measures for 17 materials listed in its Annex. So far, specific EU measures have only been adopted for five of these, notably plastics (including recycled plastic), ceramics, regenerated cellulose film and active and intelligent materials[312].

The FCMs Regulation has recently been under the spotlight of the EU legislator[313]. According to a European Parliament study[314], food contamination from FCMs is an under-estimated issue. In particular, studies have indicated that further harmonisation of legislation governing FCMs is required, as the level of enforcement is inconsistent across the EU. Specific EU measures could thus be adopted for non-harmonised materials, giving priority to those that constitute a particular risk to human health. Moreover, harmonisation of FCMs would also make the level of public health protection homogeneous in the EU.

Critics have also underlined a gap which exists between legal requirements and a de facto situation where risk assessment is not possible, because the identity of substances present in FCMs is unknown. A recent report from the European Parliament[315] highlighted that FCMs with a higher risk of migration, are of a particular concern. The report also stressed that more research is needed about non-intentionally added substances (NIASs), whose composition is often unknown. The report also highlighted that current EU risk assessment does not take into account the effects of chemical mixtures. Finally, the report pointed out tha that FCMs are a significant source of human exposure to EDCs, such as phthalates and bisphenols (BPA). EDCs are chemicals of particular concern; which recent research has linked to various diseases which are particularly harmful for vulnerable groups[316].

Given the above, the FCMs Regulation offers several opportunities for improvement. Firstly, while the current FCMs Framework Regulation allows for more particular rules to be set for any of the 17 types of FCMs, specific EU laws have only been set for five of the 17 types. Therefore, 12 types of FCMs are not covered by any specific legislative measures at EU level. Such rules are particularly important to consider as they usually involve more specific requirements for risk assessment and set limits for the maximum migration of chemicals into food. There is therefore scope for the EU to address these

[310] EFSA, webpage, 'Food Contact Materials', available at: https://www.efsa.europa.eu/en/topics/topic/foodcontactmaterials (accessed December 2016).
[311] EFSA, webpage, 'Food Contact Materials', available at: https://www.efsa.europa.eu/en/topics/topic/foodcontactmaterials (accessed December 2016).
[312] European Parliament, 2016.
[313] Ibid.
[314] European Parliament, ENVI Committee, Study, 2016.
[315] European Parliament, 2016.
[316] European Parliament, 2016.

12 uncovered types of FCMs, starting with those whose chemical contamination problems have already been established, e.g. printing inks migrating into food, bisphenol A, fluorinated substances, and other hazardous chemicals in paper/board packaging.

Secondly, further harmonisation of the legislation governing FCMs, and in particular the provision concerning EDCs, seems an option worth exploring. For instance, the majority of Member States do not have specific legal measures on the food contact uses of certain phthalates and BPA. These chemicals are particularly harmful for both the general population and vulnerable groups. In light of this, consideration should be given to the inclusion of specific provisions to protect vulnerable groups in the FCMs Framework Regulation. Provisions identifying safe levels for EDCs for the protection of both the general population and specific vulnerable groups would be a good starting point[317].

Thirdly, the issue of mixtures of chemicals in FCMs has not yet been assessed. Safety levels are, in fact, determined without taking into account multiple exposure to different FCMs at the same time. Addressing the issue of safety levels arising from exposure to such mixtures could be beneficial for both the general population and specific vulnerable groups.

Finally, the NIASs are chemicals present in FCMs as impurities or as the consequence manufacturing processes. Currently, the majority of NIASs in FCMs have not yet been identified; this circumstance makes risk assessments particularly difficult to be performed. [318]. Addressing the issue of NIAS, for instance by proving guidance on how companies should carry out the risk assessment, seems an option worth considering, in light of the exposure risk to both the general population and vulnerable groups.

Regulation (EC) No 648/2004 on detergents

Regulation (EC) No 648/2004 establishes a set of rules designed to achieve the free movement of detergents and surfactants for detergents in the internal market while, at the same time, ensuring a high degree of protection of the environment and human health. The Regulation harmonises the rules on the biodegradability of surfactants, their restrictions and bans, the information that manufacturers must provide, and the labelling of detergent ingredients.

The Regulation was amended several times in order to include all classes of surfactant. With respect to product labelling, Regulation (EC) No 907/2006 extends the rules to include fragrance ingredients that could cause allergies.

Within the scope of the Regulation on detergents, consideration could be given to the inclusion of specific provisions to protect certain categories of vulnerable groups who may either be more exposed to detergents compared to the general population (e.g. workers in the cleaning industry, clothing industry, soap industry, laundries, etc.), or those who are more vulnerable to these substances (children, especially toddlers, the elderly) and who may experience higher risk should they accidentally come into contact with these substances. Pregnant women, whose condition implies an intrinsic vulnerability of the foetus, may also need special protection.

7.2 RISK ASSESSMENT

Risk assessment is an integral part of the EU legal framework, aiming to protect people, including vulnerable groups, from the health risks associated with chemicals. Risk assessment combines the intrinsic potential of chemicals to cause adverse health effects with knowledge of human exposure to chemical substances via the possible routes. Chemical risk assessment usually encompasses four steps: hazard identification (e.g. carcinogen, endocrine disruptive etc.), hazard characterisation (dose-response relationship, mode of action etc.), exposure assessment (external or internal) and risk

[317] Geueke B *et al*., 2014.
[318] HEAL, 2016.

characterisation[319]. From the perspective of protecting vulnerable groups, it is particularly important that risk assessment considers windows of susceptibility.

Hazard identification is the identification of the adverse effects which may result from contact with a given substance. *Hazard characterisation* (an alternative name for *effects assessment* or *dose-response assessment*) is the estimation of the relationship between dose or level of exposure to a substance, and the incidence and severity of an effect. *Exposure assessment* is the determination of the emissions, pathways and rates of movement of a substance and its transformation or degradation in order to estimate the concentrations/doses to which human populations or environmental compartments are, or may be, exposed. *Risk characterisation* is an estimate of the incidence and severity of the adverse effects likely to occur in a human population or environmental pocket due to actual or predicted exposure to a substance, and may include a quantitative 'risk estimation'. *Risk management* is the decision-making process based on the risk assessment, which develops, analyses and compares regulatory options and selects the appropriate regulatory response[320].

Three scientific committees of the Commission[321] have noted that the protection of vulnerable populations is a major challenge in risk assessment. Vulnerability is understood in this context as the combination of higher susceptibility and higher levels of exposure, together with additional factors, including social and cultural parameters such as socioeconomic status and location of residence, as well as risk awareness and risk education. Given that the level of chemical exposure may vary significantly during different stages of life, and that inherent biological differences may make certain groups more susceptible to chemicals, the evaluation of exposure to chemicals and the related health risk requires population-specific information which in itself may be subject to significant variation. For example, a 2010 study measuring packaged food intake by British children aged 0-6 years showed that children, on average, consumed 1.6-3 times (depending on the more specific age group) as much plastic food packaging as estimated by the current EU model, indicating a proportionally higher exposure to substances leaching from plastic food contact materials for children than adults[322].

The International Programme on Chemical Safety (IPCS) has issued a number of publications and projects on risk assessment methodology, including principles for evaluating health risks for specific populations, such as children[323] and older adults[324], as well as for babies born following exposure to chemicals during pregnancy[325]. They have also published a document on the need for a special approach to chemical risk assessment applying to children, one which takes into account the special characteristics of infants and young children[326].

In 2013, the OECD carried out a survey on the tools and methodologies for chemical risk assessment process in the context of children's health[327]. The survey addressed the methodologies and tools currently available for assessing the risk of chemicals to children's health, as well as the need for additional guidance. Respondents were asked to identify the need for guidance and whether or not such methodologies and tools exist in the following areas: the definition of terms, hazard assessment, exposure assessment, risk characterisation, cohort studies, and combined exposure to multiple chemicals. The results showed that 49% of the respondents assess the risks generically, as part of the assessment of consumers and the general public, with only 45% assessing the risks specifically for children. 6% indicated that they do not conduct risk assessments for children, or that such assessments depend on the chemical being assessed. The chemicals reviewed by respondents included pesticides,

[319] Choi J *et al*., 2015b.
[320] Van Leeuwen CJ & Vermeire TG, 2007.
[321] SCHER, SCENIHR & SCCS, 2013.
[322] Muncke J, 2011.
[323] IPCS, 2006.
[324] IPCS, 1993.
[325] IPCS, 1984.
[326] IPCS 1986.
[327] OECD, 2013.

chemicals in consumer products, cosmetics and nanomaterials.
The survey results also demonstrated that the definitions of 'children' and sub-categories such as 'toddlers' varies by respondent and type of chemical assessed. With regard to *hazard assessments* specific to children, respondents provided six endpoints: developmental toxicity, carcinogenicity, neurotoxicity, generic alterations, reproductive toxicity and endocrine disruption. Other respondents, including ECHA, reported that they perform specific hazard assessments for children and gave the titles of existing guidance (e.g. 'Guidance on information requirements and chemical safety assessment (R7 and R8)' for REACH) and 'Guidance for chemical safety assessment (R8.4.3.1)' (for REACH) were given by ECHA, while the EHC 237 'Principles for Evaluating Health Risks in Children Associated with Exposure to Chemicals' were referred to by IPCS). Respondents also reported that they perform specific *exposure assessments* for children, including the use of specific exposure scenarios. Specific *risk characterisations* for children were also performed, with some respondents (including the EC Joint Research Centre and the German Human Biomonitoring Commission of the Federal Environment Agency) referring to guidance documents or tools used for this purpose. Cohort studies of children (e.g. by the RIVM in the Netherlands) are also undertaken. Other programmes assess the risks to children from combined exposure to multiple chemicals (e.g. the 'Expert Workshop on Combination Effects of Chemicals' report by the Danish EPA).

In addition to the tools currently available, respondents highlighted a need for additional guidance on risk assessment for children. These include, firstly, harmonised definitions for assessing the risks of chemicals to children's health. With regard to *hazard assessment*, the respondents' pointed to the following needs:

- Guidance or methodologies on extrapolation from adults to children, including age-dependent adjustment factors;
- Sensitivity guidance or studies related to children's level of development, developing markers of outcome assessment for children;
- Tools which take account of developing country scenarios;
- Epidemiological outcomes to show correlation between human biomonitoring (HBM) and health outcomes;
- Harmonisation of end-points;
- Focus on specific areas such as: adult onset effects resulting from early life exposures; effects of chemicals in psychoneuro-development and immune development; endocrine modulators and low-dose effects; developmental programming and/or epigenetics; markers of outcome assessment for children; and prenatal exposure to specific chemicals such as PCBs.

In the context of *exposure assessment*, the OECD concluded that there is a significant need for more tools. Respondents highlighted a variety of needs in this regard, including:

- General exposure scenarios for children (including time of exposure, number of hand-to-mouth events/activities, contact with pets, body weight and inhalation);
- Specific exposure behaviour or situations for children;
- Exposure scenarios from specific sources (e.g. biocides, consumer products, insecticides in domestic environments, etc.);
- Specific exposure factors, data or models (e.g. standard values for body weight and breathing volume, indoor guide values).

For *risk characterisation*, the suggestions included:

- Harmonisation of risk characterisation methodologies such as uncertainty factors, in order to account for the specificity of children and/or deviation;
- Identification of people/groups with mixed/multiple exposures;
- Risk characterisation which takes account of developing country scenarios;
- More information regarding toxicokinetics and dynamics between children and adults.

In relation to the combined exposures to chemicals, the following needs were described:

- Tools/methodologies for both children and adults;
- Guidance on combined exposure for all age groups (one response suggested harmonised guidance for cumulative/combined exposure to pesticides, including for infants and children);
- Common definitions and a common methodology to assess combined exposure;
- Guidance for assessment of uncertainty;
- Specific information on co-use scenarios, prenatal exposure to PCBs and combined exposure, and real-life scenarios in developing countries;
- Case studies employing the WHO Framework.

Finally, additional responses suggested that the following are needed:

- Identification and assessment of other pathways, such as behaviour and lifestyle;
- Harmonised approach for calculating and handling exposures for children when conducting cancer risk assessments, such as age-specific adjustment factors;
- Exchange of information on factors of exposure measurements and outcome measurements in child health;
- Data extrapolating to children, for all steps in risk assessment processes;
- Assessment of risk from engineered and non-engineered nanoparticles which are already dispersed in the environment.

The literature reviewed for this sub-study indicates that specific challenges remain in respect of chemical risk assessment for vulnerable groups, particularly in relation to certain types of substances. For example, according to the latest scientific knowledge, endocrine substances are typically subject to an 'early exposure – late effect' pattern, which poses difficulties for risk assessors.

Assessing the risks of chemical mixtures poses another specific challenge. The variety of possible chemical combinations is too vast to allow for an individual risk assessment of each combination. Also, the combination effects may vary in their level of seriousness.

Efforts to harmonise methodologies for chemical risk assessment continue, with the WHO's International Programme on Chemical Safety leading a project to harmonise approaches to a number of specific risk assessment areas, such as combined exposures to multiple chemicals, exposure assessment and mutagenicity testing[328]. A challenge here is the harmonisation of chemical risk assessment and the need to cater for the diverse circumstances of vulnerable populations, whose consumption patterns and exposure levels may differ significantly depending on age group, geographical location and lifestyle factors.

7.3 BIOMONITORING

Human Biomonitoring (HBM) is a scientific technique that allows a systematic standardised measurement of human exposures to chemical contaminants entering the body through the various possible routes. This method involves analyses of human tissues and fluids, using biomarkers (BM) as measurable indicators of changes or events in biological systems. Biomarkers are measurements of the concentrations of chemical substances, their metabolites, or reaction products in the human tissues or specimens used for analysis, such as blood, urine, hair, teeth, saliva, breast milk and semen[329]. Cord blood and placenta are also often used to measure exposure in utero. The measured concentrations are

[328] IPCS, 2004.
[329] Choi J *et al*., 2015a.

commonly referred to as 'body burdens' of the relevant chemical substances[330].
The strength of HBM as a method is that it is the only available tool which integrates exposures from all sources. Biomonitoring data reflect the internal dose of the measured chemicals in the test participant at a given point in time. With modern analytical methods, it is possible to measure a wide range of chemicals in the human body even at very low levels[331]. The use of biomarkers also enables scientists to detect early health effects[332]. According to the EU-level COPHES programme[333], HBM surveys can highlight spatial trends, help to uncover cultural and lifestyle contributing factors, and indicate specific at-risk groups, such as given age cohorts. Repeated surveys can reveal increases or decreases in chemical exposures over time, making HBM a valuable tool in tracking the results of policy initiatives.

HBM data alone cannot be used to track the source of exposure or the length of time a chemical has been in the body. In many HBM programmes, complementary questionnaires are used to collect information on factors such as occupation and lifestyle, in order to estimate potential sources of exposure. In combination with a detailed understanding of the potential analytical/methodological pitfalls and the toxicokinetics of individual chemicals, HBM data could be translated into daily exposure estimates[334].

In the context of this sub-study, a number of resources were identified that outlined the uses and value of HBM in several stages of risk assessment, from hazard identification and characterisation to risk characterisation and exposure assessment. At the *hazard identification* stage, HBM has a role in some toxicological studies, where the actual in vivo exposure can only be found via biological monitoring. HBM can also allow observation of an increased individual or group level of a potentially toxic chemical, or its metabolites, in human biological samples. Forward or reversed dosimetry comparing human and experimental animal concentrations can be used to bridge toxicology and human effects[335]. At the *hazard characterisation* level, HBM can provide useful data for either or both sides of the dose-response equation: it may help to measure the biological level of a chemical or its metabolite(s) corresponding to a given level of exposure (the dose), or it can be used to assess the proportion of individuals showing some early adverse effects at a given level of exposure (the response).

The most critical function of HBM is the provision of data on actual exposure to chemical substances, making it indispensable in *exposure assessment*. HBM data reflects the total exposure from all sources, including environmental and lifestyle exposures, as well as individual susceptibility based on gender, age, genetic background and body composition.

Risk characterisation combines the hazard identification information with exposure assessment. HBM has a role in performing or validating risk assessment where environmental monitoring and health surveillance are unavailable, or inadequate, due to an intrinsically low sensitivity and/or specificity. With HBM it is also possible to assess certain specific components of risk that would otherwise not be accessible, such as metabolic polymorphism, enzymatic inhibition or induction of the metabolising enzymes and other susceptibility factors that could cause a different response to chemicals. HBM data also has a role in risk management when combined with HBM-related guidance values, such as those under development in the USA and Germany (HBM-I and HBM-II in Germany and Biomonitoring Equivalents (BE) in the USA).

Researchers suggest that risk assessment and risk management without HBM could lead to inaccurate risk estimates and thus inadequate measures[336]. Based on this, it appears that HBM is an invaluable

[330] Choi J *et al.*, 2015b.
[331] Ibid.
[332] Choi J *et al*., 2015a.
[333] COPHES, project website, available at : www.eu-hbm.info/cophes.
[334] Choi J *et al*., 2015b.
[335] Choi J *et al*., 2015a.
[336] Ibid.

source of complementary data. Its major limitation in risk assessment, however, is the inability to differentiate exposures from different sources, with data collected by other methods needed to provide this information. As HBM results represent a snapshot of exposure for a specific time, the data is subject to significant variation and may not show past exposure for short-lived substances[337].

In occupational medicine, HBM has long been associated with vulnerable groups, due to its value in providing data of the body burden of toxic substances and their metabolites. Through the detection of exposure, HBM can indicate adverse health risks and thereby provide an incentive for risk management measures. It is also useful for assessing the effectiveness of preventative measures and for controlling workplace limit values[338]. HBM is also relevant for other vulnerable groups. In fact, its ability to identify vulnerable groups and populations with higher exposures and emerging chemical risks, as well as to establish the distribution of exposure among the general population is a key strength[339]. Additionally, HBM data can be used to provide supporting evidence of the higher susceptibility of certain population groups. For example, several HBM studies have provided support for the proposition that prenatal exposure to chemicals in infants could result in some adverse health effects. Some HBM programmes have also demonstrated higher body burdens of phthalate metabolites, PAH metabolites and PBDEs and fluorocarbons in children, highlighting these substances as a major concern for children[340]. Many existing HBM studies emphasise the need for this methodology in children in order to generate the data required for accurate risk assessment and management.

A range of HBM studies (e.g. the FLEHS and PROBE programmes outlined below) noted that several metals appear to accumulate in the elderly population. The KorSEP study also attributed higher body burdens of phthalates to older subjects. The clearance of chemicals out of the body is slower in the elderly, which increases the risk of developing adverse effects. This further supports the need for biomonitoring in the elderly to gain accurate exposure data.

The collection of complementary information from HBM programme participants through questionnaires enables researchers to combine exposure data with historical factors such as gender, living environment (urban, rural), lifestyle habits, medical history, etc. These factors have been used to determine the additional risk factors of higher body burdens of chemicals[341].

Box 7: Examples of relevant HBM programmes

A number of HBM studies have been carried out in Europe and elsewhere. Many of these studies have produced stratified data reflecting various geographical areas, sex, age and occupational sectors. The following programmes were identified during the literature review:

- U.S.: National Health and Nutrition Examination Survey (NHANES)
- Canada: Canadian Health Measures Survey (CHMS)
- Germany: German Environmental Survey (GerES)
- Belgium (Flanders): Flemish Environment and Health Study (FLEHS)
- France: French National Survey on Nutrition and Health (ENNS)
- Spain: BIOAMBIENT.ES
- Italy: Programme for Biomonitoring the Italian Population Exposure (PROBE)
- Czech Republic: Human Biomonitoring Project (CZ-HBM)
- South Korea: Korean National Survey for Environmental Pollutants in the Human Body
- (KorSEP)

[337] Choi J *et al*., 2015b.
[338] Choi J *et al*., 2015b.
[339] Choi J *et al*., 2015a.
[340] Becker K *et al*., 2009; Calafat AM *et al*., 2011; Frederiksen H *et al*., 2014.
[341] Choi J *et al*., 2015a.

Participants in HBM programmes are, usually, randomly selected adult volunteers. Children and adolescents (aged 3-12 and 13-17 years, respectively) have also participated in all of the programmes listed, with the exception of PROBE and KoSEP. FLEHS and CZ-HBM also recruited pregnant women and their newborns.

A common approach for human biomonitoring surveys, developed by the EU-funded programme 'COPHES', has been tested in 17 European countries. The purpose of this European-level human biomonitoring study, (and its predecessor, 'DEMOCOPHES') was to produce comparable data as a step towards European reference values. In line with the themes included in the EU Environment & Health Action Plan 2004-2010[342], the target population of the project included children aged 6-11 years and their mothers aged 45 years and under. Hair and urine samples were collected from a total of 3,688 volunteers, evenly split between urban and rural areas. Additional details on living environment, nutrition, smoking behaviour and other information were collected from the mothers through questionnaires. While methodological harmonisation and comparability of data remains a challenge for HBM in Europe, the DEMOCOPHES project demonstrates that it is possible to produce comparable data on a European scale[343].

In the US, the Environmental Working Group (EWG) recently conducted a review of scientific literature and publicly available human biomarker datasets, and then used this data to compile an inventory of known or likely carcinogens that have been measured in people. EWG found more than 400 known or likely carcinogens, measured across a diverse array of populations. In these cases, exposure could not solely be linked to on-the-job contact, meaning that exposure took place in a variety of environments[344].

[342] COM(2004) 416.
[343] DEMOCOPHES, 'Human biomonitoring on a European scale', available at: www.eu-hbm.info/democophes.
[344] EWG, 2016.

8 GAPS AND DEFICITS

On the basis of the literature review and the issues highlighted during the workshop: 'Strategy for a Non-toxic Environment of the 7th Environment Action Programme (EAP)', held at the Committee of the Regions on 8 and 9 June 2016, a number of gaps and deficits have been identified in relation to the protection of those groups in the population that are particularly vulnerable to the negative effects of exposure to chemicals. Different stakeholder groups had different opinions; there was no consensus on how to address the gaps on this matter.

The sections below summarise the gaps and deficits. They are structured around four themes: regulatory issues; insufficient assessment methodologies; research gaps; and information and awareness gaps.

The catalogue of available tools to respond to gaps and deficits identified in this study is a comprehensive inventory of all possible measures identified during the work of this study. The potential impacts of these tools have not been assessed as part of this study. This needs to be done in a further step, taking into account the tools identified in the better regulation agenda.

8.1 REGULATORY ISSUES

1. Lack of provisions in EU legislation defining which vulnerable groups should be ensured special protection, especially for those pieces of legislation that are of particular relevance to the protection of certain groups in society from chemical exposure.
2. Lack of references to specific windows of vulnerability; e.g. EU chemicals legislation may refer to children being a vulnerable group, but it does not distinguish between neonates, infants, toddlers and adolescents.
3. Inconsistencies in the protection of vulnerable groups in relation to specific categories of relevant chemicals legislation, e.g. legislation related to work, food, products, and environment. In each of these categories, there are pieces of legislation that consider vulnerable groups, while other legislation sharing the same objectives does not consider vulnerable groups in its provisions.
4. Annex I, part B of the Drinking Water Directive (chemical parameters) does not provide a comprehensive list of chemicals that should be considered in light of its overall aim to protect human health (and thus vulnerable groups).
5. While the current Food Contact Materials Framework Regulation allows for more particular rules to be set for any of the 17 types of food contact materials, specific EU laws have been set for only five of these 17 types. Therefore, 12 types of food contact materials are not covered by any specific legislative measures at EU level. Such rules are particularly important to consider as they usually involve more specific requirements for safety assessment and limits for the maximum migration of chemicals into the food.
6. In the absence of EU and national law, the majority of Member States do not have specific legal measures on the uses of certain phthalates or BPA in food contact materials.
7. The protection of children from harmful exposure to chemicals is sporadic at best, with a broader approach being necessary, one which takes into account their wider living environment and surroundings.
8. Chemicals having developmental neurotoxic (DNT) properties should be further regulated in order to ensure an adequate level of protection for the foetus and children.

8.2 INSUFFICIENT ASSESSMENT METHODOLOGIES AND CRITERIA

9. Assessment methodologies are not sufficient to measure the combination effects of chemical mixtures and/or environmentally induced epigenetic toxicity. This has resulted in an incomplete

picture of the disease risk, as well as the total impact that chemicals can have on different systems within the human body.

10. EU risk assessments typically focus on single substances and do not consider the risks to children and other vulnerable groups from combined exposure to toxic chemicals. Therefore, a regulatory approach for cumulative risk assessment needs to be developed.
11. Bioaccumulation effects cannot be properly measured and assessed, and thus adult onset effects resulting from early life exposures (latency period) are unknown.
12. Current risk assessment methodologies do not cater for the diverse circumstances of vulnerable populations, whose consumption patterns and exposure levels may differ significantly due to factors such as age, geographical location and lifestyle factors.
13. Certain hazards are not identified due to a lack of classification criteria and data requirements (e.g. EDCs and endocrine modulators).
14. HBM methods are unable to differentiate exposures from different sources; they currently represent a snapshot of exposure for a specific time, thus the data are subject to signification variation and may not show past exposure for short-lived substances.
15. Insufficient cooperation and linkages between risk assessment and HBM.
16. Uncertainty of test methods for screening chemicals for endocrine disrupting effects on reproductive health – the majority of such methods are based on animal models and are focused at the cellular or molecular level.
17. Lack of guidance and evidence on how to effectively perform a general risk assessment for engineered and non-engineered nanoparticles that takes into account particular risks, e.g., exposures of workers.

8.3 RESEARCH GAPS

18. Lack of knowledge of the potentially harmful effects of fragrances and phthalates contained in care products, particularly their impact on the health of female adolescents.
19. Lack of knowledge of the health impacts of the various levels of pesticides, PCBs, PAHs, plasticisers (phthalates, phenols), flame retardants, other organic xenobiotics and inorganic constituents present in furniture at home and household dust.
20. Certain substances including many pesticides and biocides have been found to have neurotoxic properties which can have major negative effects on the brains of foetuses and children. In this case, the precautionary approach should be applied.
21. Knowledge is lacking on the effects that certain toxic chemicals (e.g. NIASs and nanomaterials) can have on vulnerable groups. More research is also needed on how chemicals interfere with brain development.

8.4 INFORMATION AND AWARENESS GAPS

22. Lack of awareness of the potential toxic substances that children are exposed to through inhalation in the household, including cleaning products, home improvement supplies, gas stoves and heaters, as well as the impacts of hand-to-mouth behaviour and the likelihood that they will ingest toxic substances such as non-volatile semi-volatile chemicals, which can accumulate in household dust.
23. Lack of awareness of the impacts of indoor air pollution on the health of children and the elderly, who spend most of their times indoors.
24. Lack of awareness of the chemicals used in products such as personal care products and cosmetics, particularly those that should be avoided during pregnancy, and their associated risks.
25. Lack of awareness of chemical exposure in environments where children spend major time, such as school and playgrounds.
26. Labelling and packaging of all consumer products containing potentially harmful chemicals should be improved; this would require complete information throughout the supply chain.

27. Lack of awareness of the links between changes related to ageing (e.g. impaired vision, motor difficulties, memory problems) and increased risks for chemical exposure.

8.5 AVAILABLE TOOLS TO RESPOND TO GAPS AND DEFICITS IDENTIFIED

On the basis of the gaps and deficits described in the previous sections, a range of available tools have been identified. Some of these measures may be implemented in the short (one or two years) or medium term (three to five years), while others would need a longer time span (five years or more) as they are likely to involve new legislation or amendments to the current legislative framework.

A number of ongoing initiatives within the Commission are currently assessing the performance of chemicals legislation. These include the fitness check of all chemicals legislation except REACH and the REACH review, which are both due in 2017. The results of this study will also provide useful input to those initiatives.

The catalogue of available tools to respond to gaps and deficits identified in this study is a comprehensive inventory of all possible measures identified during the work of this study. The potential impacts of these tools have not been assessed as part of this study. This needs to be done in a further step, taking into account the tools identified in the better regulation agenda

The following tables set out, by gap or deficit identified, a short reasoning for the gap/deficit, an overview of the possible response(s) to address the issue, a qualification of the possible response (short/medium or long term; type of measure) and a short discussion, explaining the issue and reasoning for the response in further detail.

Table 7: Overview of gaps in legislation and the responses identified

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
Lack of provisions in EU legislation defining which vulnerable groups should be ensured special protection, especially for those pieces of legislation that are of particular relevance to the protection of certain groups in society from chemical exposure.	Inadequate attention to need for special protection for certain 'vulnerable groups'.	1	Consider including specific provisions in relevant EU acts to define any categories of vulnerable populations where special protection may be needed, particularly for those pieces of EU legislation relevant to the protection of vulnerable groups from chemical exposure.	Long-term, regulatory.	The inclusion of specific provisions clearly defining which vulnerable groups may need special protection would clarify and improve the scope of EU legislation.
Lack of references to specific windows of vulnerability; e.g. EU chemicals legislation may refer to children being a vulnerable group but do not distinguish between neonates, infants, toddlers and adolescents.	Not included during development of legislation.	2	Add provisions referring to specific windows of vulnerability in the EU legislation, for instance in the Directive on the safety of toys.	Long-term, regulatory.	References to specific windows of vulnerability would improve the scope of EU legislation and improve the protection of specific vulnerable groups.
Inconsistencies in the protection of vulnerable groups in relation to specific categories of relevant chemicals legislation (e.g. legislation related to work, food, products, and environment/air). In each of these categories, there are pieces of legislation that consider vulnerable groups, while other legislation with the same objectives does not consider vulnerable groups in its provisions.	Pieces of legislation were developed and implemented at different moments in time and in different contexts.	3	Conduct a review of the four different categories of legislation identified by this study (legislation related to work, food, products, environment/air) and explore opportunities to include references to vulnerable groups to ensure consistency.	Long-term, regulatory.	This would increase level of coherence and consistency among the different pieces of legislation, particularly those belonging to the same category, as identified during this sub-study.
	.	4	.	.	
Annex I, part B of the Drinking Water Directive (chemical parameters) does not provide a comprehensive list of chemicals that should be considered in light of its overall aim to protect human health (and thus vulnerable groups).	Research is evolving, the Directive may not be up to date.	5	Review and update the number of chemicals listed in Annex I, part B of the Drinking Water Directive, e.g. adding PFOA to the list.	Long-term, regulatory.	Adding more chemicals to Annex I, part B of the Drinking Water Directive will better protect the overall population as well as specific vulnerable groups such as the foetus, pregnant women and children.
While the current Food Contact Materials Framework Regulation allows for more particular rules to be set for any of the 17 types of food contact materials, specific EU laws have been set for only five of the 17 types. Therefore, 12 types of food contact materials are not covered by any specific legislative measures at EU level.	The EU Commission has not yet proposed a 'legislative text' to the Parliament and the Council on these matters.	6	Enact specific EU rules for the 12 types of food contact materials which are so far not covered by any specific legislative measures at EU level, starting with those where chemical contamination problems have already arisen, e.g. printing inks migrating into food, bisphenol A, fluorinated substances, and other harmful chemicals in paper/board packaging.	Long-term, regulatory.	Rules for food contact materials are important to consider as they usually involve more specific requirements for safety assessment and limits for the maximum migration of chemicals into the food.

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
In the absence of an EU and national specific legal framework, the majority of Member States do not have specific legal measures on the food contact uses of certain phthalates and BPA.	Lack of specific framework for FCMs using BPA or certain phthalates.	7	Further harmonise EU legislation governing FCMs, in particular the provision concerning certain phthalates and BPA.	Long-term, regulatory.	Harmonised measures at EU level will better protect the general population, as well as vulnerable groups.
The protection of children from harmful exposure to chemicals is sporadic and a wider approach is required, taking into account their wider living environment and surroundings.	Research is evolving, EU legislation may not be up to date.	8	Extend the Toys Directive regime to cover all products aimed particularly at children, such as furniture, bedding, clothing.	Long-term, regulatory.	A more comprehensive scope of protection of children is required to ensure minimal exposure to chemicals.
Chemicals having developmental neurotoxic (DNT) properties should be further regulated in order to ensure an adequate level of protection for foetus and children.					
Although the EU Toys Directive provides standards to protect children as a vulnerable group, other consumer products aimed at children such as clothing and bedding are not covered	Research is evolving, EU legislation may not be up to date.		Extend the Toys Directive regime to cover all products aimed particularly at children, such as furniture, bedding, clothing.	Long-term, regulatory.	A more comprehensive scope of protection of children is required to ensure minimal exposure to chemicals.

Table 8: Overview of gaps in risk assessment methodologies and criteria and the responses identified

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
Assessment methodologies are not sufficient to measure the combination effects of chemical mixtures and/or environmentally induced epigenetic toxicity.	New area, not much evidence and research available yet.	10	Encourage further research on the health effects stemming from multiple exposures of chemicals as well as epigenetic toxicity.	Mid-term, research.	New research could help to establish a complete picture of the disease risks, as well as the total impact that chemicals can have on different systems within the human body.
EU risk assessments typically focus on single substances and do not consider the risks to children and other vulnerable groups from combined exposure to toxic chemicals.	Lack of data		Develop a regulatory approach for cumulative risk assessment	Mid-term, research.	Although specific framework for for assessing the combination effects of chemicals are being used, a comprehensive approach across different legislation is still not in place. Developing the appropriate framework can thus guarantee better protection of vulnerable groups stemming from the combination effects of chemicals.
Safety testing of chemicals often do not include evaluation of developmental neurotoxic (DNT) properties					

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
Bioaccumulation effects cannot be properly measured and assessed, and thus adult onset effects resulting from early life exposures (latency period) are unknown.	New area, not much evidence and research available yet.	11	Encourage further research on bioaccumulation effects.	Mid-term, research.	New research could help to establish a complete picture of the disease risks, as well as the total impact that chemicals can have over a lifetime.
Current risk assessment methodologies do not cater for the diverse circumstances of vulnerable populations, whose consumption patterns and exposure levels may differ significantly due to factors such as age, geographical location and lifestyle factors.	Complex issue, difficult to capture wide range of elements.	12	Develop risk assessment methodologies that consider aspects such as: exposure levels and scenarios; age; consumption patterns; behavioural characteristics; geographical location; lifestyle factors; cultural differences.	Long-term, regulatory.	While it is a difficult task to take such wider elements into consideration, risk assessment methods would significantly improve.
		13	Set up a platform to bring together scientists and regulators, to ensure that scientific information will be made available for risk assessment.	Short-term/mid-term, support action	More programmes and actions are needed that foster collaboration and data sharing among scientists and between governmental agencies and countries - particularly those that stimulate new, adaptive approaches that break down institutional silos and traditional scientific barriers, and that stimulate interdisciplinary and multidisciplinary approaches.
Certain hazards are not identified due to a lack of classification criteria and data requirements (e.g. EDCs, endocrine modulators, and developmental neurotoxicants).	Complex issue, and hazard assessment methods might not be sufficient to identify a property of very high concern and/or might not be available.	14	Inclusion of new hazard categories in relevant EU regulations (CLP, REACH).	Long-term, regulatory.	New hazard categories would improve information availability (hazards identified and communicated).
Human biomonitoring methods are unable to differentiate exposures from different sources; they currently represent a snapshot of exposure for a specific time and the data are subject to signification variation and may not show past exposure for short-lived substances.	Complex issue, requires new research.	15	Produce a comprehensive, longitudinal, human data bank, including: - Harmonised environment and health indicators; - HBM data and human tissue measurements translated into daily exposure estimates; - HBM data that reflects the total exposure from all sources, and complement this with data on individual susceptibility based on gender, age,	Mid-term, research.	Harmonising the wealth of data and evidence available may facilitate progress in this important area.

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
			genetic background and body composition, living environment (urban vs rural), lifestyle habits, medical history, etc. in order to determine additional risk factors of higher body burden of chemicals; - Collect HBM data during all life stages.		
Further strengthen the link between risk assessment and HBM	It exists but there are opportunities to improve.	16	Ensure that HBM plays a role in several stages of risk assessment, from hazard identification and characterisation to risk characterisation and exposure assessment.	Long-term, regulatory.	HBM can be a valuable source of complementary information. Its main strength is to the ability to identify vulnerable groups and populations with higher exposures and emerging chemical risks, as well as establish the distribution of exposure among the general population
Lack of availability of test methods for screening chemicals for endocrine-disrupting effects on reproductive health.	Test methods are currently mainly based on animal models and focused at the cellular or molecular level.	17	Explore innovative methods in order to test the effects of EDCs, particularly low doses of EDCs, on human health.	Mid-term, research.	This would result in better protection of reproductive health across the life-cycle.
Lack of guidance and evidence on effective general risk assessment for engineered and non-engineered nanoparticles.	Relatively new area; needs to be explored further.	18	Encourage further research on the development of new risk assessment methods on engineered and non-engineered nanoparticles.	Mid-term, research.	This is a relatively new area and a lot of uncertainty exists about the risks of (non)engineered nanoparticles.

Table 9: Overview of gaps in research and evidence and the responses identified

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
.		20			
Lack of knowledge on the potentially harmful effects of fragrances and phthalates contained in care products and particularly their impact on the health of female adolescents.	Research area so far not yet explored (extensively).	21	Encourage further research on the potential harmful effects of chemicals used in care products (e.g. pthalates, parabens, triclosan and oxybenzone), particularly for the health of female adolescents.	Mid-term, research.	Will help to build the evidence around the potential harmful effects of chemicals used in care products.
Lack of knowledge of the health impacts of the various levels of pesticides, PCBs, PAHs, plasticisers (phthalates, phenols), flame retardants, other	Research area so far not yet explored (extensively).	22	Encourage research into the possible health implications of chemicals in household dust, particularly for young	Mid-term, research.	Will help to build the evidence around the potential harmful effects of chemicals present in

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
organic xenobiotics and inorganic constituents present in furniture at home and household dust.			children.		household dust.
Certain substances including many pesticides and biocides have been found to have neurotoxic properties which can have major negative effects on the brains of foetuses and children. In this case, the precautionary approach should be applied.	Research area to be further explored				
Knowledge is lacking on the effects that certain toxic chemicals (e.g. NIASs and nanomaterials) can have on vulnerable groups. More research is also needed on how chemicals interfere with brain development.	Research areas to be further explored		Encourage research on the possible health implication of nanomaterials on vulnerable groups, as well as on NIASs.	Long-term, research.	Will help to build the evidence around the potential harmful effects of nanonamerials and NIASs.

Table 10: Overview of gaps in awareness raising and information distribution and the responses identified

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
Lack of awareness of the potential toxic substances that children are exposed to through inhalation in the household, including cleaning products, home improvement supplies, gas stoves and heaters, as well as the impact of hand-to-mouth behaviour and the likelihood that children will ingest toxic substances, such as non-volatile semi-volatile chemicals, which can accumulate in household dust.	Evidence not known among wider audience.	23	Awareness raising about chemicals in household products and how to avoid exposure of heavily treated textiles, including stain-resistant treatments for carpets and furniture, as well as the positive impact of frequent handwashing, vacuuming, etc.	Short-term, awareness raising.	Will help to raise awareness and knowledge among policy makers and the general public, particularly parents, of the potential dangers of toxic substances in the household and how their child(ren) can be exposed to these. May also support the implementation of prevention measures.
Lack of awareness of the impact of indoor air pollution on the health of children and the elderly, who spend most of their times indoors.	Research area so far not yet explored (extensively).	24	Explore ways to reduce chemicals in indoor environments where the elderly live, e.g., through better ventilation systems.	Short-term, awareness raising.	Will help to raise awareness among policy makers and the general public on the potential dangers of indoor air pollution, particularly for children and the elderly. May also support the implementation of prevention measures.
Lack of awareness of chemicals used in products such as personal care products and cosmetics, particularly those that should be avoided during pregnancy, and their associated risks.	Evidence not known among wider audience.	25	Educate women, particularly those who are pregnant or of child-bearing age, about chemicals and products to avoid, e.g. personal care products with phthalates, deodorant with aluminium	Short-term, awareness raising.	Will help to raise awareness among policy makers and the general public, particularly women who are pregnant or of child-bearing age, on the

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
			salts.		potential dangers of chemicals used in personal care products. May also support the implementation of prevention measures.
Lack of awareness of the chemical exposure in environments where children spend major time, such as school and playgrounds.	Evidence not known among wider audience.	26	Make schools, playgrounds and other areas where children spend major time into chemical-free zones	Long-term, regulatory.	Will help to raise awareness among policy makers and the general public on the potential dangers of chemicals in children's daily environments. May also support the implementation of prevention measures.
Labelling and packaging of all consumer products containing potentially harmful chemicals should be improved; this would require complete information throughout the supply chain.	Lack of awareness among consumers as well as producers.	27	Information and labelling of the content of products should be ensured across the entire supply chain; this would improve awareness of consumers as well as producers.	Short-term, awareness raising.	Will help to increase knowledge on the content of products across the entire supply chain among consumers and producers. May also support the implementation of prevention measures.
		28	Adopt a simplified labelling system based on pictograms and symbols which are easier to understand by certain vulnerable groups, such as migrant workers, toddlers and the elderly.	Long-term, regulatory.	Will help to increase awareness among vulnerable groups on the content of products. May also support the implementation of prevention measures.
Lack of awareness of the links between changes related to ageing (e.g. impaired vision, motor difficulties, memory problems) and increased risks of chemical exposure.	Research area so far not yet explored (extensively).	29	Raise awareness of the impact of an ageing population and the increased risk of chemical exposure, as well as increased levels of chemical-related health problems due to rising life expectancy.	Short-term, awareness raising.	Will help to increase awareness among the general public and policy makers on the need to address the risks related to population ageing and chemical exposure. May also support the implementation of prevention measures.

9 CONCLUSIONS

This report outlines the particular vulnerability of certain population groups in the population, such as the foetus, children, pregnant women, elderly, occupational groups and disadvantaged communities, to chemical exposure. Whether the impacts of exposures are visible at birth or later in life, consensus is broad that such vulnerable groups need to be provided with a high level of protection in respect of their exposure to chemicals, as stated in the 7th EAP. Yet, despite the policy and legislative measures and other activities put in place, significant improvement opportunities exist to augment the protection of children and vulnerable groups from harmful chemical exposure.

Chemicals and their impact on health is a matter that affects a multitude of regulatory areas. Numerous pieces of EU legislation thus incorporate measures with the objective of (also) protecting children or other vulnerable groups from toxic exposure. However, provisions referring to vulnerable groups are often lacking or inconsistent between similar types of legislation. In particular, the study highlighted that where relevant, the EU legislation should include provisions defining any vulnerable population groups where special protection should be ensured. Other areas that could be considered in EU legislation are the specific windows of vulnerability that exist for certain groups, as well as ensuring a consistent reference to vulnerable groups within specific groups of legislation that offer a certain type of protection (e.g. at the workplace, or in relation to food). In addition, the study shows that certain EU legislation, such as the Drinking Water Directive and Food Contact Materials Framework Regulation, are not updated with the most relevant scientific evidence and lack specific measures which can strengthen the protection of vulnerable groups.

Challenges also exist with respect to chemical risk assessment for vulnerable groups. In particular, current risk assessments typically focus on single substances and do not consider the risks to children and other vulnerable groups from combined exposure to toxic chemicals. Therefore, a regulatory approach for cumulative risk assessment needs to be developed. The 'early exposure – late effect' pattern linked to, for example, endocrine-disrupting substances, poses specific difficulties for risk assessors. Bioaccumulation effects cannot yet be properly measured and assessed, and thus adult onset effects resulting from early life exposures (latency period) are unknown. The risks of chemical mixtures, new substances such as nanomaterials, and environmentally induced epigenetic toxicity are areas that need further attention.. Despite the value of HBM, current methods are unable to differentiate exposures from different sources and they therefore only represent a snapshot of exposure for a specific time. These data are also subject to significant variation and may not show past exposure for short-lived substances.

- While a wealth of information and evidence on the impacts of chemicals on specific vulnerable populations has been collected in recent decades, significant knowledge gaps remain. The scientific community has had the tendency to consistently focus on the same substances (e.g. copper, lead, zinc, cadmium, iron, nickel, chromium, etc.) when studying the harmful effects of chemicals, and there is a need to further extend this scope and study new areas, such as the non-intentionally added substances, nanomaterials, as well as on the potentially harmful effects of certain neurotoxicants on brain development. During sensitive early life stages, exposure to EDCs and neurotoxins - such as lead, arsenic, mercury, PCBs, pesticides, and solvents - can cause lifelong damages, and therefore further research on the impact of chemicals on the brain is of paramount importance.

Finally, the study shows the need to develop communication strategies targeting the general public and specific vulnerable groups on how to reduce exposure from certain toxic compounds (i.e. household dust) and classes of chemicals (EDCs and neurotoxicants), as well as on how to avoid certain harmful behaviours (i.e. hand to mouth). Improving labelling and packaging of consumer products would also help to increase knowledge on the potential harmful effects of exposure to certain ingredients or compounds.

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Study for the strategy for a non-toxic environment of the 7th EAP

Sub-study d : Very Persistent Chemicals

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August 2017

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Sub-study d: Very persistent chemicals

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ABSTRACT

This sub-study investigates the case for regulating substances solely on the basis of their persistence in the environment. Very persistent (vP) substances may remain in the natural and man-made environments for an indefinite time and eventually reach levels leading to the same type of continuous exposure as occurs with bioaccumulation and to harmful effects to health, environment and natural resources. Such contamination may be poorly reversible or even irreversible, and could render natural resources such as soil and water unusable far into the future.

The sub-study identifies a number of gaps in analytical methods and data generation/availability concerning persistence in chemicals. It also finds gaps in the risk management measures currently used to prevent releases into the natural environment and to control the use of vP chemicals in the technosphere which, among other issues could lead to build-ups in the environment as well as pose problems for the material reuse/recycling streams envisioned for the Circular Economy.

The sub-study argues that in the context of an increasingly resource-constrained world, preserving the usefulness of essential natural and material resources and ecosystem services is important. From the standpoint of public health, environmental protection and economic growth, it thus appears desirable to take a precautionary, hazard-based approach and to prevent and/or minimize all releases of vP chemicals in the future.

EXECUTIVE SUMMARY

The problem

The use and dispersal in the environment of very persistent (vP) chemicals represents a (potential) threat to health, the environment and natural resources. Due to technical/functionality reasons, such chemicals are widely used in a broad range of applications. Chemicals with a high degree of persistence will remain in the environment for a long time, and lead to exposure of humans and the environment, including i.a. vulnerable population groups, wildlife and environmental media. This may involve previously overlooked or unpredictable negative effects even for chemicals where laboratory tests did not indicate any considerable toxicity, e.g. if the effects are chronic or appear at low concentration levels.

Key findings on very persistent substances

The problem

- A range of very persistent substances, including several groups of halogenated organic compounds, are widely used in different applications, often due to the functionality of the substance.
- Very persistent (vP) substances may accumulate in the environment and man-made materials to levels harmful to human health and natural resources.
- Certain toxic effects (e.g. those occurring at low concentrations or after long periods of low-grade exposure) may take many years to identify, by which time rising concentrations/levels could have already occurred and prove irreversible.
- Highly fluorinated chemicals such as PFAS are extremely persistent and will remain in the environment for hundreds of years. They are highly mobile and have been found in groundwater used for drinking water across Europe as well as in remote areas such as the polar region and the deep sea.
- The thousands of new short-chain PFAS marketed by producers as "safer" than the long-chain PFOS and PFOA are also extremely persistent. Evidence of their toxicity and of their presence in the environment is mounting. Known technologies are not able to remove short-chain PFAS from drinking water.
- An estimated 3.5 million sites around Europe are contaminated by hazardous including vP substances. Contamination of natural resources has severe economic consequences, ranging from the extremely high costs of remediation to removal of natural resources such as drinking water, soil, land and fish stocks from productive use.

Gaps and inconsistencies in current policy

- Current EU legislation does not provide an adequate way to systematically control substances on the basis of their persistent properties.
- Major gaps in knowledge concerning vP substances are due to lack of a common framework for screening substances for persistence and inadequate requirements for persistence testing and for further testing of health and environment properties if a substance is found to be persistent.
- Evaluation of risks from exposure to vP chemicals during the use phase of products is insufficient, and almost entirely missing in the case of imported products, with a few exceptions covering a limited number of substances in certain product groups such as toys. Product regulations also seldom take account of a substance's fate at end of product life, which risks build-ups of vP substances in recycled material waste streams. Strict controls over releases of any vP substances during manufacturing, product use or end of product life may be needed to prevent build-ups in the technosphere as well as the environment.
- Criteria for maximum allowable levels of vP substances in food, drinking water and groundwater are needed to ensure that accumulations of vP pollutants in water and soil resources are given sufficient attention.

Concentrations of a vP chemical will tend to build up and can eventually reach levels where harmful effects to health and natural resources may occur. Damage from exposure to vP chemicals is poorly reversible or even irreversible and may entail considerable cost to society. With the current high levels of production and widespread use of vP substances, cases of such damages are highly likely to appear or may even be unavoidable. Moreover, some health effects may not become evident until long after exposure.

Some scientists argue that persistence is in fact the most important single factor affecting chemical exposure and risk from the environment, because build-ups of a vP chemical could lead to the same type of continuous exposure as occurs with bioaccumulation[1]. Because of uncertainty about chemical properties, a situation could arise where accumulations have already occurred by the time evidence is gathered about a chemical's propensity for harm. As already experienced in the case of persistent ozone-depleting chemicals, the disruptive effects may not be discovered until they occur on a global scale and are affecting a vital earth system process.

Exposure to the well-studied persistent organic pollutants (POPs) has been linked to a number of serious health effects including certain cancers, birth defects, dysfunctional immune and reproductive systems, greater susceptibility to disease and damages to the central and peripheral nervous system. Further, presence of POPs in the environment is associated with severe effects such as impaired reproduction in birds and mammals.

Once a vP substance is released into the environment, its breakdown or transformation products may raise new concerns. In the case of PCBs, for example, it took considerable time for scientists to discover that the process of bioaccumulation resulted in concentrations of the more toxic congeners than were found in the commercial products.

The problems related to vP chemicals are particularly challenging in view of a **circular economy** that strives to close the loops by e.g. increasing reuse and recycling of material. If the material is recycled and used again, vP substances may accumulate in recycled materials, leading to increasing concentrations of contaminants in recycled materials, along with increased dispersal and presence of vP chemicals in the technosphere as well as the natural environment.

Testing and identification of persistence in substances. A common misconception is that environmental persistence is an inherent property of the substance that can be readily measured. However, assessing the persistence of chemical substances in the environment is not straightforward. It entails an assortment of supporting information and the need to address gaps and uncertainties[2].

Moreover, current requirements for testing and test methods to screen and test chemicals for persistence are insufficient[3]. According to UNEP, only 220 chemicals out of a set of 95,000 industrial chemicals have been evaluated fully in relation to their biodegradation half-lives and only 1,000 have data on bio-concentration[4].

A major challenge is that testing for multimedia half-lives is time consuming and costly. While chemicals might be screened for persistence potential based on chemical structures and characteristics, no common framework for doing this has been adopted or accepted. As a result, knowledge and/or information available about the persistence of chemicals produced and used as well as about actual quantities and uses of many vP substances is poor.

To be included in the Stockholm Convention on persistent organic pollutants (POPs), a substance must meet the POPs screening criteria for persistence, bioaccumulation, long-range transport potential and

[1] Stephenson, 1977 ; Cousins, I.T., *et al.*, 2016.
[2] Boethling, R., *et al*., 2009.
[3] Scheringer, M. *et al*., 2012.
[4] UNEP 2013.

toxicity. At this point only 26 substances and groups of substances are covered under the POPs Convention, with another three under consideration for future inclusion. Yet as many as 1,200 of the 90,000+ substances on the market today could be potential POPs[5]. The number of substances meeting the POPs criteria for persistence alone is not known, but some 3,000 PFAS alone (a group of highly fluorinated and extremely persistent chemicals) are estimated to be on the market today.

In the regulatory context, persistence is defined by single-media half-life criteria. REACH provides, for example, that a chemical is persistent (P) if its half-life in soil exceeds 120 days or its half-life in water is more than 60 days. It is considered very persistent (vP) when the half-life in water is higher than 60 days, or when the half-life in soil or in water sediment is higher than 180 days.

The highly fluorinated chemicals – especially the per- and polyfluorinated alkyl substances known collectively as PFASs – are very stable and durable, which makes them useful for a broad range of applications. However, scientific tests to determine their degradation half-lives have found almost no degradation during the testing period, meaning they will persist in the environment for hundreds or even thousands of years[6].

In the 1950s, when highly fluorinated compounds were first commercialised, the focus was on long-chain PFASs -- the so-called C-8 substances used in the manufacture of Teflon-coated cookware, water- and stain-resistant textiles, and fire-fighting foams. In the 1980s and 1990s, evidence emerged of the toxicity and bioaccumulability of the long-chain PFAS, such as PFOS and PFOA.

Human epidemiological studies have found positive associations between exposure to PFASs and hepatocellular damage affecting liver function in adults, obesogenic effects in females, liver and kidney cancer, low birthweight and reduced length of gestation. Exposures to low levels of highly fluorinated chemicals have also been linked to reduced immune response to routine childhood immunizations[7].

PFAS are now ubiquitous in the environment. They are capable of long-range transport and found in the biota of remote regions far from any direct source, including in top predators such as polar bears. Studies on Arctic food chains have found indications of bioaccumulability. However, data concerning the specific health effects such exposures may be having on biota is sparse. Links have been found between foetal exposure to PFOA and significant delays in puberty, and between PFAA exposure in general and hepatotoxicity.

Regulatory pressure has led to phase-out of the manufacture and use of long-chain PFAS in Europe and the USA. As a result, many manufacturers have replaced the C-8s with short-chain homologues -- the C-6s and C-4s. PFAS producers argue that the short-chain PFAS are "safer" in that they are not as bioaccumulative as the long-chain PFAS. However, they are just as persistent, and evidence is emerging that the short-chain alternatives are also problematic in terms of risks to health[8].

Today, more than 3,000 different types of PFAS are estimated to be on the market. They are found in cosmetics, food contact materials, inks, medical devices, mobile phones, pharmaceuticals and textiles, and they are used in pesticide formulations, oil production and mining. They are capable of long-range transport and are found even in remote locations.

A major source has been the use or spillage of PFAS-containing aqueous film firefighting foam (AFFF); in the EU PFAS-contaminated waters have been documented in the Netherlands, UK, Germany, and Sweden. Groundwater contamination would likely be found in other countries with major airports also, if monitoring were carried out. Discharges from industrial production processes,

[5] Scheringer, M., *et al*., 2012.
[6] Russell, M.H., *et al.*, 2008; Washington, J.W., *et al*., 2009.
[7] Grandjean, P., *et al.*, 2015.
[8] Lerner, S., 2016.

wastewater treatment and landfill leachate are also important sources.

Other groupings of highly persistent substances. **Highly chlorinated substances** form another grouping of chemical compounds that tend to be very persistent and therefore problematic. Many of them are known to be toxic for health and environment. For example, the manufacture and use of polychlorinated biphenyls (PCBs) was banned by the EU and most other industrialised countries some 30 years ago, because of concerns about their extreme environmental persistence, ability to bioaccumulate and their association with adverse human health and environmental effects. While concentrations in air, soil, sediment and biota declined rapidly during the first decade of the ban, since then they have remained stubbornly at the same levels and are now ubiquitous in food from terrestrial and aquatic sources. Types of highly chlorinated substances also of concern include chlorinated paraffins, dichlorodiphenyltrichloroethane (DDT) and unintentionally formed POPs such as dioxins and furans. Other groups of highly persistent substances discussed in the study include **highly brominated substances**, **siloxanes** (D4 & D5), and **organometallics**, e.g., organotin compounds, methyl mercury and tetraethyl lead.

Contamination from vP substances has already had a significant impact on Europe's natural resource base. The use of hazardous substances in industrial production processes over the years has led to some 3.5 million potentially contaminated sites across Europe, with 0.5 million of these considered highly contaminated and needing remediation. Though it is not possible to estimate how many of these sites are contaminated by vP substances, overviews showing contamination of media by specific vPs, including PCDD/Fs[9], HCHs[10] and PFASs[11] do indicate a widespread problem.

In addition to local sources, contamination from vP substances has also been documented in soils away from point sources, e.g. highly fluorinated chemicals (HFCs) have been found at high altitudes because oftendency for long-range transport. Recently, contamination of waters by highly fluorinated chemicals (HFCs) has drawn attention in the USA, where drinking water supplies for 6 million residents were found to exceed national lifetime health advisory limits (70 ng/L) for PFOS and PFOA. While activated charcoal can remove the long-chain HFCs from drinking water, currently available technologies cannot remove the short-chain HFCs. The same type of activities that contaminated groundwater in the USA have also been carried out in the EU, e.g., releases from industrial sites and use of aqueous film firefighting foams at major airports and military bases. But because no EU-wide monitoring for HFCs in water has occurred, it is not known how many similarly contaminated drinking water supplies are to be found around the EU.

The presence of vPs in recycled products will be a particular challenge for the EU's action plan on a Circular Economy aimed at maximizing the use of, and minimizing the waste of, material resources in the economy. These substances by their nature can persist and therefore accumulate in recycling streams for long periods, including through now-restricted products made before regulations were applied. The potential for contamination of the 'technosphere' is a serious concern because of the long-term implications for human and ecosystem health.

The Current Policy and Legislative Framework

A number of EU acts consider persistence as a property of concern. However, in almost all cases, persistence is regulated only if bioaccumulability is also present. For example, the **REACH Regulation** sets criteria for identifying if a substance is persistent, bioaccumulative, and toxic (PBT) or very persistent and very bioaccumulative (vPvB). A PBT or vPvB substance may then be identified as a Substance of Very High Concern (SVHC) under Article 57 and added to the Candidate List for

[9] Weber, R. *et al*., 2008.
[10] Vijgen, J., 2006.
[11] Rumsby, P.C. *et al*., 2009; Cousins, I.T. *et al*., 2016.

eventual inclusion in Annex XIV as subject to authorisation. Alternatively, the substance may be restricted under Annex XVII.

In theory, REACH Article 57(f) might be invoked if evidence can be presented that a vP substance gives rise to an equivalent level of concern as a substance meeting the criteria for PBT/vPvB. But such an approach would also mean an ad hoc, case-by-case approach, which would not be sufficient to address e.g. the 3000+ extremely persistent highly fluorinated substances on the market today. In addition, REACH Annex I mentions the possibility of assessing particular effects such as ozone depletion, strong odour or tainting. While this provision could in theory also include the particular effect of persistence, to date, neither this provision nor Article 57(f) has been applied to a substance solely on the basis of persistence.

In addition to being persistent, the substances controlled under the 1996 **PCBs Directive**, the 2004 **POPs Regulation** implementing the Stockholm Convention, and the 2008 **Mercury Regulation** are also bioaccumulative and toxic. Similarly, the cut-off criteria for active substances set forth in the 2009 **Plant Protection Products Regulation** (PPPR) and the 2012 **Biocidal Products Regulation** (BPR) also require findings of BT and vB in addition to P or vP. The **Detergents Regulation** is an exception in that it requires surfactants used in detergents to meet biodegradability standards.

The 2011 (recast) **RoHS Directive** is one of the few pieces of legislation dedicated to controlling the use of hazardous substances in articles in order to reduce downstream impacts of the substance at the end of the product's life. By banning the use of the hazardous substance, the RoHS Directive prevents it from entering the material waste stream, i.e., the technosphere. The Directive targets four metals and two toxic and persistent flame retardants. However, the other persistent flame retardants used extensively in plastic casings of electronic goodsare not covered. These other substances are an instance of "regrettable substitution" in that plastics with added flame retardants are often unfit to be recycled. The substance-specific provisions in the other "waste stream directives", e.g. end-of-life vehicles, batteries and packaging materials, play similar (albeit incomplete) roles in keeping problematic substances out of the technosphere.

Controls over releases of pollutants during manufacturing or production are also not adequate for preventing build-ups of vP substances in the environment. The 2010 **Industrial Emissions Directive** (IED) is aimed at achieving best overall reduction of polluting emissions. This does not take into account the intrinsic quality of persistence which may require measures to prevent any releases of any vP substances in order to avoid build-ups in the environment. The use of emission limit values (concentration levels) set in integrated permits is inappropriate if the need is to prevent build-ups due to any release of a vP substance. Moreover, a vP substance not meeting the additional criteria for BT and vB would not be included in the controls over the industrial facility's emissions.

Systematic environmental monitoring and surveillance of vP substances is also needed in order to track their presence in the environment, including any build-ups, e.g., as part of an early warning system. The so-called WATCH List under the 2000 **Water Framework Directive** is an example of an instrument that could be adapted for such a purpose, though additional analytical methods may be needed to detect the range of vP substances of concern.

Moreover, under almost all of these acts, persistence may be regulated only if bioaccumulability is also present. Hence the EU regulatory system is insufficient for preventing build-ups of vP substances.

An additional gap in the EU regulatory regime is the lack of standards in the **Drinking Water Directive** for PFAS and the other vP substances now showing up in Europe's waters. PFAS have already been found in water resources used for drinking water in Germany, the Netherlands, and Sweden. Without limit values for PFAS in drinking water and EU-wide monitoring for the presence of PFAS in water, the number of other EU residents with drinking water supplies contaminated by PFAS and other chemical substances cannot be known. EU legislation for food contact materials and for

contaminants in food stuffs is also in need of revision to include health-based limit values for e.g. PFAS and brominated flame retardants.

Identified gaps and inconsistencies in current policy/legislation

The current EU regulatory framework is insufficient for protecting human health and natural resources from risks of exposure due to accumulations of very persistent substances. Four types of gaps were identified:

1. **Gaps in identifying and regulating vP substances.** Testing of chemicals to determine their half-lives is time consuming and costly, and no common framework for comprehensive screening of substances for persistence has been agreed on EU level. REACH does not require data on persistence for low volume substances. Moreover, the role of vP substances in combination effects and cumulative exposures is not adequately considered.
2. **Gaps in regimes to protect the ecosphere from releases of vPs.** Controls over releases of pollutants during manufacturing or production are usually in the form of emission limit values (concentration levels). In the case of vP pollutants, strict controls over any releases may be needed to prevent substances from building up in the environment. Related to this is the lack of controls over vP substances used in certain products, such as in cosmetics or textiles, which will end up being released into the natural environment via e.g. wastewater discharges.
3. **Deficits in controlling vP substances in the technosphere.** In general, product regulations often do not evaluate the risk of a vP during a product's entire life cycle – just the risk associated with the exposure to the chemical during the use phase. Failure to take account of the substance's fate at end of product life risks build-ups of vP substances in waste materials recycled as part of the circular economy and which could form reservoirs for future exposure.
4. **Deficits in protecting human health and in addressing vP build-ups in the ecosphere**. Systematic monitoring is not carried out to spot the presence and/or build-up of vP chemicals in environmental media and biota, such as humans. For example, the Groundwater and Drinking Water Directives do not set criteria for maximum allowable levels of vP substances, so build-ups of vP pollutants in water resources are not given sufficient attention. EU food safety legislation also lacks monitoring requirements and limit values for a number of vP substances.

Conclusions

The traditional approach in chemicals legislation has been substance by substance regulation, which is too time-consuming and not adequate to handle the range of chemicals known to be very persistent. The risk is that by the time action covering all of the problematic chemicals is taken, concentration levels in the environment will have reached levels where health or environmental impacts occur, and reversibility of contamination would take a very long time (depending on the nature of the chemicals involved) and be very costly to society, or may no longer be possible.

Very persistent chemicals released into the environment can render resources such as soil and water unusable far into the future as well as damaging ecosystem services. In the context of an increasingly resource-constrained world, preserving the usefulness of these essential resources appears important. Related to this, limiting the presence of persistent chemicals in products is an important consideration of the circular economy package, in order to avoid its goals being undermined by the accumulation of persistent chemicals in material recycling streams.

For these reasons, from the standpoint of public health, environmental protection and economic growth, it appears desirable to take a more precautionary and pro-active approach and to prevent and/or minimize releases of vP chemicals in the future.

One possibility could be to make it a principle to avoid the production and use of very persistent chemicals where persistence is not required, and where release into the environment is likely to take place, e.g. for use in cosmetics or consumer textiles. If persistence is needed for a specific use, manufacturers and down-stream users could be required to justify this. There may also be a need for some type of very strict authorisation requirement –something that would allow only so-called essential uses where persistence was required, and where manufacture and use was carried out in closed systems. Systems for recovery and destruction of the persistent chemical would also need to be in place, for production wastes and to ensure end-of-product life disposal.

ABBREVIATIONS USED

α-HCH	α-Hexachlorocyclohexane
AFFF	Aqueous film firefighting foam
β-HCH	β-Hexachlorocyclohexane
B	Bioaccumulative
BAT	Best Available Technique
BFR	Brominated flame retardants
BPA	Bisphenol A
BPR	Regulation (EU) 528/2012 concerning the placing on the market and use of biocidal products
BREF	BAT Reference Document
CAS	Chemical Abstracts Service
CEPA	Canadian Environmental Protection Act
CLP	Classification, labelling and packaging or Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures
CMR	Carcinogenicity, Mutagenicity and Toxicity for Reproduction
CO2	Carbon Dioxide
CONCAWE	Division of the European Petroleum Refiners Association
CORAP	Community rolling action plan
CP	Chlorinated paraffins
CSA	Chemical Safety Assessment
cVMS	Cyclic Volatile Methylsiloxanes
D3	Cyclotrisiloxane/ examethylcyclotrisiloxane
D4	Cyclotetrasiloxane/ octamethylcyclotetrasiloxane
D5	Cyclopentasiloxan/ decamethylcyclopentasiloxane
D6	Cyclohexasiloxane/ dodecamethylcyclohexasiloxane
DART	Decision Analysis by Ranking Techniques
DDE	Dichlorodiphenyldichloroethylene
DDT	Dichlorodiphenyltrichloroethane
DEPA	Danish Environmental Protection Agency
dl-PBBs	Dioxin-like Biphenyls
EAP	Environment Action Programme
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemicals Agency
EEA	European Environment Agency
EFOA	European Fuel Oxygenates Association
ELINCS	European List of Notified Chemical Substances
ELV	Emission Limit Value
EU	European Union
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
GWP	Global Warming Potential
HBCD	Hexabromocyclododecane
HCB	Hexaclorobenzene
HCH	Hexachlorocyclohexane
HFC	Highly fluorinated chemical substance
HMPD	Directive 2001/83/EC on medicinal products for human use
IARC	International Agency for Research on Cancer
ICCM	International Conference on Chemicals Management
IED	Directive 2010/75/EU on industrial emissions (recast)
INCI	International Nomenclature of Cosmetic Ingredients
IPCC	Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control) (recast)
IPEN	International POPs Elimination Network
IQ	Intelligence Quotient
KEMI	Swedish Chemicals Agency
LCCP	Long Chain Chlorinated Paraffins
LRTP	Long-Range Transport Potential
M	Mobile
MCCP	Medium Chain Chlorinated Paraffins
MS	Member State
MTBE	Methyl *tert*-butyl ether
ODS Regulation	Regulation (EC) No 1005/2009 on substances that deplete the ozone layer
OECD	Organisation for Economic Co-operation and Development
P	Persistent
PAH	Polycyclic Aromatic Hydrocarbon
PBB	Polybrominated Biphenyls

PBDD	Polybrominated dibenzo-p-dioxins
PBDF	Polybrominated dibenzofurans
PBDE	Polybrominated Diphenyl Ethers
PBT	Persistent, Bioaccumulative and Toxic
PCB	Polychlorinated Biphenyls
PCDD	Polychlorinated dibenzo-p-dioxins
PCDF	Polychlorinated dibenzo-p-furans
PCN	Polychlorinated Napthalenes
PCT	Polychlorinated Terphenyls
PET	Polyethylene terephthalate
PFASs	Per- and polyfluorinated alkyl substances
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctane sulphonate
PMT	Persistent, Mobile and Toxic
POPs	Persistent Organic Pollutants
POPs Convention	2001 Stockholm Convention on Persistent Organic Pollutants
POPs Protocol	1998 Aarhus Protocol on Persistent Organic Pollutants
POPRC	Persistent Organic Pollutants Review Committee
PPPR	Regulation (EC) No 1107/2009 concerning the placing on the market of plant protection products on the market
PVC	Polyvinyl chloride
QSAR	Quantitative Structure Activity Relationships
RAC	ECHA Committee for Risk Assessment
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RIVM	National Institute for Public Health and the Environment, Netherlands (Rijksinstituut voor Volksgezondheid en Milieu)
RoHS 2	Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast)
SAICM	Strategic Approach to International Chemicals Management
SCCP	Short Chain Chlorinated Paraffins
SDS	Safety Data Sheet
SVOCs	Semi-volatile organic compounds
SVHC	Substances of very high concern
T	Toxic
TBT	Tributyltin
TBBPA	Tetrabromobisphenol A
TEL	Tetraethyllead
TPhT	Triphenyltin
T2D	Type 2 Diabetes
TEQ	Toxic Equivalent
UK	United Kingdom
UNECE	United Nations Economic Commission for Europe
UNEP	United Nations Environment Programme
US EPA	United States Environmental Protection Agency
USSR	Union of Soviet Socialist Republics
UWWTD	Urban Wastewater Treatment Directive
VMPD	Directive 2001/82/EC relating to veterinary medicinal products
vP	Very Persistent
vPvB	Very Persistent, Very Bio-accumulative
WHO	World Health Organization

1 INTRODUCTION

This sub-study focuses on "very persistent" chemical substances, i.e., those substances that are resistant to degradation and therefore will remain in the environment for a long time. One of the most well-known examples of very persistent substances is the grouping of highly fluorinated chemicals, also known as per- and poly-fluorinated alkyl substances, or PFASs. The sub-study aims to provide:

- An overview of the status quo regarding very persistent chemicals, including a description of the most important health and environmental issues relating to very persistent chemicals, according to current knowledge;
- An overview of current legislation and policy measures on the EU level;
- Activities in international and regional organisations as well as Member States and other countries, and of industry and civil society organisations;
- An analysis of the main gaps in relevant legislation and policies;
- A review of ongoing activities aimed at developing alternatives to or substitutes for very persistent chemicals, including non-chemical solutions.

The study considers the following problem:

Problem Statement
The use and dispersal in the environment of very persistent chemicals represents a threat to health, the environment and natural resources. Due to technical/functionality reasons, such chemicals are widely used in a broad range of applications. Chemicals with a high degree of persistence will remain in the environment for a long time, and lead to exposure of humans and the environment, including i.a. vulnerable population groups, biodiversity and environmental media. This may involve previously overlooked or unpredictable negative effects even for chemicals where laboratory tests did not indicate any considerable toxicity, e.g. if the toxic effects occur at low concentration levels or the do not appear until many years later. Concentrations of a (very) persistent chemical will tend to build up and eventually reach levels where harmful effects to health and natural resources may occur. Damage from exposure to very persistent chemicals is poorly reversible or even irreversible and may entail considerable cost to society. With the current high levels of production and widespread use of very persistent substances, cases of such damages are highly likely to appear or may even be unavoidable. The current EU regulatory framework identifies chemicals that combine persistence with bioaccumulation and toxicity (PBT) or high persistence and high degree of bioaccumulation (vPvB) as substances of very high concern (SVHC), which may be subject to authorisation or restriction. However, it is not clear whether EU legislation allows for the possibility to regulate substances based on persistence alone, or whether current requirements for testing and/or test methods to screen and test chemicals for persistence are adequate for identifying those chemicals where persistence is likely to lead to accumulations of concern.

The sub-study's findings are based on a thorough review of the available literature, including academic articles and reports and stakeholder input obtained through a June 2016 workshop and selected interviews. On the basis of the overview and analysis, the sub-study identifies a number of possible responses in the short, medium and long term, which could contribute to the protection of health and the environment.

The process of fact-finding has also drawn on work carried out in other EU policy processes, notably a project for the European Commission - "Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation", which includes a case study on 'Inconsistencies in assessment procedures for PBT and vPvB as properties of concern'. The case study is an ex-post assessment of the coherence and effectiveness of the current regulatory framework. It does not consider 'persistence' as a characteristic apart from BT or vB, nor does it look at the scientific literature concerning the health and environmental issues linked to very persistent substances. It therefore complements rather than duplicates this sub-study.

1.1 THE PROBLEM WITH PERSISTENCE

Persistency in chemicals is a desirable quality, as well as an issue of concern. Chemicals that are not readily biodegradable last longer, which can be important for particular applications where durability is a requirement. For various technical or functionality reasons, such chemicals are used widely in a broad range of applications. However, because persistent substances tend not to degrade through natural processes, they may remain in the environment for an indefinite time.

Some stakeholders have questioned why this persistence should be considered a problem, and compared such substances to the stones found in nature. But chemical substances are not like inert stones, fixed to one place. They are molecules and, if persistent, will "have time" to be transported over long distances and reach remote regions in all parts of the world[12]. They may accumulate to high levels in the environment and become sources of exposure. If these substances turn out to be toxic at a later point and if exposure levels have become sufficient to cause adverse effects in humans, domestic animals, or wildlife, it may not be possible to reverse their impacts.

Concern about persistence in chemicals is long-standing. One of the earliest warnings dates from 1977[13]:

> *'On the face of it there appears little reason to be concerned about a material which, even though present in the environment, is not causing any detectable damage. On the other hand, persistent materials, because of this property, will accumulate in the environment for as long as they are released. Since the environment is not effective at cleansing itself of these materials, they will remain for indefinite periods, which were not recognized at the time of their original release. The problem could become entirely out of control and it would be extremely difficult if not impossible to do anything about it. Materials which are strongly persistent can accumulate to rather high levels in the environment and effects which would not otherwise be important could become so.'*

Because of their long half-lives and tendency for bioaccumulation and long-range transport, they can accumulate in remote polar regions, far from their origins. Some scientists argue that persistence is in fact the most important single factor affecting chemical exposure and risk for the environment[14]. While many environmental exposures may occur close to the point of origin, such as discharges from industrial plants, in the case of very persistent chemicals the main concern may be exposures that occur far afield. An additional challenge lies in the difficulty to detect/demonstrate harmful effects given the multitude of organisms across ecosystems and the still limited knowledge concerning some toxicological aspects. Because very persistent substances stay around for a long time, their role in such aspects as combination effects, low dose and long term exposure, and sensitivities of certain vulnerable populations may require special attention.

Several of the world's major threats to the human health and the environment are closely related to this aspect of persistence. For example, the threat to the stratospheric ozone layer comes from ozone-depleting chemicals -- highly persistent fluorinated compounds with a very slow turnover in the atmosphere (see section 2.4 below for more on highly fluorinated compounds). Climate change caused by the increased greenhouse effect of the atmosphere is related to how long the various greenhouse gas compounds remain in the atmosphere. These compounds (F-gases, methane and CO_2) are also more or less persistent, with CO_2 eliminated only through photosynthesis. In both cases, the persistence of the compounds involved means that a very long time is required for "repairing" the environment, if such effects can even be reversed.

[12] Scheringer, M. *et al*., 2012.
[13] Stephenson, M.E., 1977.
[14] Mackay, D., *et al*., 2014.

Unease about the global spread of some types of pollutants, e.g., the persistent organic pollutants (POPs) covered by the Stockholm Convention[15], has led some to identify chemical pollution as one of nine so-called 'planetary boundaries' – thresholds beyond which non-linear, abrupt environmental change might occur on a global scale[16].

Scientists have proposed three conditions that must be met at the same time for a chemical or mixture of chemicals to be considered a planetary threat[17]:

> (1) The chemical or mixture of chemicals has a disruptive effect on a vital earth system process of which we are ignorant;
> (2) The disruptive effect is not discovered until it is, or inevitably will become, a problem at a planetary scale; and
> (3) The effects of the pollutant in the environment cannot be readily reversed.

The problem of ignorance is an important factor, in that the disruptive effects are not discovered until they already occur on a global scale and are affecting a vital earth system process. In light of this problem of ignorance, , the scientists argued for a regulatory approach based on hazard rather than risk, with a focus on persistence seen as particularly important. The depletion of the stratospheric ozone layer because of the production and release of halocarbons was cited as a clear example of a global-scale environmental impact that no one foresaw at the time of the design and initial commercialisation of these substances.

In 2015, the Stockholm Resilience Centre[18], the leading proponent of the planetary boundaries concept, replaced the term '**chemical pollution'** with the term '**introduction of novel entities'**, to include other potential human-driven global risks such as the release of plastics, nanomaterials and radioactive materials. Its website notes: "*These compounds can have potentially irreversible effects on living organisms and on the physical environment (by affecting atmospheric processes and climate). Even when the uptake and bioaccumulation of chemical pollution is at sub-lethal levels for organisms, the effects of reduced fertility and the potential of permanent genetic damage can have severe effects on ecosystems far removed from the source of the pollution. For example, persistent organic compounds have caused dramatic reductions in bird populations and impaired reproduction and development in marine mammals…At present, we are unable to quantify a single chemical pollution boundary, although the risk of crossing Earth system thresholds is considered sufficiently well-defined for it to be included in the list as a priority for precautionary action and for further research."*

If a substance with a rather low or unknown toxicity is very persistent (and particularly if it is volatile or highly mobile), concentration levels will increase over time across the environment, in the different compartments such as air or water, depending on chemical properties. When concentrations reach certain levels, toxic effects will start to appear. If exposure is widespread (geographically and/or in different compartments), the risk for adverse effects increases. Since a multitude of organisms and ecosystems with varying sensitivities will be exposed, it will be hard to predict at what concentrations the effects will appear, but over time the probability of adverse effects will increase. If such an impact is discovered too late to have a disruptive effect on a vital earth system, the effects of the pollutant may be irreversible[19].

The problems related to very persistent chemicals are particularly challenging in view of a circular economy that strives to close the loops by e.g. increasing reuse and recycling of material. Exposure might occur throughout the material cycle, from manufacturing of the chemicals to manufacturing and use of products, during waste management and recycling as well as in connection to use of recycled

[15] UNEP, 2001 (the 'Stockholm Convention').
[16] Rockström, J., *et al*., 2009.
[17] Persson, L.M., *et al*., 2013.
[18] http://www.stockholmresilience.org/21/research/research-programmes/planetary-boundaries.html
[19] Diamond, M.L., *et al*., 2015.

materials. Even less persistent substances may be persistent if integrated into a material. If they continuously leak, levels will build up in the environment (see section 2.5.5 below on the special case of 'pseudo-persistence'). If the material is recycled and used again, very persistent substances may accumulate in recycled materials[20]. If this problem is not properly managed, it might lead to increasing concentrations of contaminants in recycled materials, along with increased dispersal and presence of very persistent chemicals in the technosphere as well as the natural environment.

1.2 IMPACT ON HEALTH AND THE ENVIRONMENT OF VERY PERSISTENT CHEMICALS

Making any generalizations on the health and environmental impacts of very persistent chemicals is a difficult proposition. However, overall, humans, domestic animals, and wildlife are more likely to be exposed to a chemical if it does not easily degrade or is dispersed widely in the environment. The structural characteristics that enable a chemical to persist in the environment can also help it to resist metabolic breakdown in people or wildlife. For example, synthetic chemicals that contain halogen atoms (particularly fluorine, chlorine, or bromine) are often resistant to degradation in the environment or within organisms[21].

Metals are basic elements and cannot be further broken down in the environment. Because of human activities, some highly toxic metals, such as lead, mercury and arsenic, may accumulate in the environment in ways similar to the accumulations of very persistent substances, leading to increased exposures. For example, lead contamination of air, soil, or drinking water can ultimately result in significant exposures in fetuses, infants, and children, resulting in impaired brain development[22]. Although this sub-study will focus on synthetic organic chemicals the potential health effects of exposure to certain metal compounds should not be overlooked, as discussed in more detail in section 2.5.3 on organometallics.

The different chemicals that have been classified as persistent or very persistent exhibit a wide range of impacts on health and the environment. For example, the negative health and environmental effects of a number of POPs are well documented. Exposure to the well-studied POPs can lead to serious health effects including certain cancers, birth defects, dysfunctional immune and reproductive systems, greater susceptibility to disease and damages to the central and peripheral nervous system[23]. Further, presence of POPs in the environment is associated with severe effects such as impaired reproduction in birds and mammals. The specific health and environmental impacts of the groups of chemicals looked at more closely in this study are discussed in more detail in sections 2.5 and 2.6.

Persistence in itself relates to both health and environmental impacts. In this respect, persistence can be viewed as a factor in exposure and risk. How persistent the chemical or substance is means that the chemical is present longer in the environment and in turn affects present and future routes and rates of exposure. For this reason, persistence of chemicals in the body and/or the environment is considered one of the important factors to take into account when figuring out how to target those combinations of chemicals that pose the highest risk for human and environmental health[24].

An illustrative example of this are the highly fluorinated chemicals, more specifically the per- and poly-fluorinated alkyl substances known collectively as PFASs (discussed in greater detail in section 2.4). The highly fluorinated chemicals are anticipated to have long term effects on the environment and health in the foreseeable future due to their extremely persistent nature in the environment, their continued formation from precursor compounds and their continued production in other parts of the world. These chemicals were originally perceived as being inert because the compounds did not break

[20] Ionas, A.C., *et al*., 2014.
[21] Heath, E. and Kosjek, T.,2012.
[22] WHO, 2005b.
[23] Wong, M.H., *et al*., 2012.
[24] SCHER, SCCS, SCENHIR, 2012.

down in the environment. However, the interpretation of human health risks associated with PFASs has changed over time gradually as evidence relating to the effects of persistence and bioaccumulation has emerged[25]. It is also suggested that the lack of initial evidence was in fact related to their persistence or the compounds' resistance to breakdown, i.e. it was assumed that the compounds were inert and thus would not pose a health risk.

New health risks are also a concern as new evidence for "old" persistent chemicals, e.g., the highly chlorinated persistent organic pollutants (POPs) such as DDT and the PCBs, has emerged. Recently, for example, a substantial volume of research has focused on chemicals with endocrine disrupting properties, and especially on POPs and possible associations with increased risk for Type 2 diabetes (T2D) and obesity[26].

1.3 WHY PERSISTENCE ALONE IS A CONCERN

At this point REACH and other EU legal acts regulate persistent chemicals only if other hazardous properties are also present. Article 57 of REACH setting forth the substances that may be included in REACH Annex XIV as subject to authorisation as substances of very high concern (SVHC) specifies three categories where persistence plays a role, i.e.:

- Persistent, bio-accumulative and toxic (PBT)
- Very persistent and very bio-accumulative (vPvB)
- Substances, such as those having PBT or vPvB properties which do not fulfil the criteria set in REACH Annex XIII, but for which there is scientific evidence of probably serious effects to human health or the environment which give rise to an equivalent level of concern. Note that this category can only be applied on a case by case basis and not to a grouping of chemicals of concern.

Thus regulators must show that a substance that is persistent or very persistent in the environment is also bio-accumulative and toxic, or very bio-accumulative in order to put in place controls under EU legislation. But, as section 2.5.2 on siloxanes discusses briefly, it is not straightforward to determine whether a substance is bioaccumulative, and there is a strong possibility of missing substances that should be considered as of very high concern.

More recently, German authorities have argued that the characteristic of mobility (M) should be a criterion giving rise to a level of concern equivalent to bioaccumulability. They have proposed a methodology for determining when a substance registered under REACH should be considered persistent, mobile and toxic (PMT), particularly with respect to protection of water resources used for human consumption[27]. The concept of mobility is discussed further in later sections.

The degree of persistence means that chemicals can accumulate in the different environmental compartments, and become sources of exposure to substances. As noted earlier, if these substances turn out to be toxic at a later point and if exposure levels have become sufficient to cause adverse effects in humans, domestic animals, or wildlife, it may not be easy or even impossible to reverse their impacts. This may lead to the loss of an important natural resource, and to increased pressures on other resources as well as increased overall pressure on human health and the ecosystems.

It should be noted that one of the 12 principles of Green Chemistry is:

> **10. Design chemicals and products to degrade after use**: Design chemical products to break

[25] Grandjean, P., & Clapp, R., 2014.
[26] Lee, D. *et al*., 2014.
[27] Kalberlah *et al*., 2014a.

down to innocuous substances after use so that they do not accumulate in the environment[28].

Recent studies have pointed out how persistence alone becomes a concern if accumulations of a substance that lead to exposure are found to be poorly reversible. For example, the widespread use of highly fluorinated firefighting foams in trainings around military and other airports has resulted in contamination of underlying groundwater reserves in those localities. Since highly fluorinated chemicals are known not to degrade for decades or longer, and since exchange of groundwater reserves due to rain or other flows can also take a very long time, drinking water supplies contaminated by such chemicals will become a constant source of exposure, unless substitute drinking water sources are found[29].

Once a very persistent substance is released into the environment, its breakdown or transformation products may raise new concerns. In the case of PCBs, for example, it took considerable time for scientists to discover that the process of bioaccumulation resulted in concentrations of the more toxic congeners than were found in the commercial products[30]. DDT is another example in that the compound itself is considered to have low toxicity for humans, but when released into the environment its transformation products include the more toxic DDE[31]. Moreover, some health effects may not become evident until long after exposure[32].

The question has arisen whether all vP substances are of concern, or whether there might be examples of vP substances which have already accumulated to high levels and still do not induce any impacts. In the research for this sub-study, no such examples came to light. But in the case of vP substances, there will always be uncertainty about whether and when an adverse effect will occur and where, and this uncertainty will never be removed.

The logic is as follows: risk is the ratio of exposure (i.e. concentration in the environment) versus the no-effect threshold. If a substance is very persistent, and assuming that emissions continue at a constant rate, it will attain higher and higher concentration levels in the environment. In this case the risk quotient also increases continuously up to the point that the concentration exceeds the no-effect threshold. This is an inevitable process. When and where the adverse effect occurs will depend on the sensitivity of the species that are exposed.

Accordingly, this sub-study focuses on whether very persistent substances, as well as those substances that combine persistence with mobility, should be regulated.

[28] Anastas & Warner, 1998.
[29] Cousins, I.T. *et al*., 2016.
[30] EEA, 2001.
[31] U.S. Dept of Health and Human Services, 2002.
[32] Grandjean & Clapp 2014; Rücker, C. & Kümmerer, K., 2015.

2 THE STATE OF PLAY REGARDING THE SUB-STUDY AREA

2.1 DEFINING PERSISTENT AND VERY PERSISTENT

Persistence is normally defined in terms of the biodegradability of a substance or chemical substance in different environmental media or compartments, such as water or soil. In the environment, many chemicals are degraded by sunlight, destroyed through reactions with other environmental substances, or metabolized by naturally occurring micro-organisms. Some chemical substances, however, have features that enable them to resist environmental degradation. They can accumulate in soil and aquatic environments. Substances with properties that enable them to bind strongly to soil particles may stay in the place they were deposited, but other substances may evaporate into air (volatilize) or dissolve in water. These may then migrate considerable distances from where they are released.

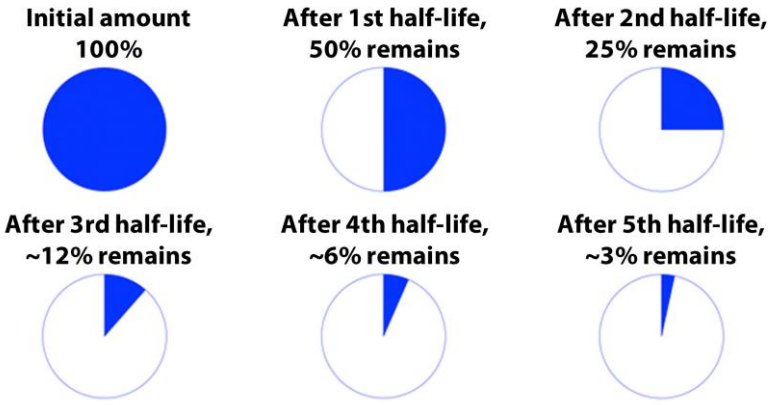
In the regulatory context, persistence is defined by single-media half-life criteria. REACH provides, for example, that a chemical is persistent (P) if its half-life in soil exceeds 120 days or its half-life in water is more than 60 days. It is considered very persistent (vP) when the half-life in water is higher than 60 days, or when the half-life in soil or in water sediment is higher than 180 days.[33] The table below compares the REACH Annex III criteria for persistence to those set by other national and international fora:

Table 1: Degradation half-lives for identification of PBT/vPvB/POP substances

Criteria	PBT (REACH)	vPvB (REACH)	PBT (US EPA)	vPvB (USEPA)	POP (Stockholm Convention)	PBT (OSPAR)
- in marine water	>60 days	>60 days	>60 days	>180 days	>60 days	>50 days
- in fresh or estuarine water	>40 days	>60 days	>60 days	>180 days	>60 days	>50 days
- in marine sediment	>180 days	>180 days	>60 days	>180 days	>180 days	>50 days
- in fresh or estuarine sediment	>120 days	>180 days	>60 days	>180 days	>180 days	>50 days
- in soil	>120 days	>180 days	>60 days	>180 days	>180 days	

A very persistent chemical with a half-life of more than 180 days, or approximately six months, may remain in the environment for much longer than that. The figure below illustrates how a significant amount of a substance may still remain even after a fourth or fifth half-life. If releases of the substance continue, accumulations will occur.

Figure 1: Amounts of a substance remaining after multiple half-lives



[33] Regulation (EC) No 1907/2006.

No criteria have been developed to define when a substance might be considered extremely persistent, i.e., when no evidence of degradation potential has yet been identified, as with some of the highly fluorinated chemicals.

2.2 SCREENING AND TESTING FOR PERSISTENCE

One of the major challenges relating to persistent and very persistent chemicals is that testing multimedia half-lives is time consuming and costly. According to UNEP[34], only 220 chemicals out of a set of 95,000 industrial chemicals have been evaluated in relation to their biodegradation half-lives and only 1,000 have data on bio-concentration. A number of studies have suggested ways in which chemicals can be screened based on chemical structures and characteristics to estimate their persistence. However, no common framework for doing this has been adopted or accepted. Scheringer et al.[35] pointed out the need for concepts and tools that make it possible to screen large numbers of chemicals for persistence.

While a number of studies[36] have published lists of priority chemicals, or chemicals of concern, including because of persistence, they differ in their approach and focus, and are based on different criteria, such as the REACH PBT criteria, which do not include long-range transport potential (LRTP); and the POPs criteria under the Stockholm Convention, which do include LRTP[37].

A common misconception is that environmental persistence is an inherent property of the substance that can be readily measured. However, assessing the persistence of chemical substances in the environment is not straightforward. A review of the current state of science for POP fate assessment in order to prepare guidance for the development and review of POP risk profiles found that evaluating persistence entailed an assortment of supporting information and the need to address gaps and uncertainties[38].

The persistence criterion under REACH is defined in terms of degradation half-lives in water, soil or sediment. Degradation processes that transform a chemical – ultimately into water, CO2 and salts – include microbial and chemical transformation reactions. In particular, microbial transformation ("biodegradation") depends strongly on a variety of factors such as type of bacteria, composition of soil, temperature, humidity, presence of other chemicals, adaptation of microbes, etc. For these reasons, results from biodegradation tests are generally highly variable even for the same chemical. This means that the measurement of biodegradation half-lives is a challenging task that involves many uncertainties[39].

Established degradation tests include: (i) the test for ready biodegradation ("ready test"), described by OECD guidelines 301; (ii) the test for inherent biodegradability, described by OECD guidelines 302; and (iii) so-called simulation tests, for example as described by OECD guidelines 303[40]. The ready test shows whether or not a chemical is easily biodegraded even under conditions that are not supportive of the biodegradation process. If a chemical passes this test, i.e. is readily biodegradable, its degradation half-life is on the order of 1–10 days. In such cases it can be concluded almost with certainty that the chemical is not persistent. If a chemical does not pass the test, i.e. is not readily biodegradable, its half-life cannot be quantified on the basis of the test result. It can be anything between 20–30 days and many years or even decades.

[34] UNEP 2013b.
[35] Scheringer, M. *et al*., 2012.
[36] Brown, T.N. & Wania, F., 2008; Walker, J.D. & Carlsen, L., 2002; Muir, D.C.G. & Howard, P.H., 2006; Howard, P.H. & Muir, D.C.G. 2010.
[37] Scheringer, M. *et al*., 2012.
[38] Boethling, R. *et al.*, 2009.
[39] Brillet, F. *et al.*, 2016.
[40] OECD, 2001; OECD, 2002; and other tests.

The test for inherent biodegradability is not very common; it applies conditions that are more supportive of the biodegradation process (such as a co-substrate for the bacteria to metabolize) than those of the ready test. If a chemical passes this test, this means that the chemical has at least a potential for biodegradation (this is meant by "inherent biodegradability") and it may or may not be persistent[41].

The most informative results in terms of biodegradation half-lives are obtained from simulation tests, where the conditions in a sewage treatment plant or soil are simulated. Often these tests are performed with carbon 14 (14C)-labeled chemicals because then all the carbon that was provided in form of the test chemical can be tracked with a Geiger counter and the transformation products on the way from the test chemical to CO2 may be identified. However, this procedure is time- and labor-intensive and expensive. Under REACH, simulation tests are required only for chemicals manufactured or imported above 100 tonnes per year. For many chemicals where persistence is predicted, e.g., because of chemical structure, no simulation test results are available[42].

While lower tier tests such as ready and inherent biodegradability tests (OECD 301 and OECD 302 test series) are relatively inexpensive (between €1,500 and €3,200 per test), simulation tests as described above using 14C labeling are expensive and time consuming. The costs associated with these tests depend on the exact test design, and with this caveat the costs are estimated to be between €80,000 and €120,000. The additional cost for synthesis of 14C-labeled test items of around €20,000 to €40,000 should also be considered when estimating the costs associated with these tests[43]. As mentioned previously, chemicals behave differently under different environmental conditions, so more thorough testing requires not just testing in different media, but simulation of different environmental conditions in these media. The following table gives cost estimates for different simulation studies in different media.

Table 2 Estimated costs associated with multimedia simulation tests[44]

Test type	Estimated cost
OECD 307 study (Aerobic and anaerobic transformation in soil) with 4 different soils and radiolabeled test item:	€88,000
OECD 308 study (Aerobic and anaerobic transformation in aquatic sediment systems) with 2 different water/sediment systems and radiolabeled test item	€109,000
OECD 309 study (Aerobic mineralisation in surface water) with 1 natural water and radiolabeled test item	€55,000

Note that the costs of simulation tests depend strongly on the properties and behaviour of the substance being tested.

Long or very long half-lives are particularly difficult to measure in simulation tests because the test has to be run for many weeks or months. This obviously increases the costs substantially. It also means that the degradation half-lives of (very) persistent chemicals have to be extrapolated from results of a few percent degradation during the time for which a test was run (for example, a three-month long simulation test might result in 6% degradation; because the point in time when 50% are degraded will not be reached, the degradation half-life is calculated on the basis of the partial degradation).

In addition, degradation half-lives can be estimated from field data in cases where a chemical was applied (pesticides such as DDT) or spilled (PCBs) at a given time and its residues in the soil are determined over several years. This is the source of soil degradation half-lives of many POP

[41] OECD, 2009.
[42] Scheringer, M. *et al*., 2006.
[43] Cost estimates provided by Hydrotox GmbH.
[44] Cost estimates provided by Eurofins Agroscience Services EcoChem GmbH.

pesticides; these half-lives are often on the order of 10 to 20 years or more. However, this source of information on biodegradation is limited to just a few chemicals that have been monitored over many years, and is not a testing strategy[45].

Another option is provided by estimation methods that calculate a degradation half-life on the basis of the structure of the test chemical. In particular for (very) long half-lives, this may be the most efficient method for obtaining half-life data. An estimation tool that is often used because it is available from the US EPA website free of charge is BIOWIN™. This method was derived from biodegradation information for 200 chemicals with different structural elements (alkyl chains, amino groups, nitro groups, etc.). For each of these structural elements, a contribution to the degradation half-life is added to the estimate of the chemical's degradability. However, the BIOWIN model tends to catch a range of chemicals, not all of which are persistent.[46]

A number of models that use Quantitative Structure- Activity Relationships (QSARs) exist, such as: KOWWIN, BIOWIN 2, BIOWIN 3, BIOWIN 6, OECD 301 C model and OECD 301 F model. Different combinations of tests can be used to derive estimates of persistence using estimated half-lives [47].

Current screening methods are based on limited information, and rely on data that is limited to structures and activity. The reliability of QSAR results strongly depends on whether or not the predicted substance is within the applicability domain of the model. The PROMETHEUS study attempted to integrate computer models to provide more accurate results, and the results suggests that integrations of computer models can produce more accurate predictions of persistence[48].

For a large number of existing substances on the (European) market, potential hazard has never been evaluated, since such an evaluation was not required in the past, or because their market volumes were so small. RIVM in the Netherlands has developed a Persistence/Bioaccumulation score that can be used as a tool to rapidly screen and assess data-poor substances for their potential persistence and bioaccumulation in the food chain[49]. The tool was developed building on previous studies on PBT prioritization and selection and to improve on the set of chemicals, which could be analyzed. The aim of the study was to develop a methodology to screen a large set of chemicals and to identify those substances that show the most POP- or PBT-like properties.

The estimation methods described above could provide a way forward, e.g., for screening of new chemicals to avoid having those that are very persistent from entering the market or reaching high production volumes. They could also be used to cross-check whether the very persistent chemicals already on the market have been identified and the appropriate measures taken. However, no common framework for carrying out such screenings has been adopted or accepted.

A ECETOC task force[50] that reviewed recent literature linked to the 2011 amendments of Annex XIII of the REACH Regulation (introduction of new information and a 'weight-of-evidence' approach to assess whether a chemical meets the criteria for PBT or is regarded as vPvB) focused on certain aspects of persistence and bioaccumulation assessment. While the task force developed an integrated evaluation strategy, it also recommended further research on other topics where it found the science not sufficiently developed to allow regulatory conclusions to be drawn.

Weight-of-evidence is an approach used to evaluate evidence, where a number of studies exist showing different aspects of the problem, i.e. different exposure routes or where good quality studies

[45] See section 2.5.1.1 for examples of monitoring of PCBs and PDDE.
[46] Benfenati, E., *et al*, 2016; Pizzo, F. *et al*., 2013.
[47] Böhnhardt, 2013; Pizzo, F. *et al*., 2013.
[48] Benfenati, E., *et al*, 2016.
[49] Rorije, E. *et al*., 2011.
[50] ECETOC, 2014.

show conflicting results. Relative weights are assigned to different sources of information/studies based on the following factors: quality of the data; consistency of results/data; nature and severity of effects; and the relevance of the information for the given regulatory endpoint. In all cases the relevance, reliability and adequacy for the purpose should be considered. The weight of evidence approach uses expert judgement to assign weights and assess the information.

Weight-of-evidence approaches provide a system for analysis where gaps in knowledge and outright contradictions between information or sources of information exist. Existing weight-of-evidence approaches have been criticized as either too formulaic or too vague, simply calling for professional judgment that is hard to trace to its scientific basis[51]. Hypothesis-based weight of evidence—that emphasizes articulation of the hypothesized generalizations, their basis, and span of applicability has been suggested as a way to improve upon weight of evidence approaches[52].

Given the amount of chemicals that are potentially P or vP, better screening and testing methods are needed. Opportunities for improvement seem to lie between inherent biodegradability tests and simulation tests. There are several areas that should be explored. One is to improve accuracy of QSARs by using multiple *in silico*[53] methods as PROMETHEUS has illustrated. Another possibility is to improve the data or to add additional properties to the models that would improve their accuracy in predicting persistence.

2.3 WHICH (GROUPS OF) SUBSTANCES ARE PERSISTENT AND VERY PERSISTENT

The Stockholm Convention covers 26 substances and groups of substances which are acknowledged to meet the screening criteria to be considered persistent organic pollutants (POPs) within the meaning of the Convention. Three additional substances are under consideration for regulation under the Convention.

However, many more substances have been identified that meet the criteria for POPs. For example, a 2008 study[54] looked at a group of known Arctic contaminants and the extent of their resemblance to other chemicals, to develop a screening methodology that was then used to identify 120 high production volume chemicals out of 100,000 industrial chemicals with structural similarities or with partitioning properties that suggested they were potential Arctic contaminants.

Another study[55] applied screening criteria for persistence, bioaccumulation, long-range transport potential, and toxicity to a set of 93,144 organic chemicals. In addition to those chemicals already acknowledged as POPs under the Stockholm Convention or under review as POP candidates, another 510 chemicals were identified that exceeded all four criteria but had not been evaluated under the Convention. The study's dataset of substances did not include many pesticides, biocides, and pharmaceuticals. It also did not include siloxanes. Finally, inorganic substances, metallorganic substances and salts were removed from the database before the analysis took place. Because no experimental data on persistence was available for most of the chemicals, data on persistent properties had to be estimated on the basis of chemical structure, using BIOWIN™. Ranges of uncertainty for the chemical property data were used to estimate a lower (190) and upper (1200) bound for the numbers of potential POPs. Of these, 98 percent were halogenated, including the highly fluorinated chemicals.

Within the EU, the European Chemicals Agency (ECHA), Member State and Commission experts collaborate in mass screening, assessing and ultimately in identifying additional substances that are

[51] Rhomberg, L., 2015.
[52] Lutter, R. *et al.*, 2015.
[53] *In silico* is used to refer to a computer-based methodology, as opposed to an *in vitro* (test tube) or *in vivo* (animal)-based test methodology.
[54] Brown, T.N. & Wania, F., 2008.
[55] Scheringer, M. *et al*., 2012.

PBT or vPvB and that should be added to the REACH Candidate List of substances to consider for inclusion in Annex XIV of REACH. The preparatory discussions are held in ECHA's PBT expert group. To date it has provided advice on some 160 substances under review as potentially PBT or vPvB. As of June 2016, 25 substances were evaluated as not PBT or vPvB, 19 were evaluated as appropriate for risk management action, and 10 were deemed potentially PBT but further action was postponed. Reviews were ongoing for the other 106 chemicals. New potential PBT/vPvB substances are added annually to the pool of on-going assessments. From the information available on the ECA website, it was not possible to determine how many substances may be of concern due to persistence alone.

A 2012 study[56] that screened a set of 95,000 chemicals for P, B and T thresholds as defined in REACH legislation highlighted that uncertainty concerning the number of potential PBT chemicals was particularly due to uncertainty with respect to persistence data.

The first chemicals to be classified as persistent were hydrophobic, or water repelling[57], including the original set of POPs listed in the Stockholm Convention. However, today a number of chemicals considered hydrophilic, i.e. with an affinity for water[58], are also recognised as very persistent. With the addition of perfluorooctanesulfonate (PFOS), chlordecone, hexachlorocyclohexane (HCH) isomers and endosulfan, the chemicals addressed by the Stockholm Convention are no longer solely hydrophobic.

While many persistent and hydrophobic compounds can be removed from water by sorption processes in the environment or during water treatment, the hydrophilic substances cannot, and there is a higher likelihood that they might be found in drinking water[59]. Some scientists are therefore arguing that persistent, mobile and toxic (PMT) substances should be considered of equivalent concern as PBT substances[60]. The persistence and mobility of the highly-fluorinated chemicals is discussed below and other persistent hydrophilic compounds are covered in section 2.5.4.

2.4 THE CASE OF HIGHLY FLUORINATED CHEMICALS

Highly fluorinated chemicals (HFCs) have been widely produced and marketed for use since the 1950s. The term is used here to cover the large group of compounds characterised by a fluorine-carbon bond. The persistence of the fluorine-carbon bond means that these chemical compounds are also very stable and durable. They are very efficient surfactants as well, and useful for a broad range of applications, e.g., cosmetics, firefighting foams, food contact materials, inks, medical devices, oil production, pesticide formulations, mining, textiles, apparel, and home furnishings[61].

This case study focuses largely on the per- and polyfluorinated alkyl substances known collectively as PFASs. However, it recognises that other man-made chemicals with this fluorine-carbon bond may also pose problems due to their environmental persistence. In addition to historical uses of PFAS, other significant sources of HFCs may include (bio)degradation of various side-chain fluorinated polymers, and atmospheric degradation of hydrofluorocarbons and hydrofluoroethers[62]. For example, the dominant atmospheric source of trifluoroacetic acid (TFA) -- one of the haloacetic acids found in polar regions that is resistant to degradation -- is from decomposition of the fluorocarbons HFC-134a, HCFC-123, and HCFC-124[63].

[56] Strempel, S. *et al*., 2012.
[57] Chandler, D.L., 2013.
[58] Ibid.
[59] Reemtsma, T, *et al.*, 2016.
[60] Ibid.
[61] KEMI, 2015.
[62] OECD, 2015b.
[63] Martin, J.W. *et al.*, 2003.

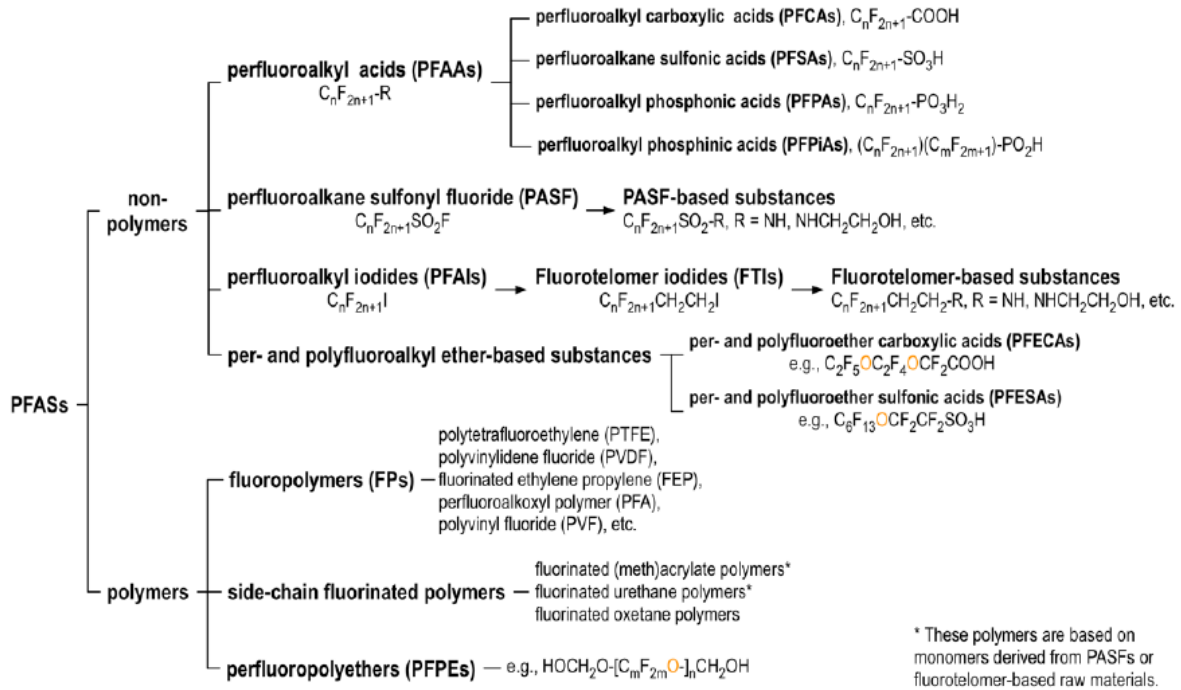
Moreover, as section 1.1 already notes, two of the biggest threats to our global environment are linked to highly persistent fluorinated compounds – the ozone-depleting substances which react chemically with the molecules comprising the stratospheric ozone layer, and the contribution of the F-gases with high Global Warming Potential (GWP) to climate change. In fact, a direct F-gas connection exists in that combustion of some fluorinated polymers is known to release F-gases[64]. This source of F-gases has not yet been taken into account under the Montreal Protocol.

The per- and polyfluorinated alkyl substances (PFAS) are a subgroup of the group of highly fluorinated chemicals, and they are characterised by chains of carbon and fluorine bonds. The focus during the first decades of commercialisation of these compounds was on long-chain PFASs – the so-called C-8 substances used in the manufacture of Teflon-coated cookware, water- and stain-resistant textiles, and fire-fighting foams. Of these, PFOS and PFOA were the most widely produced. In the 1980s and 1990s, evidence emerged of the toxicity and bioaccumulability of the long-chain PFAS, and regulatory pressure has led to phase-outs of their manufacture and use in the USA and Europe.

At the same time, a geographical shift in their manufacture has taken place and the long-chain PFASs are now produced in large volumes in the emerging Asian economies, notably China and India[65]. The concern about harm to human health and the environment due to emissions to the environment of long-chain PFAS is now global, as reflected by the designation of PFOS as a persistent organic pollutant under the Stockholm Convention[66].

In many cases the long-chain PFAS have been replaced by short-chain homologues -- the C-6s and C-4s. The diagram on the below gives an idea of the many different types of compounds that form part of the overall grouping of PFAS[67].

Figure 2: Different types of compounds in the grouping PFAS



[64] Huber, S. *et al.*, 2009.
[65] OECD, 2015b.
[66] UNEP, 2001.
[67] OECD, 2015b, p. 24.

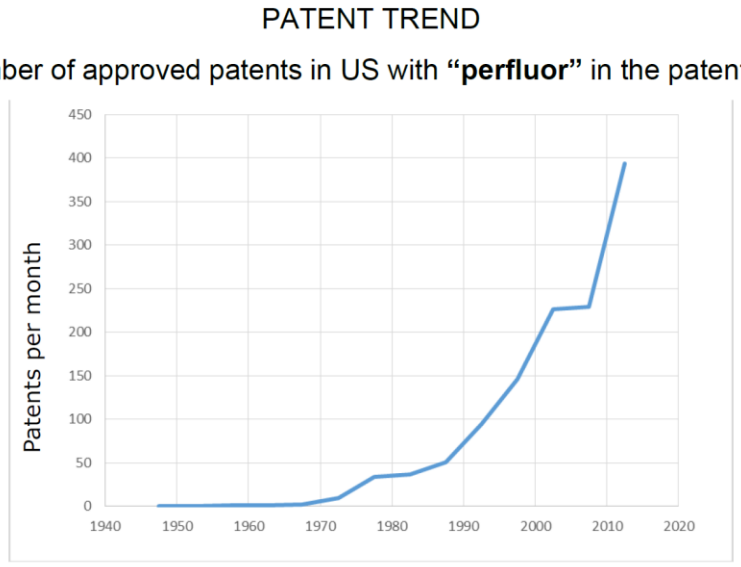
Two statements issued by scientists in the last two years -- the Helsingør Statement[68] and the Madrid Statement[69] -- have highlighted the health and environmental risks posed by the highly fluorinated chemicals as a group. The statements emphasise the extreme persistence of the carbon-fluorine bond in nature, and call for regulatory as well as non-regulatory actions to address the risks associated with all highly fluorinated chemicals, including the short-chain PFAS.

The FluoroCouncil, which represents the major producers of per- and polyfluorinated chemicals at global level, has responded to the Madrid Statement by acknowledging the problems of toxicity and bioaccumulability associated with the long-chain PFASs but emphasising that development of the short-chain alternatives had addressed these problems[70]. It has pointed out that the environmental persistence of these compounds is closely related to the stability and durability which makes them useful, and asserted that '[d]ecisions on the societal acceptability of strategic materials such as PFASs cannot be wisely made on a single attribute such as persistence'.

Two types of PFAS chemistries -- fluoropolymers and fluorotelomers – are commercially important. The fluoropolymers are widely used as linings for pipes, valves and tanks for chemical and pharmaceutical manufacturers; as lightweight, durable tubing and hoses for aircraft and land vehicles; and to enable high speed data transfer via communication devices. The fluorotelomer-based polymers provide water and oil repellency and are used in surface finishes for textiles and food packaging, and in firefighting foams.

Some 3,000 PFAS are estimated to be on the global market at this time[71]. A large proportion are polymers and therefore exempted from registration under REACH; of the others, only a few are registered. Very little information is available on quantities produced and, for half of all PFAS, almost no information can be found concerning their uses. However, the figure below, which shows how many patents with "perfluor" in the patent text are approved in the USA each month, gives an idea of how the number of uses for perfluorinated substances is burgeoning.

Figure 3: Number of approved patents in US with "perfluor" in the patent text[72]



[68] Scheringer, M. *et al.*, 2014a.
[69] Blum, A. *et al.*, 2015.
[70] Bowman, J.S., 2015a.
[71] KEMI, 2016.
[72] Fischer, S., 2017.

Today, more than 3,000 different types of PFAS are estimated to be on the market. They are found in cosmetics, food contact materials, inks, medical devices, mobile phones, pharmaceuticals and textiles, and they are used in pesticide formulations, oil production and mining. They are capable of long-range transport and are found even in remote locations.

While the environmental and health effects of PFOS and PFOA have been widely studied, many of the thousands of other PFAS still produced and used have been overlooked by researchers, and few control measures set in place. Indeed, the issue of PFAS as a whole has been called *"an intractable, potentially never-ending chemicals management issue that challenges the conventional chemical assessment and management paradigm adopted by society since the 1970s"* [73].

Environmental persistence and pathways to the environment

As discussed earlier in this sub-study, the criteria under REACH for determining if a substance is 'very persistent' is whether its half-life for biodegradation is shown to be more than 60 days in water, and more than 180 days in sediment or soil[74]. The degradation half-lives of PFASs, where such information is available, indicates a persistence of a totally different magnitude. One study estimated the half-life for PFOS as >41 years[75], but conceded it could be significantly longer than 41 years, because almost no degradation was observed during the period of the test. Scientists who study these chemicals have estimated that they will persist for hundreds of years[76].

The evidence available to date indicates that the new short-chained alternatives are also extremely persistent. Some degradation may occur by the chains breaking into smaller molecules but these still have the persistence of the fluorine-carbon bond. A report for the FluoroCouncil concluded that all of the five short-chain alternatives evaluated met the Stockholm Convention's criteria for persistence – whether as the actual substance evaluated or as their terminal degradation products (PFHxA/PFHx)[77]. Since data on the degradation half-life of perfluorohexanoic acid (PFHxA) in soil, sediment, and water was not available, the Environ study carried out a read-across from degradation studies of PFOA and concluded that PFHxA is not likely to degrade under normal environmental conditions[78]. Other studies also conclude that the perfluorinated parts of fluorinated alternatives, i.e., the short-chained PFASs, will form transformation products that will persist in the environment[79].

Per- and polyfluorinated alkyl substances reach the environment through a number of routes. According to a Swedish Environmental Protection Agency study, the largest direct point source of PFAS is its use in firefighting foams primarily at airports and military bases[80]. Water supplies with measurable PFAS levels were higher within 1 km of a potential source of PFAS, though PFAS was also found in water supplies far from known point sources. The use of firefighting foams has resulted in widespread contamination of groundwater at airports and military bases[81], including in The Netherlands, Germany, and Sweden. Because PFAS contamination of groundwater near firefighting practice sites has been found so frequently once it is looked for, it is highly likely that similar contamination underlies the commercial or military airfields of the other Member States.

[73] Wang, Z., *et al.*, 2017.
[74] These are also the criteria used under the Stockholm Convention for determining whether a substance is persistent.
[75] Hekster, F.M. *et al.* 2002.
[76] Russell, M.H. *et al.*, 2008; Washington, J.W. *et al.*, 2009.
[77] ENVIRON International Corporation, 2014.
[78] See also Post, G.B. *et al.*, 2012.
[79] Hurley, M.D. *et al*., 2004; Liou, J.S. *et al.*, 2010; Liu, J. *et al.*, 2013.
[80] Naturvårdsverket, 2016.
[81] Cousins, I.T. *et al*., 2016.

Why is the persistence of PFASs different from that of other chemicals?[82]

Typically, the persistence of an organic chemical depends on the interplay of chemical properties (and the underlying chemical structure, which defines the properties), on the one hand, and the environmental conditions, such as intensity of light or presence of certain bacteria, on the other hand. This is why in many cases the persistence of a chemical is not just a certain value, but varies widely depending on the environmental conditions. Of course, there is still an important or even dominant influence of the chemical structure: chemicals that are readily biodegradable such as ethanol or glucose are degradable under virtually all relevant environmental conditions; chemicals such as PCBs that are hard to degrade because of the stability of the carbon-chlorine bond will never be readily biodegradable under any kind of environmental conditions. However, even for PCBs or DDT, in particular when they reside in the soil, there is a wide range of degradation half-lives depending on soil conditions (soil moisture, presence of bacteria, adaptation status of bacteria, presence of other substances that can be metabolized easily by the bacteria and support co-metabolizing of the contaminant, etc.). This is why in some studies on environmental persistence of DDT residues of many years or decades is reported whereas others report faster disappearance. Even for the herbicide, atrazine, there is a study where the authors found atrazine residues in soil samples that were more than 20 years old. Normally, the persistence of atrazine is assumed to be on the order of months.

For PFASs, specifically for perfluorinated carboxylic and sulfonic acids (PFCAs and PFSAs), the situation is different. PFCAs and PFSAs are so stable that they do not degrade under *any* environmental conditions. In other words, their persistence does *not* depend on the environmental conditions; none of the many variable factors that are present in the environment does modify the persistence of PFCAs and PFSAs. This is unique and makes PFCAs and PFSAs different as a class. This is also why we are fully certain that their persistence is so high: we know that there are no conditions that would lead to an increase in their degradation rates. For other chemicals, we do not have this certainty just because of the influence of environmental factors that modulate the persistence, even for PCBs or DDT. PFCAs and PFSAs can be broken down, of course, but only under conditions that are so harsh, e.g. incineration at very high temperatures, e.g. 1,100°C, they do not occur in the normal environment[83].

Other PFASs such as fluorotelomer alcohols etc. eventually are transformed into PFCAs or PFSAs. This transformation process depends on environmental conditions as described above; it may take a few days, weeks or months. However, in the end they always form a totally persistent acid and that is why they should certainly be included in the persistence assessment in the same way as PFCAs and PFSAs.

Wastewater treatment and disposal and treatment of waste are also considered important secondary point sources, along with releases from industrial production processes. Laundering of PFAS-treated textiles or use of personal care products containing PFASs has led to their presence in urban wastewater and in the treated biosolids subsequently used as agricultural soil supplements[84].

The behavior of the HFCs in the environment is due in part to their physical properties. Many are water-soluble and mobile in soil, thus posing a threat to groundwater. Certain HFCs are volatile, and prone to long-range atmospheric transport. The two most widely studied PFAS -- PFOS and PFOA -- are non-volatile and only moderately water soluble; yet they are found even in remote regions like the European Arctic areas[85].

Because of the extreme persistence of these substances, concerns have been expressed about whether their releases into the environment might reach concentration levels that could breach so-called 'planetary boundaries' – a point at which the earth is no longer able to assimilate or degrade a human-released chemical which is discovered only too late to have a disruptive effect on a vital earth system, and the effects of the pollutant cannot be readily reversed[86]. The Helsingør Statement points out that the short-chain PFASs being introduced as alternatives are less efficient from a technical point of view, and therefore larger quantities may be needed to achieve the same performance as the longer chained PFAS, with the potential of increasing the overall load of highly fluorinated chemicals in the environment[87].

[82] Personal communication from Martin Scheringer, 21 May 2016.
[83] Wang, Z. *et al.*, 2015.
[84] Ahrens, L. *et al*., 2011.
[85] Jahnke, A., 2007.
[86] Persson, L.M. *et al*., 2013; Diamond, M.L. *et al*., 2015.
[87] Scheringer, M. *et al*., 2014a.

Health impacts

Human exposure to highly fluorinated chemicals is a growing concern. Significant sources of human exposure to PFAS include drinking water[88], diet[89] andhousehold dust[90]. Studies of plants grown in PFAS-contaminated soils and reclaimed water demonstrated that these substances can bioaccumulate, with long chain PFAS tending to stay in shoot or root crops and short chain PFAS moving into leaves and fruits, e.g., lettuce and strawberries[91].

Migration to food from food contact materials[92] is another concern. A 2017 study carried out by consumer groups in Belgium, Italy, Denmark, Spain and Portugal found that a third of the 65 samples of fast food packaging tested contained high levels of fluorinated compounds[93].

Most of the studies of health impacts from highly fluorinated chemicals to date have focused on PFOS and PFOA, the long-chained substances that have been in use since the 1950s, and the evidence of their risks to human health has only been discovered over time[94]. Some of the long-chain PFAS are known to be toxic, as well as bioaccumulative. However, in contrast to persistent chlorinated and brominated compounds, which are lipophilic and bioaccumulate in fatty tissues, the PFAS bioaccumulate in organ and muscle tissues. They have been detected in human blood and breast milk as well as in other biota around the globe. The table below indicates half-lives for selected PFAS in mouse and human serum.

Table 3: Persistence of selected PFAS in mouse and human serum[95]

Serum half-life	PFBS (C4)	PFHxS (C6)	PFOS (C8)	PFBA (C4)	PFHxA (C6)	PFOA (C8)	PFNA (C9)
Mouse	5 hours	30 days	40 days	12 hours	2 hours	20 days	60 days
Humans	28 days	8.5 years	4-5 years	3 days	32 days	3-4 years	unknown

Elevated exposures to PFASs in adults have been linked to hepatocellular damage affecting liver function in adults[96] and obesogenic effects in females[97]. Fetal exposure to PFAS has been associated with reduced birthweight and length of gestation[98], as well as reduced immune response to routine childhood immunizations[99].

Particularly convincing evidence of effects on human health has emerged because of a legal settlement in 2005 with the company Dupont, because of the exposure of some 70,000 persons via drinking water contaminated by discharges from a West Virginia manufacturing facility operated by Dupont. The legal settlement included an obligation to monitor the exposed population. The resulting C8 Health Project Monitoring has gathered epidemiological evidence of associations between PFOA exposures and later age of sexual maturation[100], alterations of thyroid hormone levels among children[101], ulcerative colitis[102] and kidney and testicular cancer[103].

[88] Post, G.B. *et al*., 2012; Rahman, M.F. *et al*., 2014; Eschauzier, C. *et al*. 2012.
[89] Tittlemier, S.A. *et al*., 2007.
[90] Björklund, J. *et al*., 2009 ; Shoeib, M. *et al*., 2011 ; Liu, J. *et al*., 2013.
[91] Higgins, C.P., 2017.
[92] Begley, T.H. *et al*., 2008; D'Eon, J.C. *et al*., 2007.
[93] *ENDSEurope*, 10.03.2017.
[94] Grandjean, P. & Clapp, R., 2014.
[95] Stynar, M., 2017.
[96] Gallo, V. *et al*., 2012.
[97] Halldorsson, T.I. *et al*., 2012.
[98] Fei, C. *et al*., 2007.
[99] Grandjean, P. *et al*., 2012.
[100] Lopez-Espinos, M. *et al*., 2011.
[101] Lopez-Espinos, M. *et al*., 2012.
[102] Steenland, K., *et al*., 2013.
[103] Barry, V. *et al*., 2013.

While producers of the short-chain alternatives have put forward data showing that they do not pose the same risks to human health and the environment[104], information on the structures, properties and toxicological profiles of the short-chain fluorinated alternatives needed to confirm this reduction in risk is not publicly available[105]. However, evidence is emerging that the new short-chain alternatives are also problematic in terms of risks to health. For example, tests carried out using the chemical sold by Dupont as an alternative to PFOA under the name GenX have found numerous health effects in animals, including changes in immune responses, cholesterol levels, reproductive problems and cancer[106]. In the meantime, levels of some alternatives or their degradation products in the environment and in human tissues have been rising[107]. This implies more frequent exposures.

From an environmental point of view, the widespread occurrence of highly fluorinated substances is also a concern. PFOA has been found in the biota of remote regions where no direct source of PFOA is known, including in top predators such as polar bears[108]. Studies on dolphins, caribou and Arctic food chains have found indications of bioaccumulability. On the other hand, PFOA shows low bio-concentration in fish because it is eliminated quickly through the respiratory system of fish due to its high solubility, in contrast to humans where elimination is on the scale of years[109].

Data concerning the specific health effects such exposures may be having on biota is sparse. Female mice exposed as foetuses to low doses of PFOA had significant delays in puberty progress, which is in line with the findings of human epidemiological studies[110]. Moreover, PFAA exposure in general appears to be linked to hepatotoxicity, i.e. the capacity to injure the liver[111].

Regulatory and voluntary actions to date

International level

At international level, both the Stockholm Convention and the UNECE POPs Protocol list perfluorooctane sulfonic acid and perfluorooctane sulfonyl fluoride (PFOS) as POPs to be restricted, except for a number of 'acceptable purposes' and 'specific exemptions' for which production and use may continue. PFOA is among the substances currently under consideration for addition to the Stockholm Convention as a POP[112].

In the context of the Strategic Approach to International Chemicals Management (SAICM), the second (2009) session of the International Conference on Chemicals Management (ICCM2) adopted resolution II/5 on "managing perfluorinated chemicals and the transition to safer alternatives"[113]. A progress report distributed at the 2012 session[114] describes the work carried out since 2009. Most notably, in light of the geographical shift in production of long-chain PFAS from the OECD countries to the emerging Asian economies and to facilitate the participation of all interested governments and stakeholders, the previous OECD PFC Steering Group was replaced by- a global PFC group. Secretariat support is provided jointly by the OECD and UNEP.

In addition to establishing a PFC web portal[115], the Global PFC Group has published a consolidated

[104] Bowman, J.S., 2015b.
[105] Scheringer, M. *et al*., 2014a.
[106] Lerner, S., 2016a.
[107] Ahrens, L. *et al*., 2011; Glynn, A. *et al*., 2012.
[108] Vierke, L., *et al.*, 2012.
[109] Ibid.
[110] Wang, Z, *et al*., 2017.
[111] Wang, Z., *et al*., 2016.
[112] UNEP/POPS/POPRC.11/5 (2015)
[113] SAICM/ICCM.2/15 (2009).
[114] SAICM/ICCM.3/18 (2012).
[115] www.oecd.org/ehs/pfc.

synthesis paper[116], which inter alia summarises scientific evidence on potential adverse effects on humans of PFASs, regulatory approaches to date, and recent developments on alternatives to long-chain PFASs. A survey conducted by the Global PFC Group resulted in a 2015 publication that provides a snapshot of risk reduction approaches for PFASs in selected countries, as well as information about options for risk reduction of PFASs[117].

EU level

At EU level, PFOS is restricted under the 2004 POPs Regulation[118] implementing the Stockholm Convention, except for a number of 'acceptable purposes' and 'specific exemptions' for which production and use may continue. PFOA is also under consideration for restriction under the Stockholm Convention.

A few PFASs are regulated under REACH. Annex XVII on Restrictions, Entry 30, restricts substances classified as CMR 1A or 1B from being placed on the market or used as substances, as constituents of other substances or in mixtures for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than the relevant concentration limit. The following PFASs are listed as being toxic to reproduction 1B (R1B) [119].

Table 4: HFCs listed as toxic to reproduction (1B) under Annex XVII

REACH Annex XVII	Reason for inclusion & reference to amending legislation
Perfluorooctane sulfonic acid	R – 1B (M14)
Heptadecafluorooctane-1-sulfonic acid;	R – 1B (M14)
Potassium perfluorooctanesulfonate	R – 1B (M14)
Potassium heptadecafluorooctane-1-sulfonate;	R – 1B (M14)
Diethanolamine perfluorooctane sulfonate;	R – 1B (M14)
Ammonium perfluorooctane sulfonate;	R – 1B (M14)
Ammonium heptadecafluorooctanesulfonate;	R – 1B (M14)
Lithium perfluorooctane sulfonate;	R – 1B (M14)
Lithium heptadecafluorooctanesulfonate	R – 1B (M14)
Ammoniumpentadecafluorooctanoate	R – 1B (M25)
Perfluorooctanoic acid	R – 1B (M25)

Under REACH Article 59, substances identified as meeting the Article 57 criteria are to be placed on a candidate list for eventual inclusion in Annex XIV as subject to authorisation. The following highly fluorinated substances are on the candidate list maintained by the ECHA[120]:

Table 5: HFCs on candidate list for Annex XIV

Candidate List	Reason for inclusion
Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts: ■ Nonadecafluorodecanoic acid; ■ Decanoic acid, nonadecafluoro-, sodium salt	Toxic for reproduction; PBT
Perfluorononan-1-oic-acid and its sodium and ammonium salts (PFNA): ■ Ammonium salts of perfluorononan-1-oic-acid; ■ Perfluorononan-1-oic-acid; and ■ Sodium salts of perfluorononan-1-oic-acid	Toxic for reproduction; PBT
Pentadecafluorooctanoic acid (PFOA)	Toxic for reproduction; PBT

[116] OECD, 2013.
[117] OECD, 2015a.
[118] Regulation (EC) No 850/2004, p.7.
[119] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:LATEST:EN:PDF (accessed 17.05.2016).
[120] http://echa.europa.eu/web/guest/candidate-list-table (accessed 17.05.2016).

Note that REACH exempts polymers from registration[121]. There is concern that, while the fluoropolymers are true polymers, the side-chain fluorinated polymers and polyfluorinated ethers increasingly found on the market may not be true polymers[122] and therefore may be falling through the controls set in place under REACH.

The PBT working group coordinated by the European Chemicals Agency (ECHA) is jointly developing a work plan to restrict the use of PFAS in the EU through classification, SVHC/authorisation and restrictions. The network foresees regulating PFAS by utilising methods of grouping[123].

For example, Germany and Norway put forward a proposal for restriction of the manufacturing, marketing and use of PFOA (considered a group comprising some 500 substances) for discussion by the REACH committee of Member States in early July 2016. In December 2016 the committee approved a proposed restriction which would ban the use of the chemical in fire-fighting foams and certain other uses three years after the entry into force of the amendment to REACH. It included a number of deferrals for specific products which were less strict than those proposed by Germany and Norway[124]. The proposed amendment is now with the European Parliament and the Council, and is expected to be adopted by the end of April 2017.

Other substance evaluations which are under way or envisioned include:

- **PFHxS** (perfluorohexane sulfonic acid). Sweden has submitted a proposal for identification of this substance as vPvB and to include it on the Candidate List.
- **PFCA C9-C14.** Sweden and Germany are cooperating on preparation of a restriction dossier for PFCAs and their precursors, with submission expected early 2018. The substances are on the Candidate List.
- **PFNA** (perfluorononanoic acid). This is now on the Candidate List. Sweden and Germany are cooperating on the compilation of a dossier proposing a restriction as part of the C9-C14 grouping.

In 2017, the European Food Safety Authority (EFSA) initiated a reevaluation of its 2008 scientific opinion on health impacts of PFOS and PFOA in the food chain[125]. The reevaluation will review the total daily intake (TDI) levels of 150 nanograms per kilogram of body weight per day for PFOS and 1,500 nanograms per kilogram of body weight per day for PFOA established in the 2008 opinion.

Finally, a review of Annex X to the Water Framework Directive (2000/60/EC) led to a 2012 proposal to revise the list of priority substances in the field of water policy and inter alia to include perfluorooctane sulfonic acid and its derivatives (PFOS) as a priority hazardous substance presenting a significant risk to or via the aquatic environment[126].

National level in Europe

The Swedish Government commissioned the Swedish Chemicals Agency (KEMI) to prepare a national action plan on PFASs, aimed at increasing awareness and reducing use of these extremely persistent chemicals[127]. The first target is to eliminate the use of highly fluorinated substances in

[121] REACH, Article 3.5 defines a polymer as meaning a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units.
[122] Posner, S., 2017.
[123] Communication from the Danish Environmental Protection Agency.
[124] "Commission moves forward with PFOA restrictions", *ENDsEurope*, 17.01.2017.
[125] EFSA, 2008.
[126] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52011PC0876 (accessed 17.05.2016).
[127] KEMI, 2016.

firefighting foam, since this has been the main source of releases to the environment of HFCs. Other actions foreseen include facilitation of voluntary measures by companies to reduce use of PFAS in sectors such as textiles and food packaging, and requirements to report to Sweden's product register targeting PFASs.
In Denmark, some efforts have been taken to restrict PFASs both at government and company level. In 2015, the government issued a guideline limit ("advisory ban") on the use of PFASs in paper and cardboard food packaging, with the aim of ultimately turning the guideline into a binding prohibition[128]. In response, the country's largest retailer (Coop) speeded up a commitment it had already made to phase out PFASs. It announced that it would refuse to distribute popcorn products packaged in PFASs-coated cardboard and noted that alternative packaging was available[129].

Norway enacted regulations in 2013 to restrict the production, import, export or sale of consumer products containing PFOA in consumer products if certain limit values were exceeded. This resulted in a legal reprimand from the European Free Trade Association in the form of a reasoned opinion, which found that the 2013 regulations were an inappropriate unilateral action. As already mentioned earlier in this section, Norway then teamed up with Germany in putting forward a proposal to restrict PFOA at EU level. The proposal is for a total ban on manufacture, marketing and use of PFOA, its salts, and related substances, though a number of derogations would be allowed, e.g., manufacturing and use of short chain alternatives as long as no other alternatives are available, use in semiconductor photolithographic processes, certain photographic coatings, firefighting foams already on the market, etc.

National level elsewhere

The US EPA has targeted PFASs for special action for several decades, starting with PFOS, which has not been reported as manufactured or imported into the UEA since 2002. In 2006, it invited eight companies (Arkema, Asahi, BASF, Clariant, Daikin, 3M/Dyneon, DuPont, Solvay Solexis) to join the PFOA Stewardship Program, under which they committed to achieve, by 2010, a 95 percent reduction in global facility emissions of PFOA to all media; in precursor chemicals that break down to PFOA, and in product content levels. They also committed to work towards elimination of PFOA from emissions and products by 2015[130], and to submit annual progress reports on their reductions of PFOA.

In 2015, the US EPA proposed 'Significant New Use Rules: Long-chain perfluoroalkyl carboxylate and perfluoroalkyl sulfonate chemical substances', which would require notification of any manufacturing (including importing) of certain long-chain PFACs at least 90 days in advance, in order to provide the opportunity to evaluate the intended use and, if necessary, to protect against potential unreasonable risks by prohibiting or limiting that activity before it occurs. This action is still pending[131].

In the same vein, the US Food and Drug Administration (FDA) issued a rule in 2016 banning the use of three specific perfluoroalkyl ethyl containing food-contact substances (FCSs) as oil and water repellents for paper and paperboard for use in contact with aqueous and fatty foods in the face of new information on the substances' toxicity. The order was in response to a petition filed by the Natural Resources Defence Council and a number of other organisations and came into effect on February 4th, 2016.[132]

Most recently, in May 2016, the US EPA issued a lifetime drinking water health advisory (HA) for PFOA of 0.07 micrograms per liter based on a reference dose (RfD) derived from a developmental

[128] TAPPI, 2016.
[129] Buck, 2015.
[130] EPA, 2014a; also https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/and-polyfluoroalkyl-substances-pfass-under-tsca (accessed 19.05.2016).
[131] https://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2013-0225-0001 (accessed 19.05.2016).
[132] US FDA, 2016.

toxicity study in mice; the critical effects included reduced ossification in proximal phalanges and accelerated puberty in male pups following exposure during gestation and lactation. It also issued a similar lifetime drinking water health advisory (HA) for PFOS of 0.07 micrograms per liter based on a reference dose (RfD) derived from a developmental toxicity study in rats; the critical effect was decreased pup bodyweight following exposure during gestation and lactation. The guidance recommends that when these two chemicals co-occur at the same time and location in a drinking water source, a conservative and health-protective approach would be to compare the sum of the concentrations ([PFOA] + [PFOS]) to the HA.[133] Dozens of US municipalities now find themselves in non-compliance with this advisory standard [134].

Canada has targeted PFOS for regulatory action since 2006, when it published an assessment of PFOS and concluded that they were entering the environment under conditions that could have immediate or long-term harmful effects on the environment. Regulations adopted in 2008[135] prohibit the manufacture, use, sale, offer for sale and import of PFOS and products containing PFOS, with certain exceptions (aqueous film forming foam, products manufactured and imported before May 2008; and coatings for photographic films, papers and printing plates). In 2009 Environment Canada issued regulations adding PFOS and its salts to Canada's Virtual Elimination List [136].

In 2010 it negotiated a voluntary 'Environmental performance agreement respecting PFCAs and their precursors in perfluorochemical products sold in Canada' with four companies (Arkema Canada, Asahi Glass, Clariant Canada and Dupont Canada) which committed them to work toward the elimination of residual PFOA and long-chain PFCAs[137]. The agreement expires in 2015.

Canada's efforts also include a 2015 proposal to amend the 2012 Prohibition of Certain Toxic Substances Regulations to add PFOA and long-chain PFCAs to the regime covering PFOS. The proposed amendments would prohibit the manufacture, use, sale, offer for sale, or import of PFOA and LC-PFCAs, unless present in manufactured items, from the coming into force of the amendments. Use in aqueous film-forming foams (AFFF) used in fire protection applications would still be allowed, as well as a temporary permitted use for these substances in water-based inks and photo media coatings until the end of 2016.[138]

Note that these regulatory efforts are almost all targeted at the long chain PFAS, i.e., the C-8s. While the short chain PFAS are also extremely persistent, to date they have not received equivalent regulatory attention.

Voluntary efforts

The Greenpeace DETOX campaign is an effort to get highly fluorinated chemicals out of brand-name goods. It started by focusing on production and use of PFOS and PFOA in East Asia, particularly by the textile industry as a downstream user. According to Tianjie Ma, head of Greenpeace East Asia's Toxics Campaign, "we are currently working on the textile industry as a downstream user of PFCs. Downstream users have more incentives to change faster than up-stream suppliers of chemicals."[139]

Pressure by Greenpeace has resulted in some 66 brands, retailers and suppliers, including Marks & Spencers, H&M, Zara, Puma, and Adidas, to make the commitment to eliminate all hazardous chemicals from across their entire supply chain and product life-cycle by the year 2020 and, in the short term, to eliminate the worst chemicals, including all per- and poly-fluorinated chemicals as well

[133] US EPA, 2016.
[134] Lerner, 2016b.
[135] Environment Canada, 2008.
[136] Environment Canada, 2009.
[137] http://www.ec.gc.ca/epe-epa/default.asp?lang=En&n=AE06B51E-1 (accessed 19.05.2016).
[138] https://www.ec.gc.ca/toxiques-toxics/Default.asp?lang=En&n=ECD5A576-1 (accessed 19.05.2016).
[139] ChemicalWatch, 2012.

as alkylphenols. Greenpeace states that their goal is to get the manufacturers to collaborate with their suppliers, rather than to cancel existing contracts. As part of their commitment, the manufacturers have agreed to implement right-to-know, by providing data on discharges to the environment and on chemicals in their products, thereby setting a standard for transparency and accountability across their sector.

In early 2017 GoreTex, a market leader in water repellency technologies, also joined in making a commitment to phase out the use of per- and polyfluorinated compounds in its fabrics[140].

As part of its DETOX campaign, Greenpeace frequently carries out new PFC-relevant research. Its 2015 publication *Footprints in the Snow*[141] describes eight expeditions that were organised to some of the most remote places on three continents to take samples of new-fallen snow and water from pristine lakes for laboratory analysis. Evidence of PFC chemicals was found in each location, documenting how PFCs (which do not occur naturally) can travel around the world until they are washed out of the atmosphere in rain or snow. The expeditions were organised to educate the outdoor industry about how use of PFCs in their products ends up contaminating the regions so appreciated by outdoor aficionados.

Another notable effort is the cooperation entitled Zero Discharge of Hazardous Chemicals (ZDHC). In 2011 six major brands, Puma, C&A, H&M, Nike, Ni Ling and Adidas came together to initiate the ZDHC programme aimed at bringing about change across the textile and footwear product industry. The companies have set forth a "joint roadmap" setting out plans to achieve zero discharge of the hazardous chemicals used in all their products by 2020, including the elimination of products associated with PFOA and PFOS by the end of 2012. The ZDHC programme will initially replace C8 chemistry with short-chain alternatives; efforts to find non-fluorinated water- and stain-repellent alternatives are still having only limited success.

As of 2015, a total of 19 global sports, fashion and outdoor brands had joined the ZDHC programme. A number of joint roadmap milestones have now been completed, including

- Manufacturing Restricted Substances List (MRSL)
- Framework for the Prioritisation of Hazardous Chemicals
- Audit Protocol
- Right-to-Know Chemical Disclosure Methodology Research
- Chemical Management Systems Manual
- Chemical Management Training for suppliers in Bangladesh, China, India and Vietnam
- 20 supplier site visits to observe chemicals management and inventory practices and to test
- influent, effluent and sludge discharges in Bangladesh, China, India, Taiwan and Vietnam
- 25 audits across regions, mills and dye houses in Bangladesh, China, El Salvador, India, Taiwan, Turkey, South Korea and the United States[142].

Outside of the Greenpeace campaign, other manufacturers, retailers and/or commercial users have voluntarily suspended the marketing or use of PFC-containing products, because of their persistence and toxicity. IKEA, Crate & Barrel, and Kaiser Permanente (a major US hospital chain) are among the entities that have committed to eliminating PFCs from the products they sell and/or use.

Most important gaps and deficits with respect to PFAS

The phasing out of emissions of long-chain PFASs by US and European manufacturers has been offset

[140] http://www.greenpeace.org/international/en/press/releases/2017/Gore-hazardous-PFCs-outdoor-gear-pledge/ (accessed 23.04.2017).
[141] Cobbing, M. *et al.*, 2015.
[142] ZDHC, 2015.

by a geographical shift of their manufacture and use to countries in Asia [143]. This global dimension has implications for the types of actions available to the EU for addressing impacts on health and environment from the PFASs, including the short-chain alternatives. Any action on EU-level should at the same time pave the way for equivalent global measure in the context of SAICM and the Stockholm Convention.

Information concerning the many types of PFAS on the market is incomplete. Efforts to develop inventories of the PFAS manufactured and used since the 1950s have identified a number of sources, but quantification remains difficult due to gaps in data [144].

Although information on health and environmental impacts of the short-chain alternatives has been provided to regulatory agencies to seek approval of specific uses in the context of new chemical regulatory frameworks, the information available in the public domain is limited. Given the high number of both long chain and short chain PFAS on the market today, it is critical to consider how to apply grouping approaches for regulating these extremely persistent substances.

2.5 OTHER GROUPINGS OF HIGHLY PERSISTENT SUBSTANCES

In the course of the research for this study, a number of groups, including a number of highly chlorinated groupings, were singled out for special discussion below.

2.5.1 Highly chlorinated substances

Background

The pesticide DDT was the first highly persistent organic pollutant (POP) to come to international attention because of its adverse effect on the environment. Though first synthesized in 1873, its insecticidal effect was not recognised until 1939, shortly before World War II. It quickly became widely applied to combat insect-borne diseases, including malaria, for which it is still permitted to be used today. The 1962 publication of Rachel Carson's book *Silent Spring* highlighted how DDT and other organochlorine pesticides affected wildlife, particularly birds. This led to the phase-out of DDT in Europe and North American during the 1970s, followed by bans and/or restrictions on other highly chlorinated organic pesticides in the following decades.

Some chlorinated organic substances are highly lipophilic, tend to accumulate in biological systems, and degrade slowly in the environment, particularly those having a carbon ring structure and multiple chlorine substitution[145]. In contrast to highly fluorinated substances, which tend to be both persistent and mobile, many of the highly chlorinated substances have a low mobility and are mainly adsorbed on soil or other particles. This strongly depends on the degree of chlorination. Though the highly chlorinated compounds with larger molecules will not easily enter the gas phase, they may become adsorbed to small particles which could be found in air.

However, other chlorinated organic chemicals with lesser degrees of chlorine substitution do not have the same physical and chemical properties. For example, chlorinated compounds with smaller molecules like dichlorobenzene may slowly evaporate into the environment. This is also the case for hexachlorocyclohexane (HCH) and hexachlorobutadiene (HCBD). A site in Spain containing 10,000 tonnes of HCH releases HCH to water and to air continuously, in the range of

[143] OECD, 2015b.
[144] Wang, *et al.*, 2014b
[145] Willes, R.F. *et al*., 1993.

100 kg/year[146]. Similarly, houses near a UK site where HCBD had been disposed were found to have high levels of the substance in their indoor environments[147].

While it is not possible to generalise about the persistence and bioaccumulability of all chlorinated organic chemicals, it is noteworthy that 18 of the 22 chemicals listed for elimination in the Stockholm Convention are highly chlorinated substances.

Table 6: Highly chlorinated substances listed for elimination under the Stockholm Convention

Highly chlorinated POPs listed for elimination	
■ Aldrin ■ Chlordane ■ Chlordecone ■ Dieldrin ■ Endrin ■ Heptachlor ■ Hexachlorobenzene ■ Hexachlorobutadiene ■ α-Hexachlorocyclohexane (α-HCH) ■ β-Hexachlorocyclohexane (β-HCH)	■ Lindane (γ-Hexachlorocyclohexane) ■ Mirex ■ Pentachlorobenzene ■ Pentachlorophenol and its salts and esters ■ Polychlorinated biphenyls (PCBs) ■ Polychlorinated naphthalenes ■ Technical endosulfan and its related isomers ■ Toxaphene

Polychlorinated biphenyls (PCBs)

Polychlorinated biphenyls (PCBs) are a group of highly chlorinated organic pollutants that were mass-produced starting in 1929. PCBs were primarily used in electrical equipment, such as capacitors and transformers, due to their resistance to high temperatures and insulating properties, and over time were also used as ingredients in paints, adhesives, lubricants and PVC plastics. Total global production of PCBs from 1929 to 1988 (not counting China and the USSR) is estimated at 1.5 million tons[148], not a large amount when compared to the 360 million metric tons of bulk organic chemicals estimated to have been produced globally in 2010[149]. Though never intentionally released into the environment e.g. as pesticides, the high persistence and mobility of PCBs led to their transport around the world. They are found everywhere on the globe today, including in the polar regions.

PCBs became the target of regulatory action at EU level and in the United States in the mid-1970s, because of concerns about their extreme environmental persistence, ability to bioaccumulate and their association with adverse human health effects[150]. In the 1980s evidence emerged that PCBs can change during bioaccumulation and biodegradation in the environment, producing concentrations of congeners with higher chlorine content and toxicity than commercially produced PCBs[151]. Studies of children whose mothers had consumed large amounts of fish from Lake Michigan found that those more highly exposed *in utero* had lower IQ-test scores, difficulties in verbal comprehension and reduced ability to concentrate[152].

A 2010 study of PCB stocks and emissions in the city of Toronto concluded that efforts under the Stockholm Convention to eliminate exposure to PCBs has had only partial success. When their manufacture was banned by most industrialised countries some 30 years ago, concentrations in air, soil, sediment and biota declined rapidly during the first decade of the ban, but since then have

[146] Fernandez, J. *et al.*, 2013.
[147] Barnes, G., *et al.*, 2002.
[148] EEA, 2001, p. 64.
[149] UNEP, 2013b.
[150] Grossman, E., 2013.
[151] EEA, 2001.
[152] Jacobson, J.L., & Jacobson, S.W., 1996.

remained stubbornly at the same levels and are now ubiquitous in food from terrestrial and aquatic sources[153].

In the past decade, studies have found a relationship between exposure to PCBs and the rise of Type 2 diabetes[154] as well as with obesity. And at least one animal study found that prenatal exposure to low doses of PCBs can change the developing brain in an area involved in metabolism, with some effects apparent even two generations later[155].
The evidence as a whole suggests that, rather than a few individual POPs, background exposure to POP mixtures including organochlorine pesticides and polychlorinated biphenyls – can increase risk for T2D[156]. This review of current evidence also examines relationships between POPs and obesity in humans. Evidence from animal studies have shown a link between POPs and obesity. However, results on the relationship between POPs and obesity in human studies have been inconsistent and the study highlights some important gaps in knowledge and suggests that large prospective studies with serial measurements of a broad range of POPs, adiposity, and clinically relevant biomarkers are needed to disentangle the interrelationships among POPs, obesity, and the development of T2D.

Another study based on a National Toxicology program workshop review in the US suggests that collectively the data was not sufficient to show a causal relation between POPs and T2D, and that experimental data are needed to confirm the causality of these POPs, which will shed new light on the pathogenesis of diabetes[157]. Both studies highlight a lack of evidence, but suggest that new evidence and uncertainty relating to exposure and risk should be considered by governmental bodies involved in the regulation of persistent, environmental contaminants.

Chlorinated paraffins
Chlorinated paraffins (CPs) are high volume semivolatile organic compounds (SVOCs) with an estimated annual global production volume of more than 1 million tonnes[158]. CPs are subdivided according to their carbon chain length into short chain CPs (SCCPs, C10–13), medium chain CPs (MCCPs, C14–17) and long chain CPs (LCCPs, C>17). SCCPs were previously listed under Annex XVII of REACH as well as a Substance of Very High Concern (SVHC). SCCPs were incorporated in the EU POP-Regulation (European Commission 2015)[159] and the entry in Annex XVII of REACH has now been deleted. Thus, SCCPs are now classified as persistent organic pollutants (POP) in the EU. SCCPs are currently under consideration for listing in the Stockholm Convention. MCCP has been included in the Community rolling action plan (CORAP) (ECHA, 2012).

CPs are used for a wide range of industrial applications including flame retardants, plasticisers, as additives in metal working fluids, in sealants, paints, adhesives, textiles, leather fat and coatings[160] and have substituted here PCBs in many open applications[161]. The chlorination degree of CPs can vary between 30 and 70 wt%. The chlorination degree determines the persistence and higher chlorinated SCCPs meet the criteria for PBT and vPvB under REACH[162].

Levels in Swiss sediments have been found several times higher compared to the peak levels of PCB[163]. In wildlife in China CPs were by far the most abundant contaminant, contributing over

[153] Diamond, M. *et al*, 2010.
[154] Lee, D. *et al*., 2006.
[155] Steinberg, R.M. *et al*., 2008.
[156] Lee, D. *et al.*, 2014.
[157] Taylor, K.W. *et al*., 2013.
[158] Tong, X.C. *et al.*, 2009.
[159]Commission Regulation (EU) 2015/2030.
[160] de Boer J. *et al.*, 2010.
[161] Fantke, P. *et al*., 2015.
[162] van Wijk D. & Presow S. , 2011
[163] Iozza S. *et al.*, 2008.

90% of the total OHCs in snake, toad, and falcon[164]. Global CP contamination has been revealed by the WHO human milk study as being comparable to levels of PCBs[165].

One additional concern, which has not been assessed in relation to persistence in the environment, is the formation of degradation products of chlorinated paraffins. For oxidative degradation the chain lengths might be shortened resulting in an increase in mobility. Also, such degradation likely results in hydroxylation and carboxylation resulting also in higher mobility of the molecules of the degradation products. Due to the oxidation and reduction of hydrogen, such degradation could lead to an increase in persistence for further oxidation. Such an increase of persistence has been shown for the degradation of polyfluorinated PFAS to the extremely persistent shorter chain perfluorinated PFAS.

For CPs the possible increase in persistence by degradation needs attention and assessment. Furthermore, the degradation of long and medium chain CPs could result in the formation of persistent molecules with a chain length of less than 13 and associated mobility and possibly bioaccumulation potential and need to be further assessed. The assessment of degradation products is also required under REACH.[166]

Unintentionally formed POPs

Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDFs) are particularly highly persistent chlorinated POPs often found in other chemicals as contaminants, i.e., as unintentional by-products of manufacturing processes[167] [168]. Polychlorinated biphenyls (PCBs) and hexachlorobenzene (HCB) may also come to be present as unintentional contaminants formed during a manufacturing proces. These unintentional POPs are frequently present in consumer goods, particularly where chemical additives have been used.

PCDD/PCDF are some of the most toxic chemicals known to science. The International Agency for Research on Cancer (IARC) lists certain congeners as class 1 carcinogens, together with PCBs.

The half-lives of PCDD/PCDF and PCBs in soils and sediments are estimated to be between several years to centuries and longer[169]. An assessment of PCDD/PCDF congener profiles and levels in a contaminated site in Lampertheim, Germany (where an industrial process operated from 1840 to 1890) found no significant degradation of PCDD/PCDF in affected soils and deposits over the last 120 to 170 years, indicating half-lives of longer than a century for the PCDD/PCDF at this site[170]. Another study found PCDD/PCDF present in kaolin/ball clay that had been formed millions of years before, and considered this an indication of their extreme persistence in this environmental setting[171].

Important examples of products containing unintentional POPs today include pigments, paints and pesticides[172]. For example, in recent years PCBs have been detected in a range of pigments used in

[164] Zhou Y. *et al*., 2016.
[165] Malisch R., 2012.
[166] In REACH (Regulation (EC) No 1907/2006) it is stated (p. 34) "The PBT/vPvB assessment should normally be carried out for each relevant transformation or degradation product. It is not possible to draw an overall conclusion for the substance if the assessment of persistence has been concluded for one transformation/degradation product and the assessment of bioaccumulation or toxicity for another transformation/degradation product." and what is relevant is described as "An elevated threshold value should not exceed 10% (w/w) for the total amount of all constituents, impurities, additives and transformation/degradation products with PBT/vPvB properties, and the total amount of these within the manufactured/imported substance should in no case exceed 1 tonne/year."
[167] Grossman, E., 2013.
[168] UNEP (2015) UNEP/POPS/TOOLKIT/BATBEP/2015/2
[169] Balzer, W. *et al*. 2007, 2008; Ferrario, J.B. *et al*. 2000; Lake, J.L. *et al*. 1992; Nauman, C.H. & Schaum, J.L., 1987 ; Kjeller, L.O. & Rappe, C., 1995 ; Sinkkonen, S. & Paasivirta, J., 2000.
[170] Balzer, W. *et al*., 2007 ; Balzer, W. *et al*., 2008.
[171] Ferrario, J.B. *et al*., 2000.
[172] UNEP, 2013; Weber, R. *et al*., 2008.

consumer products such as paints, plastics, print/magazines or packaging (including food packaging)[173]. Monitoring of the PCB content of pigments imported and used in Japan found PCB levels up to 2000 ppm in some pigments, exceeding the Basel Convention low POPs limit for PCBs of 50 ppm[174].

Chlorinated paraffins (discussed above) may also be a source of unintentional POPs in consumer products such as leather. A recent assessment found that these chemicals can contain high levels of PCDD/F, PCBs and polychlorinated naphthalenes (PCNs)[175]. The study estimated that the annual production and use of 1 million tons of chlorinated paraffins could produce some 100 tons of PCB per year, with related contamination of consumer products[176].

In addition to the highly toxic PCDD/PCDFs), polybrominated dibenzo-p-dioxins and dibenzofurans (PBDD/PBDFs) are also of concern, given their similar toxicities[177]. PBDD/PBDF are present in brominated flame retardants (BFRs) and products and articles containing BFRs[178], due to their unintentional formation and release throughout the life-cycle of BFRs[179]. PBDD/Fs can be formed or released during the production of BFRs[180]; during the manufacture of BFR-containing products[181]; and in the recycling and disposal of BFR-containing polymers[182]. A WHO expert panel concluded that PBDD/PBDFs and some dioxin-like biphenyls (dl-PBBs) may contribute significantly to the daily human background exposure to total dioxin toxic equivalents (TEQs)[183].

Recent studies on unintentional POPs in chemicals and consumer products show their contemporary relevance. For example, the Washington State Department of Ecology recently looked for PCBs in a range of consumer products (packaging, paper products, paint and colorants, caulks and printer inks)[184]. Unintentional PCBs were found in most samples. Concentrations were in the ppb level with the highest PCB contamination of 320,000 µg t^{-1} in a green paint. The study concluded that PCBs found in consumer products may affect people directly through contact with those products.

House dust is an excellent indicator for chemicals in consumer products and other indoor sources and their release and exposure[185]. Research in Japan and the US demonstrated high levels and relevance of dioxin-like compounds in house dust with levels of dioxin-like toxicity comparable to fly ash from waste incinerators[186]. It is important to note that in the majority of the house dust samples, the known dioxin and dioxin-like compounds (PCDD/PCDFs, PBDD/PBDFs and dl-PCBs) only accounted for a minor fraction (often less than 20%) of total dioxin-like toxicity. What other dioxin-like compounds are present in house dust and the indoor environment remains unknown[187].

A recent survey on dioxins in British food by the UK food authority highlighted that up to 30% of the total dioxin-related toxic equivalents (TEQs) could stem from polybrominated dioxins/furans, and additional 20-50% could come from brominated-chlorinated dibenzo-p-dioxins/furans (PXDD/Fs)[188].

[173] Anezaki, K. & Nakano, T., 2014; Anezaki, K. *et al*. 2015; Hu, D. & Hornbuckle, K.C., 2010.
[174] Japanese Ministry of Economy, Trade and Industry, 2013.
[175] Takasuga, T. *et al*. 2012a ; Takasuga, T. *et al*. 2012b.
[176] Takasuga, T. *et al*. 2012b.
[177] Behnisch, P.A. *et al*., 2003; Birnbaum, L.S. *et al*., 2003; van den Berg, M. *et al*., 2013.
[178] WHO, 1998; Ebert, J. & Bahadir, M., 2003.
[179] Shaw, S. *et al*., 2010.
[180] WHO, 1998; Hanari, N. *et al*., 2006, Ren, M. *et al*., 2011.
[181] Luijk, R. & Govers, H.A.J., 1992; Ota, S. *et al*., 2009; Ren, M. *et al*., 2011.
[182] Ebert, J. & Bahadir, M., 2003; Zennegg, M. *et al.*, 2014; Shaw, S. *et al.*, 2010.
[183] Van den Berg, M. *et al*., 2013.
[184] Stone, A., 2014.
[185] Butte, W. & Heinzow, B., 2002; Maertens, R.M. *et al*., 2004; Mercier, F. *et al*., 2011.
[186] Suzuki, G. *et al*., 2007 ; Suzuki, G. *et al*., 2010, Tue, N.M. *et al*., 2013.
[187] Suzuki, G. *et al.* 2010, Tue, N.M. *et al.* 2013.
[188] Mortimer, D. *et al*. 2013.

Regulations in place
In the EU, PCDD/PCDFs and PCBs are only regulated in food and feed, through legislation establishing residue limits, and for air emissions of industrial sources. No EU-level regulations are in place for control of PBDD/PBDFs or for brominated-chlorinated dibenzo-p-dioxins and furans (PXDD/PXDFs).

The EU REACH framework does not regulate unintentional POPs that may be present in chemical formulations or in consumer products. Unintentional POPs and other residues found in products as a result of cross-contamination (e.g. from using recycled materials in the production of products) are currently also not regulated within REACH.

On national level some regulations exist for restricting some unintentional POPs in products. For example, Germany has limits for chlorinated and brominated PCDD/PCDFs and PBDD/PBDFs for chemicals and products in its *Chemikalien-Verbotsverordnung*[189]. In addition, Japan has recently restricted the import of pigments to Japan with PCB levels above 50 ppm[190] -- the Basel Convention's low POPs content which is also the EU limit for PCBs in waste oils. Japan has also established regulatory limits for PCDD/PCDFs in pesticides[191].

2.5.2 Highly brominated substances

Organobromine substances are compounds with a number of commercially significant applications. They are used primarily as flame retardants but also as fumigants and biocides, dyes, and certain pharmaceuticals.

The most widely used brominated flame retardants are the polybrominated diphenyl ethers (PBDEs), tetrabromobisphenol A (TBBPA) and hexabromocyclododecane (HBCD). They are used in a wide array of products, including building materials, electronics, furnishings, motor vehicles, airplanes, plastics, polyurethane foams, and textiles.

The total global production of brominated flame retardants increased from 150,000 t/y in 1994 to approximately 360,000 t/y in 2011. The increase in production and consumption has primarily been in Asia[192]. The brominated flame retardants account for approximately 20% of the consumption of flame retardants world-wide. Globally, the majority of the brominated flame retardants are manufactured by four major manufacturers, and the substances are manufactured in the EU at one site only[193], in The Netherlands.

DecaPBDE is one of the most well-understood of the brominated compounds with respect to its environmental fate. Laboratory tests using aerobic and anaerobic soils and sediment have shown a much longer degradation half-life – typically more than one year[194]. Bromine is heavier then chlorine and therefore the effect of adsortion is even stronger compared to chlorine. However, since the carbon-bromine bond is weaker compared to the carbon-chlorine bond, the highly brominated compounds degrade easier.

Exposure to brominated flame retardants has been associated with numerous health effects in animals and in humans, including endocrine disruption, immunotoxicity, reproductive toxicity, effects on fetal/child development, and cancer[195]. Experiments have found that PBDEs have the potential to

[189] *Chemikalienverbotsverordnung*, 2003.
[190] Japanese Ministry of Economy, Industry and Trade, 2013.
[191] Japanese Ministry of Agriculture, Forestry and Fisheries, 2007.
[192] Lassen *et al*., 2014.
[193] Ibid.
[194] Ibid.
[195] Shaw *et al*. 2010

disrupt endocrine systems resulting in effects on thyroid, ovarian and androgen functions. Similarly, HBCD has shown a range of endocrine disrupting and reproductive developmental effects in animals.

A particular concern with respect to bromine-containing plastics is the risk of formation of brominated and mixed brominated/chlorinated dioxins and furans upon incineration. Although emissions from incinerators with modern flue gas controls may be of little concern, many studies have indicated that the emissions of dioxins and furans from fires such as incidental landfill fires and uncontrolled burning of BFR-containing plastics may be significant.

Brominated flame retardants are not the only type of brominated compound of concern. A recent study of house dust using a novel screening method found 549 unique brominated compounds in 23 samples from eight Canadian homes[196]. Of the 140 most abundant compounds, only 24 were known brominated flame retardants. Closer investigation of the unknown compounds identified 2-bromo-4,6-dinitroaniline (BNA) – a raw material for synthesizing brominated azo dyes -- as a common motif. In order to confirm that such dyes were the source of the unknown compounds, the scientists analysed snippets of clothing using the same screening method and found similar high concentrations of BNA. Use of a standard, cell-based test showed significant mutagenicity of the BNA-containing house dust.

International and EU regulation has focused on PBBs and PBDEs. Recently HBCD has become subject to authorisation under REACH and listed under the Stockholm Convention on Persistent Organic Pollutants (POPs)[197]. Table 5 shows the highly brominated substances listed for elimination under the Stockholm Convention as POPs.

Table 7: Highly brominated substances listed for elimination under the Stockholm Convention

Highly brominated POPs listed for elimination
▪ Hexabromobiphenyl
▪ Hexabromocyclododecane (HBCD)
▪ Hexabromodiphenyl ether and heptabromodiphenyl ether
▪ Tetrabromodiphenyl ether and pentabromodiphenyl ether

The EU has recently amended its Regulation on persistent organic pollutants (POPs), to ban hexabromocyclododecane (HBCD). This substance will now be listed in Annex 1 of the POPs Regulation[198] prohibiting its production, use, import and export.

The RoHS Directive[199] restricts polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) from being used in new electrical and electronic equipment placed on the market. DecaBDE was exempted from the RoHS directive in 2005, but since 2008 Deca-BDE can no longer be used in electronics and electrical applications. However, a number of other brominated flame retardants are frequently added to the plastic casings of televisions and other electronic products, despite findings that this use does not increase fire safety[200]. Examples of persistent flame retardants of concern used widely in electronics but not covered by RoHS include TBBPA and HBCD.

One legal instrument at the EU level addresses the brominated flame retardants as a group: The Directive on waste electrical and electronic equipment (WEEE)[201] requires selective treatment and proper disposal for materials and components of WEEE with brominated flame retardants. In addition, the criteria for Nordic ecolabelling for some product groups address all brominated flame retardants as a common class, while the Nordic and EU ecolabelling criteria for many products focus on specific brominated flame retardants or brominated flame retardants assigned specific risk-phrases.

[196] Peng *et al*., 2016.
[197] Lassen *et al*., 2014
[198] (EC) No 850/2004.
[199] Directive 2002/95/EC.
[200] Shaw *et al*., 2010.
[201] Directive 2012/19/EU.

The flame retardant decaBDE, assessed as both PBT and vPvB, was added to REACH Annex XVII in February 2017. Restrictions on its manufacture and use will apply as of 2 March 2019. Deferral periods were granted to aircraft or spare parts for aircraft produced before 2.03.2027 to give the industry "sufficient time to adapt".

Use of TBBPA is not currently restricted, but was included in EU's draft Community Rolling Action Plan (CoRAP) for evaluation in 2015. Based on currently available information TBBPA does not meet the REACH PBT criteria as concluded in the risk assessment report from 2008. However, it is possible that it fulfils Article 57(f) as quasi PBT on the basis of its environmental toxicity and persistency.

Restrictions and bans on the use of traditional brominated flame retardants such as PBDE, HBCD and TBBBA have created a market for the use of Novel Brominated Flame Retardants (NBFR). A wide range of alternative BFRs, such as decabromodiphenyl ethane and tribromophenol are increasingly used as replacements, though they may possess similar hazardous properties as the replaced substances. Most information on NBFRs comes from research designed principally to study more "traditional" BFRs, such as PBDEs[202]. However, their biotransformation in the environment is still poorly understood and data on PBT properties is limited[203]. Further research is needed in these areas, in order to avoid the large- scale use of potentially harmful and recalcitrant substances.

Some studies have questioned the relative effectiveness of flame retardants in reducing fire hazards, especially when compared to the potential negative health and environment impacts[204]. This has been cited as an example of an application where policy makers might well consider if such a use is really needed.

2.5.3 Siloxanes (D4 & D5)

Siloxanes are silicone-based compounds used in cosmetics to soften, smooth, and moisten. They make hair products dry more quickly and deodorant creams slide on more easily. They are also used extensively in moisturizers and facial treatments. Siloxanes can also be found in medical implants, water-repelling windshield coatings, building sealants and lubricants. In recent years these compounds have increasingly been in focus because of their persistence and bioaccumulation[205]. About 200 siloxanes and siloxane derivatives are listed in the inventory of ingredients used in cosmetic products compiled by the European Commission INCI [206]. Globally the total consumption of siloxanes is approximately 850,000 tonnes, with Western Europe accounting for about 296,000 tonnes [207].

Recent regulatory discussions regarding the environmental and health impact of siloxanes have focused on D4 (cyclotetrasiloxane) and D5 (cyclopentasiloxane). These cyclic volatile methylsiloxanes (cVMS), such as D4 and D5, are commonly used in personal care products and have a strong tendency to partition from water to air. Because of the ongoing discussion in Europe and Canada regarding the potential persistent, bioaccumulative and toxic classification of cVMS a number of monitoring and research programs are being conducted[208].

Environmental occurrence and fate

Volatile siloxanes are released into the atmosphere and non-volatile siloxane fluids are released via wastewater and then are directed to wastewater treatment plants. Siloxanes mainly follow the sludge and are either spread on agricultural fields, incinerated or disposed of for landfills. Siloxanes in solids will be disposed of for incineration and are nearly 100% mineralised by this process. Siloxanes are

[202] Covaci *et al*. 2011
[203] Steiger *et al*., 2014; Ezechiáš *et al*., 2014.
[204] Shaw *et al*., 2010.
[205] Rücker, C. & Kümmerer, K., 2015.
[206] INCI, 2000.
[207] Will, R. *et al*. 2003.
[208] Tolls, J., *et al*., 2009.

resistant to chemical reactions such as oxidation, reduction and photodegradation. As varying information exists, it is not clear whether it is possible for siloxanes to undergo hydrolysis under environmental conditions[209].

cVMS have been detected in air, biogas, biosolids, and waste water influent and effluent from waste water treatment plants in many countries[210] The presence of linear and cyclic cVMS has been detected urban, background, and Arctic sites, and that concentrations of D3 and D4 are significantly correlated, as are D5 and D6, which suggests different sources for these two pairs of compounds. Elevated concentrations of D3 and D4 on the West coast of North America and at high elevation sites suggest these sites are influenced by trans-Pacific transport, while D5 and D6 have elevated concentrations in urban areas, which is most likely due to personal care product use (ref).

A number of studies have examined fate and different paths of exposure to D4 and D5. Even though there has been some uncertainty expressed regarding bioaccumulation and biomagnification of siloxane in the environment, significant levels of cVMS have been detected in marine animals, with a significant correlation between the fat content and cVMS (ref). Siloxanes D4 and D5 behave differently than other persistent organic pollutants, and how they behave is not yet clearly understood. cVMS are superhydrophobic, and behave differently in relation to bioaccumulation and biomagnification, and better regulatory evaluation requires specially designed test protocols addressing biotransformation and dietary uptake[211].

Regulatory Status

As of April 2017, the ECHA Committees for Risk Assessment (RAC) and for Socio-Economic Assessment (SEAC) have both issued opinions supporting a UK proposal for restricting D4 and D5 in personal care products because of their potential harm to the environment. The RAC assessment identified D4 (octamethylcyclotetrasiloxane) as being persistent, bioaccumulative and toxic (PBT) and D5 (decamethylcyclopentasiloxane) as very persistent and very bioaccumulative (vPvB)[212]. Under the proposed restriction, wash-off personal care products would not be allowed to contain more than 0.1% of D4 or D5. The proposed restriction is pending decision by the Commission.

The UK's proposal for restriction[213] concluded that of the measures available under the REACH Regulation, restriction is preferred to authorisation because:

- It provides a more flexible approach to achieve the aims of emission reduction as it can be targeted to those applications that pose the greatest risk (i.e. waste water discharges from relatively minor uses of the substance).
- It is likely to achieve a significant reduction in environmental concentrations more quickly.
- It can cover all relevant parts of the life cycle, including the presence of D5 as an impurity in polymeric products (where relevant) and higher molecular weight homologues like D6.
- It can address the D4 content of D5 (which is relevant as D4 is a PBT substance).
- It will avoid the creation of an unnecessary burden on companies whose products do not lead to significant waste water discharges.

The UK proposal also highlighted that alternative products already exist, and the fact that the manufacturers of personal care products are already substituting this substance indicates that they have (or are developing) effective substitutes[214].

In Canada, CEPA assessments concluded that cyclotetrasiloxane and cylcopentasiloxane — also

[209] TemaNord, 2005.
[210] Wang, D., *et al*. 2014.
[211] Mackay, D., *et al*. 2015.
[212] ECHA, 2016
[213] ECHA, 2015.
[214] REACH UK Competent Authority, 2015.

known as D4 and D5 — are toxic, persistent, and have the potential to bioaccumulate in aquatic organisms[215]. In laboratory experiments, exposure to high doses of D5 has been shown to cause uterine tumours and harm to the reproductive and immune systems. D5 can also influence neurotransmitters in the nervous system[216].

Structurally similar to D4 and D5, cyclohexasiloxane (or D6) is also persistent and has the potential to bioaccumulate. Environment Canada's assessment of D6 concluded that this third siloxane is not entering the environment in a quantity or concentration that endangers human health or the environment, but noted significant data gaps concerning its toxicity[217.] Cyclomethicone is a mixture of D4, D5, and D6 siloxanes.

In January 2009, Environment Canada and Health Canada proposed to add D4 and D5 siloxanes to the List of Toxic Substances pursuant to the *Canadian Environmental Protection Act, 1999* (CEPA), and to develop regulations "to limit the quantity or concentration of D4 and D5 in certain personal care products."[218] A Notice of Objection was filed by one of the affected stakeholders, and consequently the Minister of Environment appointed a review board of three academic toxicologists. The Board submitted its report in 2011 and concluded that although D5 exceeded regulatory thresholds for persistence and it bioaccumulates; it does not biomagnify and there is no evidence that it is toxic to any organism tested up to the limit of solubility in environmental phases, it will not cause adverse effects in organisms in air, water, or sediment, and that projected future uses will not pose a danger to the environment[219]. Following the review, the restriction for D5 was repealed in 2012, and only D4 remains restricted.

More recent work reviewing organosiloxanes' environmental chemistry[220] highlights that the biological effects research is still in its infancy. In particular, very little research has been done on degradation products and the role of siloxanes in the methylation of mercury and bismuth compounds to highly toxic organometals. Because siloxanes are able to interconvert depending on environmental conditions, it was suggested that it does not make sense to regulate D4 and not D5 as in Canada, but rather oligomeric siloxanes should be considered as a group[221].

2.5.4 Organometallics

Organometallics are characterized by having both organic and inorganic moieties, the latter being a metal or metalloid[222]. Their level of persistence depends on the chemical structure and how they react in the environment. Organometallics may dissolve and dissociate into the separate organic and inorganic moieties to some extent, or may transform into other products via processes such as ligand exchange, nucleophilic substitution and hydrolysis, oxidation-reduction and photolysis. The relevant compound for the ecological assessment may thus be the original organometallic or a transformation product[223].

Organometallics can be classified into three groups as presented in Table 8: Organometallics classification. Coordination complexes may be grouped with organometallic compounds due to the covalent bond. Organometallics with heavy metal moieties are some of the most common, and also present the greatest potential harm for human health and the environment.

[215] Environment Canada and Health Canada, 2008a; Environment Canada and Health Canada, 2008b.
[216] California Office of Environmental Health Hazard Assessment, 2008.
[217] Environment Canada and Health Canada, 2008c.
[218] Environment Canada and Health Canada, 2009.
[219] Siloxane D5 Board of Review, 2011; Mackay, D., 2015.
[220] Rücker, C. & Kümmerer, K., 2015.
[221] *ibid*
[222] Atkins, P. *et al*, 2010.
[223] OECD, 2015.

Table 8: Organometallics classification

	Organic moiety	Inorganic moiety*	Bond
Organometallic compounds	Carbon	Lead, chromium, cadmium, antimony, arsenic, mercury	Covalent
Organic metal salts	Carbon		Ionic
Coordination complexes	Oxygen, Nitrogen, Sulphur, Phosphorus		Covalent

*This overview focuses on this selection of metals and metalloids.

Routes of exposure to organometallics and their transformation products are multiple and can present a significant hazard to human health. Organometallics can be found in foods due to their usage as food additives or from contamination with industrial byproducts including heavy metal emissions. Moreover, organometallics present in low concentrations in the environment may undergo biomagnification through the food chain, resulting in higher concentrations in some foods such as large fish. Organometallics also have a wide range of applications in consumer products including plastics and surface protectants, as well as in medicine for the treatment of carcinoma and lymphoma, glucose utilisation and inflammation[224].

The half-life of an organometallic may not provide sufficient indication of its persistence due to factors including biomagnification, and the potential to degrade into separate moieties including heavy metals. Organometallics usually stabilize in aqueous and sediment environments, while they typically do not persist in the atmosphere. They can travel in surface and groundwater increasing exposure and the costs of removal. Another consideration regarding the impact on human health and the environment is toxicity. The combination of heavy metals with salts or organic compounds are often more toxic than the heavy metal alone[225].

Several organometallics are of particular concern due to their widespread use and highly adverse impacts on health and the environment. One of the major health and environment catastrophes of the 20th century is linked to the 1920s introduction of tetraethyllead (TEL) in petrol as an anti-knocking agent to improve fuel economy. Despite warnings of the likely health impacts from lead and the availability of a safer alternative fuel additive, it came to be used as a fuel additive around the world. At the high point of its use in the 1970s, some 200,000 tonnes of lead were released into the atmosphere in the EU and USA combined, and some body burdens of lead were of times higher than in pre-industrial times[226]. Studies at this time found strong correlations between high levels of lead in children's bones and neurotoxic effects including IQ loss and chronic anti-social behaviour. In 2000, the EU banned the use of leaded petrol in road vehicles and it was phased out in most other industrial countries around the same time. It is still used in some grades of aviation fuel as well as in some developing countries resulting in an estimated 100 tonnes of lead released each year.[227]

Organotin compounds are also of concern. They were commonly used in anti-fouling paints and pesticides until their ban in the European Union in January 2008. By that time, numerous studies had documented the leaching of these substances, which are highly toxic to many organisms beyond those they are intended to kill, into the marine and coastal environments[228]. The most well-known of these compounds include tributyltin (TBT) and triphenyltin (TPhT). Studies have indicated that TBT disrupts the endocrine system for invertebrates, resulting in higher androgen levels in females, and lower immunity in vertebrates and mammals and possible hearing loss in some mammals.[229]

Methylmercury is a well-known transformation product of mercury, through biotic methylation. This process, which typically occurs in oxygen deficient sediments, can transform an organometallic into a

[224] Mudi, S.Y. *et al*, 2015.
[225] Craig, P.J., 2003.
[226] EEA, 2013.
[227] Masiol, M. & Harrison, R.M., 2014.
[228] Cavalheiro, J., 2016.
[229] Segner *et al*, 2003.

methyl organometallic, considered to be one of the most toxic derivatives[230]. With a half-life in water of 72 days, it is considered to be very persistent. Today the usage and disposal of mercury is regulated by the Minimata Convention, a global treaty adopted in October 2013[231]. The treaty's name reflects the disaster that occurred in Minimata, Japan, when thousands of children were born with deformed limbs, mental retardation and muscular spasms, due to the consumption of fish with high levels of methylmercury from waters contaminated by mercury-containing chemical industrial waste.[232]. Despite high-profile international attention, methylmercury contamination remains a significant public health concern in Europe. A cost benefit analysis found that the benefits of preventing exposure within the EU include more than 600,000 IQ points a year, translating to an economic benefit between €8,000 million and €9,000 million per year[233].

Another organometallic whose persistence and consequent impact on public health has been debated is antimony trioxide, which is used in the manufacture of polyethylene terephthalate (PET plastic) and can also be found in some flame retardants applied to clothing, carpets, upholstery and plastics. About 130,000 tonnes of antimony trioxide was produced globally in 2012. Like many metals, antimony is suspected to be carcinogenic and can severely affect the lungs, heart and stomach. The compound can travel through ground and surface waters, and can also be biomagnified through some plant species[234]. The EU undertook a risk assessment of the compound in 2008 and concluded that the main concern was potential pulmonary toxicity from exposure in the workplace with less attention to the issue of persistence[235]. In Canada, the compound met the criteria for persistence, but the levels being released to the environment were not considered sufficient to present a danger to public health or the environment[236]. The United States commenced a review of the compound in 2014 with a focus on the carcinogenic potential[237].

Another interesting case is presented by the widespread usage of some organometallics which degrade into metals, which are elements and inherently not degradable, but may be more toxic when ingested. For example, organoarsenic compounds, which include roxarsone, nitrasone, carbason and arsanilic acid, were used until recently in the United States as feed additives for livestock, though they are not approved for such use in the European Union[238]. When waste from animals that consumed these additives is used as fertilizer, the organoarsenic compounds can contaminate soil, surface water and groundwater.[239] Organic forms of arsenic are considered to be less toxic than inorganic arsenic, which is recognized to be a neurotoxin and carcinogenic. However, organoarsenic compounds can be degraded into inorganic forms of arsenic within the animal's digestive system and emitted in their waste[240].

A similar example is provided by organocadmium compounds in phosphate fertilizers. While the EU has restricted their use, the United States has not. These compounds may be responsible for excessive levels of cadmium found in whey-based protein shakes. It is postulated that organocadmium from fertilizer-treated grains and grasses is consumed by dairy cows, where the chemical is broken down into cadmium, and then transfers to their milk. In addition to being a carcinogen, exposure to cadmium compounds can adversely affect kidney function, the liver, the central nervous system as well as the respiratory system.

[230] Craig *et al.*, 2003.
[231] EEA, 2013.
[232] *Ibid*.
[233] Bellanger, M. *et al*, 2013.
[234] Reimann, C. *et al*, 2010.
[235] ECHA, 2008; Newton, P.E. *et al*, 2004.
[236] Environment Canada, 2010.
[237] EPA, 2014.
[238] Hileman, B., 2007.
[239] Liu, X., 2013.
[240] Sapkota, A.R. *et al*. 2007; Arai, Y. *et al*., 2003.

The market for new organometallics and applications is projected to grow significantly especially in the Asia Pacific region, where they are sought after as catalysts to accelerate the manufacture of bulk and specialty chemicals[241]. This trend is concerning given that little is known about their health and environmental impacts, how they may transform into other products in the environment, and the potential irreversibility. While minimal growth is expected in Europe in terms of production, this class of chemicals nonetheless poses potential health and environmental risks in the EU due to its mobility and cross-border trade in food and consumer products.

Although guidance for conducting ecological risk assessments of metals exists, there is a need for specific approaches regarding organometallics[242]. Such guidance could support the development of a regulatory framework in Europe to reduce the risk of exposure to organometallics. In addition, regular monitoring of organometallics under the Water Framework Directive could also provide valuable information regarding exposure[243]. Following the *National Action Plan on Micropollutants in the Aquatic Environment*, a large-scale screening study was undertaken in France which included a wide range of micro-pollutants including some organometallics[244].

2.5.5 The persistent 'hydrophilics'

The persistent substances that first drew scientific attention due to their health and environmental impacts were hydrophobic and bioacccumulable. But in recent years strong concerns have been raised concerning a number of persistent substances that are hydrophilic, i.e., having a strong affinity for water. Because of their mobility in water, they pose particular threats to the quality of water resources. Some scientists argue that mobility should be considered of equivalent concern to bioaccumulability[245].

For example, **Germany's** *Umweltbundesamt* (UBA) is on record as considering the REACH Regulation and guidelines related to REACH as insufficient to protect water resources from chemical contamination[246]. It has established precautionary guidance which combines three parameters – persistence (P), mobility (M) and toxicity (T), for the evaluation of potential contaminants of waters used as sources for drinking water[247]. The methodology is aimed at identifying substances registered under REACH which are emitted by registrants (manufacturers, importers), formulators or other downstream users. The guidance provides a methodology for identifying chemicals which are likely to contaminate water in its raw state. This is defined as untreated water from groundwater or surface water or bank storage water (dune recharges).

The methodology is a tiered assessment that first considers whether environmental emissions may or may not occur[248]. If environmental releases cannot be excluded, the assessment considers whether the substance is persistent (P). The criteria for the assessment of P follows the REACH-guidance R.11. If yes, the assessment considers whether it is mobile (M). A substance that has the physiochemical properties of P and M, and where annual tonnage figures and uses provided in REACH registration dossiers indicate releases to the environment are NOT low is considered 'critical to raw water'. If the substance is also assessed as toxic as well as persistent and mobile (PMT) and which occurs in raw water is considered as setting up a scenario that "gives rise to equivalent concern" under Article 57f, REACH.

[241] Grand View Research, 2014.
[242] OECD, 2015.
[243] Dulio, V. & Andres, S., 2012.
[244] ONEMA, 2012.
[245] Reemtsma, T. *et al*., 2016.
[246] http://www.reach-info.de/dokumente/Neumann_Klein_2011_Drinkingwater_REACH_SETAC_Europe_Poster.pdf .
[247] Kalberlah *et al*., 2014a.
[248] Kalberlah *et al*., 2014b.

A 2016 study[249] explains that two of the quantifiers of aquatic mobility are water solubility and sorption tendency, both of which are governed by the compound's molecular polarity. The study identifies challenges in predicting aquatic mobility on the basis of sorption behaviour and gives evidence for a current modelling gap for PM substances. It notes that persistent and mobile compounds can pass through wastewater treatment plans as well as drinking water treatment. The limited number of very polar compounds found in groundwater so far does not indicate that only a few such contaminants are present, but that they are rarely searched for and therefore a gap in monitoring for such compounds exists.

Two cases, atrazine and methyl *tert*-butyl ether (MTBE), are described below, to illustrate how persistent hydrophilic compounds behave in the environment and can remain a potential threat to groundwater and drinking water supplies even after controls are in place.

Atrazine

Atrazine is an agricultural herbicide that was used extensively in Europe until the late 1980s, after which its application declined due to restrictions on its use and increasing substitution by less persistent herbicides.[250] In the US, where atrazine is currently permitted, it is amongst the top, if not the top, most heavily used pesticide.[251]

Atrazine is highly water soluble[252] and is referred to in the scientific literature as a moderately hydrophilic substance.[253] Its affinity for water[254] gives it a propensity to penetrate into surface runoff and groundwater.[255] The persistence and time that it takes atrazine to leach into groundwater depends on a variety of environmental factors, including: soil and subsoil type, hydrological conditions and aquifer structure.[256] Similarly, its persistence in soil depends on soil type, levels of organic matter, soil pH, temperature, clay content, presence of other species, presence of surfactants, surface area and soil structure.[257] For example, atrazine is more likely to degrade in soils high in organic matter as the processes facilitating degradation are mostly biological (but also chemical).[258]

Though atrazine can take years to reach groundwater[259], once it has reached an aquifer, it is highly persistent, more so than in soil.[260] One study found atrazine to be extremely persistent in stagnant aquifer conditions, with a half-life of 206 to 710 days, posing a high risk of build-up under natural conditions[261]. The same study found that in well recirculated water, the half-life of atrazine was lower at 66 to 106 days. Atrazine also has a propensity for being highly mobile in water, and has been found far from its point source—in fog, ambient are, artic ice and seawater.[262]

Germany and Italy banned atrazine in 1991 due to its detection at consistently high levels in drinking water.[263] It was then banned in Austria, Slovenia, Denmark and Sweden also[264], and restricted in other

[249] Reemtsma, T, *et al*., 2016.
[250] PAN UK, 2002
[251] Jablonowski, 2011; Hoshaw, 2016
[252] Graymore *et al*., 2001
[253] Graymore *et al*., 2001 ; Xu *et al*., 2014
[254] Chandler, 2013
[255] Xu, 2014
[256] Tappe *et al*., 2002 ; European Commission, 2009
[257] Graymore *et al*., 2001 ; Mudhoo & Gar, 2011
[258] Graymore *et al*., 2001
[259] Jayachandran *et al*., 1994.
[260] Schwab *et al*., 2006
[261] Ibid.
[262] Jablonowski, 2011
[263] Mergel, 2010
[264] Graymore, 2001

EU countries such as France and the UK.[265] In 2004, the European Commission Decision 2004/248/EC banned atrazine for use as an active substance in plant protection products, except for a few exemptions for essential uses, due to 'ubiquitous and unpreventable water contamination'.[266] The Decision specifically cited the 'large area concentrations' in groundwater exceeding the EU Directive 91/414/EEC limit of 0.1 µg/l for individual pesticides.[267] This limit value corresponds to those provided in the Groundwater Directive (2006/118/EC) and Drinking Water Directive (98/83/EC). At its core, the decision was precautionary in that the quality limit of 0.1 µg/l is a precautionary limit and because of the properties of atrazine continued use would lead to exceedance of the limit. The Decision noted the inability to guarantee the 'satisfactory recovery of groundwater quality' in areas exceeding the 0.1 µg/l limit if use continued elsewhere.

Studies on health and environmental impacts of atrazine have been subject to controversy. Though several studies[268] have shown adverse effects of atrazine on health and wildlife, others[269] have argued that no consistent positive associations can be found across studies, such that no conclusions can be drawn concerning any health or environmental impacts from atrazine. Many of the latter studies have attracted criticism for being funded by atrazine's main manufacturer, Syngenta.[270]

Some studies have linked atrazine to a range of direct and indirect health impacts in animals or humans, including: endocrine disruption in fish and amphibians[271], impacts on reproduction and development, and to certain cancers in laboratory rodents, and also in humans, especially when exposure is combined with other agricultural chemicals.[272] A particularly well-publicised study[273] found that atrazine chemical castrated and induced feminization in African clawed frogs at low ecologically relevant doses (≥0.1 ppb). The author's findings were confirmed in a follow-up study in 2010, and extended across vertebrate classes in 2011[274].

A 2009 US EPA-guided study found that atrazine exposure did not have endocrine disrupting effects.[275] However, other subsequent studies documented adverse reproductive effects or developmental effects on fish, amphibians at concentrations of around 1 $\mu g/l^{-1}$ in water, and on rats at more elevated concentrations.[276] On the other hand, according to a 2014 study funded by Syngenta, no consistent positive evidence has come to light of atrazine's impact on pregnancy outcomes in humans, such as: birth defects, small for gestational age birth weight, prematurity, miscarriages, and problems of fetal growth and development[277].

Despite these mixed results in the scientific literature, in 2016 California listed atrazine on its Proposition 65 list of toxic chemicals due to its association with reproductive harm.[278] The US EPA is currently undertaking a draft ecological risk assessment for atrazine, and will publish a report at the end of 2016 on its human impact.[279]

Other environmental impacts linked to atrazine are also controversial. On the one hand atrazine has been found to inhibit photosynthesis, resulting in decreased production of algae, periphyton,

[265] PAN UK, 2002
[266] Sass & Congelo, 2006, p. 260
[267] Commission Decision 2004/248/EC
[268] Such as Hayes *et al*., 2002, 2010 and 2011; Rohr & McCoy, 2010.
[269] such as Solomon *et al*. 2008, van der Kraak *et al*., 2014 and Goodman *et al*., 2014
[270] Sass & Colangelo, 2006
[271] Hayes *et al*., 2002, 2010 and 2011; Rohr & McCoy, 2010
[272] Sass & Colangelo, 2006.
[273] Hayes *et al*., 2002.
[274] Hayes *et al*., 2011
[275] Kloas *et al*, 2009, cited in Jablonowski, 2011
[276] Jablonowski, 2011
[277] Goodman *et al*., 2014
[278] Hoshaw, 2016
[279] Hoshaw, 2016

phytoplankton and macrophytes, with impacts up the food chain.[280] For example, it has been linked to decreases in fish and wildfowl populations in the Chesapeake Bay in the US.[281] However, other studies (largely industry-funded) have criticized these results and asserted that atrazine poses no significant acute or chronic risks to amphibians or aquatic organisms at environmentally relevant concentrations.[282]

Atrazine continues to be detected across Europe decades after its agricultural use stopped. Despite the EU-wide ban in 2004, atrazine and its degradation product desethylatrazine are still the pesticides that are most commonly detected at levels above the EU Groundwater Directive (2006/118/EC) limit of 0.1µg/l for individual pesticides.[283] A 2010 German study found that atrazine was still the most abundant pesticide in groundwater 18 years after its ban.[284] Similar results were found at Germany's Zwischenscholle aquifer, where atrazine remained at largely stable levels close to 0.1 µg/l 20 years on from its ban.[285] A 2009 French study of Brevilles Spring found that 8 years after its application was stopped, atrazine was still in spring water at concentrations above the limit for drinking water.[286]

Certain environmental conditions can contribute to the degradation of atrazine, although its metabolites have different toxological and degradability profiles, with some being less toxic but more persistent.[287] Another study found that the combination of ultrasound (sonolysis) and UV radiation could break down atrazine into less hydrophilic intermediates.[288]

Nonetheless, atrazine is an example of how persistent hydrophilic substances can remain in water resources for long periods after the source is stopped.

Methyl tert-butyl ether (MTBE)

Methyl *tert*-butyl ether (MTBE) is an aromatic organic chemical used as an octane boosting agent in petrol. MTBE was originally introduced as on alternative to lead based anti-knocking agents (tri-ethyl lead). Production of MTBE started in Europe in 1973 and in 1979 in the US[289], and legislation in both the USA (Clean Air Act amendments in 1990) and EU (Fuel Quality Directive) promoted using octane boosters to improve combustion of fuels and limit emissions of volatile organic compounds.

Global MTBE production and consumption peaked in 1999, with total worldwide annual production at about 21.4 million. At this time roughly 3.3 million tonnes of MTBE were produced in the EU and approximately 2.3 million tonnes were used domestically[290].

During the 1990s it became apparent that MTBE could render drinking water unfit for consumption because of unpleasant odor and taste at relatively low concentrations. Several cases of contamination of groundwater in the USA[291] were documented mainly due to leakages in underground containers. The cost of cleaning up leaks and spills was estimated to be in the order of tens to hundreds of millions of dollars and led to several US states restricting or banning the use of MTBE as an additive to petrol[292].

MTBE usage bans in the US and Canada led to sharp decreases in global demand for MTBE, from

[280] Graymore *et al*., 2001
[281] Graymore *et al*., 2001
[282] Soloman *et al*., 2008 ; Van der Kraak *et al*., 2014
[283] Eurostat, n.d.
[284] Jablonowski *et al*., 2011
[285] Vonberg, D., 2015. N.b. Tappe *et al*., 2002, also recorded only slightly decreasing levels of atrazine in German aquifers 10 years on from its ban, but noted that this could be in part due to continued illegal application, estimated around 6%.
[286] European Commission, 2009
[287] Jablonowski *et al*., 2011
[288] Xu *et al*., 2014
[289] ECOTOC, 2003.
[290] EEA, 2001.
[291] EEA, 2001.
[292] Ibid.

19.3 million tons in 2000 to 12.1 million tons in 2011. However global demand is expected to grow slowly in the longer term due to increased demand in Asia Pacific and Middle East regions.[293]. Demand for MTBE in Europe has remained relatively stable between 2 and 3 million tonnes, though it is being gradually replaced by other octane boosting agents such as ethanol and bio-based additives such as ethyl tert-butyl ether (ETBE)[294]. Production capacity of MTBE in Europe has decreased to approximately 1.5 million tonnes in 2010[295], indicating that it is still a high production volume chemical.

MTBE is persistent. Degradation half-lives in surface waters are dependent on a number of conditions such as current, depth of water and temperature; the estimated half-life for MTBE in rivers ranges from 30 minutes to 52 days and for lakes from 10 to 193 days[296]. Degradation in ground water aquifers is slow to non-existent under both aerobic and anaerobic conditions. If degraded, the primary degradation product in soil and groundwater is TBA (Tertiary Butyl Alcohol)[297]. The atmospheric half-lives of MTBE are dependent on atmospheric conditions, and range between 3 and 6 days in summer and winter respectively[298]. The bioconcentration potential of MTBE is insignificant[299].

MTBE is highly soluble in water -- up to 30 times more soluble than other components of petroleum. Unlike many other organic chemicals, MTBE is poorly sorbed to carbon based substrates such as soil. These two physical properties have important consequences for the movement of MTBE in groundwater and the types of remediation technology that are likely to be effective in removing it from contaminated groundwater[300].

MTBE is ubiquitous in the environment. Because of its unique properties relating to water solubility, affinity for water (hydrophilic) and mobility, it has been detected in groundwater, drinking water, surface waters such as rivers, lakes and coastal waters, and in wastewater[301]. Unlike other VOCs, storm water runoff and atmospheric transportation are low contributors to water concentrations of this pollutant; higher concentrations of MTBE are usually attributed to point sources such as spills, industrial discharges or illegal dumping of tank washings from tanker ships. The main mechanisms for pollution of groundwater include leaking storage tanks, accidental spillage during production, transportation of and issue of gasoline products in retail filling stations, depots and refineries. While fewer incidents of point source contamination of groundwater have been identified in Europe compared to the United States, cases of contamination from point sources have been documented in Germany, the Netherlands, Denmark and the UK[302]. Concentrations of MTBE in surface water and groundwater are strongly connected to urban areas, population density and amount of MTBE used in petrol[303].

Risk assessments of MTBE have found limited evidence of risks to human health, especially at levels that are realistic in terms of exposure either through occupational exposure or exposure through the environment[304]. In fact, the World Health Organization (WHO) decided not to establish a health-based guideline value for MTBE because any such value based on any adverse effects would be significantly higher than the concentration at which it would be detected by odor[305].

[293] EFOA, 2016; Merchant Research and Consulting Ltd. 2016.
[294] Ibid.
[295] CONCAWE, 2012.
[296] Rosell, M. *et al*., 2006.
[297] Kjølholt, J. *et al*., 2014.
[298] Kolb, A. & Püttmann, W., 2006.
[299] Kjølholt, J. *et al*., 2014.
[300] National Groundwater and Contaminated Land Centre, 2000.
[301] Rosell, M. *et al*., 2006.
[302] Chisala, B.N. *et al*. 2007: National Groundwater and Contaminated Land Centre 2000; Rosell, M. *et al*., 2006.
[303] Achten *et al*., 2001.
[304] Finnish Environment Institute, 2002.
[305] WHO, 2005a.

More recently, concerns have been raised about the possible endocrine disrupting properties of MTBE, along with the high tonnage/exposure potential of the substance. A substance evaluation of MTBE under REACH is currently underway with France as Rapporteur MS[306]. A recent weight of evidence approach evaluating endocrine activity using multiple endocrine endpoints concluded that the evidence thus far does not support a direct effect on the endocrine system in terms of the hypotheses tested[307]. MTBE has also been linked to asthma and Diabetes Type II[308], but so far very little research is available on this.

MTBE is not considered as either PBT or vPvB under REACH, because its bioaccumulation potential is considered insignificant. Under the CLP Regulation, MTBE is classified as a flammable liquid (cat. 2) and a skin irritant (Cat. 2). MTBE is not classified with regard to environmental properties. An EU-level indicative Occupational Exposure Limit is in place.

Most EU legislation mentioning MTBE focuses on its use in petrol. Directive 2009/30/EC on the specifications for petrol, diesel and gas oil establishes, among other aspects, the maximum content of MTBE ("ethers containing 5 or more carbon atoms per molecule") in market fuel at 22 % v /v. Directive 2009/28/EC on the promotion of energy from renewable energy sources establishes a target value for Bio-MTBE in Annex III, according to which 22 % of the energy content in MTBE produced on the basis of bio-methanol (35 MJ/kg) can be considered to originate from renewable resources (the target is for 10 % of total energy used for transportation purposes to be produced from renewable resources in 2020).

Because of concerns related to potential latent health risks, and because its persistence in groundwater and mobility in soil have contributed to water contamination, both academics and regulators have suggested that environmental fate and presence of MTBE in groundwater and drinking water should be closely monitored.

2.5.6 The special case of 'pseudopersistence'

In terms of regulatory frameworks persistence is defined by the chemicals' biodegradability measured by their half lives in different media or their long-range transport potential. As explained above, persistence is considered as a factor in exposure and risk. The chemical or substance's degree of persistence determines how long the chemical is present and in turn affects routes and rates of exposure.

In certain cases, substances that would not be considered persistent because of their relatively short half-lives might nonetheless, because of their continuous release, result in the type of continuous exposure associated with persistent chemicals[309].

The term '*pseudo-persistence'* was first coined with respect to traces of pharmaceuticals continuously discharged to the aquatic environment[310]. It is considered misleading in that it does not refer to an intrinsic property of a substance, but rather describes widespread patterns of use or modes of entry into the environment. The term '*continuously present*' has been proposed as being more descriptive and less likely to be misinterpreted as an intrinsic property of a substance[311]. Such substances do not need to be persistent in the environment to cause negative effects. The key factor is that their supply is continually replenished, even if their half-lives are short. If this continuous supply of a chemical takes place in an indoor environment or with respect to the aquatic environment, the likelihood of a constant exposure becomes heightened.

[306] Kjølholt, J. *et al*., 2014.
[307] Peyster, A. & Mihaich, E., 2014.
[308] Saeedi, A. *et al*., 2016.
[309] Mackay, D *et al*., 2014.
[310] Daughton & Ternes, 1999.
[311] Mackay, D. *et al*., 2014.

For example, Bisphenol A (BPA) – a known endocrine disruptor -- is one of the highest volume chemicals produced worldwide[312]. It is a building block of polycarbonate plastics often used for food and beverage storage, as well as a component of epoxy resins that are used to line food and beverage containers. Studies have shown that BPA can leach from these and other products in contact with food and drink, and as a result, routine ingestion of BPA is presumed. This compound is also found in an enormous number of other products that consumers come into contact with daily, and has been detected in the majority of individuals examined. Although many questions remain to be answered concerning the effects of this endocrine disruptor, exposure to BPA is apparently ubiquitous.

Other groupings of so-called 'pseudo-persistent' or 'continuously present' compounds include certain phthalates, polyaromatic hydrocarbons (PAHs), and other phenols such as perchlorate.

Because '*pseudo-persistence'* is not related to an intrinsic property of a substance, it will not be considered further in this study.

2.6 ACTIVITIES IN INTERNATIONAL ORGANISATIONS AS WELL AS AT NATIONAL LEVEL

A number of recent activities within international organisations are relevant for the governance of POPs and other very persistent substances. In 2015, in the context of the **Strategic Approach to International Chemicals Management (SAICM)**, stakeholders at the fourth meeting of the International Conference on Chemicals Management (ICCM4) adopted a resolution designating environmentally persistent pharmaceutical pollutants as a new emerging policy issue[313]. Based on a proposal by Peru, Uruguay and the International Society of Doctors for the Environment, the resolution included an invitation to IOMC organisations to "facilitate collaborative action", to develop a workplan on environmentally persistent pharmaceutical pollutants and to report back on these activities at ICCM5 in 2020.[314]

At ICCM4 stakeholders also discussed other issues of concern including perfluorinated chemicals (PFCs). While no resolutions were adopted on PFCs, an update was given on progress and an information document circulated containing an update on managing PFCs and the transition to safer alternatives, prepared by the OECD and UNEP.[315] Two representatives called for the proposed workplan for the Global PFC group to address the hazards of short-chained PFCs.[316]

Within the **United Nations Environment Programme (UNEP),** activities related to POPs are ongoing through the implementation of the Stockholm Convention. At its seventh Conference of the Parties (COP7), Parties agreed to list three additional substances as POPs: hexachlorobutadiene, pentachlorophenol and its salts and esters, and polychlorinated naphthalenes.[317] This takes the total number of POPs listed under the Stockholm Convention to 26.

The **Persistent Organic Pollutants Review Committee (POPRC**) is charged with examining proposals for listing of additional chemicals under the Stockholm Convention. At the 12th meeting of the POPRC in September 2016 it decided to initiate steps towards listing PFOA in the Convention. It also made recommendations for global bans on short-chain chlorinated paraffins and the flame

[312] Rubin, 2011.
[313] SAICM, 2015, ICCM4 Meeting report
[314] SAICM, 2015, ICCM4 Meeting report, p 17
[315] SAICM/ICCM.4/INF/21, cited in SAICM, 2015, ICCM4 Meeting report, p 26
[316] SAICM, 2015, ICCM4 Meeting report, p 27
[317] UNEP, 2015, Report of the Conference of the Parties to the Stockholm Convention on Persistent Organic Pollutants on the work of its seventh meeting, UNEP/POPS/COP.7/36
http://chm.pops.int/TheConvention/ThePOPs/TheNewPOPs/tabid/2511/Default.aspx

retardant decaBDE (with certain exemptions), and recommended global action on dicofol[318]. A proposal to list hexachlorobutadiene (HCBD) (an unintentional POP) in Annex C to the Convention was not agreed by the POPRC[319].

The UNEP continues various monitoring activities on POPs within the context of the Stockholm Convention. Its Global Monitoring Plan (GMP) for POPs collects global data on levels of the 26 POPs listed in the environment and in humans. Its aims include providing globally comparable data on POPs and strengthening in-country capacity for monitoring POPs where this is lacking. The GMP is now implementing the second of its regional projects, which will run from 2016 to 2019, focusing on building in-country capacity for the sampling and analysis of POPs[320].

The **United Nations Globally Harmonised System of classification and labelling of chemicals (GHS)** published its 6th edition in 2015. This included clarification of criteria for some hazard classes, including substances classed as hazardous to the aquatic environment. Persistence, or a 'lack of rapid degradability', in combination with acute toxicity or bioaccumulation potential, qualifies a substance to be classed as a hazard to aquatic ecosystems[321]. This is based on the fact that persistent substances in water threaten to 'exert toxicity over a wide temporal and spatial scale'[322].

The GHS defines 'rapid degradation' in the aquatic environment as at least 70% degradation of a substance within 28 days (equivalent to a degradation half-life of 16 days).[323] This can be biotic or abiotic (e.g. hydrolysis). This also applies to a substance's degradation products.[324] Apart from some exceptions, these levels must be achieved within 10 days of the start of the degradation process. Degradability is determined by biodegradability tests (A-F) of OECD Test Guideline 301 for freshwater, and OECD Test Guideline 306 for marine environments.[325] In the absence of these data, a BOD(5 days)/COD[326] ratio of greater than or equal to 0.5 is considered to indicate rapid degradation. However, if a substance fails an OECD test for rapid degradability, it can still be classed as such if rapid degradation in the real environment can be proven.[327]

At the national level, **Canada** has progressed action on the management of persistent chemicals. In 2016 the Canadian government launched the third phase (running 2016 to 2021) of its Chemicals Management Plan, to address the remaining 1550 priority substances out of the original 4300 chemicals identified as requiring health and ecological assessment on Canada's Domestic Substance List. These include numerous persistent chemicals, for example D3 (hexamethylcyclotrisiloxane) D4 (cyclotetrasiloxane) and persistent chemicals within other groups of substances such as siloxanes and organometallics. [328] This autumn (2016) the government is expected to publish its final screening assessment decisions under the Canadian Environmental Protection Act (1999) of 10 organic flame retardants chosen on the basis of their potential environmental persistence and their potential exposure to consumers and children.

In the **USA** a new chemicals act—the Frank R. Lautenberg Chemical Safety for the 21st Century Act—came into force in June 2016, updating the US Toxic Substances Control Act (TSCA). It includes a specific section on persistent, bioaccumulative and toxic (PBT) chemicals. Under this, PBT

[318] IPEN, 2016.
[319] Ibid.
[320], http://www.unep.org/chemicalsandwaste/POPs/AnalysisandMonitoring/GMPcopy/tabid/1061031/Default.aspx# (Viewed 26 September 2016)
[321] GHS, 2015, p .222.
[322] Ibid., p. 222.
[323] Ibid.
[324] Ibid., p. 223
[325] Ibid., p. 218
[326] Biochemical oxygen demand/ chemical oxygen demand.
[327] GHS, 2015, p. 223
[328] List of Substances in the next phase of the Chemicals Management Plan (CMP) and Two-year Rolling Risk Assessment Publication Plan, viewed 29 September 2016, http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=2A33EEC9-1

chemicals identified in the 2014 update of the TSCA Work Plan for Chemical Assessments will be subject to 'expedited action'.[329330331] According to this 'fast track' process, risk evaluation for the substances is not needed, only assessment of their use and exposure, and rules on the substances involved must be proposed within three years of the Act and finalised 18 months later.[332] In the 2014 TSCA Work Plan, 12 out of 89 substances are classed as highly persistent in the environment, but with low bioaccumulation potential.[333]

In 2009, **Japan** amended their Chemical Substances Control Law, bringing in new laws for the classification and regulation of chemicals. Prior to 2009, chemicals were assessed for persistence first (those readily biodegradable were automatically authorized) and then assessed for their bioaccumulability and then toxicity.[334] Since 2009 around 1,000 'priority' chemicals have been identified based on whether they have 'highly residual properties'. If they are found to have such properties, they are then assessed for their T and B properties. From there they are put into Class I (PBT chemicals) or Class II (PT, but this also includes since 2009 non-persistent chemicals).[335] OECD test guideline 301C for ready biodegradability is the most common test used to assess biodegradation in Japan.[336] The importance attached to biodegradability in testing the environmental fate of chemicals stems back to the original impetus for the Chemical Substances Control Law in 1973, brought in following environmental and health hazards caused by PCBs.[337]

2.7 REGULATORY FRAMEWORK RELEVANT FOR VERY PERSISTENT CHEMICALS

2.7.1 International efforts to control vP chemicals

Very persistent chemicals are increasingly a global problem requiring international action, because of the potential for long-range transport as well as internationalized production and trade. The most targeted international instrument for control of persistent substances is the **2001 UN Stockholm Convention on Persistent Organic Pollutants** (POPs Convention)[338], already mentioned in the case study on highly fluorinated substances. The Convention sets forth measures to eliminate or reduce the release of POPs into the environment at the global level.

The Convention lists the chemicals it regulates in three Annexes. As of July 2016, Annex A lists 22 chemicals for which Parties are to take measures to eliminate their production and use. Eighteen of these are highly chlorinated POPs and four are highly brominated POPs (see below).

[329] https://www.epa.gov/sites/production/files/2016-06/documents/bills-114hr2576eah.pdf
[330] Those added in 2014 which demonstrate high environmental persistence on this list include: Decabromodiphenyl ethers (DecaBDE); Hexabromocyclododecane (HBCD); 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (TBBPA); Molybdenum and Molybdenum Compounds; Pentachlorothio-phenol; Phenol, isopropylated, phosphate (3:1) (iPTPP).
[331] https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf
[332] https://www.epa.gov/sites/production/files/2016-06/documents/bills-114hr2576eah.pdf
[333] See TSCA 2014 Work Plan for Chemical Assessments, viewed 28 September 2016, https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf
[334] Ikeda *et al*., 2001
[335] Naiki *et al*., 2010
[336] Nabeoka *et al*., 2016
[337] Ibid.
[338] UNEP, 2001.

Table 9: Substances listed for elimination in the Stockholm Convention

Stockholm Convention substances listed for elimination
Highly chlorinated POPs
1. Aldrin
2. Chlordane
3. Chlordecone
4. Dieldrin
5. Endrin
6. Heptachlor
7. Hexachlorobenzene
8. Hexachlorobutadiene
9. α-Hexachlorocyclohexane (α-HCH)
10. β-Hexachlorocyclohexane (β-HCH)
11. Lindane (γ-Hexachlorocyclohexane)
12. Mirex
13. Pentachlorobenzene
14. Pentachlorophenol and its salts and esters
15. Polychlorinated biphenyls (PCBs)
16. Polychlorinated naphthalenes
17. Technical endosulfan and its related isomers
18. Toxaphene
Highly brominated POPs
19. Hexabromobiphenyl
20. Hexabromocyclododecane (HBCD)
21. Hexabromodiphenyl ether and heptabromodiphenyl ether
22. Tetrabromodiphenyl ether and pentabromodiphenyl ether

Annex B lists two chemicals (DDT; perfluoro-octane sulfonic acid and perfluorooctane sulfonyl fluoride, or PFOS) that are to be restricted by Parties to the Convention, except for a number of 'acceptable purposes' and 'specific exemptions' for which production and use may continue. Finally, Annex C covers six unintentionally produced substances, including dioxins and furans, for which Parties must take measures to minimize and, where feasible, eliminate their production and release.

The Convention foresees that additional chemicals will need to be included in its regime if the problem of POPS is to be fully addressed. Four additional substances (DBDE, dicofol, short-chained chlorinated paraffins, PFOA) are currently under review for possible listing in one or more of the annexes.
Adding a new substance to one of the Convention's three Annexes is not easy. In order for a substance to be designated as a POP, it must be shown to be persistent, bioaccumulative, and toxic, as well as known to travel long distances by various pathways. A proposal for listing a new chemical may be submitted by a party to the Convention, either a State or a regional economic integration organisation such as the EU, at any time. The Persistent Organic Pollutants Review Committee (POPRC)[339] then evaluates the proposals. This process involves *inter alia*, putting together a risk profile and risk management evaluation in consultation with Parties and observers.[340]

The POPRC then makes recommendations to the Conference of the Parties as to whether the chemical should be listed for elimination (Annex A); restriction (Annex B); or for measures to minimize unintentional production (Annex C). The Conference has the final decision-making power, taking due account of the recommendations of the Committee whether to list the chemical and specifies the potential control measures. Overall, the process can take several years.

The **1998 UNECE Aarhus Protocol on Persistent Organic Pollutants** (POPs Protocol)[341] and the

[339] The POPRC consists of 31 government-designated chemicals assessment experts representing the regions to the Convention: 8 from African states; 8 from Asian and Pacific States; 3 from Central and Eastern European Sates; 5 Latin American and Carribean States,and 7 from Western European and other States.
[340] Moermond, C., *et al.*, 2012, p. 363.
[341] http://www.unece.org/env/lrtap/pops_h1.html.

2013 Minamata Convention on Mercury[342]should also be noted. Other international efforts include the UNEP-led Strategic Approach to International Chemicals Management (SAICM) and the four International Conferences on Chemicals Management (ICCM) held under its aegis to date[343], already discussed above

2.7.2 The EU regulatory framework for control of vP chemicals

As noted in the Technical Specifications, a number of EU acts consider persistence as a property of concern. However, in almost all cases, persistence is regulated only if bioaccumulability is also present. The one exception is the **Detergents Regulation** [344], which requires surfactants used in detergents to meet biodegradability standards.

The **REACH Regulation**[345] is of course the overarching framework, together with the **CLP Regulation**[346]. It covers all substances placed on the EU market, except for those exempted because other acts apply. As already noted, REACH Annex XIII sets criteria for identifying if a substance is PBT or vPvB. The identification of a substance as PBT or vPvB automatically requires the registrant to carry out an estimate of emissions, to identify and implement measures to minimise emissions, to indicate in the safety data sheet (SDS) that the substance is PBT/vPvB, and to communicate measures for minimizing emissions to downstream users via the SDS[347].

REACH also provides for the possibility of control of a PBT or vPvB substance through the mechanism of authorization. Under the REACH system, a compound must first be identified as a Substance of Very High Concern (SVHC) and then added to the Candidate List for eventual inclusion in Annex XIV as subject to authorisation or, alternately, to restrict it under Annex XVII.

While REACH does not explicitly provide for the possibility of controlling a substance on the basis of persistence alone, it might be possible to make a case under Article 57(f) that there is scientific evidence of probably serious effects to human health or the environment giving rise to an equivalent level of concern as a substance meeting the Annex XIII criteria for PBT/vPvB. In addition, REACH Annex I mentions the possibility of assessing particular effects such as ozone depletion, strong odour or tainting, in which case the manufacturer or importer shall assess the risks associated with such effects on a case by case basis and include a full description in the chemical safety report and a summary in the safety data sheet. To date, neither of these provisions has been applied to a substance because of persistence.

[342] http://www.mercuryconvention.org/Convention/tabid/3426/Default.aspx .
[343] http://www.saicm.org/index.php?option=com_content&view=article&id=78&Itemid=480.
[344] Regulation (EC) No 648/2004 on detergents.
[345] Regulation (EC) No 1907/2006 (REACH).
[346] Regulation (EC) No 1272/2008 (CLP).
[347] Case study on 'Inconsistencies in assessment procedures for PBT and vPvB as properties of concern' (as mentioned in introduction; not yet published, December 2016).

Table 10: PBT/vPvB substances on the Candidate List

PBT/vPvB substances on the Candidate List	
5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane	PBT/vPvB
Perfluorononan-1-oic-acid	PBT
Henicosafluoroundecanoic acid	vPvB
Bis(pentabromophenyl) ether (decabromodiphenyl ether) (DecaBDE)	PBT/vPvB
Anthracene	PBT
2-(2H-benzotriazol-2-yl)-4,6-diterpentylphenol (UV-328)	PBT/vPvB
Tricosafluorododecanoic acid	vPvB
Pentadecafluorooctanoic acid (PFOA)	PBT
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	PBT/vPvB
Perfluorononan-1-oic-acid	PBT
Heptacosafluorotetradecanoic acid	vPvB
Ammonium pentadecafluorooctanoate (APFO)	PBT
2-benzotriazo-2-yl-4,6-di-tert-butylphenol (UV-320)	PBT/vPvB
Bis(tributyltin) oxide (TBTO)	PBT
Pitch, coal tar, high-temp.	PBT/vPvB
Pentacosafluorotridecanoic acid	vPvB
5-tert-butyl-2,4,6-trnitro-m-xylene (Musk xylene)	vPvB
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	PBT/vPvB
Anthracene oil	PBT/vPvB
Anthracene oil, anthracene paste	PBT/vPvB
Hexabromocyclododecane	PBT/POP

Note that the **CLP Regulation**, which implements the Globally Harmonised System of Classification and Labelling of Chemicals, does not include the possibility of classification for PBT/vPvB, since these are not part of the GHS. However, the classification "Hazardous for the aquatic environment" (chronic hazard toxicity for organisms such as fish and algae) includes 'ready degradability' or 'potential to bioaccumulate' as criteria to consider and therefore some aspects of persistence are taken into account.

Several EU acts are aimed at restricting specific chemical substances because of their persistence as well as their toxicity and potential for bioaccumulation. These include the 1996 **PCBs Directive**[348], the 2004 **POPs Regulation**[349] implementing the Stockholm Convention, and the 2008 **Mercury Regulation**[350]. As noted earlier, persistence is also a factor with respect to the substances regulated through the 2009 **Ozone-Depleting Substances Regulation**[351], and the 2014 **F-Gases Regulation**[352], both implementing the Montreal Protocol.

The EU regulatory framework relevant for very persistent substances also includes controls over products released directly into the environment, such as the 2009 **Plant Protection Products Regulation** (PPPR)[353], the 2012 **Biocidal Products Regulation** (BPR)[354], and the **Directives on medicinal products for human use** (HMPD)[355] or **for veterinary use** (VMPD)[356]. Both the PPPR and the BPR provide that active substances cannot be approved for use in pesticides or biocides if they are found to be PBT or vPvB; however, the BPR foresees the possibility of a derogation, e.g. if the

[348] Directive 96/59/EC on disposal of polychlorinated biphenyls and polychlorinated terphenyls.
[349] Regulation (EC) No 850/2004 on persistent organic pollutants.
[350] Regulation (EC) No 1102/2008 on the banning of exports of metallic mercury and certain mercury compounds.
[351] Regulation (EC) No 1005/2009 on substances that deplete the ozone layer
[352] Regulation (EU) No 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006
[353] Regulation (EC) No 1107/2009 concerning plant protection products.
[354] Regulation (EU) 528/2012 concerning biocidal products.
[355] Directive 2001/83/EC relating to medicinal products for human use.
[356] Directive 2001/82/EC relating to veterinary medicinal products

active substance is needed on the grounds of public health or public interest and no alternatives are available. While both the HMPD and the VMPD provide for Member States to suspend marketing authorisation if necessary to protect human health, only the Directive on veterinary medicinal products permits the refusal of authorisation in order to protect the environment, e.g. on the basis of PBT or vPvB. In addition, as already noted above, the 2004 **Detergents Regulation**[357] is the one EU act that regulates substances on the basis of their persistence, by requiring surfactants used in detergents to meet biodegradability standards.

Also important to mention are those acts aimed at controlling processes that result in releases to the environment, including of certain PBT/vPvB substances, during manufacturing or product use. The 2010 **Industrial Emissions Directive** (IED)[358] covers 52,000 major industrial installations across the EU. It requires the operation of these installations in accordance with best available techniques (BAT) for the particular industrial process, and as per the emission limit values (ELVs) for hazardous substances set in each installation's integrated permit.

The IED's list of polluting substances to be covered by ELVs includes some groups of persistent substances covered in EU legislation for air and water quality protection, and refers to the CLP Regulation for a general definition of 'hazardous substances'. As explained above, the CLP Regulation includes a classification for 'hazardous to the aquatic environment'. While this includes the criterion of ready biodegradability, it is not equivalent to the criteria for persistence under REACH and it is likely that many vP substances would not be caught, e.g., a vP substance not meeting additional criteria for BT and vB and not specifically listed in the IED would not be included in the controls over the industrial facility's emissions.

The conditions considered best available techniques (BAT) for the industrial processes covered under the IED are defined inter alia on the basis of BAT reference documents (BREFs) developed by stakeholders under the coordination of the Commission's Joint Research Centre. These are aimed at achieving best overall reduction of pollution emitted to the environment and do not take into account the intrinsic quality of persistence which may require special measures to prevent any releases of vP substances in order to avoid build-ups in the environment. As already noted, releases of vP substances not yet determined to be B or T would not be covered. Moreover, the use of ELVs or concentration values is inappropriate for vP substances likely to lead to accumulations in the environment. Another gap is that emissions of vP substances from smaller industrial installations are not covered.

The 1991 **Urban Wastewater Treatment Directive**[359] is primarily aimed at reducing the nitrogen content of receiving waters, so as to prevent eutrophication. It includes a general requirement that industrial waste water discharged into sewage systems must be pre-treated to ensure that discharges from treatment plants do not adversely affect the environment. The emerging problem of chemical loads from household chemicals, pharmaceuticals and cosmetics collected via sewerage and which cannot be removed via conventional sewage treatment is not covered.

In addition, several acts are important for their relevance in controlling hazardous substances in the technosphere. Among these is the 2011 **(recast) RoHS Directive**[360], one of the few pieces of legislation dedicated to controlling the use of hazardous substances in articles in order to reduce downstream impacts of the substance at the end of the product's life. RoHS requires Member States to prevent the placing on the market of new electrical and electronic equipment (EEE) containing lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE). The first four substances are metals and hence primary elements, while the last two are POPs used as flame retardants. By banning the use of these substances, they are prevented from entering the material waste stream, i.e., the technosphere. Note that other flame retardants not

[357] Regulation (EC) No 648/2004 on detergents.
[358] Directive 2010/75/EU on industrial emissions (IPPC).
[359] Directive 91/271/EEC concerning urban waste-water treatment
[360] Directive 2011/65/EU (RoHS Directive).

covered under RoHS but which are frequently added to the plastic casings of televisions and other electronic products -- such as tetrabromobisphenol A (TBBPA), and hexabromocyclododecane (HBCD) -- are also problematic and an instance of "regrettable substitution" in that plastics with added flame retardants may not be recyclable and in any case the flame retardants should be kept out of recycled material flows. The substance-specific provisions in the other "waste stream directives", e.g. end-of-life vehicles[361], batteries[362] and packaging materials[363], play similar (albeit incomplete) roles in keeping problematic substances out of the technosphere.

The 2000 **Water Framework Directive**[364], together with the 2008 **Environmental Quality Standards Directive** (EQSD) [365], form another essential element of the overall EU regulatory regime. The Water Framework Directive. provides for establishment of a list of priority substances, which present a significant risk to or via the aquatic environment, identified on the basis of risk assessment. Within this list, substances that are toxic, persistent and liable to bio-accumulate or which give rise to an equivalent level of concern, are to be identified as priority hazardous substances. The classification of substances as priority substances and priority hazardous substances triggers specific risk management measures. Priority substances should be subject to controls for the progressive reduction of discharges, emissions and losses of the substances concerned. In the case of priority hazardous substances such controls aim at the cessation or phasing-out of discharges, emissions and losses by 2020. Amendment by the EQS Directive has resulted in a list of 45 substances considered priority substances. Within these are 21 substances considered priority hazardous substances, including PBDE, chloroalkanes (C_{10-13}), DEHP, hexachlorobenzene, PCB, PCP, PAH, PFOS, dioxins, and HBCDD.

Directive 2013/39/EC[366] amending the Water Framework and EQS Directives recognises the need for special consideration of substances behaving as ubiquitous persistent, bioaccumulative and toxic (UPBT) substances. Because of long-range transport and their persistence in the aquatic environment, special monitoring requirements may be called for, as well as more stringent emission controls. Substances identified as UPBTs include brominated diphenylethers, mercury and its compounds, polyaromatic hydrocarbons (PAH), tributyltin compounds, perfluorooctane sulfonic acid and its derivatives (PFOS), dioxins and dioxin-like compounds, hexabromodyclododecane (HBCDD) and heptachlor. In addition, the Directive recognises the contamination of soil and water with pharmaceutical residues as an emerging environmental concern. Finally, the Directive sets up a new monitoring mechanism to provide high-quality information on the concentration of substances in the aquatic environment, with a focus on emerging pollutants. This includes a provision for a watch-list mechanism designed to allow targeted EU-wide monitoring of a limited number of substances of possible concern.

Table 11: The WATCH List under the Water Framework Directive

The WATCH List under the Water Framework Directive
The WATCH List established under Directive 2013/39/EU will focus on ten compounds. The first three compounds selected are the pharmaceuticals diclofenac, 17-beta-estradiol (E2) and 17-alpha-ethinylestradiol (EE2). The candidate compounds for the remaining seven positions on this shortlist are: trichlorfon, cyclododecane, imidacloprid, diflufenican, oxadiazon, tri-allate, methiocarb, 2,6-di-tert-butyl-4-methylphenol, thiacloprid, aminotriazole, clothianidin, chromium trioxide, thiamethoxam, 2-ethylhexyl 4-methoxycinnamate, dichlofluanid, formaldehyde, dimethenamid-P, triphenyl phosphate, acetamiprid, erythromycin, clarithromycin, ciprofloxacin, tolylfluanid, azithromycin and free cyanide[367].

[361] Directive 2000/53/EC on end-of-life vehicles.
[362] Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators.
[363] Directive 94/62/EC on packaging and packaging waste
[364] Directive 2000/60/EC establishing a framework in the field of water policy.
[365] Directive 2008/105/EC on environmental quality standards in the field of water policy.
[366] Directive 2013/39/EU amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy.
[367] https://www.gov.uk/government/news/european-commission-publishes-candidate-compounds-for-watch-list-under-water-framework-directive (accessed 26.09.2016).

While there is surely a need for systematic environmental monitoring and surveillance of vP substances in waters and soils in order to track their presence in the environment, including any build-ups, efforts towards this end are impeded by the lack of analytical test methods and technical standards from producers.

Other relevant EU acts that merit mention include the 1998 Drinking Water Directive[368], the Cosmetics Regulation[369] and the regulations on food contact materials[370] and food safety[371]. While the **Drinking Water Directive** sets 26 chemical parameters in its Annex I, these have not been revised since 1998. A recent evaluation of the Directive[372] concluded that these quality standards no longer fully reflect scientific progress, improved risk assessments, changes in behaviors, and environmental pressures. Emerging substances mentioned by the study as in need of drinking water parameters were chromium VI, perfluorinated substances, and nanoparticles. EU legislation on food safety is also in need of revision to include health-based limit values for e.g. PFAS and brominated flame retardants.

More detailed descriptions of each act are provided in Annex 1 on the regulatory framework relevant for very persistent substances.

2.8 IMPACT ON NATURAL RESOURCES AND THE TECHNOSPHERE.

This section considers the impact that very persistent substances have had on Europe's natural resource base. In the absence of comprehensive information, it relies on the many examples in the literature of contamination of natural resources by persistent chemicals in Europe and elsewhere. They cover environmental media such as groundwater, surface water, soil, sediment and air. Major sources are industrial production of POPs or their precursors, industrial spillages, inadequate waste treatment, agricultural inputs and firefighting foams. However, releases from uses and disposal of consumer products containing vPs, such as pharmaceuticals, cosmetics and textiles treated for water and stain resistance are increasingly problematic also.

In numerous cases resources have been taken out of use because they contain levels of vPs which exceed regulatory limits, such as those set by the Groundwater Directive, or national health authority guidelines. The effects on resources can extend to decades after their production or release due to their inherent properties[373]. Levels of vPs below regulatory limits are also well documented throughout Europe and elsewhere. The resulting chronic exposure could in some cases pose a greater risk to ecosystems than acute incidents[374].

The contamination of resources with persistent chemicals is of concern for several reasons, including: 1) the inability to use—often scarce—resources for long periods of time, 2) the endurance of vPs in ecosystems even once acute contamination incidents have become dispersed through transfer to other environmental media and long-range transport, and the threats of chronic toxicity therein[375], 3) the extremely high costs of remediation of contamination, which often contains rather than destroys or irreversibly transforms the contaminants—as required under the Stockholm Convention[376], and 4) the implications for human and ecosystem health of contaminated resources being used in recycling processes, especially in light of the EU's Circular Economy Package (contamination of the 'technosphere').

[368] Directive 98/83/EC on the quality of water intended for human consumption.
[369] Regulation (EC) No 1223/2009 on cosmetic products.
[370] Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food.
[371] Regulation (EC) No 178/2002 on the general principles and requirements of food law.
[372] http://www.safe2drink.eu/news/final-evaluation-report-available/ (accessed 27.09.2016).
[373] Wilhelm, M. *et al*., 2010.
[374] Giger, W., 2009.
[375] *Ibid.*; Pico, Y. *et al*, 2012.
[376] Weber, R. & Varbelow, H.G., 2013.

Several overviews exist of contamination of specific media or by specific vPs, including PCDD/Fs[377], HCHs[378] and PFASs[379]. However, few synthesis studies could be found on the state of contamination of various natural resources in Europe by vPs. To address this, this review presents a range of salient cases of contamination of groundwater, surface water, soil and sediment by persistent chemicals, mainly in Europe, including where resources have become unusable as a result[380]. Finally, it presents a preliminary analysis of the implications of recycling of persistent chemicals through circular economy activities.

2.8.1 Groundwater and surface water

The contamination of groundwaters and surface waters by persistent chemicals has occurred in multiple locations across Europe and elsewhere[381] [382]. Because of hydrological cycles and flooding, contaminated surface waters can filter into groundwater, and become sources of contamination of aquatic food webs[383] and land-based food webs[384]. Both groundwater and surface water are sources for drinking water, so contamination by persistent chemicals is a major concern.

In particular, the persistence of highly fluorinated chemicals (HFCs) and also of water-soluble organo-chlorines in groundwater has been documented[385].Where concentrations of particular substances have been above regulatory limits, e.g. drinking water or groundwater standards, authorities in several cases have prohibited the consumption of water from contaminated groundwater sources, whilst in others measures such as mixing the water with non-contaminated sources has brought levels of particular substances within regulatory limits[386].

Highly chlorinated substances have been involved in several cases of contamination of surface waters in Europe. In Switzerland, fishing from rivers in three Cantons was prohibited due to excessive levels of PCBs (including PCDDs and PCDFs) leaching from local landfill waste[387]. Industrial waste incineration led to contamination by the same groups of chemicals in Bolsover, UK[388]. In France, some 550 sites were estimated in 2013 to be polluted by PCBs, prompting various fishing bans between 2007 and 2012[389].

Other cases of contamination by PCFF/Fs and PCDE have been documented in rivers in Finland and the Baltic Sea, even though the industrial sources stopped operating in 1984[390]. In Aragón, Spain, HCH wastes from lindane manufacturing in the 1970s and 1980s deposited at landfills has led to levels of HCH in the Gallégo river that exceed the limit set by the Water Framework Directive[391], leading to several bans on drinking water[392]. Surface water was also impacted by organochlorine contamination at the former HCH/DDT production site at Bitterfeld Wolfen in Germany, which operated between the 1950s and 1980s, where total costs of remediation are estimated at EUR700-2000 million[393].

[377] Weber, R. *et al*., 2008.
[378] Vijgen, J., 2006.
[379] Rumsby, P.C. *et al*., 2009; Cousins, I.T. *et al*., 2016.
[380] Therefore, whilst this overview is mainly structured according to different media, some overlap occurs due to the fact that many cases involve contamination of several media at the same time because of the exchange of different vPs between air, soil and water.
[381] See Table Appendix 3.
[382] And is now the subject of monitoring programmes and investigation in Germany.
[383] Choi, S. & Wania, F., 2011; Castro-Jiménez, J. *et al*. (eds.), 2007.
[384] See for example Holoubek, I. & Klánová, J., 2008; Holoubek, I. *et al*., 2003.
[385] Fawell, J. & Ong, C.N., 2012; Rumsby, P.C. *et al*., 2009; Götz, R. *et al*., 2013.
[386] See for example: Rumsby, P.C. *et al*., 2009; Wilhelm, M. *et al*., 2010.
[387] Häner, A., & Urmann, K., 2012.
[388] Weber, R. *et al*., 2008.
[389] Soullier, L., 2013 ; Robin des Bois, 2013a.
[390] Weber, R. *et al*., 2008.
[391] Fernández, J. *et al*., 2013.
[392] Heraldo, 2014.
[393] Wycisk, P. *et al*., 2012.

A common source of vP contamination of groundwater has been the production and disposal in landfills of pesticides, in particular of HCH (lindane), and other persistent chemicals, including in: Hamburg, Germany[394]; Bitterfeld-Wolfen, Germany[395]; Aragón, Spain[396]; at Spolana Neratovice, Czech Republic[397]; Schweizerhalle, Switzerland[398]; in 18 other locations in Switzerland[399]; and at various sites in the Netherlands[400]. Organochlorines are more water-soluble and therefore pose a particular challenge for groundwater management[401]. For example, in Hamburg, Germany, the groundwater below a landfill where HCH/PCDD/PCDF waste was deposited in the 1980s, appears to be permanently polluted, necessitating expensive 'pump and treat' activities well into the future[402]. These examples highlight that these substances remain in environmental media and transfer between them long after the source is stopped.

Highly fluorinated chemicals (HFCs) have become an increasingly widespread groundwater and surface water contaminant. In groundwater, they can persist for a very long time after the source is stopped[403]. A particularly well-documented case of surface water contamination by HFCs, especially PFOA, occurred in 2006 in the Ruhr and Moehne rivers in Germany following the application of contaminated fertiliser on adjacent fields[404]. This affected drinking water supplies of around 40,000 residents, prompting bottled water to be distributed to families with babies and pregnant women. A follow-up investigation in North-Rhine Westphalia identified several cases of contamination in river and ground waters used for drinking water[405].

A major source of HFC contamination has been the use or spillage of PFASs-containing aqueous film firefighting foam (AFFF)[406]. In Schiphol Airport in the Netherlands in 2008, an accidental release of AFFF led to contamination—mainly by PFOS—of local water, sediment and fish[407]. AFFFs have contaminated ground and surface water around Buncefield Oil Depot, UK[408]; East Anglia in the UK[409]; in several private wells in Cologne in Germany[410]; at a number of civilian and military airports in Sweden[411]; and at Jersey Airport in the UK[412]. This has implications for drinking water supplies drawn from groundwater.

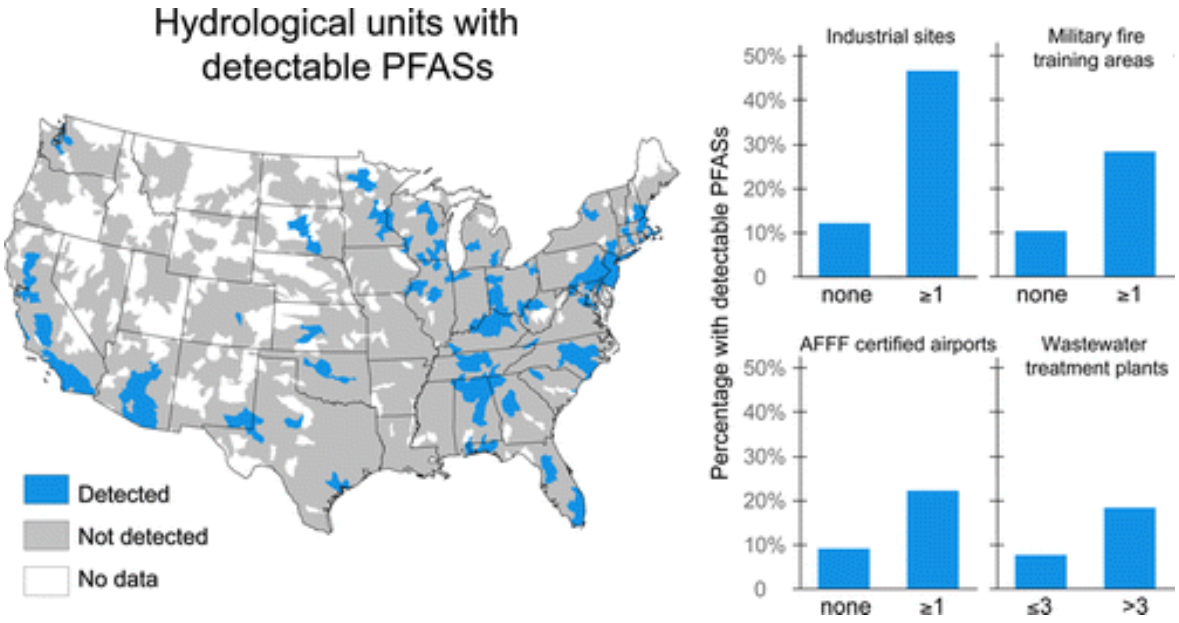
For example, in Cologne the City's Public Health Department prohibited the consumption of well water in 2009[413] and in Cologne and Jersey affected residents were supplied with bottled water or connected to the mains supply[414]. The persistence of these substances in groundwater was demonstrated in Jersey, where PFOS was still being detected two decades on at above $10 \mu g 1^{-1}$ in some areas[415], and in East Anglia, UK, where the level of PFOS in raw water was around the same level

[394] Weber, R. & Varbelow, H.G., 2012 ; Weber, R. *et al*., 2013 ; Götz, R. *et al*., 2013.
[395] Wycisk, P., P. *et al*., 2012.
[396] Fernández, J. *et al*., 2012; Morgan, S., 2016.
[397] Holoubek, I. *et al*., 2003a.
[398] Giger, W., 2009.
[399] Weber, R. *et al*., 2008.
[400] Vijgen, J., 2006.
[401] Götz, R. *et al*., 2013.
[402] *Ibid.*
[403] Fawell, J. & Ong, C.N., 2012.
[404] Skutlarek, D. *et al*., 2006; Schaefer, A., 2006; Hölzer, J. *et al*., 2008.
[405] Wilhelm, M. *et al*., 2010.
[406] Cousins, I.T. *et al*., 2016.
[407] Kwadijk, C. *et al*., 2014.
[408] Rumsby, P.C. *et al*., 2009.
[409] *Ibid.*
[410] Weiß, O. *et al*., 2012.
[411] Norström, K. *et al.*, 2015 ; Naturvårdsverket, 2016; KEMI, 2016; Cousins, I.T. *et al*., 2016.
[412] Rumsby, P.C. *et al*., 2009.
[413] Weiß, O. *et al*., 2012.
[414] *Ibid.*; Rumsby, P.C. *et al*., 2009.
[415] Rumsby, P.C. *et al*., 2009.

approximately three years after the incident[416]. The drinking water works in Kallinge, Sweden were shut down following groundwater contamination by HFCs linked to the use of firefighting foam.

Recently, the issue of HFC contamination of surface waters (and groundwater) used as sources of drinking water has become a particular concern in the US. The US EPA monitored PFAS concentrations in 2013-2015 as part of its third Unregulated Contaminant Monitoring Rule program. A review of that data found that drinking water supplies for 6 million U.S. residents exceed the US EPA's May 2016 lifetime health advisory limits (70 ng/L) for PFOS and PFOA[417]. Significant predictors of PFAS detection frequencies and concentrations in public water supplies included the number of industrial sites that manufacture or use these compounds, the number of military fire training areas, and the number of wastewater treatment plants. The number of civilian airports with personnel trained in the use of aqueous film-forming foams was also significantly associated with the detection of PFASs above the minimal reporting level.

Figure 4: Areas in the USA where PFAS has been detected in surface or groundwater



No comparable EU-wide monitoring of water resources has been carried out, and the number of drinking water supplies contaminated by PFAS in Europe is not known. However, the range of sources of PFAS indicates that contamination may be widespread. A Dutch study identified waste water treatment plants as a main direct source of PFAS in surface waters and corresponding drinking water, along with landfill leachate and water draining from a nearby military base. In addition, it found that infiltrated rainwater was a significant indirect source, suggesting a widespread diffuse contamination from atmospheric deposition.[418]

The presence of persistent substances in surface water and groundwater serves as a reservoir of contamination for aquatic ecosystems, drinking water and human food webs. On this basis, the Association of Waterworks from Central Europe (IAWR) argued that more weight should be placed on persistence and exposure as opposed to toxicity when assessing limits for drinking water[419].

[416] *Ibid.*
[417] Hu, X.C. *et al.*, 2016.
[418] Eschauzier, C., *et al.*, 2013.
[419] Giger, W., 2009.

2.8.2 Soil

The contamination of soils in Europe by vPs covers a variety of sources and substances. The Commission Staff Working Document accompanying the 2006 Thematic Strategy for Soil Protection estimated that because of the use and presence of dangerous substances in many production processes, some 3.5 million sites may be potentially contaminated across Europe, with 0.5 million sites being really contaminated and needing remediation[420]. In addition to local sources, contamination has also been documented in soils away from point sources, e.g. at high altitudes due to long-range transportation[421].

In Central and Eastern Europe, contamination has often been related to former pesticide production. Various industrial soils in the Czech Republic are heavily contaminated, most notably the Spolana Neratovice factory, involving HCH compounds, DDT and DDE from production which ceased in 1975, at levels which made it one of the most highly dioxin-contaminated sites in the world in the early 2000s[422]. In Romania around 200 contaminated soil sites exist (with a potential 2000 more), mainly due to pesticide manufacturing, with an estimated EUR8.5 billion clean-up cost[423]. Former pesticide production has also caused soil contamination in Galicia, Spain[424]; Hamburg, Germany[425]; Aragón, Spain[426]; Bitterfeld Wolfen, Germany[427]; Dielsdorf, Switzerland, which has since been remediated[428]; and at various sites in the Netherlands[429].

Table 11: Costs of cleaning up some very persistent chemicals

Costs of cleaning up very persistent chemicals
Estimates for addressing organochlorine contamination of natural resources: ■ Remediation of former HCH/DDT production site at Bitterfeld Wolfen (DE): total est. costs 700-2000 million EUR[430]. ■ Clean-up of 200 Romanian sites contaminated by pesticide manufacturing: 8.5 billion EUR Estimates for addressing PFAS contamination of drinking water: ■ Charcoal filtering of water in Uppsala (SE): annual cost 10 million SEK (1 million EUR) ■ New water supply in Ronneby (SE) (population 12,000): 30 million SEK (3 million EUR) ■ Larger new water supplies for Växjö (pop. 63,500) and Alvesta (pop. 15,900): 455 million SEK (45,5 million EUR)[431] ■ Collection and carbon filtration of the drainage water at one site on Möhne River (DE), with regular exchange of filters: 2 million EUR (initial)[432] ■ Pumping out & treating polluted groundwater at Buncefield (UK) to remove fuel and PFOS: 1 million GBP a year[433] Options for remediation of fire training ground at Jersey Airport in the Channel Islands[434]: ■ Removal of the entire Fire Training Ground to a depth of 30 meters and construction of a replacement Fire Training Ground -- total estimated cost of 30 million GBP. ■ Removal of contaminated stone to depth of 10 meters – total estimated cost of 22 million GBP (at 1999 prices) ■ Removing 2 meters of contaminated soil and placing it on impermeable base, insertion of deep concrete wall to prevent groundwater running through site; and placing concrete cap on an impermeable base and containment of all firewater runoff contaminated with foam – estimated cost between 3.7 and 4.9 million

[420] {COM(2006)231 final} {SEC(2006)620} /* SEC/2006/1165 */
[421] Holoubek, I. *et al*., 2013b; Kukučka *et al*., 2009
[422] Ruzicková, P. *et al*, 2008; Holoubek, I. *et al*. 2003a
[423] Mogos, A., n.d.
[424] Concha-Graña, E. *et al*., 2006
[425] Weber, R. & Varbelow, H.G., 2012 ; Weber, R. *et al*., 2013 ; Götz, R. *et al*., 2013
[426] Fernández, J. *et al*., 2013; Morgan, S., 2016
[427] Wycisk, P. *et al*., 2012
[428] Häner, A., & Urmann, K., 2012
[429] Vijgen, J., 2006
[430] Wycisk, P. *et al*., 2012
[431] KEMI, 2016
[432] Wang, Z. *et al*., 2017.
[433] Ibid.
[434] Klein, R., 2013.

Costs of cleaning up very persistent chemicals
GBP (at 2000 prices); ■ Doing nothing (considered environmentally and politically unacceptable) Disposal of foam contaminated firewater runoff or legacy stock is also costly, since these compounds are difficult to destroy. Incineration must be carried out at >1,100°C in special furnaces with scrubbing of the flue gases using calcium carbonate or quicklime to remove the hydrogen fluoride produced.

The contamination of soils in Aragón, Spain related to disposal of HCH waste from lindane manufacturing at two unsecured landfills, recently received attention due to the region's plan to apply for Horizon 2020 funding to clean up the pollution[435]. The transfer of the waste to secured sites is estimated to cost EUR19 million over three years, along with other annual costs for each site estimated at hundreds of thousands of euros.

Other vPs are also implicated in soil contamination in Europe. In England, PAHs are the most common organic substances that lead to land being categorised as contaminated, with other vPs such as PCBs/dioxins/furans playing a smaller role [436]. In Wales, Benzo(a)pyrene (a PAH) is the single most common compound leading to land being legally designated as contaminated, accounting for 76% of sites[437]. Soil contamination has also occurred from the application of agricultural products which contained recycled materials contaminated with vPs. These are discussed in the below section on the impact on the technosphere. Other cases of soil contamination in Europe are summarised in appendix III.

2.8.3 Sediment

In Europe releases of vPs into the environment have also transferred into river, lowland and marine sediment. The release of AFFF at Schiphol Airport in the Netherlands, led to 0.5-14 ng/g dw PFOS being measured in sediment, which remained at similarly high levels compared to the reference location ten weeks following the incident, as well as three years afterwards[438]. Low levels of PFCs—under regulatory limits—were found in water and sediment in the Albufera Natural Park in Valencia, Spain. However, because they are bioaccumulative and persistent they carry the risk of longer term toxicity, especially as they travel up the aquatic food chain[439]. In France, high concentrations of POPs in sediment in the Seine river floodplain were the subject of a national Plan of Action on PCBs[440].

Two surveys of PCBs, DDTs and HCBs in Mediterranean marine sediments found several 'hotspots' of contamination, especially around industrial and urban areas and around the mouths of the main Mediterranean rivers[441]. Further, despite a significant decline in emissions in recent decades, the same study found significant amounts of DDT in sediment, highlighting the persistence of these compounds and their transfer across different environmental media.

The contamination of sediment has also been associated with the re-mobilisation of chemicals when flooding occurs. Two notable cases of this were in the Czech Republic in 2002[442] and in Bitterfeld Wolfen in 2002, around which site there is a 60km2 wide lowland containing around 20,000 tons of sediment heavily polluted with POPs, and where the re-mobilisation of sediment presents a major problem[443].

[435] Morgan, S., 2016
[436] UK Environment Agency, 2016
[437] Cyfoeth Naturiol Cymru, 2016
[438] Kwadijk, C. *et al*., 2014
[439] Pico, Y. *et al*., 2012
[440] Lorgeoux, C. *et al*., 2016 ; République Française, 2008
[441] Gómez-Gutiérrez, A. *et al*., 2007a, b
[442] Holoubek, I. *et al*., 2003
[443] Wycisk, P. *et al*., 2012

2.8.4 Technosphere

The EU's action plan on a circular economy to maximise the use of, and minimize the waste of, material resources in the economy includes "the development of strategic approaches on plastics and chemicals"[444]. A particular challenge will be the presence of POPs in recycled products. These substances by their nature can persist and therefore accumulate in recycling streams for long periods, including through now-restricted products made before regulations were applied[445].

Cases of persistent chemicals being recycled through agricultural inputs had already been documented in Europe and globally. The contamination in Arnsberg Germany in 2006 described above occurred because a fertilizer containing food industry sewage sludges was applied, which was likely contaminated with mislabeled waste[446]. In Decatur, Alabama, in the US, the application of biosolids from wastewater treatment which had received waste from local fluorochemical manufacturing, caused soil, surface water and well water contamination with HFCs[447]. This highlights the risk of persistent chemicals being transmitted from waste water recycling into drinking water and biosolids used in agriculture, especially of HFCs due to their persistence and potential toxicity and their presence in certain cases in large concentrations in sludge[448]. This could become an increasingly important issue in the context of increasing population pressures and circular economy goals which are likely to prompt greater recycling of waters[449].

Contamination of human food chains has also occurred through recycling of other inputs. A survey of cases of contamination by PCDD/Fs highlighted various cases: 1) in 1998, citrus pulp made from lime deposits from the choline/organochlorine industry caused contamination of meat and dairy products with high levels of PCDD/Fs, 2) the 'Belgian dioxin scandal' in 1999, where chickens, eggs and other animal products were contaminated due to animal feed containing fats mixed with PCB oil, and 3) in 2002, the contamination of animal feed mixture in Europe with high levels of PCDD/Fs from PCP via saw mill dust that had been added to the feed[450].

Non-food related contamination has also resulted from recycling processes. Recycled paper products including napkins and toilet paper have been shown to contain concentrations of Bisphenol A in the µ/g range[451]. A recent series of studies in Denmark on chemical contaminants in recycled paper and plastics found 157 hazardous chemicals in paper, of which over 50% were persistent and included PCBs. The study results indicated that phasing out of chemicals is the most effective measure for reducing chemical contamination in material flows. However, assuming a recycling rate of 70% of paper in Europe, the time lag between stopping a chemical contaminant such as BPA (commonly found in thermal cash register receipts) before the presence of the chemical in paper products could be considered insignificant was between 10 to 30 years[452]. In the case of PFAS contamination in recycled paper (e.g. from food containers like pizza boxes), since PFAS do not degrade, it will take a very long time indeed to get rid of the organofluorine contamination, even if the deliberate addition of PFAS to paper stopped.

In other cases, sites have been contaminated with PCDD/Fs by waste incineration, secondary metal industries, and the recycling or depositing of certain wastes like electronic or car shredder wastes[453]. This highlights the importance of addressing the linkages between chemicals legislation and circular economy activities in a range of product recycling activities to prevent acute and chronic exposure to

[444] European Commission COM(2015) 614 final
[445] *Ibid.*
[446] Schaefer, A., 2006
[447] Lindstrom, A.B. *et al*., 2011
[448] Clarke, B.O.& Smith, S.R., 2011
[449] Loos, R. *et al*., 2007
[450] Weber, R. *et al*., 2008 ; Weber, R. *et al*., 2013
[451] Liao, C. & Kannan, K., 2011
[452] Pivnenko, K., *et al.*, 2016
[453] Weber, R. *et al*., 2008

POPs.

3 GAPS AND DEFICITS

On the basis of the literature review and the issues highlighted during the NTE workshop, a number of gaps and deficits in EU policies related to very persistent chemicals have been identified. The section below summarising these gaps and deficits is structured from a life cycle point of view. It first considers gaps in identifying those substances which may be very persistent, in view of their potential impacts on health and the environment. It then looks at gaps in the current system of controls over how these substances reach the natural environment (ecosphere) as well as the technosphere, i.e., through manufacturing processes to uses in products and to recycling and end-of-life disposal. It also considers deficits in policies related to how to address very persistent chemicals once they reach the environment and persist, leading to accumulations, exposures and possible irreversibility.

The catalogue of available tools to respond to gaps and deficits identified in this study is a comprehensive inventory of all possible measures identified during the work of this study. The potential impacts of these tools have not been assessed as part of this study. This needs to be done in a further step, taking into account the tools identified in the better regulation agenda.

3.1 GAPS IN IDENTIFYING AND REGULATING VP SUBSTANCES

1. REACH and other EU legal acts regulate persistent chemicals only if other hazardous properties such as bioaccumulability are also present (except for the 2004 Detergents Regulation). While in theory 'very persistent' might be considered as giving rise to an equivalent level of concern under REACH Article 57(f), such an analysis would need to be carried out on a case-by-case basis, and regulation of similar vP substances on the basis of a grouping might not be possible.
2. Testing chemicals to determine their half-lives in the various environmental compartments (water, soil, etc.) is time consuming and costly, and only some 200 chemicals have been fully tested for persistence to date, which is a large information gap.
3. In part because of this gap in analytical methods and data on persistence in chemicals, no common framework for comprehensive screening of substances for persistence has been agreed on EU level.
4. The criteria and methodologies (both testing and screening methods) for identifying substances considered extremely persistent – such as for the highly fluorinated substances – are particularly inadequate. Given that the criteria for vP is for degradation half-lives of >180 days in certain environmental media, other criteria are needed for substances where no evidence of degradation potential could be identified, or when degradation half-lives could be decades to centuries.
5. The role of vP substances in combination effects and cumulative exposure from chemicals is not given adequate consideration.
6. The persistence of a substance's transformation (including degradation) products are not sufficiently taken into account when that substance's health and environmental impacts are considered.
7. REACH does not require data on persistence for low volume substances, i.e., substances produced or imported <10 tonnes per annum, and therefore a large information gap continues. For example, the Swedish Chemicals Agency estimates that some 3000 PFAS are on the global market today, yet only a few of these have been registered under REACH[454] – hence another information gap.
8. Some unintentionally produced vP chemicals, e.g., polybrominated dioxins/furans (PBDD/F) or brominated-chlorinated dioxins/furans (PXDD/F), are not explicitly recognised under the EU regulatory framework, and therefore very little monitoring of human and environmental exposure

[454] Note that only substances produced or imported in quantities over 100 tonnes per annum have been registered to date. The deadline for registration of substances over 1 tonne per annum is 1 June 2018 at which time the number of registered PFAS will increase.

to these vPs is carried out.

9. International controls of vP substances have not kept pace with globalisation of chemicals industry and downstream product manufacturing.

3.2 GAPS IN REGIMES TO PROTECT THE ECOSPHERE FROM RELEASES OF VPS

A number of gaps have also been identified in the existing controls concerning how very persistent substances may be emitted to the natural environment due to anthropogenic activities, such as releases during manufacturing processes, while being used in products including articles, and due to end-of life disposal.

10. Data is lacking on the quantities of vP chemicals produced and/or emitted to the environment, which makes it very difficult to determine the overall load of vPs released to date.
11. The Industrial Emissions Directive (IED) applies only to major industrial activities, so some vP polluting emissions from smaller industrial activities often lack controls entirely.
12. The IED's list of polluting substances that must be covered by emission limit values in integrated permits cross-refers to the definition of hazardous substances and mixtures under the CLP, which does not include harmonized criteria for persistence, bioaccumulability, or the combinations of PBT or vPvB, so vP substances which do not fall under one of the groups of substances listed in the IED's Annex II will not be covered.
13. The BAT guidance documents developed to define 'best available techniques' for the industrial activities covered under the IED do not sufficiently address the measures needed to control emissions of vP substances.
14. Use of emission limit values is not appropriate in the case of vP substances, where overall limits may be needed to prevent undue loading of the natural environment.
15. Current controls are inadequate to prevent diffuse sources of vP substances from being released into the natural environment, e.g. due to uses of vP chemicals in certain kinds of products, such as in cosmetics or in textiles which will definitely result in releases to the environment due to bathing or laundering, or via discharges from waste water treatment plants or application of sewage sludge to soil. Controls are particularly insufficient concerning uses of vP substances in imported articles.
16. Lack of attention to substances that are both persistent and mobile. Chemical substances with this important and highly problematic combination of properties are not identified and not made subject to risk management measures. This puts surface and groundwater resources at particular risk.

3.3 DEFICITS IN CONTROLLING VP SUBSTANCES IN THE TECHNOSPHERE

17. Information is lacking concerning which vP substances might be used in products, including articles – whether they are produced within the EU or imported.
18. Controls over the use of vP substances in products/articles, including imports, are inadequate and only on a case-by -case basis, e.g., via REACH authorisation or restrictions or in certain product-related legislation such as RoHS.
19. Few mechanisms are in place to control vP substances that may be present in chemical formulations or in consumer articles and which then become recycled material waste streams at the end of product life. A related problem can occur as a result of unintended cross-contamination, e.g. from unintentional POPs in materials that are then recycled.
20. No tracking or monitoring is in place to determine which vPs are present in products, waste and recycled materials. Indeed, vP substances are allowed to be used in various product legislation, such as in food contact materials and as adjuvants in pesticides, cosmetics and pharmaceuticals.
21. Assessments of substances for use in certain products, e.g. cosmetics and food contact materials, focus primarily on limiting exposure to humans during the use/contact/intake of the product and

do not consider emissions occurring during the production or disposal of the product.

22. Few controls are in place over vP chemicals in end-of-product-life materials entering the material re-use/recycling streams and which could form reservoirs for future exposure.

3.4 DEFICITS IN PROTECTING HUMAN HEALTH AND IN ADDRESSING VP BUILD-UPS IN THE ECOSPHERE

23. Systematic monitoring is lacking for the presence and/or build-up of vP chemicals in the environment, including in specific environmental media and biota, e.g. humans.
24. The current EU regulatory regime provides no possibility for intervention/clean-up of reservoirs of contamination by P substances.
25. The Groundwater and Drinking Water Directives do not set criteria for maximum allowable levels of vP substances, so accumulations of vP pollutants in water resources are not given sufficient attention. Similarly, the EU food safety legislation also lacks monitoring requirements and limit values for a number of vP substances.

3.5 REASONS FOR GAPS AND DEFICITS

One of the major challenges relating to persistent and very persistent chemicals is that testing including screening for a substance's half-lives in the various environmental compartments such as water and soil is time consuming and costly. A number of studies have suggested ways in which chemicals can be screened based on chemical structures and characteristics to estimate their persistence. However, because the data available on various chemical structures and their biodegradability/persistence is limited, current methodologies for screening chemicals for possible persistence based on this limited information are problematic.

A related challenge concerns the difficulties involved in environmental monitoring, e.g., to detect actual presence/accumulation of chemical substances in the environment or biota. Because producers/importers of chemical substances are not required to provide samples (standards) of their products or analytical methods for their detection, scientists must often play a guessing game to determine which substances are present.

The EU regulatory framework does not allow controls over substances on basis of persistence alone. Legislation to protect the environment from polluting discharges covers substances only if they can be shown to be B and T also. Finally, product regulations often do not evaluate the risk of a product's entire life cycle – just the risk associated with the exposure to the chemical during the use phase. Failure to take account of the substance's fate at end of product life risks build-ups of vP substances in waste materials recycled as part of the circular economy.

In addition, the traditional approach in chemicals legislation has been substance by substance regulation, which is too time-consuming and not adequate to handle the range of chemicals known to be very persistent. The risk is that by the time action covering all of the problematic chemicals is taken, concentration levels in the environment will have reached levels where health or environmental impacts occur, and reversibility of contamination would take a very long time (depending on the nature of the chemicals involved) and be very costly to society, or may no longer be possible.

3.6 AVAILABLE TOOLS TO RESPOND TO GAPS AND DEFICITS

The gaps and deficits identified in current policy are not new. Member States and stakeholders have to a smaller or larger extent identified the gaps and have developed or are developing measures to address the gaps. The catalogue of available tools listed below comprises a listing of existing measures practiced in Member States and/or by other stakeholders as well as measures described in the reviewed

literature.

The available tools below are grouped according to the four areas of gaps and deficits identified above, i.e., identification of very persistent substances, controls over emissions to the natural environment, controls over vP chemicals in the technosphere, and addressing vP accumulations. The basic starting point for the tools identified is that they contribute to a non-toxic environment by decreasing the human and/or environmental exposure to and dispersal of vP substances. They are aimed at addressing the problems, gaps and deficits identified above, and either go beyond current legal requirements or other aspects of current policy or facilitate the implementation and compliance with legislation.

Care has been taken to consider a range of possible tools to the gaps and deficits identified above, from 'soft' policy responses such as knowledge generation and awareness raising to 'command and control' regulation.

A number of ongoing initiatives within the Commission are currently assessing the performance of chemicals legislation. These include the fitness check of all chemicals legislation except REACH and the REACH review, which are both due in 2017. The results of this study will also provide useful input to those initiatives.

The catalogue of available tools to respond to gaps and deficits identified in this study is a comprehensive inventory of all possible measures identified during the work of this study. The potential impacts of these tools have not been assessed as part of this study. This needs to be done in a further step, taking into account the tools identified in the better regulation agenda.

3.6.1 Tools for gaps in identifying and regulating vP substances

1. Consider substances determined to be vP as giving rise to equivalent levels of concern under REACH Article 57(f), so that they can be added to the REACH Candidate List of substances for possible restriction/authorisation. Note that Article 57(f) can only be applied on a case by case basis so grouping approaches would not be possible.
2. Develop a harmonized framework for comprehensive screening for persistence, for use in identifying priority chemicals and for requiring more rigorous testing of actual environmental media half-lives where indications of lack of biodegradability are found.
3. Improve accuracy of screening results by combining screening methods currently available, such as described in PROMETHEUS, and/or by developing better screening methods.
4. Support development of additional analytical tests for determining half-lives of vP substances, including when a substance is characterised by extreme persistence.
5. Factor in the additional exposure due to a vP substance's persistence in assessing its role in combination effects and cumulative exposure.
6. Set in place drinking water standards to limit presence of vP substances, similar to the current group limit value for pesticides in drinking water.
7. Ensure that the persistence of any transformation or degradation products are considered when a substance is evaluated for health and environmental effects.
8. Automatically oblige industry to perform simulation tests for substances identified through screening as potentially vP.
9. Require registrants of low volume substances (<10 tonnes) to provide data on persistence/biodegradability.
10. Require producers to deliver validated analytical test methods for persistent substances, along with technical or authentic chemical standards, to enable better detection and monitoring of their presence in the environment or technosphere.
11. Apply the grouping approaches possible under REACH more vigorously with respect to vP substances with similar chemical structures, so as to facilitate evaluation, risk assessment and risk management as well as to avoid regrettable substitution.

12. Amend the CLP regulation to include P, vP, PBT, vPvB, M (mobility) and PM as additional hazard categories. This may require work at international level on the GHS framework.
13. Include additional unintentionally produced vP chemicals such as polybrominated dioxins/furans in the EU framework for POPs, as a first step towards a more comprehensive regulatory regime for monitoring of exposure and for setting product safety standards.
14. Consider the possibility of an additional classification for extreme persistence for those chemicals that may not degrade for decades or longer.
15. Encourage more ambitious international implementation of controls over vPs through the Stockholm Convention mechanism.

3.6.2 Tools for gaps in controls for vP emissions to the ecosphere

16. Establish transparent collection of data on quantities of vP substances produced and/or emitted to the environment, in order to better determine overall loads of vPs in the environment.
17. Require all emissions of vP substances to the natural environment from industrial activities to be subject to permit, including those from smaller installations not covered by the current Industrial Emissions Directive (IED).
18. Revise all BAT guidance documents as necessary to take account of all potential releases of vP substances to the environment, and to keep such releases to a minimum.
19. Require the production and/or industrial use of vP substances to take place only in closed systems.
20. Instead of using emission limit values (concentration levels) for controlling vP substances in discharges, set fixed maximum amounts for restricting vP substances released to the environment.
21. Include consideration of the environmental impacts of a vP throughout a product's lifecycle, including any releases of vP substances into wastewater that will result in contamination of UWWT discharges and of sewage sludge applied to land
22. Consider fixed limits at EU level to amounts of vP substances that can be produced/used/released, as per the restrictions in place for ozone-depleting substances, and allocate allowances of substances subject to strict limits via economic instruments such as tradeable permits.
23. Establish [hazard-based] bans on all unessential releases of vP substances to the environment, e.g., use of PFAS-based foams in fire-fighting training.

3.6.3 Tools for deficits in controls for vPs in the technosphere

24. Encourage voluntary bans or restrictions on use of vP chemicals by product designers, manufacturers and retailers.
25. Carry out public awareness campaigns to inform consumers and institutional purchasers (public procurement) concerning vP chemicals in products, including safe disposal at end-of-product life, so that they can make informed choices.
26. Establish labelling of products where vP chemicals are present, and traceability to prevent passing on accumulations of vP chemicals via materials recycling.
27. Establish central registries of products containing vP substances, along with annual statistical data of the volumes of vP substances produced, used and emitted, as part of a comprehensive monitoring system for persistent substances. The registries should include information on the chemical structures, elemental composition, CAS no. and include the possibility for authorities to have access to physical standards in order to set up testing and analysis for the presence of vP substances in the environment as well as the technosphere.
28. Limit the use of persistent substances to certain essential uses which due to technical reasons/functionality absolutely require such persistence.
29. In collaboration with the Member States, establish product standards that balance performance of vP substances against the health and environmental risks of that substance.
30. Set limit values and develop testing methods that can be used to check for/enforce compliance with such product standards.
31. Consider cradle-to-grave producer responsibility for vP substances, from production to its

downstream use in a product or article and the subsequent use phase, through to collection and destruction at the end of the product's useful life.

32. Establish European infrastructure for the safe transport, disposal of and final destruction (e.g. high temperature incineration) of vP substances and vP-containing products, at end of their useful product life.
33. Support research to enable the development of better, less persistent alternatives to highly persistent substances used in consumer products.

3.6.4 Tools for gaps in controls over environmental build-ups of vPs

34. Set in place systematic environmental monitoring and surveillance of substances known to be very persistent, including human bio-monitoring and monitoring in e.g. waste streams and products, in order to track their presence and to be aware of any build-up in the environment, e.g., as part of any early warning system.
35. Develop better analytical methods for determining which substances are mobile (M) as well as persistent.
36. Design sampling and monitoring programs to look for contaminated resources where point sources of discharges have been identified, e.g., PFAS contamination of groundwater around all commercial and military airfields as well as landfills.
37. Facilitate environmental and human monitoring of vP substances by requiring producers to provide scientists with standard samples, including information on all transformation products formed upon release into the environment, as is required for pesticides and pharmaceuticals.
38. Develop and maintain inventories of all vP substances produced and used in products or released to the environment as emissions or waste, in order to keep track of overall loads of vPs in the environment.
39. Carry out a comprehensive survey of the overall natural resource base within the EU and its Member States, including inventories of all natural resources already contaminated by vP substances (central registries of contaminated land/water), and develop estimates of the costs of clean-up or of finding alternative resources.
40. Design and implement programs for limiting further contamination and for prioritising clean-up and explore liability and redress mechanisms for funding costs of clean-up.
41. Support development of and knowledge sharing on remediation methodologies/technology.

3.7 INITIAL EVALUATION OF AVAILABLE TOOLS

The following table presents the identified responses measures in a structured manner. The first column lists the gap or deficit addressed by the possible response, and the second column summarises the reason for the gap/deficit. The fourth column lists the possible responses (also identified by number in the third column) for addressing the gap or deficit. The next column characterises or qualifies the possible response by indicating if the response is short (1-2 years), mid (3-5 years) or long-term (over 5 years) and whether the identified response could be implemented through existing regulations or if new legislation would be required. The final column discusses the identified response from a qualitative point of view. This includes consideration of the following points.

- Does the measure spur the development of methods for identification and risk assessment of vP chemicals?
- Does the measure improve the knowledge of and access to information on vP chemicals?
- Does the measure promote the substitution and phasing out of vP chemicals, including the use of grouping approaches?
- Does the measure prevent the release of vP chemicals into the environment or the technosphere?
- Does the measure support the development of a health and environmental monitoring system of vP chemicals?

Table 12: Overview of available tools with respect to very persistent substances

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
Identified responses to gaps in identifying & regulating very persistent substances					
Insufficient regulation of very persistent substances (vPs)	REACH requires showing of bioaccumulability in addition to persistence; no recognition of P as hazard category in own right (surfactants an exception)	1	Consider substances determined to be vP as giving rise to equivalent levels of concern under REACH Article 57(f) & add them to Candidate List. Note that Article 57(f) can only be applied on a case by case basis, so grouping approaches would not be possible.	Short-term, implementation; address under REACH	Recognition of vP as equivalent level of concern could happen without amending REACH and would enable better controls of vP substances where needed. The possibility of bringing in additional factors such as mobility (M) in order to get more political support has been put forward.
		11	Apply grouping approaches more vigorously with respect to vP substances with similar chemical structures, so as to facilitate evaluation, risk assessment & risk management, & avoid regrettable substitution	Short-term, implementation; address under REACH	Grouping approaches would lead to faster screening and identification of vPs. While ECHA already facilitates this during its screening processes, there is a need to increase collaboration of assessors of related substances during the assessment stage.
		12	Include P, vP, vPvB and PM (mobile) as hazard categories under CLP Regulation	Mid-term, regulatory; address under CLP	New hazard categories would improve information availability b/c hazards would be identified and communicated
Data gap because only ≈200 chemicals fully tested for persistence to date	Testing chemicals to determine half-lives is costly & time-consuming	4	Develop additional, less costly analytical tests for determining half-lives of vPs	Mid-term, implementation; address under REACH	Better testing methods would spur the identification and risk assessment of vPs, and improve knowledge about them
	Data on persistence for substances <10 tpa not required	9	Require registrants of low volume substances to provide data on persistence/biodegradability	Mid-term, implementation; address under REACH	Filling this data gap would increase the information available concerning numbers of vPs on the market and their uses
Total number of P/vP substances on EU market today is not known	No common framework for comprehensive screening for P/vP agreed at EU level	2	Develop harmonised framework for comprehensive screening for persistence & require more rigorous testing of half-lives where lack of biodegradability is found	Mid-term, implementation; address under REACH	A harmonised framework would facilitate the screening of substances concerning their potential for persistence and improve availability of information
		3	Improve accuracy of screening results by combining screening methods currently available &/or developing better screening methods	Short-term, implementation; address under REACH	This would increase confidence in screening methodologies and facilitate more comprehensive screening of the universe of substances, e.g., in commercial use
	Information lacking on degree of persistence (length of half-lives)	8	Require simulation tests for registered substances identified through screening as potentially vP	Mid-term, implementation; address under REACH	This would enable better understanding of degree of persistence and therefore the potential for occurrences of build-ups in the natural and material environment
Criteria & methodologies for identifying extreme	Analytical difficulties in determining half-lives >180 days	4	Develop additional, less costly analytical tests for determining half-lives of vPs, including when a substance is extremely persistent	Mid-term, implementation; address under	Better testing methods would spur the identification and risk assessment of vPs, including when no evidence of degradation by natural processes is found

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
persistence are lacking				REACH	
		14	Add additional classification for extreme persistence for those substances that may not degrade for decades or longer	Mid-term, implementation; address under CLP or REACH	Better identification of vP substances needed for understanding of potential for build-ups in the natural and material environment
Information gap concerning vP substances' contribution to combination effects/ cumulative exposure	Lack of attention to role of vP substances in combination effects/cumulative exposure	5	Factor in the additional exposure due to a substance's persistence in assessing its role in combination effects and cumulative exposure	Short-term, implementation; address under REACH	This would contribute to better knowledge and understanding concerning how continuing exposure because of a substance's persistence could have health and environment impacts
vP transformation products not sufficiently taken into account in looking at environmental impacts	Lack of information on transformation products	7	Require persistence of transformation products to be considered in evaluations of a substance for health &/or environmental impacts	Short-term, implementation; address under REACH	This would contribute to better information concerning the types of health & environmental impacts due to transformation products
Insufficient monitoring of impacts of unintentionally produced chemicals found in some products	EU regulatory framework does not account for all unintentionally produced contaminants	13	Take steps towards a more comprehensive regulatory regime for POPs by including additional unintentionally produced vP chemicals, as a first step towards more inclusive monitoring of exposure & product safety standards.	Mid-term, implementation; address under REACH or POPs	This would support development of better information concerning unintentionally produced contaminants in products, including human and environmental exposure
Inadequate international controls of production & releases of vP substances	International controls of vPs have not kept pace with globalisation of chemicals industry	12	Encourage inclusion of P, vP, vPvB and PM (mobile) as internationally recognised hazard categories under GHS	Mid-term, implementation; address under CLP	Internationally recognised hazard categories for persistence would improve information availability and communication
		15	Encourage more ambitious international implementation of controls through the Stockholm Convention mechanism	Mid-term, implementation; address under POPs	This would bring more vPs under the international POPs regime and contribute to elimination of their production and environmental release
Identified responses to gaps in controls over vP emissions to the natural environment					
Little information on overall loads of vPs released to environment or technosphere to date	Data not collected on quantities of vP chemicals produced/emitted	16	Establish transparent collection of data on quantities of vP substances produced and/or emitted to the environment	Mid-term, implementation; address under REACH	This would increase the availability of information on amounts of vP substances produced, and enable to better determination of overall loads of vPs in the natural environment
		10	Require producers to deliver validated analytical test methods for vPs along with technical standards, to enable better detection and monitoring of their presence	Mid-term, implementation; address under REACH	Scientists & regulators currently have to guess at what to look for. This support from producers would greatly facilitate environmental monitoring for the presence of vPs.

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
Incomplete controls over industrial emissions of vPs	Industrial Emissions Directive (IED) only applies to major installations	17	Require all industrial emissions of vP substances to the ecosphere to be subject to permit, including from smaller industrial installations	Mid-term, implementation; address under IED or other legislation	This would increase awareness of emissions of vPs to the natural environment and enable permitting authorities to set controls where necessary to prevent build-ups in the environment
	Use of emission limit values (ELVs) inappropriate to prevent build-ups of vP loads in environment	20	Establish fixed maximum amounts rather than ELVs (concentration levels) for vPs discharged to ecosphere, in order to avoid accumulations of vPs in the environment	Mid-term, regulatory; address under IED and Water Framework Directive	This would provide legal basis for preventing accumulations of vPs in the environment due to industrial discharges
	Some BAT guidance not adequate for controlling emissions of vP substances	18	Revise BAT guidance documents as necessary for industries utilizing vPs, to minimize all potential releases of vP substances to the environment	Mid-term, implementation; address under IED	Better guidance on best available techniques focusing on those industrial activities where vPs are used, e.g., as biocides, would improve access to information on how to prevent releases to the environment
		19	Require the production and/or industrial use of vP substances to take place only in closed systems	Mid-term, regulatory; address under IED and other legislation	This would provide legal basis for preventing any further discharges of a vP of high concern into the natural environment
Incomplete coverage of vPs in lists of polluting substances covered by IED	IED lists some vPs but only PBT & vPvB as categories	17	Require industrial emissions of all vP substances to the ecosphere to be subject to permit, including from smaller industrial installations	Mid-term, regulatory; address under IED and other legislation	This measure would extend awareness to other vPs not covered by integrated permitting to date and help to prevent their release into the environment
Inadequate controls to prevent vP releases during manufacturing/uses of certain products	Lack of attention to impacts of vPs during product use and end-of-life	21	Ensure consideration of a vP's environmental impacts throughout a product's lifecycle, including possible releases into wastewater that will result in contamination of UWWT discharges and in sewage sludge applied to land	Mid-term, regulatory; address under new legislation	This will lead to better knowledge about the impact of a vP substance throughout its life-cycle, and encourage the substitution and phase-out of vPs where undesirable risks of impacts cannot be otherwise managed
	No legal basis for restricting overall amounts of vPs released to environment	22	Set fixed limits at EU level to amounts of vPs be produced/used/released, as per restrictions in place for ozone-depleting substances.	Mid-term, regulatory; address under new legislation	Fixed limits for production and use of ozone-depleting substances is recognised internationally as an effective measure for preventing releases of ODS; similar limits for certain vP substances would prevent releases where necessary
		22	Allocate allowances for production/use of vPs via economic instruments such as tradeable permits	Mid-term, regulatory; address under new legislation	Economic instruments could promote the substitution and phasing out of vP substances, and minimise releases to the environment
Lack of attention to	Mobility of vPs not	23	Establish [hazard-based] bans on all unessential	Mid-term,	Mobility is increasingly acknowledged as a

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
risk to water resources when substances are P & mobile	recognised as hazard (risk) factor for water resources		releases of vP and mobile substances to the environment, e.g., use of PFAS-based foams in fire-fighting training	implementation; address under REACH	characteristic that can give rise to equivalent concern, particularly with respect to water resources including groundwater. This measure would prevent any unessential releases of PM substances in the interests of protecting water quality
Identified responses to deficits in controls over vPs in the technosphere					
Lack of information on vP substances used in articles, incl. imported articles	No data on what substances used in what products	26	Establish labelling of products where vPs present, together with traceability mechanisms	Mid-term, regulatory; address under REACH	This would improve access to information on vPs in particular products and enable buyers/consumers to make informed choices. Traceability mechanisms would help prevent vP contamination of material recycling streams
		27	Establish central registries of products containing vPs, & collect annual data on volumes of vPs produced, used & emitted, as part of a comprehensive vPs monitoring system	Mid-term, regulatory; address under REACH	Central product registries would improve information on vPs of concern in products and help in determining overall volumes, i.e., loads in the natural environment and ecosphere
	Lack of awareness of vPs & their impact on health & environment	25	Carry out public awareness campaigns to inform consumers and institutional purchasers (public procurement) concerning vP chemicals in products	Short-term; self-regulation	More consumer knowledge and awareness about the potential costs to health and environment from vP substances would lead to more informed choices & promote substitution/phase out of vPs
Few controls over use of vPs in products/articles	No controls on basis of persistence alone	24	Encourage voluntary bans or restrictions on use of vP chemicals by product designers, manufacturers and retailers	Short-term; self-regulation	This identified response would promote the voluntary substitution and phasing out of vPs
		28	Limit uses of vPs to certain essential uses which absolutely require such persistence due to technical reasons/functionality	Mid-term; implementation; address under REACH	Bans on non-essential uses would promote innovation and substitution of less harmful alternatives
	RoHS-type control only for EEE; missing for other products	29	Establish product standards that balance performance of vP substances against the health and environmental risks of that substance	Mid-term, regulatory; address under product legislation	Product standards that balance health and environmental concerns against a substances performance could promote substitution of less harmful alternatives
		30	Set limit values and develop testing methods that can be used to check for/enforce compliance with such product standards	Mid-term, regulatory; address under product legislation	This identified response would support the implementation of product standards aimed at minimising non-essential uses of vP substances
Alternatives to certain vPs with high performance sometimes lacking		33	Support research to enable the development of better, less persistent alternatives vPs used in consumer products.	Mid-term; implementation	The development of better alternatives would promote substitution and phase-outs of vP substances of concern
Lack of mechanisms	No tracking/	26	Establish labelling of products where vPs present,	Mid-term,	Labelling of products would improve access to

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
for preventing vPs contamination of the technosphere	monitoring of vPs in products, waste & recycled materials		together with traceability mechanisms	regulatory; address under product legislation	information on vPs in particular products, while traceability mechanisms would help prevent vP contamination of material recycling streams
	No restrictions on vPs in end-of-product materials entering recycling streams	31	Consider cradle-to-grave producer responsibility for certain vP substances, from production to downstream use in a product and the subsequent use phase, through to collection & destruction at end of product life	Mid-term, regulatory; address under waste legislation	This identified response would help to prevent the release of vP substances into the technosphere
Limited possibilities for safe destruction of vP substances	No requirements for end-of-life destruction of vP substances (market failure)	32	Establish European infrastructure for the safe transport, disposal of and final destruction (e.g. high temperature incineration) of vP substances and vP-containing products, at end of their useful product life	Long-term; implementation; address under waste legislation	This response would improve the availability of methods for preventing release and build-up of vP substances in the environment
Identified responses to gaps in controls over environmental build-ups of vPs					
Inadequate protection of groundwater & other raw water resources used for drinking water	Lack of attention to substances both P and mobile, including in monitoring programs	35	Develop better analytical methods for determining which substances are mobile (M) as well as persistent	Short-term; implementation; address under REACH	Better methods for identifying substances that are both persistent and mobile would support risk assessment of vPs and help to prevent releases to the environment
		36	Design sampling and monitoring programs to look for contaminated resources where point sources of discharges have been identified,	Short-term; implementation; address under water quality & soil legislation	Sweden's research into PFAS contamination of groundwater around all commercial and military airfields has set an example here.
Lack of information concerning presence &/or build-up of vPs in environmental media	Inadequate monitoring of vPs in the environment	34	Set in place systematic environmental monitoring and surveillance of vPs, including human bio-monitoring, to track presence and any build-up in the environment, e.g., as part of an early warning system	Short-term; implementation; address under water quality & soil legislation	This response would support the development of a health and environmental monitoring system
	Lack of access to information of vPs and their transformation products	37	Facilitate environmental/human monitoring of vPs by requiring producers to provide scientists with standard samples, including information on all transformation products formed upon release into the environment, as with pesticides & pharmaceuticals	Short-term; implementation; address under REACH	This would improve scientific knowledge of vP substances in the environment, and support the development of a comprehensive monitoring system
		38	Develop inventories of all vP substances produced/used in products or released to the environment as emissions or waste	Mid-term; implementation; address under EPRTR	This identified response would support the development of a monitoring system to keep track of overall loads of vPs in the environment
Lack of knowledge concerning extent of	No overview of vP contamination of	39	Carry out a comprehensive survey of the overall natural resource base within the EU and its	Mid-term; implementation;	A better understanding of the extent of vPs contamination of Europe's natural resources and the

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
accumulations of vPs in the environment & related costs	the EU's natural resource base		Member States, including inventories of all natural resources already contaminated by vPs (central registries of contaminated land/water), along with estimates of the costs of clean-up or of finding alternative resources	address under soil or water legislation	costs of remediation would help to inform policy choices
		40	Design and implement programs for limiting further contamination and for prioritising clean-up and explore liability and redress mechanisms for funding costs of clean-up	Long-term; implementation; address under soil or water legislation	This long-term response would aim to prevent spreading of contamination and to protect important natural resources such as water reserves.
		41	Support development of and knowledge sharing on remediation methodologies/ technology.	Mid-term; implementation	This response would help to improve the knowledge base concerning methodologies for clean-up, and act to encourage clean-ups where a priority.,

4 CONCLUSIONS

This sub-study has investigated the case for regulating substances solely on the basis of their persistence in the environment. Substances that are determined to be very persistent (vP) are resistant to degradation. Because vP substances tend not to degrade through natural processes, their use and dispersal in the environment means they may remain there for an indefinite time and eventually reach levels where harmful effects to health and natural resources may occur.

Some scientists argue that persistence is in fact the most important single factor affecting chemical exposure and risk from the environment. Build-ups of a persistent chemical could lead to the same type of continuous exposure as occurs with bioaccumulation. Because of uncertainty about chemical properties, a situation could arise where accumulations have already occurred by the time evidence is gathered about a chemical's intrinsic hazard leading to harm.

As already experienced in the case of persistent ozone-depleting chemicals, the disruptive effects may not be discovered until they occur on a global scale and are affecting a vital earth system process. This uncertainty about the properties of vP chemicals in combination with potentially severe and long term health and/or environmental damages would seem to suggest the need for a precautionary (hazard-based) approach.

In particular, build-ups of persistent chemicals in the environment are not sustainable. Contamination of natural resources with persistent chemicals is not easily reversed, and often continues even after the source of the pollution is stopped. For example, the propensity of persistent hydrophilics to remain in soil and groundwater for long periods of time, even after they cease to be emitted, presents particular concerns for water resources and aquatic ecosystems. Where remediation measures have been implemented, the costs have been extremely high and in many cases have only contained rather than reversed the contamination caused.

The sub-study has identified a number of gaps in analytical methods and data concerning persistence in chemicals. It has also found gaps in the risk management measures in place to prevent releases into the natural environment and to control the use of very persistent chemicals in the technosphere, which could pose problems for the material reuse/recycling streams envisioned as part of the Circular Economy.

On the basis of the research for this sub-study, a wide range of responses to these gaps were identified. It is clear that better screening and testing methods are needed, in order to target those chemicals were persistence is of high concern. There is also a need for various responses concerning very persistent chemicals in products.

One possibility could be to make it a principle to avoid the production and use of very persistent chemicals where persistence is not required and where release into the environment is likely to take place, e.g. for use in cosmetics or consumer textiles. If persistence is needed for a specific use, manufacturers and down-stream users could be required to justify this. There may also be a need for some type of very strict authorisation requirement – something that would allow only so-called essential uses where persistence was required, and where manufacture and use was carried out in closed systems. Systems for recovery and destruction of the persistent chemical would also need to be in place, for production wastes and to ensure end-of-product life disposal.

Very persistent chemicals released into the environment can render resources such as soil and water unusable or requiring expensive and resource demanding purification and remediation measures far into the future. In the context of an increasingly resource-constrained world, preserving the usefulness of these essential resources appears important. Related to this, limiting the presence of persistent

chemicals in products is an important consideration of the circular economy package, in order to avoid its goals being undermined by the accumulation of persistent chemicals in material recycling streams.
For these reasons, from the standpoint of public health, environmental protection and economic growth, it appears desirable to take a more precautionary and pro-active approach and to prevent and/or minimize releases of vP chemicals in the future.

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Study for the strategy for a non-toxic environment of the 7th EAP

Sub-study e: Policy means, innovation and competitiveness

Written by Marco Camboni (Risk & Policy Analysts)
August 2017

This sub-study report has been prepared by Marco Camboni of Risk & Policy Analysts (RPA).

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ABSTRACT

The 7th Environment Action Programme highlights that a non-toxic environment should be conducive to innovation and the development of sustainable substitutes including non-chemical solutions. This sub-study aims to provide information on the complex set of factors and driving forces that influence the development of the European chemical industry and its downstream sectors, and how chemical policy can be used to strengthen the competitiveness of industry and aid innovation. Areas covered in this sub-study include: the current situation and economic development (innovation, productivity and competitiveness), including development trends; the main factors that influence economic development, including the impact of chemical policy; the extent to which current chemicals policy and other associated policy means are effective at ensuring a high level of protection to human health, the environment and the enhancement of the competitiveness and innovation; the possible use of, need for and the potential associated with the use of additional policy measures and means, other than regulation, including economics-based, informative and supporting/enabling measures.

EXECUTIVE SUMMARY

The chemical industry underpins many different sectors of the economy, resulting in there being a strong correlation between economic growth and growth within the chemicals industry. Chemical production is expected to grow by 3% annually, compared to a growth in global population of 0.77% per year. According to forecasts by the OECD, the American Chemistry Council and the United Nations, by 2050 chemical production will have increased of 330%, compared to a 47% in population (University of California, 2008).

At present, China accounts for the largest share in global chemicals sales (34%), followed by the EU28 (17%) and the US (16%). It has been observed that growth in the chemicals industry can be closely linked to increases in GDP. Global chemicals sales are forecast to reach €6,300 billion by 2030. It should be noted that this expansion will not be evenly distributed across geographical regions; instead, it will be primarily driven by emerging economies, such as China, India and Korea. In these emerging economies, the consumption and production of chemicals is growing faster than the global average.

Literature concurs that the following factors are the key determinants of the competitiveness of the European chemical industry:

- Energy prices (in particular oil price, given that oil is the primary energy source for the industry and raw material for many chemicals);
- GDP growth and chemical demand;
- Currency appreciation (exchange rate);
- Access to raw materials and new markets (trade agreements);
- R&D intensity, innovation rate, investment in primary production and technological capability;
- Labour costs;
- Efficiency within the industry;
- Regulation.

The chemical industry is the most energy-intensive manufacturing sector in the EU, accounting for 12% of total EU energy demand and approximately one third of all EU energy use (High Level Group on the Competitiveness of the European Chemicals Industry, 2009). Oil and gas are vital inputs for the chemical industry, not just as energy sources, but also as principle raw materials for final products. A drop-in oil prices results in different impacts along the chemicals value chain, based on the strength and elasticity of the links between product costs and prices. In general, a 50% oil-price drop results in a 10-20% reduction in the raw material spend at the end of the chemicals value chain. This raw materials price change is experienced with a 2 to 6 months delay at the end of the value chain. The product-price decrease, in case of full pass-through, is 15-30% at the start of the chemicals value chain and just 3-6% at the end, with the product-price decrease released in 1 to 3 months at the start of the chemicals value chain and from 3 months to over one year at the end of the value chain. Raw material and energy costs put the EU at a disadvantage compared with the USA and the Middle East. While it is high labour costs, capital costs and other fixed costs that have the biggest impact on competitiveness in relation to China.

The importance of the European common market is demonstrated by the fact that nearly 50% of all EU chemical sales in 2014 were intra-EU 'exports' (Cefic, 2016, p.10). The removal of trade and non-trade barriers within the EU and the enlargements of the European Union in 2004 and 2007 underpinned the increase in intra-EU trade during the period 2004-2014. Economic growth is key to the development of the chemicals industry. For the EU's chemicals industry, it will be crucial to secure extra-EU markets, where more than 90% of the global GDP growth will occur. EU chemical companies are strongly positioned in terms of exports and in order to enhance efficiency and to better exploit their technical strengths, they are strong advocates of new trade agreements (in particular with

key partners such as the US and Japan).

The chemicals industry is one of the most R&D-intensive manufacturing sectors within advanced economies. As an input provider for other industries, it is considered to be at the forefront of innovation and a solution provider for many societal and environmental challenges[1]. For instance, the development of a new sustainable material by a chemicals company can lead to innovation downstream (e.g. circular business models). One of the key objectives of the European Commission is to ensure that 20% of the EU total GDP comes from industry by 2020, in order to attempt to prevent the decline in primary production, with potential repercussions on technological capabilities and risks for high value chains. Capital investment in existing infrastructure and production facilities also has a part to play in this. International evidence suggests that the EU is falling behind globally in terms of capital investment as, while many other countries are expanding and creating new production facilities, the EU is consolidating. Absolute levels of capital investment in the EU chemicals industry rose from €15.1 billion to €21.2 billion over the period 2004-2008 but have since experienced a decline, registering €18.6 billion in 2014. Capital intensity, defined as the ratio of capital spending to sales, has declined since 1999 from 5.8% to 3.4% in 2014.

It has been witnessed that patterns of innovation and productivity growth within the chemicals industry not only have a profound effect on the industry itself, but also on the growth of the wider economy (Roland Berger, 2015). Moreover, R&D in customer industries drives purchasing decisions in the chemical industry, so that R&D co-operation within chemicals value chains will increase in the future (ATKearney, 2012).

At present, the USA spends the most on R&D. The EU has now been overtaken by China in terms of R&D spending in absolute terms and it remains fourth in terms of research intensity. One reason for the decline in European R&D intensity over the past couple of decades is that base chemicals, which require a low level of investment in R&D, have accounted for a large proportion of total EU sales (61.8% in 2013). As a result, much higher R&D investments in specialties and fine chemicals are far less visible (High Level Group on Competitiveness of the European Chemicals Industry, 2009).

The chemical industry has outpaced other industrial sectors in terms of increased efficiency. However, future opportunities to further decrease fuel consumption in the sector appear limited in the absence of any major shifts towards recycling and bio-based chemicals (U.S. EIA, 2016). Climate change has strengthened the call from civil society and the commitment of industry to improve efficiency.

Key findings on innovation – Sub-study e

The problem

- The chemical policy may constitute an administrative burden that, in a context of adverse global trends, may have negative effects on the competitiveness and innovation capacity of European companies, in particular SMEs, against extra-EU companies.
- However, stricter environmental requirements can also stimulate innovation towards sustainability, providing first move competitive advantages to the more pro-active companies.

Gaps and inconsistencies in current policy

- The use of EU funding in supporting transformative technologies with strong innovative potential and added value for manufactured products and services is inadequate.
- The funding available for innovation projects does not meet the ambition of industrial scale projects, mainly due to scattering of support over calls and topics across a large range.
- There is a lack of support or encouragement for co-operation within and/or between sectors (e.g. between large businesses and SMEs; between industry and academia).
- There is an insufficient capacity to attract foreign investment to enable innovation.

[1] European Commission (DG Growth), Chemicals, What the Commission is doing. Available at: http://ec.europa.eu/growth/sectors/chemicals/ec-support/index_en.htm

- Regulatory signals to investments in innovation are lacking.

Regulation has the potential for both negative and positive impacts on the competitiveness and innovation of the EU chemical industry: negative impacts can occur when the cumulative costs of the environmental legislation on the industry add to other adverse global trends; positive impacts can be achieved by regulation through the promotion of green innovation and by ensuring an even playing field for all the actors. Stricter environmental legislative requirements can stimulate innovation towards sustainability (WWF, 2003, CIEL 2013, OECD, 2014) and may provide first movers with competitive advantages to the EU industry, where the environment is recognised as a megatrend for the short, medium and long term. In a survey on the impacts of REACH on competitiveness, innovation and SMEs (CSES et al, 2015), approximately two thirds of respondents were of the opinion that REACH did not affect their competitiveness versus extra-EU companies. In terms of impacts on innovation, it was concluded that REACH has had a certain impact on innovation in the chemical industry, but also that it affects resources that are allocated for R&D, with a third of respondents saying that they have had to allocate some R&D staff to compliance.

A number of incentives can be used to stimulate and encourage innovation and further boost competitiveness:

Economic instruments	■ Taxes and subsidies; ■ Payments; ■ Tradable rights; ■ Public procurement; ■ Liability/ insurance.
Co-regulation	■ Covenants and negotiated agreements
Information-based instruments	■ Targeted information provision; ■ Registration, labelling and certification; ■ Naming and faming/ shaming.
Civic and self-regulation	■ Voluntary regulation; ■ Civic regulation; ■ Regulation by professions; ■ Private corporate regulation; ■ Self-regulation.
Support and building capacity	■ Research and knowledge generation; ■ Demonstration projects/ knowledge diffusion; ■ Network building and joint problem solving; ■ Crowd-funded research.

On the basis of the literature review, of the issues highlighted during the NTE workshop and of the results of the online surveys, the following gaps and deficits have been identified[2]:

1. Unsatisfactory synergies between chemical policies;
2. Lack of (eco)toxicological information for low volume production substances;
3. Lack of information on chemicals in articles;
4. Relatively high administrative burden of EU legislation (especially on SMEs), causing the diversion of resources from innovation;
5. Lack of appropriate and strategic use of EU funding in supporting transformative technologies with strong innovative potential and added value for manufactured products and services;
6. Funding available for innovation projects does not meet the ambition of industrial scale projects, mainly due to scattering of support over calls and topics across a large range;

[2] It should be noted that different stakeholder groups have diverging opinions; what is regarded as a deficit by one stakeholder group, may be considered an incentive by another stakeholder group.

7. Lack of support or encouragement for co-operation within and/or between sectors (e.g. between large businesses and SMEs; between industry and academia);
8. Insufficient capacity to attract foreign investment to enable innovation;
9. Lack of skilled European workforce;
10. Contradictory regulatory signals to investments in innovation.

ABBREVIATIONS USED

bn	Billion
CATI	Computer-assisted telephone interviewing
Cefic	European Chemical Industry Council
CFP	Chemical Footprint
COSME	EU Programme for the Competitiveness of Small and Medium-sized Enterprises
EAP	Environment Action Programme
ELVD	End-of-Life Vehicles Directive
EU	European Union
GDP	Gross Domestic Product
GHG	Greenhouse Gases
NAFTA	North America Free Trade Agreement
OECD	Organisation for Economic Co-operation and Development
PVC	Polyvinyl chloride
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals
R&D	Research and Development
SME	Small-Medium Enterprise
TBT	Tributyltin
UNEP	United Nations Environment Programme
US	United States of America
UK	United Kingdom

1 INTRODUCTION

The problem

Health and environmental aspects on one hand and economy related aspects, such as jobs, growth, innovation, productivity and competitiveness on the other hand, are often perceived as conflicting, with a trade-off between social and environmental benefits and private costs.

According to recent studies, more stringent environmental policies can be introduced without hampering competitiveness and actually stimulating innovation and long term investments on solutions benefiting the economy, health and the environment. Such policies should be:

- Associated with strong signals, making pollution costlier and less hazardous solutions more attractive;
- Flexible, to enable businesses to choose the most efficient way to innovate;
- Proportionate and accompanied by initiatives to ensure the ease of the entry into the market of new players.

A wide range of instruments is available to design strong, flexible and proportionate policies. However, most of the research on the effects of these instruments on competitiveness and innovation has been carried out in environmental policy areas such as climate, air and water pollution, energy and transport. There is therefore the need for more research on the application of these instruments in chemicals policy.

Moreover, the rate of innovation in a society is the result of a complex system of factors, which legislation needs to take into account to result effective in its objectives. Among these factors, there are: logistics and infrastructure, access to raw materials, investments, public and private research and development expenditure, energy prices, level of education of the general population and level of knowledge and training of the workforce.

In 1970s, Barry Commoner, Paul Ehrlich and John Holdren proposed the so called IPAT equation to explain how the impact of human activity on the environment (I) is the product of multiple factors, namely, the size of the human population (P), its affluence (A) (also described as resource consumption or, in other words, lifestyle) and the technology (T) used, broadly meaning the processes used to obtain and transform the resources into goods and waste.

The equation also highlights the role that innovation can play in the context of sustainability. In a world characterized by:

- An ever-growing population (P); and
- Developing countries catching up in terms of affluence (and, therefore, use of resources) with developed countries, and the latter not willing to give up their lifestyle (A);

Technology (T) is the parameter on which most of the policies tend to focus to try to limit the impact of human activity on the environment. Technological change towards more efficient uses of resources and, in general, more sustainable solutions, is a type of innovation[3]. In the context of this study, innovation is defined as any product innovation, process innovation, marketing innovation and organizational innovation that contribute in lowering resource consumption and environmental degradation, and more specifically, which contribute in decreasing the consumption of hazardous

[3] The OECD define innovation as "*…the implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organisational method inbusiness practices, workplace organisation or external relations"* (OECD, 2005, Oslo Manual, Guidelines for collecting and interpreting innovation data).

substances and in minimizing chemical pollution.

The 7th Environment Action Programme highlights that a non-toxic environment should be *conducive to innovation and the development of sustainable substitutes including non-chemical solutions.* Innovation is an important prerequisite for the enhanced substitution and phase-out of hazardous substances/substances of very high concern. That includes innovation in the field of chemicals as well as other kinds of technical solutions or methods that enable substitution or reduce exposure or risk through other means.

Spurring innovation is a general political priority of the EU and the Commission as a means by which to achieve economic growth, create jobs and maintain competitiveness of EU industries. The chemical industry is the third largest industry of the EU – in many areas a world leader, with large spending on research and development. Further, chemical policy impacts not only chemical manufacturers, but also other industry branches that use or otherwise rely on chemicals.

One of the objectives of the non-toxic environment strategy should be to outline a policy that enhances innovation for the purposes of improved protection of health and the environment as well as the economic development of EU industry. Areas of particular interest are e.g. chemicals with good health and environmental properties, the use of waste, recycled raw materials and innovative business models.

The present sub-study aims to provide information on the large and complex set of key factors and driving forces influencing the development of the chemical industry and its downstream sectors, and how chemical policy can strengthen the competitiveness of the industry and foster innovation.

More precisely, the sub-study provides information on:

- The current situation and findings regarding economic development (e.g. innovation, productivity and competitiveness) including development trends in the main industrial branches relevant in the context of chemicals policy, in the EU and worldwide (Sections 2.1 and 2.2);
- The main factors influencing economic development (e.g. innovation, productivity and competitiveness, feedstock, customer demand), including the impact of chemical policy (Section 2.3);
- The extent current legislation and other chemical policy means are effective in providing both a high level of protection for health and the environment and the enhancement of competitiveness and innovation (Sections 3 and 4);
- The possible use of, need for and potential associated with the use of additional policy measures and means, other than regulation, including economics-based (e.g. taxes, fees, permit trading schemes, public procurement), informative (e.g. collection and dissemination of information aimed at producers, professional users and consumers, eco-labelling) and supporting/enabling measures (e.g. grants and funding schemes, technology procurement) (Section 4).

In order to present an overview of the current economic situation of the chemical industry, and its downstream sectors globally and at the European level (Task 1), we consulted databases and reports produced by international organisations such as UNEP and OECD. These sources have been complemented with data from Eurostat and statistics provided by Cefic.

Additional sources have been identified following a snowball approach, checking the references in the literature reviewed. This material will be analysed and used for the provision of conclusions with regards to the main factors influencing the economic development (Task 2).

The initial search has been carried out using the following key words to identify examples:

Searches in Google Scholar:

- Batteries deposit refund effectiveness;
- Tradable rights chemicals;
- Environmental liability effectiveness;
- Public procurement chemicals effectiveness;
- Effectiveness EU Emissions Trading Scheme;
- "Responsible care";
- Vinylplus.

Searches in Google:

- Chemicals environmental tax;
- Chemicals co-regulation;
- Information campaign chemicals;
- Green chemistry research funding;
- Green chemistry research funding EU;
- "Demonstration project" green chemistry.

All the information sources have been included in the literature overview fiche shared among the partners through the BOX® tool. The initial findings have been presented in the section concerning Desk research.

Additional elements have been drawn from the review of the findings on competitiveness and innovation from projects that were running in parallel to the present study. These are:

- The "Monitoring the impacts of REACH on innovation, competitiveness and SMEs" report (CSES et al, 2015);
- The "Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation" (RPA et al, 2017);
- The "Study on the Calculation of the Benefits of Chemicals Legislation on Human Health and the Environment Development of a System of Indicators" (RPA et al, 2016);
- The "Study on the cumulative health and environmental benefits of chemical legislation" (Amec et al, ongoing[4]).

[4] January 2017. Review of the summary of provisional findings for stakeholder workshop.

2 OVERVIEW OF THE STATUS QUO REGARDING THE SUB-STUDY AREA

2.1 GLOBAL OUTLOOK

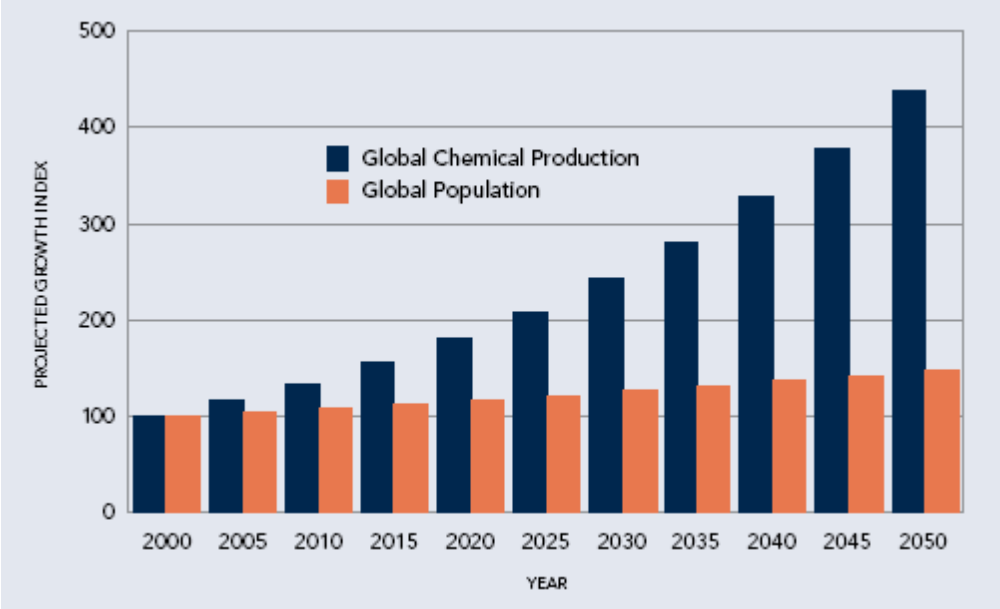
The global chemicals industry comprises a range of diverse and complex products, many of which are precursors or intermediates for other industries. According to Cefic (2016), in 2014 total global chemicals sales amounted to €3,232 billion, which represented a 2.6% increase (+€81 billion) from the previous year.

China accounted for the largest share of global chemicals sales (34%), followed by the EU28 (17%) and the US (16%) (Figure 2). Other countries with significant shares of total sales included Japan (5%), South Korea (4%) and India (2%). Nevertheless, China's share of total sales is larger than the next seven countries combined and nearly equal to the NAFTA and EU28 put together (Figure 3). China seeks to consolidate and to strengthen the leadership of its chemical industry with an ambitious plan centred on technology innovation (Cefic, 2016, p.5).

Between 2004 and 2014, world chemicals sales more than doubled (from €1,458 billion to €3,232 billion) and the total value of EU sales has continuously grown too (around 80% increase). However, world growth outpaced EU growth, with European Union chemicals sales passing from 30.9% of the world market in 2004 to 17% in 2014. World trends have been mostly dictated by the outstanding growth of China, passing from 9.3% in 2004 to 34.4% of global chemicals market sales in 2014 (Cefic, 2016, p.6).

Chemical production is expected to grow by 3% annually, compared to a growth in global population of 0.77% per year. According to forecasts by the OECD, the American Chemistry Council and the United Nations, by 2050 chemical production will have increased of 330%, compared to a 47% in population (University of California, 2008).

Figure 1: Projected growth in chemicals production in comparison to growth in global population



Source: Green Chemistry: Cornerstone to a Sustainable California (2008).

Growth in the chemicals sector is closely linked to increases in GDP and global chemicals sales are forecast to reach the level of £6,300 billion by 2030. However, this expansion will not be evenly distributed across geographical regions. Instead, it will be primarily driven by emerging economies,

such as China, India, Korea and Brazil, where consumption (Figure 4) and production of chemicals have grown faster than the global average. For instance, production in China grew at a rate of nearly 14% per year over the period 2003-2013, which was significantly faster than the advanced economies: EU (0.6%), the USA (0.2%), and Japan (-1.7%) and other emerging economies such as India (5.2%), Korea (4.0%), Russia (3.5%) and Brazil (1.8%) (Cefic, 2014).

Figure 2: Global chemicals sales: geographical background (2014) – Source: adapted from Cefic Chemdata International

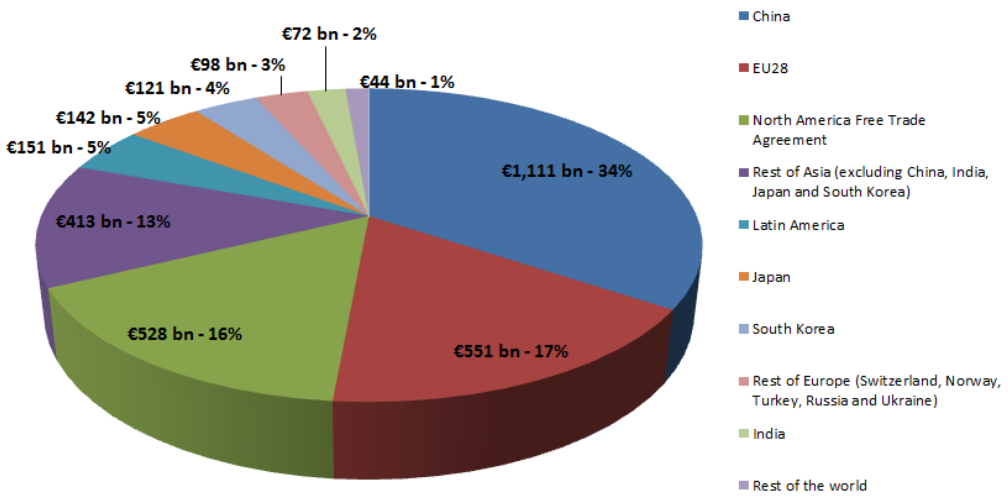


Figure 3: Top ten countries by global chemicals sales – Source: Cefic Chemdata International

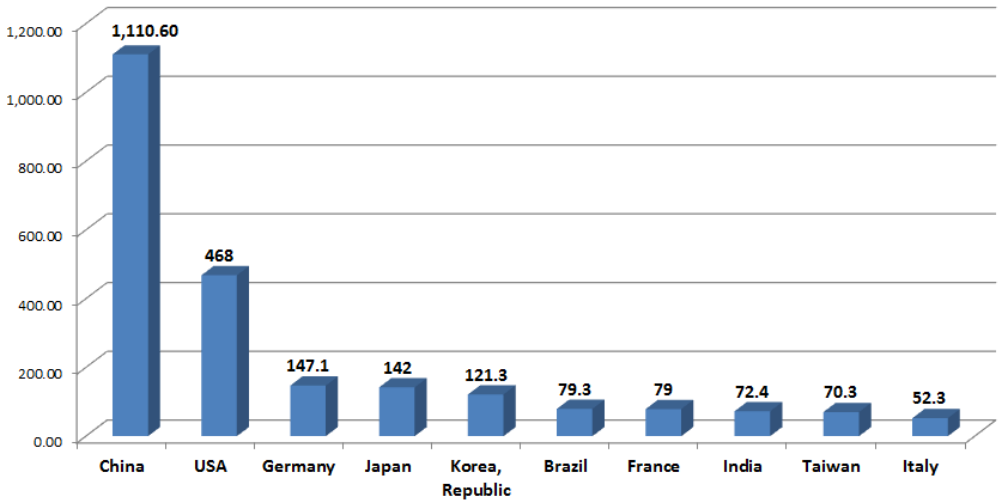
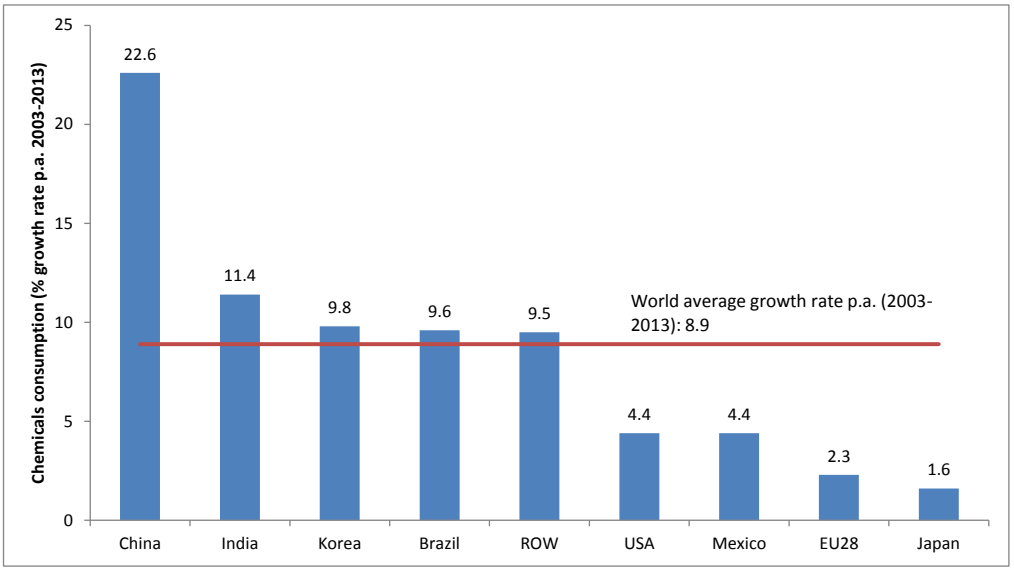


Figure 4: Chemical consumption growth rates in countries and regions, 2003-2013 – Source: Cefic Chemdata International



China will keep holding the first place in sales, with the NAFTA area overtaking the EU28, the switch being due to the availability of cheap energy (shale gas boom in the US) and the consequent attraction of billions of dollars of investment (including from European companies) in production facilities for the manufacturing of high volume building blocks in the chemical industry, such as ethylene (Cefic, 2016, p.25). Growth in China is expected to benefit European producers as well, via both increased exports and local investments.

With strong links to domestic oil producers, some companies in emerging economies are already beginning to overtake large multi-nationals headquartered in advanced economies to become global leaders themselves. For instance, Sinopec, based in China, is now larger than Exxon Mobil (USA) with revenues of $58 billion in 2014. Likewise, SABIC, a conglomerate based in Saudi Arabia, is bigger than LyondellBasell Industries, Bayer and Mitsubishi Chemical (Table 1).

Table 1: Top 10 Chemicals Companies by Revenue, 2014 - Source: C&EN, Global Top 50 Chemical Companies[5]

Company	Chemicals sales $ billion	Headquarters
BASF	78.7	Ludwigshafen, Germany
Dow Chemical	58.2	Midland, USA
Sinopec	58.0	Beijing, China
SABIC	43.3	Riyadh, Saudi Arabia
ExxonMobil	38.2	Irving, USA
Formosa Plastics	37.1	Taipei, Taiwan
LyondellBasell Industries	34.8	Houston, USA
DuPont	29.9	Wilmington, USA
Ineos	29.7	Rolle, Switzerland
Bayer	28.1	Leverkusen, Germany

According to Eurostat[6], the export of chemicals and related products by the EU28, plus the top 10 non-EU countries, reached €781.2 billion (Table 2). In 2014, the EU28 accounted for the largest share (35.7% of the total) with exports amounting to €278.8 billion. The United States followed with 20.4% of the total exports and in third place was China with 13%. Between 2014 and 2015, chemicals

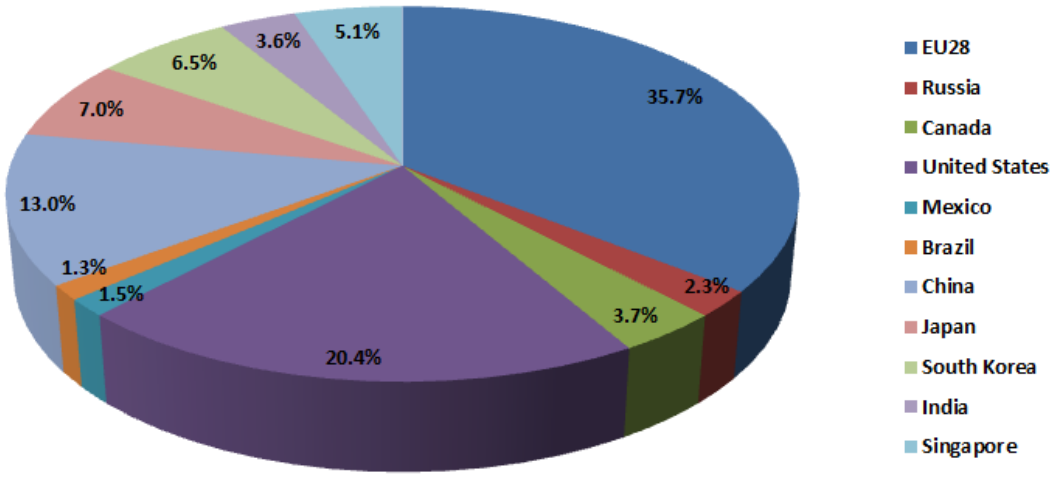
[5] Available at: http://cen.acs.org/articles/93/i30/Global-Top-50.html
[6] Eurostat database / International trade / International trade data / International trade long-term indicators / International trade / Share of EU in the World Trade / SITC06 Chemicals and related products, n.e.s. Available at: http://ec.europa.eu/eurostat/data/database

exports in the EU28 grew by 13%, increasing from €278.8 billion to €315 billion. Over eleven years (2005-2015), EU chemicals exports grew at an average of 6.9% per year, while the top ten non-EU countries grew at a yearly average of 9% (China and India exports growing the fastest with, respectively, 16.4% and 13.9% per year) (Figure 6). EU export growth has indeed been outpaced by growth in total global exports over the past couple of decades.

Looking closer at the European export competitiveness, it can be observed that the slow-down is due to the petrochemicals sector. This is closely linked to the oil refining industry, which has suffered hugely recently due to energy prices being driven by the supply of shale oil and gas in the US[7] and, more recently, by decisions taken by Middle Eastern producers to maintain very low prices in response to the growing shale oil and gas sector in the US.

The EU28 is also the biggest importer of chemicals; however, when compared to the top ten non-EU countries, the EU28 has a very positive trade balance (around €129.9 billion) and managed to maintain the export/import ratio constant at around 1.7 over the period 2005-2015.

Figure 5: Chemicals exports (%) of the EU28 and the top ten non-EU countries (2014) – Source: Eurostat International trade



[7] http://www.platts.com/news-feature/2014/petrochemicals/europe-2014-outlook/index

Figure 6: Chemicals export trends (2005-2015 - €million) of the EU28 and the top ten non-EU countries – Source: Eurostat International trade

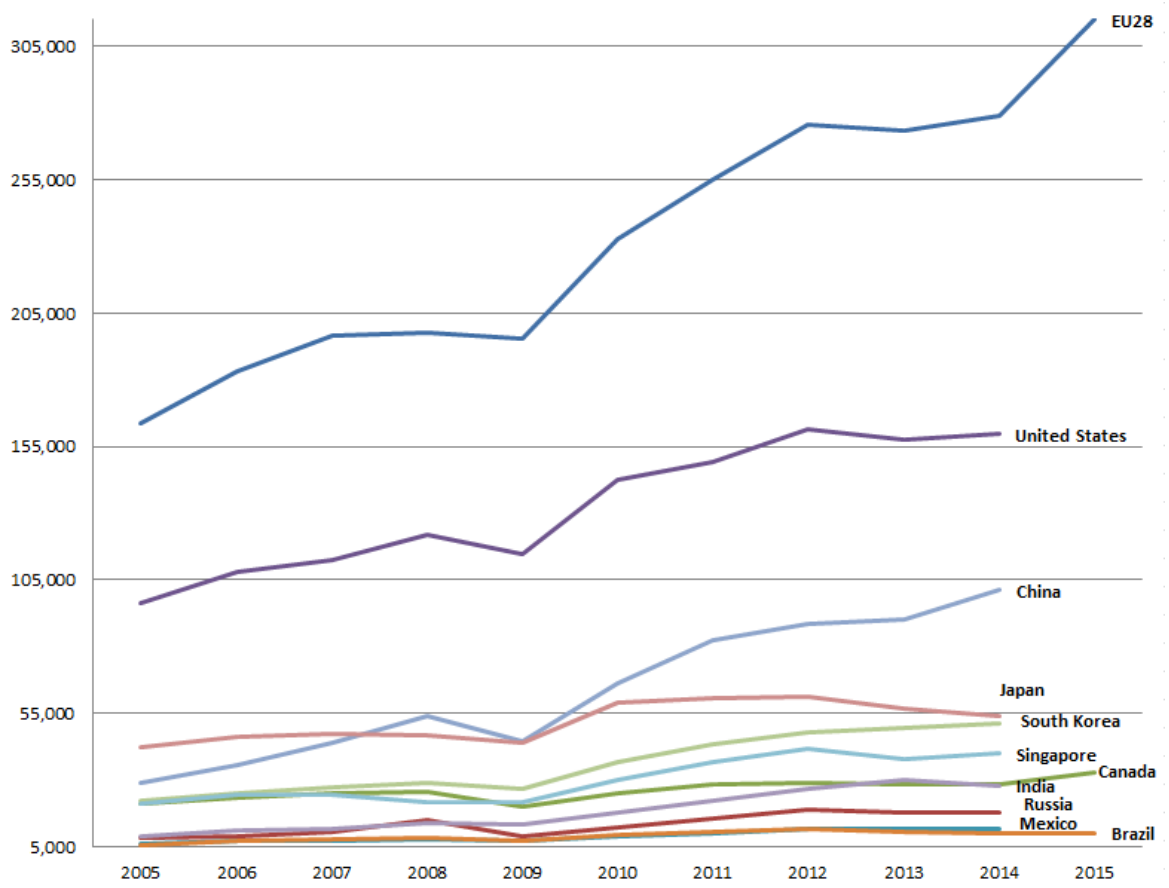


Table 2: Exports, Imports and Trade balance (€ millions) of the EU28 and the top ten non-EU countries (2005-2015) – Source: Eurostat database – International trade

		2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
EU28	**Exports**	163,799	183,429	196,763	197,608	195,594	232,707	254,889	275,500	273,302	278,763	314,974
	Imports	96,348	109,129	120,696	124,286	112,514	137,322	155,269	163,385	157,895	165,383	185,085
	Trade balance	67,451	74,300	76,067	73,321	83,080	95,385	99,621	112,115	115,407	113,380	129,889
Russia	**Exports**	8,123	9,220	10,715	15,203	8,951	12,124	15,663	19,164	17,732	17,721	:
	Imports	10,039	13,419	15,335	18,384	16,113	22,105	25,670	29,870	30,292	28,173	:
	Trade balance	-1,916	-4,199	-4,620	-3,180	-7,163	-9,981	-10,007	-10,705	-12,560	-10,452	:
Canada	**Exports**	21,005	23,447	25,328	25,790	20,015	25,016	28,339	28,845	28,518	28,598	32,918
	Imports	25,651	28,616	28,642	28,264	26,280	31,430	32,963	36,565	36,110	36,609	40,641
	Trade balance	-4,646	-5,168	-3,315	-2,474	-6,264	-6,415	-4,624	-7,720	-7,592	-8,011	-7,723
United States	**Exports**	96,383	107,840	112,695	121,796	114,481	142,772	149,038	161,368	157,543	159,734	:
	Imports	106,091	116,738	116,293	123,163	110,496	133,542	145,561	156,106	150,334	159,648	:
	Trade balance	-9,708	-8,898	-3,598	-1,367	3,985	9,230	3,477	5,262	7,209	86	:
Mexico	**Exports**	6,332	7,034	7,353	7,750	7,226	8,942	10,194	11,985	11,741	11,839	:
	Imports	19,692	21,922	22,069	23,038	19,948	25,739	28,476	32,590	32,539	34,354	:
	Trade balance	-13,360	-14,888	-14,717	-15,288	-12,722	-16,797	-18,283	-20,605	-20,798	-22,515	:
Brazil	**Exports**	5,870	7,388	7,791	8,602	7,535	9,259	10,862	11,716	10,781	9,980	10,343
	Imports	11,770	13,127	16,756	23,136	18,132	24,421	30,128	32,881	34,141	33,973	34,222
	Trade balance	-5,900	-5,739	-8,964	-14,535	-10,597	-15,162	-19,266	-21,165	-23,360	-23,994	-23,879
China	**Exports**	28,753	35,465	44,035	53,948	44,485	66,085	82,460	88,396	90,067	101,277	:
	Imports	62,482	69,327	78,478	81,036	80,387	112,854	130,076	139,549	143,291	145,019	:
	Trade balance	-33,729	-33,862	-34,443	-27,088	-35,902	-46,769	-47,615	-51,152	-53,224	-43,742	:
Japan	**Exports**	42,315	46,074	47,573	47,015	44,038	59,161	60,719	61,469	57,108	54,303	:
	Imports	30,420	32,519	33,305	37,202	34,989	46,033	54,559	57,318	49,552	48,559	:
	Trade balance	11,895	13,555	14,268	9,813	9,049	13,128	6,160	4,151	7,556	5,744	:
South Korea	**Exports**	22,301	25,331	27,395	29,039	26,824	36,925	43,613	47,707	49,821	50,996	:
	Imports	19,695	21,960	23,664	24,924	22,587	31,038	34,663	36,865	35,322	35,744	:
	Trade balance	2,607	3,371	3,731	4,115	4,237	5,887	8,950	10,842	14,499	15,252	:
India	**Exports**	9,190	11,241	11,940	13,907	13,323	17,842	22,562	26,949	29,846	28,097	:
	Imports	10,900	12,817	15,062	23,377	19,667	21,105	30,538	34,790	33,672	36,363	:
	Trade balance	-1,710	-1,576	-3,123	-9,470	-6,344	-3,263	-7,976	-7,841	-3,826	-8,266	:
Singapore	**Exports**	21,007	24,561	24,568	21,700	21,686	29,976	37,020	42,029	37,738	39,872	:
	Imports	10,010	11,389	11,511	11,376	10,494	15,702	18,225	20,173	19,135	19,400	:
	Trade balance	10,997	13,172	13,057	10,323	11,193	14,274	18,794	21,856	18,603	20,472	:

2.2 EU 28

The chemicals industry is vital to the European economy. The industry directly employs around 1.2 million people, generates nearly three times this number in indirect jobs (Cefic, 2016, p.31) and accounts for 7% of EU industrial production[8]. It is internationally competitive and supplies nearly all sectors of the economy, from manufacturing and processing, to agriculture and services. The EU has long been one of the top chemicals-producing regions in the world, although trends have shown that its overall market share is decreasing.

EU chemical sales cover three broad areas: base chemicals (petrochemical, polymers and basic inorganics), specialty chemicals and consumer chemicals. In 2014, base chemicals represented 59.6% of total EU chemical sales, with petrochemicals being the largest individual segment (Figure 7). Specialty chemicals, which include paints, dyes, inks and pigments, accounted for 27.8% of total EU chemicals in 2014. Meanwhile, consumer chemicals (e.g. soaps, detergents, perfumes, cosmetics etc.) made up 12.6% of total EU chemicals sales.

The EU chemicals industry produces thousands of different products that are utilized for a broad range of end-use applications. It underpins many different sectors within the economy, which results in there being a strong correlation between economic growth in the region and the growth of the chemicals industry (ECF, 2014). The biggest downstream users of chemicals are the plastics and rubber industry, construction, the pulp and paper industry and automotive manufacturing. In total, two thirds of EU sales go to the industrial sector and one third to agriculture, services and other industries (Figure 8).

Figure 7: Percentage of sales by chemical sector - Source: Cefic Chemdata International

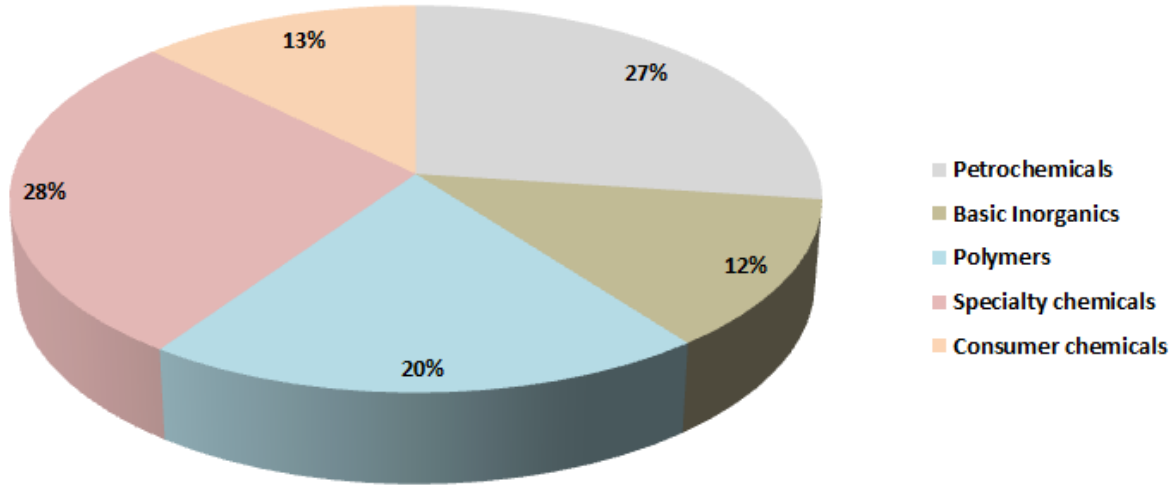


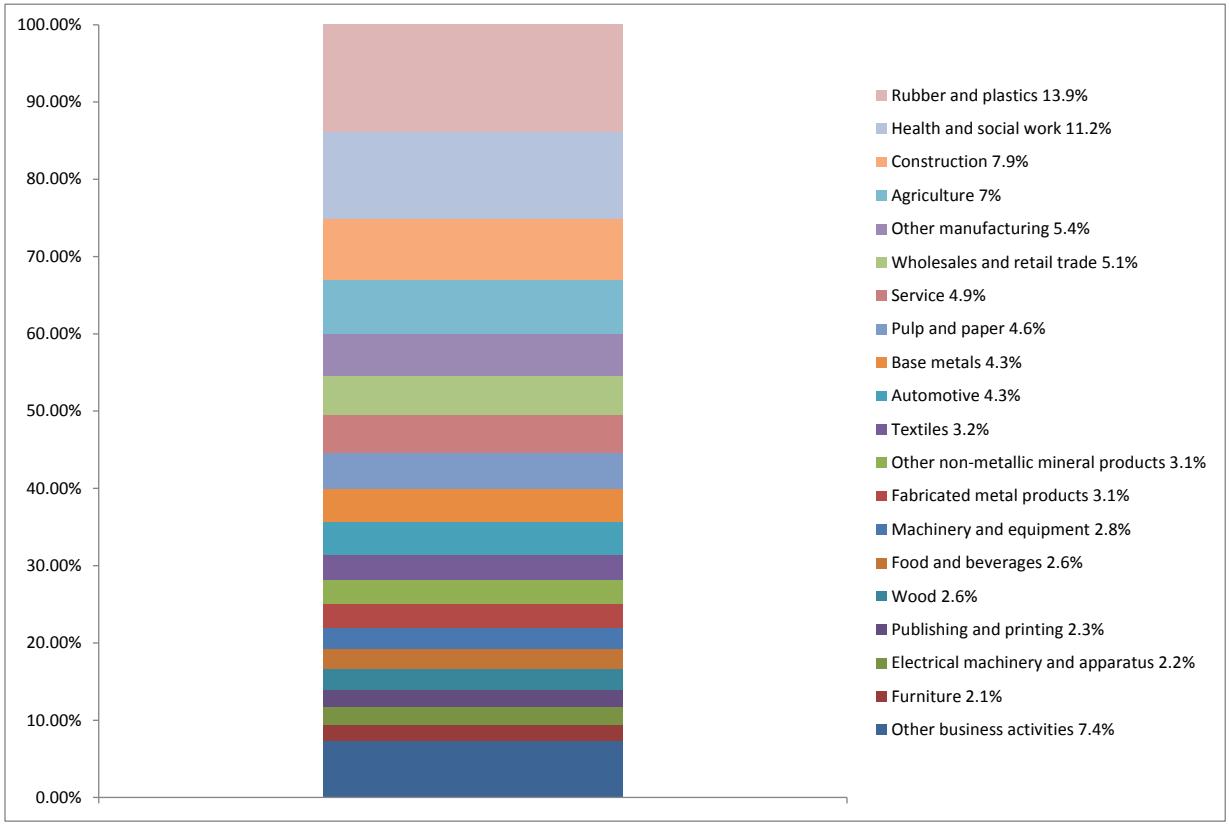
Table 3: EU28 chemicals sales by chemical sub-sector - Source: Cefic Chemdata International

Chemical sub-sectors	Sales - € billion	Sales - Share
1. Petrochemicals	**149.2**	**27.1%**
2. Basic Inorganics	**69.3**	**12.6%**
Other inorganics	29.9	5.4%
Industrial gases	14.7	2.7%
Fertilisers	24.7	4.5%
3. Polymers	**109.9**	**19.9%**
Plastics	91.8	16.7%
Synthetic rubber	11.8	2.1%

[8] DG Growth, Chemicals, Available at: http://ec.europa.eu/growth/sectors/chemicals/index_en.htm

Chemical sub-sectors	Sales - € billion	Sales - Share
Man-made fibres	6.3	1.1%
4. Specialty chemicals	**152.9**	**27.8%**
Dyes & pigments	11.6	2.1%
Crop protection	10.7	1.9%
Paints & inks	42.7	7.8%
Auxiliaries for industry	88.0	16.0%
5. Consumer chemicals	69.6	**12.6%**
Chemicals excluding pharmaceuticals	**551.0**	**100.0%**

Figure 8: Percentage of output consumed by customer sector – Source: Cefic, 2014



2.3 MAIN FACTORS INFLUENCING THE ECONOMIC DEVELOPMENT OF THE CHEMICAL INDUSTRY

2.3.1 Introduction

Literature concurs that the following factors are determinants of the competitiveness of the European chemical industry:

- Energy prices (in particular oil price, given that it is the primary energy source for the industry and raw material for many chemicals);
- GDP growth and chemical demand;
- Currency appreciation (exchange rate);
- Access to raw materials and new markets (trade agreements);
- R&D intensity, innovation rate, investment in primary production and technological capability;
- Labour costs;
- Efficiency within the industry;
- Regulation.

Growth within the global chemicals industry is determined both by countries' domestic needs and by global trade. Meanwhile, the geographic distribution of chemicals production is influenced by a number of factors such as proximity to raw materials and end markets, factor costs, capital investment, and regulation, among others. For instance, in some chemical segments (e.g. petrochemicals), the proximity to raw materials can have a significant impact on the costs of production and this has resulted in the emergence of the Middle East as a key producer of petrochemicals.

According to UNEP, investment by large multinationals in emerging countries has been a key driver of the growth in the global chemicals industry. This investment has been driven by a number of factors such as lower labour costs, global economic growth, trade liberalisation and advances in communication and transport. Consequently, the landscape of chemicals production has shifted, with over 80% of new production capacities being developed in emerging economies (UNEP, 2013). Meanwhile, capacities in some of the advanced economies (e.g. Europe) have been consolidated (Roland Berger, 2015).

More recently, the US shale gas boom has lowered costs of production and stimulated investment in the region. Europe, on the other hand, has experienced a fall in capital investment and its competitiveness is being squeezed upstream (e.g. petrol chemicals) due mainly to relatively higher feedstock costs (Roland Berger, 2015). In order to remain a global player in the international chemicals market, analysts (Roland Berger, Cefic) remark that Europe must maintain its positive trade balance and boost its exports through the enhancement of its competitiveness. To this end, the following sections discuss the key drivers of growth and competitiveness in the EU chemicals industry as well as some potential challenges that may arise in the future.

The main determinants of the competitiveness of the chemical industry are discussed in the following subsections. The impacts of the regulation on the competitiveness and innovation of the EU industry and on its efficiency in ensuring the protection of human health and the environment is discussed in Section 3.

2.3.2 Energy and oil price

Energy products, such as oil and gas, are important to the chemicals industry not only as a source of energy, but also as a principle raw material for its final products. The chemicals industry is the most energy intensive manufacturing sector in the EU, accounting for 12% of total EU energy demand and approximately one third of all EU energy use (High Level Group on the Competitiveness of the European Chemicals Industry, 2009). The price and availability of energy and feedstock are, therefore, important determinants of competitiveness within the industry (UNEP, 2013). According to McKinsey & Company (2015), changes in oil prices have immediate and significant impact on the cost structures of key chemical building blocks for two reasons:

- Some key chemicals, such as chlorine, are manufactured through highly energy-intensive production processes and, therefore, have strong links to oil prices;
- Many key chemicals (e.g. aromatics, ethylene and propylene) are directly produced from oil and its derivatives (around 10% of crude oil is used for the manufacturing of chemicals, including a 4% used for plastics manufacture)[9].

The impact of the oil-price drop is differentiated along the chemicals value chain and changes depend on the strength and elasticity of the links between products costs and prices. In general, a 50% oil-price drop results in a 10-20% reduction in raw material spend at the end of the chemicals value chain, and the raw materials price change is experienced with 2- to 6-monthdelay at the end of the value chain. The product-price decrease, in case of full pass-through, is of 15-30% at the start of the

[9] http://www.technologystudent.com/prddes1/plasty1.html

chemicals value chain and of just 3-6% at the end, with the product-price decrease released in 1 to 3 months at the start of the chemicals value chain and from 3 months to over one year at the end of the value chain. In terms of the strength and elasticity of the cost-price link, three general categories can be defined:

- Strong price and cost linkages to oil: examples are the commodity chemical benzene (refinery by-product) and its derivatives (such as styrene and polystyrene), where most of the oil cost passes through to the customers;
- Price and cost asymmetric to oil price: examples are polyvinyl chloride (PVC) and many specialty chemicals, for which prices are set by value in use while costs follow oil price;
- Price and cost not linked to oil price: examples are specialized lubricant additives and bio-based chemicals. Indeed, one of the main selling points of bio-based chemicals is their less volatile price if compared to oil-based chemicals (McKinsey, 2015).

A key indicator of competitiveness is the cost of producing ethylene, a major building block in the chemicals industry (being the foundation for plastics, detergents and coatings). Due to the USA shale gas boom, making ethylene in the EU is now three times more expensive than it is in the USA. Moreover, with its large reserves of fossil fuels, close proximity to the Asian market and high levels of downstream value chain integration, the Middle East is emerging as a key competitor to the EU chemicals industry. Ethylene accounts for half of the region's petrochemical production (21.7 million tonnes in 2013) and the production cost per tonne is less than half of what it is in Europe. This has enabled some Middle Eastern producers, such as Sabic and OCI, to leverage their access to cheap feedstock to improve their relative position and market share.

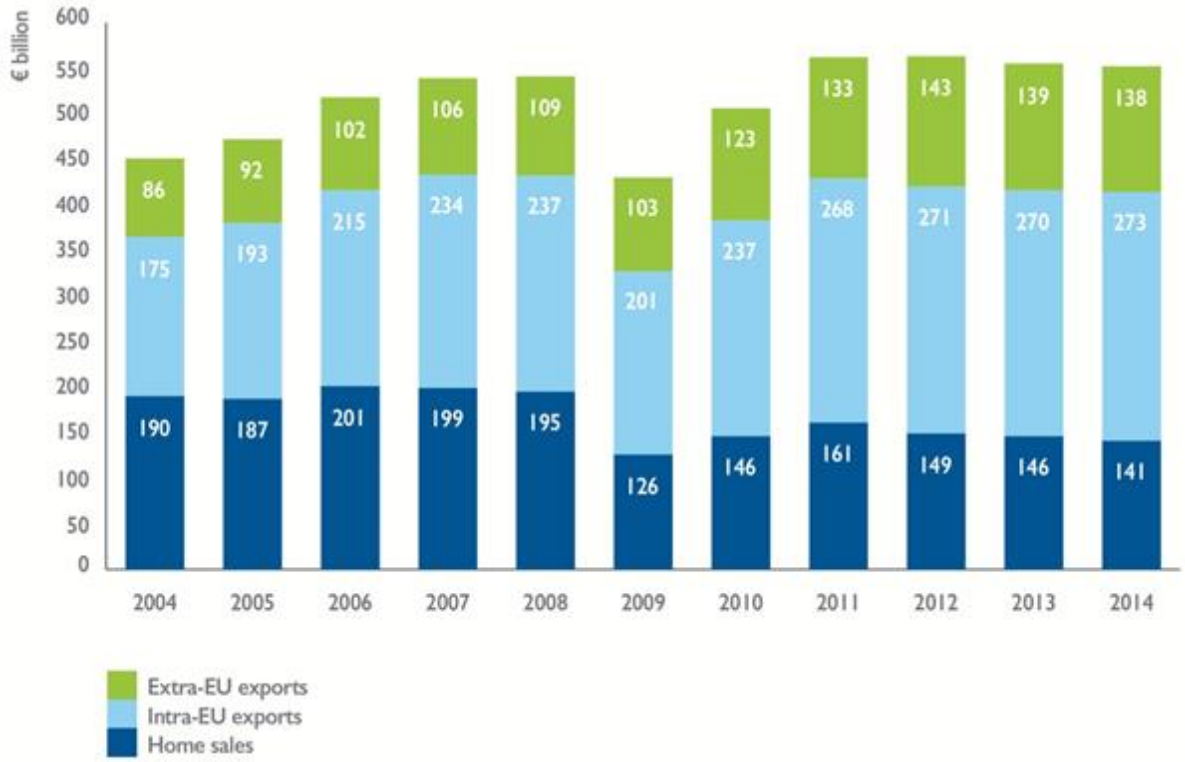
Europe's raw material and energy disadvantage is also evident from the relocation of some EU producer's activities to the US, where feedstock is relatively cheaper. For instance, DSM recently built a new polymerisation plant in the USA to manufacture its polyamide 6 polymer, which is used to make film grades for food packaging and other end-uses. The investment has allowed DSM to take advantage of lower cost propylene made from US shale gas. Other large EU producers that have recently invested in US operations include BASF, Ineos and Sasol (Roland Berger, 2015).

While Europe suffers a competitive disadvantage against the USA and Middle East in terms of raw material and energy costs, the high labour costs, capital costs and other fixed costs are the main weaknesses versus China (ECF, 2014). Nevertheless, an econometric assessment by Oxford Economics finds that while higher labour costs have a negative impact on competitiveness of the EU chemical industry, the quantitative effect is not significant (Oxford Economics, 2014).

2.3.3 GDP growth, chemical demand growth and access to raw materials and new markets

With over 500 million consumers, Europe has a large and integrated domestic market with strong customer industry clusters. The importance of the internal market is demonstrated by the fact that nearly 50% of all EU chemical sales in 2014 were intra-EU 'exports' (Cefic, 2016, p.10). The removal of trade and non-trade barriers within the EU and the enlargements of the European Union in 2004 and 2007 underpinned the increase in intra-EU trade during the period 2004-2014.

Figure 9: EU chemicals sales: structure by destination – Source: Cefic Chemdata International



The development of the chemicals industry is closely linked to economic growth due its strong linkages with different sectors of the economy. Global chemical sales and consumption were hit by the 2008 economic crisis and EU sales contracted by 0.1% per year between 2008 and 2013 (Cefic, 2014). This contraction was driven by reductions of economic activity in key internal customer segments such as construction and automotive, for which chemical demand is highly dependent (PWC, 2016).

Despite the strength of the internal market, there are some concerns regarding future growth. The EU market is mature with high levels of saturation, an ageing population, low levels of population growth and a shrinking working class; internal demand growth is therefore expected to be slow in the future (Cefic, 2016, p.6). Moreover, chemicals made in the EU have been losing share in the domestic market over the past ten years. In 2003, EU-made chemicals accounted for 86.8% of total sales in the EU market. By 2013, this proportion had fallen to 81.1%, suggesting that EU companies are losing competitiveness in their own domestic market (Cefic, 2015). For the EU chemical's industry, it will be crucial to secure extra-EU markets, where more than 90% of the global GDP growth will occur. EU chemical companies are strongly positioned in terms of exports and in order to enhance efficiency and better exploit their technical strengths, they are strong advocates of new trade agreements (in particular with key partners such as the US and Japan).

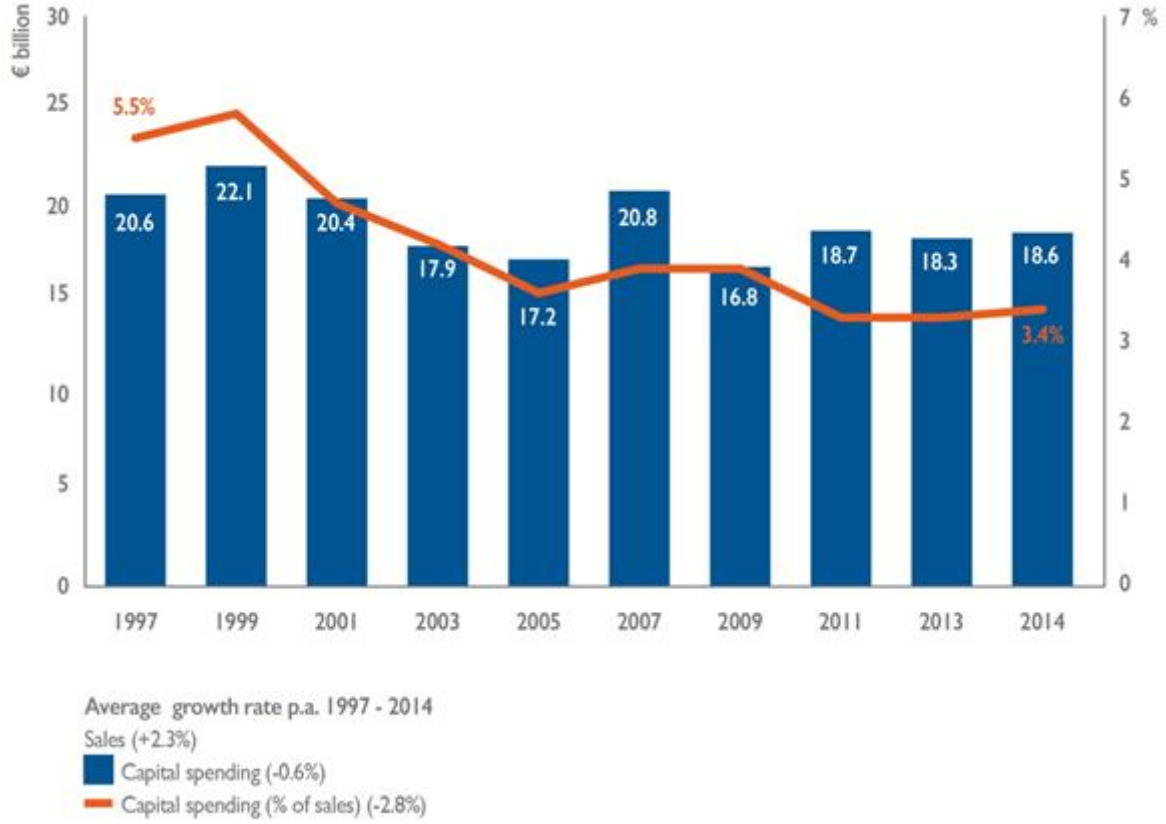
2.3.4 R&D intensity, innovation rate, investment in primary production and technological capability

In order to fight the decline in primary production, with potential repercussions on technological capabilities and risks for high value chains, one of the key objectives of the European Commission is to ensure that 20% of the EU total GDP comes from industry by 2020.

Capital investment in existing infrastructure and production facilities, as well as research and development, is considered a driver of future competitiveness and growth in the EU chemicals industry. Absolute levels of capital investment in the EU chemicals industry rose from €15.1 billion to

€21.2 billion over the period 2004-2008 but have since experienced a decline, registering at €18.6 billion in 2014. Capital intensity, defined as the ratio of capital spending to sales, has declined since 1999 from 5.8% to 3.4% in 2014 (Figure 10).

Figure 10: EU capital investment in chemicals: spending and intensity – Source: Cefic Chemdata International



Internationally, evidence suggests that the EU is falling behind globally in terms of capital investment. While many countries are expanding and creating new production facilities, the EU is consolidating. For instance, the Middle East plans to open five new steam crackers for ethylene production in 2015 and six more are planned in Asia (Roland Berger, 2015).

China currently attracts the bulk of chemicals investment. Between 2004 and 2014, it saw an increase in capital investment by a factor of 7, from €10.5 billion to €76.5 billion. The US has also seen large increases due to its improvement in energy and feedstock costs. On the other hand, the EU has witnessed a smaller increase in overall capital investment (Figure 11), with steady capital investment intensity (capital investment as percentage of sales). This could have implications for future competitiveness (Figure 12).

The chemicals industry is one of the most R&D intensive manufacturing sectors within advanced economies. As an input provider for other industries, it is considered to be at the forefront of innovation and a solution provider for many societal and environmental challenges[10]. For instance, the development of a new sustainable material by a chemicals company can lead to innovation downstream (e.g. circular business models). Patterns of innovation and productivity growth within the chemicals industry, therefore, not only have a profound effect on the industry itself but also on the growth of the wider economy (Roland Berger, 2015). Moreover, R&D in customer industries drives

[10] European Commission (DG Growth), Chemicals, What the Commission is doing. Available at: http://ec.europa.eu/growth/sectors/chemicals/ec-support/index_en.htm

purchasing decisions in the chemical industry, so that R&D co-operation within chemicals value chains will increase in the future (ATKearney, 2012).

Figure 11: Chemicals capital investment by region – Source: Cefic Chemdata International

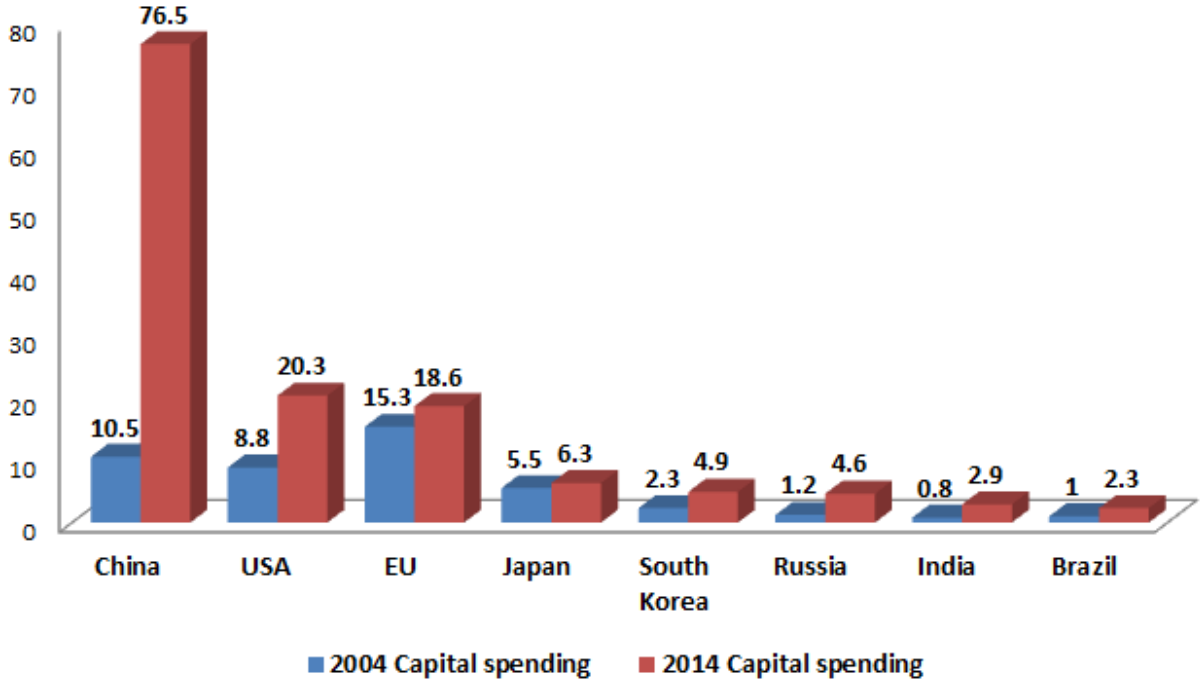
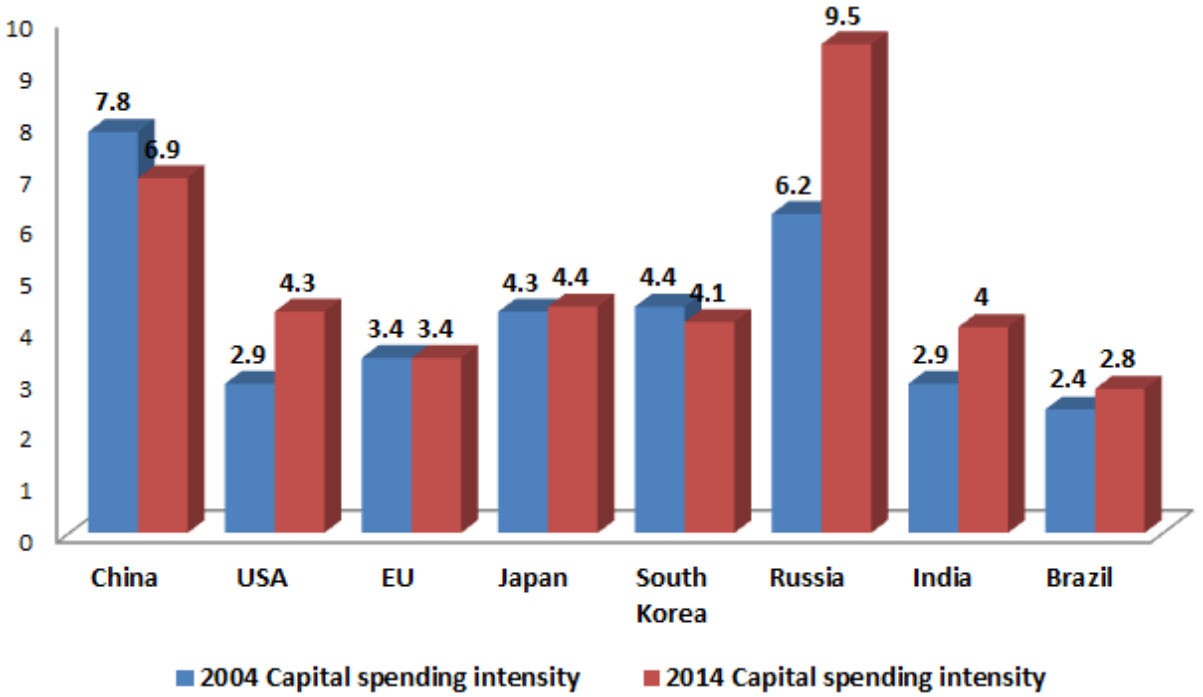


Figure 12: Chemicals capital spending intensity by region - Source: Cefic Chemdata International



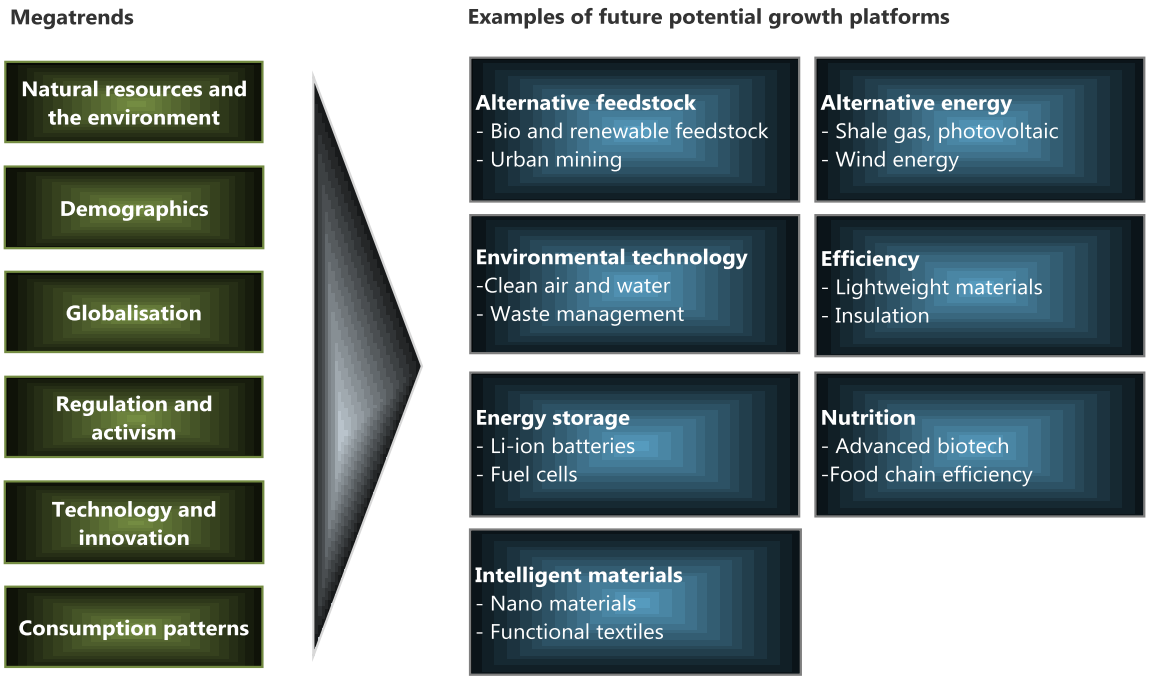
2.3.5 Factors driving innovation in the use and management of chemicals

In the latter half of the twentieth century, two major factors drove innovation and growth within the chemical industry: polymer chemistry and chemical engineering. The former was a key source of many major product innovations and is the foundation for many sectors that form the core of the chemicals industry, such as synthetic fibres, plastics, resins, adhesives and paintings and coatings. Chemical engineering led to various process innovations that allowed the production of such products at a low enough cost to guarantee their success (Cesaroni et al, 2004).

More recently, so-called "megatrends" are acting as catalysts for innovation in the industry with customer demands shifting to incorporate long term global issues, such as sustainable development and climate change (ATKearney, 2012). Changes in anti-fouling marine coatings are one example of this trend. Due to a restriction on the most widely used anti-fouling substance (TBT), the chemicals industry is being forced to develop new coatings and meet the shipping industry's demand for sustainable, high performance coatings. These trends mean that chemicals companies are becoming more focused on providing innovative solutions rather than just products (Roland Berger, 2015). BASF, for example, has stated that around a third of its research and development expenditure is aimed at energy efficiency and climate change[11].

Unlike other regions, the EU chemicals industry is unable to base its growth on inexpensive resources and labour. With a high level of technological development, a skilled workforce and a strong research base, innovation is one area where the EU chemicals industry has some competitive advantage (High Level Group on Competitiveness of the European Chemicals Industry, 2009). By continually improving products, technologies and processes, European chemicals companies can find new ways to meet customer demands and increase market share. According to ATKearney (2012), Europe's growth opportunities are primarily in highly innovative products related to the megatrends. Figure 13 presents an overview of these trends alongside future potential growth platforms for the EU's chemicals industry.

Figure 13: Megatrends and future growth platforms for the EU's chemicals industry – Source: ATKearney (2012)



[11] http://report.basf.com/2012/en/managementsanalysis/innovation.html

For the purposes of the non-toxic environment strategy, it is important to notice that natural resources and the environment have been recognised as megatrends, with examples of future potential growth platforms being environmental technology and alternative feedstock (e.g. bio and renewable feedstock).

A close co-operation between the chemical industry and the downstream sectors is fundamental for the competitiveness and innovative capacity of the EU economy as a whole, but also for achieving the 2020 goal of sound chemicals management globally, set by the United Nations' Strategic Approach to International Chemicals Management (SAICM). The Overall Orientation and Guidance document adopted during the fourth International Conference on Chemicals Management held in Geneva in 2015 recognises the "need for stronger engagement and increased assumption of responsibility by downstream entities, in particular industries, to address the distribution and use of chemicals in the manufacture of products and throughout their lifecycle, and for a more extensive approach to stewardship"[12]. Moreover, companies in downstream sectors are closer to consumer demands for safer and greener products and have different perspectives on how to develop and implement safer chemical and non-chemical alternatives.

There are several examples in different downstream sectors of initiatives trying to improve the collaboration with the chemical industry.

One of these is the recent[13] development by the European Automotive Industry Association (Acea) of criteria for selecting 'non-regulated' alternative substances to help vehicle manufacturers in avoiding regrettable substitutions and support chemical manufacturers in identifying safer alternatives.

The initiative aims to involve vehicle manufacturers much earlier in the process of assessing and selecting the alternatives, as the decision of which substitute to use in order to comply with both the product specifications and new chemical legislation is usually made by the chemical providers. However, the consequences of selecting a substance with similar (eco)toxicological properties are borne by both vehicle and chemical manufacturers.

Acea propose that an alternative substance must:

- Have a completed registration under REACH;
- Be listed in all global legally binding chemical inventories;
- Not meet the SVHC criteria and must not be expected to;
- Not be already regulated or in the 'regulatory pipeline' in the EU or other regions;
- Not be listed on the Global Automotive Declarable Substance List (Gadsl) or the Global List of Automotive Process substances (GLAPS);
- Not belong to the same substance group as the original substance;
- Be less hazardous than the original substance (to be defined case by case);
- Be available, or have the potential to be, in amounts sufficient to supply customer needs; and
- Fulfil customers technical requirements.

Car manufacturers have also been among the firsts in pioneering new concepts for managing chemicals. In the 1980s, General Motors partnered with chemical suppliers and transferred elements of chemical management to them on a facility-by-facility basis, developing the so called Chemical Management Services (CMS) and Chemical Leasing (ChL) business models (Stoughton and Votta, 2003). European companies started adopting these business models from the mid-1990s (Mont et al, 2006). CMS and ChL are service-focused business models, new ways of creating value that were born in the 1970s as a responses to new revolutionary trends, such as an increase and change in nature of international competition, improved education level and standard of living of employees and

[12] http://www.saicm.org/Portals/12/Documents/OOG%20document%20English.pdf (accessed 30.03.2017), p. 5.
[13] April 2017.

consumers and increased awareness of consumers about available options as a result of the development of information technology (Grönroos, 1994). The new focus on service allowed companies to create distinctive and sustainable value, more easily defendable from competition based in lower cost economies than the value created with traditional business models, where the focus is more on cost reduction and scale economies (Normann, 1982; Tian et al, 2012).

CMS and ChL are very close concepts and can be defined as business models "in which a customer engages with a service provider in a strategic, long-term contract to supply and manage the customer's chemical and related services" (Stoughton and Votta, 2003). When these new approaches are accompanied by a change in the supplier compensation, from volume of product supplied to quality/quantity of services provided, this change realigns the incentives in the supplier-user relationship and allows achieving significant economic and environmental gains.

In particular, ChL is seen as part of the wider concept of Cleaner Production (CP), namely an integrated preventive environmental strategy to increase resource efficiency and reduce risks to humans and the environment. The CP concept was developed at the United Nations Conference on Environment and Development in Rio de Janeiro in 1992 (Schwager, 2008). At the 2002 Johannesburg World Summit on Sustainable Development, the commitment to cleaner production was renewed and, as a consequence, the Strategic Approach to International Chemicals Management (SAICM) was agreed and signed in Dubai in 2006. In November 2016, UNIDO and the governments of Austria, Germany and Switzerland have signed a Joint Declaration of Intent on Chemical Leasing to increase awareness on the business model and foster its adoption by companies.[14]

The ChL concept stems from the idea of reversing the fundamental economic relationship between chemical supplier and chemical customer which creates supply side incentives for increased chemical use. In the ChL model, the chemical supplier is compensated on the basis of the services delivered, instead of the volumes of chemicals sold. In this configuration, the chemical supplier and the chemical user enter in a strategic partnership, with the common goal of reducing chemical consumption. Both the provider's and customer's incentives are aligned and can achieve benefits from improved performance, chemical handling and waste management.

The automotive is not the only sector engaging with chemical manufacturers to develop more sustainable solutions. In the Nordic countries, for example, there are several initiatives implemented by companies, industry associations and endorsed by authorities, aimed at chemical downstream users in the construction sector (e.g. building owners, contractors, architects, structural engineers):

- BASTA, developed by the Swedish Environmental Research Institute and the Swedish Construction Federation, is a database where suppliers and manufacturers of building and construction products register products that comply with the concentration limits on hazardous substances defined by the two organisations[15];
- Byggvarubedömningen, or BVB, is a tool for assessing the chemical content of construction products[16];
- SundaHus, a company providing consultancy services and material data to phase out hazardous substances in buildings' lifecycles.

Another sector where stricter regulation and consumers' pressure provide an incentive to substitute hazardous substances is the textiles manufacturing sector. Twenty-one major apparel and footwear brands joint their efforts in minimizing the environmental impact of the industry through the Zero Discharge of Hazardous Chemicals initiative. Apart from having compiled a list of manufacturing restricted substances, they are encouraging chemical manufacturers to develop safer alternatives to

[14] http://www.unido.org/news/press/joint-declaration-of.html
[15] http://www.bastaonline.se/wp-content/uploads/2017/03/Basta-properties-criteria_2017-A1-2016-12-14-CLP.pdf
[16] https://www.byggvarubedomningen.se/

hazardous substances for which alternatives do not currently exist (e.g. ethylbenzene, toluene, methanol, DMF and short-chained perfluorinated chemicals).

2.3.6 Energy efficiency, production and consumption of hazardous chemicals

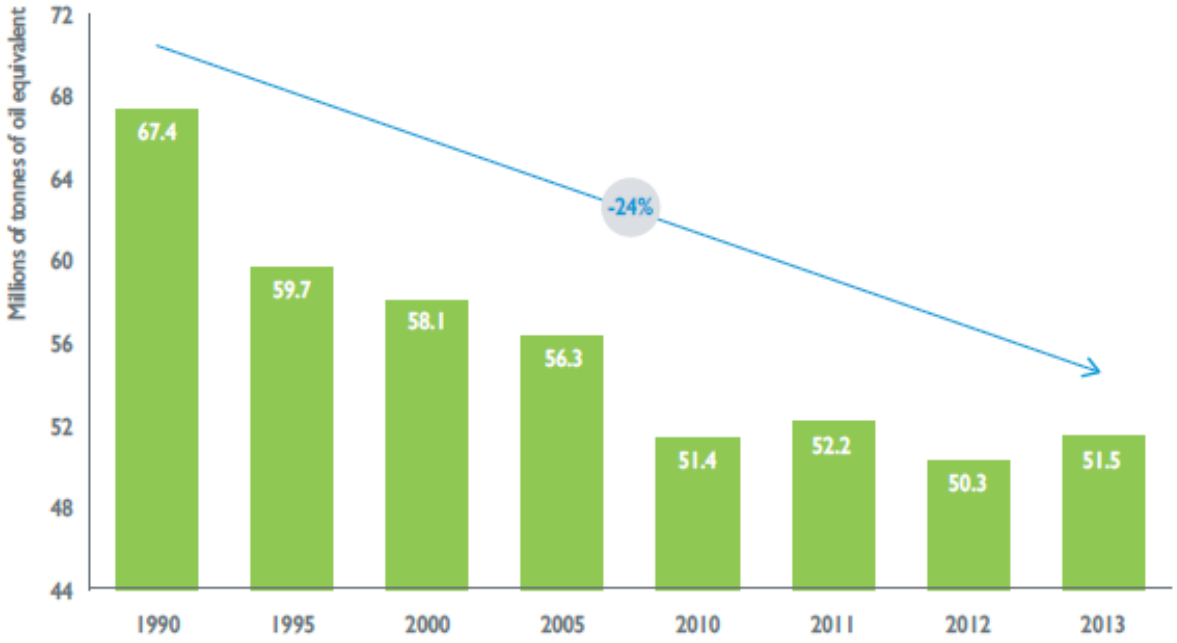
The rise in oil prices in the 1990s and the first part of the new millennium has driven the increase in fuel and power consumption efficiency in the EU chemical industry. The global challenge of climate change has strengthened the call from civil society and the commitment of industry in ever-increasing efficiency. Moreover, given the limited availability of domestic sources, efficiency in the consumption of energy and raw materials is a key factor for the competitiveness of the industry.

According to Cefic (2016), between 1990 and 2013, fuel and power consumption in the EU chemical industry decreased by 24% (Figure 14), mainly thanks to the following factors:

- Decrease in fossil-based sources in favour of an increase in renewable sources in the energy mix for the whole industry;
- Within the chemical industry, decrease in fossil-based energy consumption in favour of derived heat, thanks to new less-energy intensive production processes and the enhanced design of production plants and sites.

The chemical industry has outpaced other industrial sectors in terms of increased efficiency[17] (Figure 14 and Figure 15). The manufacturing of chemicals is a high energy-intensive sector and some savings have been realised across all major chemical producer countries (Mulder and de Groot, 2011). However, future opportunities to further decrease fuel consumption in the sector appear limited in the absence of any major shifts toward recycling and bio-based chemicals (U.S. EIA, 2016).

Figure 14: Fuel and power consumption in the EU chemical industry (including pharmaceuticals) – Source: Cefic (2016)



[17] Energy intensity is measured by energy input per unit of chemicals production (Eurostat).

Figure 15: Energy intensity in the EU chemical industry – Source: Cefic (2016)

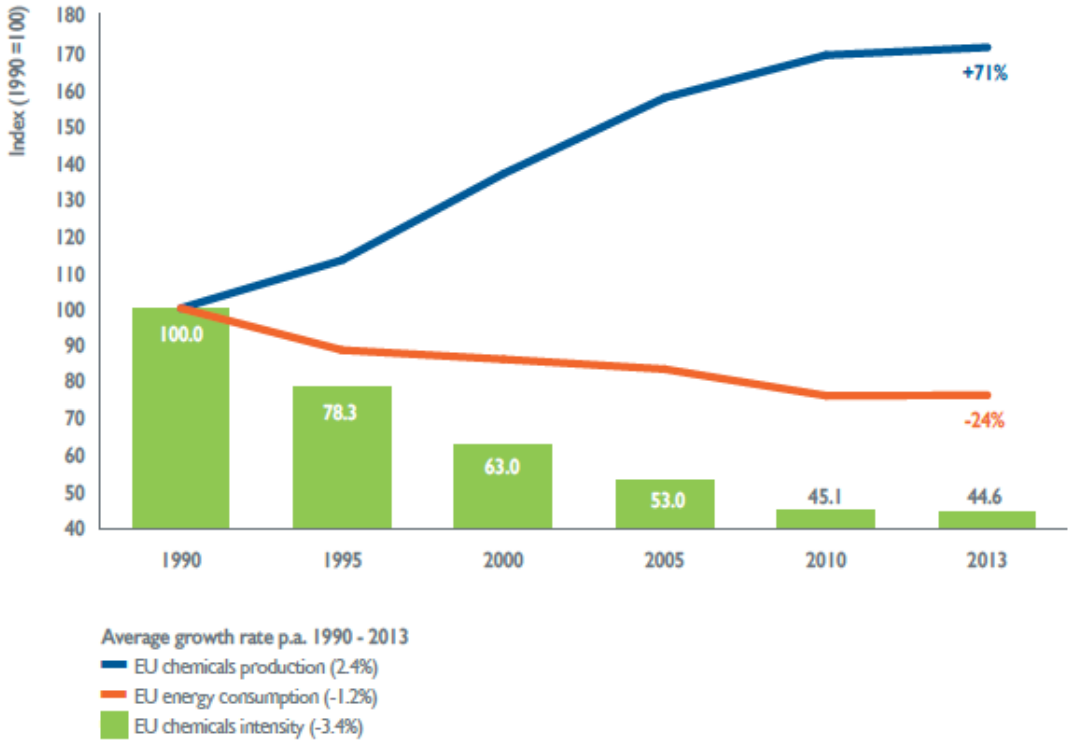
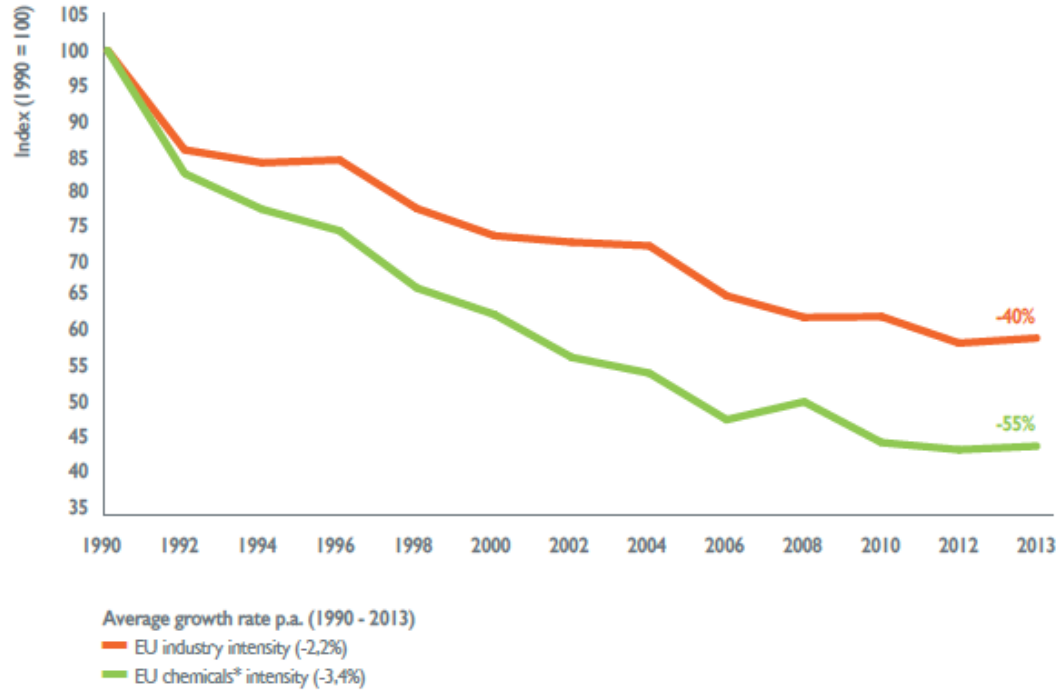
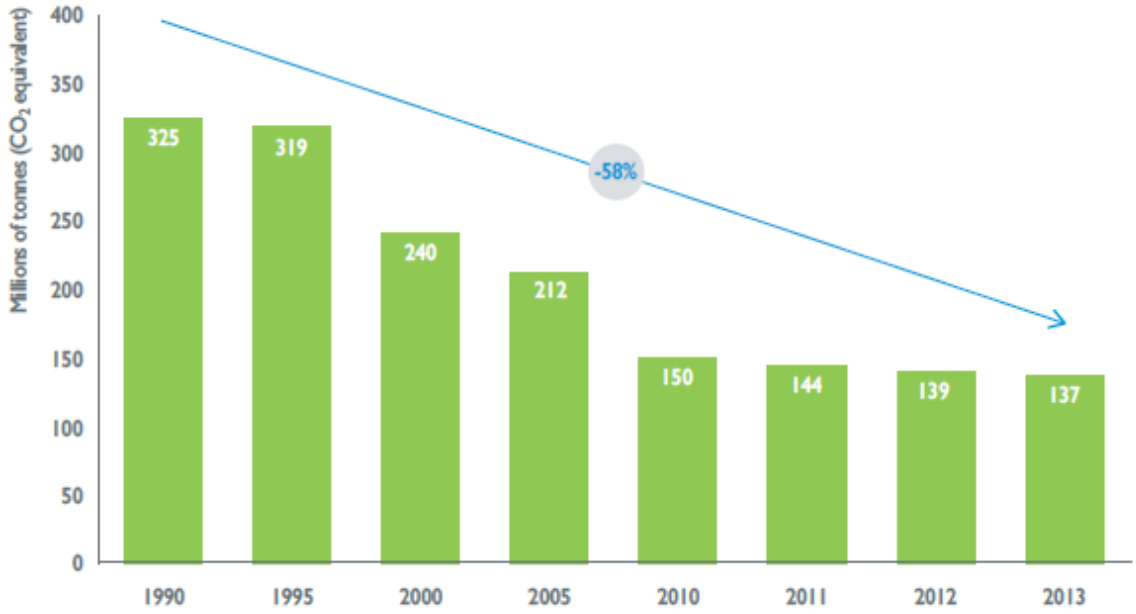


Figure 16: Energy intensity: chemicals and pharmaceuticals vs total industry – Source: Cefic (2016)



The increased efficiency in energy consumption and the increased use of renewable sources in the energy mix have determined a 58% decrease in the greenhouse gas emissions of the EU chemical industry (Figure 17).

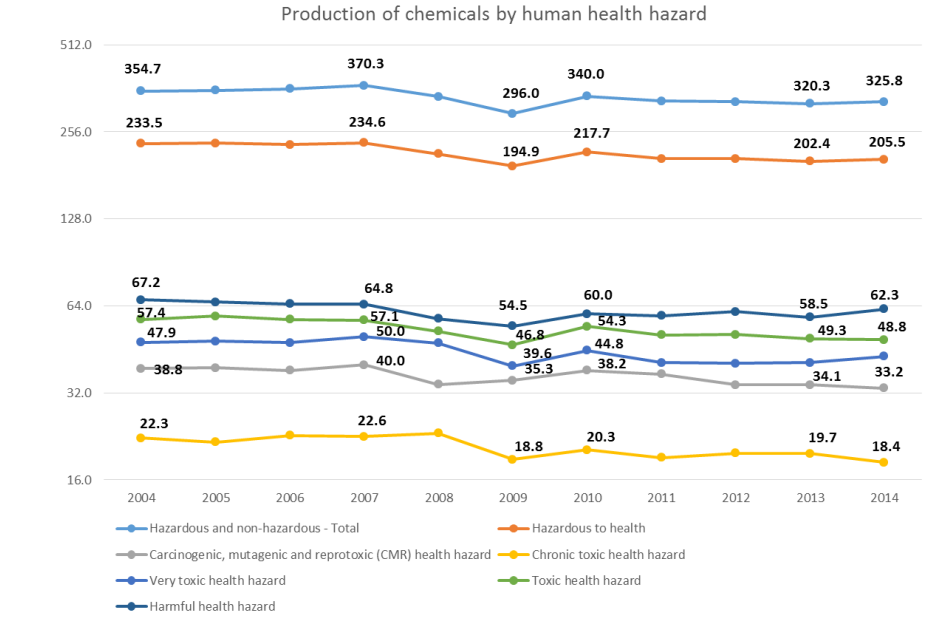
Figure 17: Total greenhouse gas emissions in the EU chemical industry – Source: Cefic (2016)



Eurostat has developed two indicators on the production and consumption of hazardous chemicals in the EU28. These are broken down by toxicity class. The trends for the different toxicity classes follow the same pattern of the trend for the total EU production of chemicals, characterized by a significant decrease in coincidence with the 2007-2009 economic crisis, from which both chemical production and consumption have just started to recover. Between 2013 and 2014, the production of CMR substances has gone down, opposite to the total chemical production, while consumption of hazardous substances has grown, but less so proportionally than the total consumption of chemicals. It should be noted that the indicators on production and consumption of hazardous substances maintained by Eurostat are only an imperfect proxy for exposure, as this depends upon a number of other factors[18], such as how a substance is used, any safety measures in place to control emissions and exposures during the substance's life cycle, and any imports of substances, including articles containing them.

[18] http://www.eea.europa.eu/airs/2016/environment-and-health/production-of-hazardous-chemicals.

Figure 18: Production of chemicals by human health and environmental hazard (Eurostat)



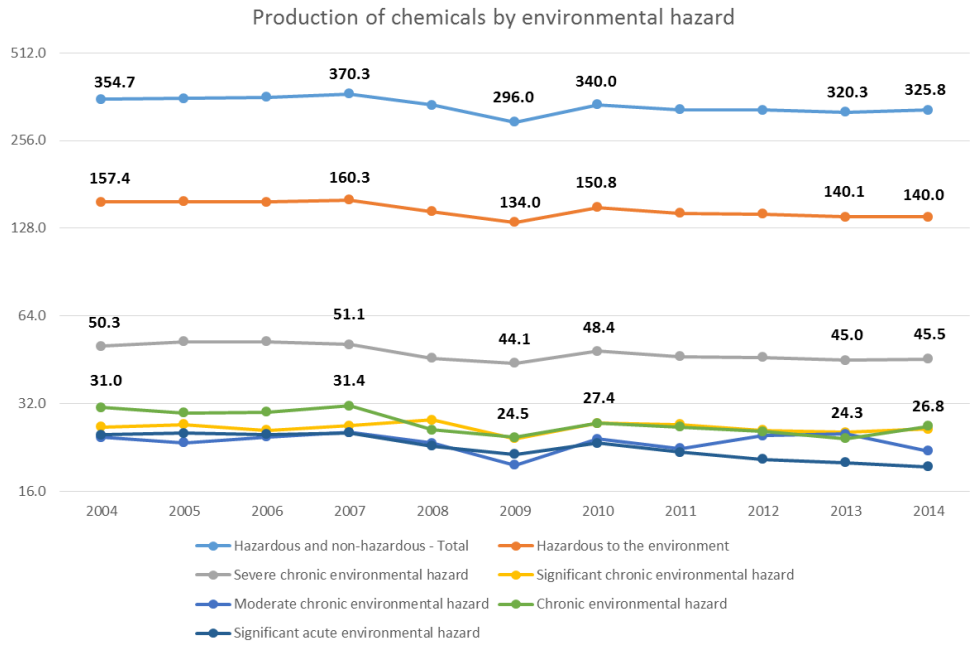
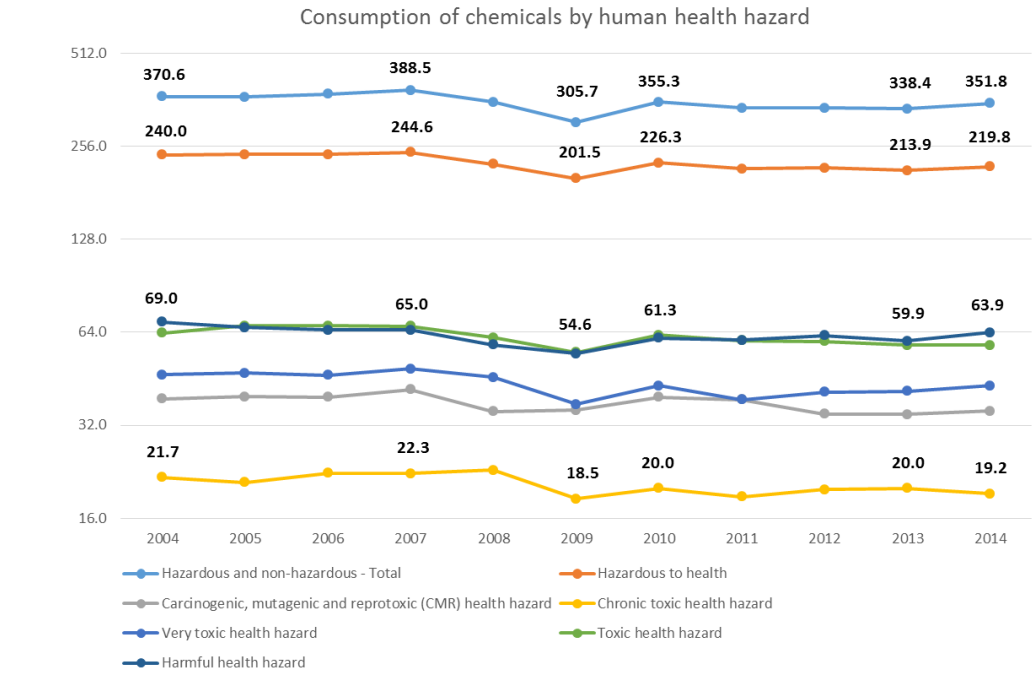
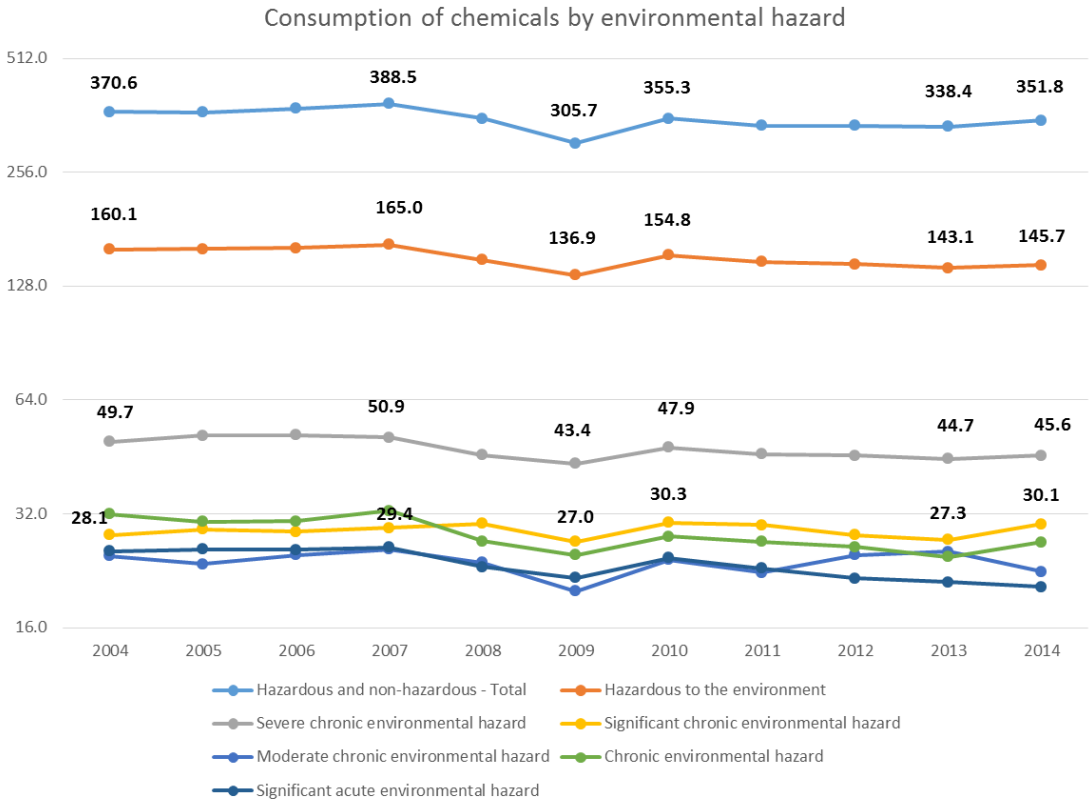


Figure 19: Consumption of chemicals by human health and environmental hazard (Eurostat)





3 EFFECTIVENESS OF CHEMICALS LEGISLATION IN ENSURING THE PROTECTION OF HUMAN HEALTH AND THE ENVIRONMENT AND IN FOSTERING INNOVATION AND COMPETITIVENESS

3.1 FOSTERING INNOVATION AND COMPETITIVENESS

The European Commission is firmly convinced that a stable and predictable regulatory environment is a key requirement for the future competitiveness of the EU chemicals industry[19]. Due to the inherent nature and energy intensive activity of the chemical industry, the sector is subject to strict environmental, workers' and consumers' health and safety legislation.

Regulation has the potential for both negative and positive impacts on the competitiveness and innovation of the EU chemical industry: negative impacts can occur when the cumulative costs of the environmental legislation on the industry add to other adverse global trends; positive impacts can be achieved by regulation through the promotion of green innovation and by ensuring an even playing field for all of the actors involved. While on the one hand the EU environmental legislation, and in particular the legislation of the chemical industry, is one of the most ambitious in the world and may constitute an additional burden to EU industry against extra-EU chemical companies (Cefic, 2015 and Cefic, 2016, p.27), the legislation does ensure the internalisation of the externalities of the industry, enforcing the "polluter pays" principle and delivering benefits to the whole society in terms of human health and the environment on the other. Moreover, stricter environmental legislative requirements can stimulate innovation towards sustainability (WWF, 2003, CIEL 2013, OECD, 2014) and may provide first mover competitive advantages to the EU industry, where the environment is recognised as a megatrend for the short, medium and long terms.

The European Commission is carrying out a number of ex-post evaluations, including a fitness check of the chemical legislation and the second five-years review of REACH, to be concluded in 2017. In the context of these evaluations, a number of supporting studies have been commissioned by the European Commission. Some of the findings are presented below.

CSES et al (2015) aimed at monitoring the impacts of REACH on competitiveness, innovation and SMEs. This study was centred on the consultation of industry stakeholders through CATI and online surveys, phone and face-to-face interviews. When asked about the impacts of REACH on competitiveness, about two thirds of CATI respondents were of the opinion that REACH did not affect their competiveness against extra-EU companies. Among those that did think there are impacts, opinions varied significantly depending on the position in the supply chain; where chemicals manufacturers reported negative impacts, around 60% of article suppliers reported positive impacts of the REACH Regulation on their competitiveness. In terms of impacts on innovation, the authors of the study concluded that, based on the responses gathered through the surveys, the REACH Regulation has had a certain impact on innovative activity in the chemical industry, giving rise to R&D into substitutes and reformulation, and changes in manufacturing processes, but also affecting the resources allocated to R&D: a third of respondents said they had to reallocate (mostly temporarily) some R&D staff to compliance activity.

While the REACH Regulation encourages companies to invest money in the R&D of safer alternatives and in strengthening the communication between different actors in the supply chain, increasing knowledge on substances characteristics and uses, business opportunities arise when these factors are in combination with favourable conditions, such a supportive business culture, availability of public and private investment funds and resources to dedicate to the optimal management of information.

[19] European Commission (DG Growth), Chemicals. Available at: http://ec.europa.eu/growth/sectors/chemicals/index_en.htm

Large enterprises tend to have more resources to dedicate to information management and, therefore, to be in a better position in terms of identifying potential threats or spotting opportunities, beyond being able to influence the dialogue at the policy-making level. Although there are successful cases of SMEs, with a strong focus on innovation, developing new products in response to regulatory pressure on certain substances, SMEs with consolidated businesses require more attention by regulators. Public funding and the facilitation by the public authorities of the matching between private investors and SMEs through, e.g. substitution research programmes, are therefore recommended and of primary importance.

According to the supporting project on the cumulative costs of the EU environmental and H&S legislation on the chemical industry, the total cost of legislation for the companies operating in the plastics, petrochemicals, soap and detergents, inorganic chemicals, specialty chemicals and agrochemicals subsector amounts to 12% of the value added or 30% of the Gross Operating Surplus (GOS). However, when put into context and compared to the other factors of the competitiveness of the EU chemical industry, regulatory costs do not seem to be among the most important determinants, either positively or negatively. Indeed, in a study commissioned by Cefic, Oxford Economics could not find any consistent international data to allow for robust comparisons to be made on the links between chemicals regulation and international competitiveness (Oxford Economics, 2014).

The OECD (2014) concludes that environmental policies do not affect the overall productivity growth[20]. However, industry stakeholders maintain that the REACH Authorisation mechanism does have an impact on competitiveness and innovation and on investment decisions particularly. Investors need regulatory certainty over the use of substances critical to some industrial processes or applications that might be included in Annex XIV (CSES et al, 2015).

It must be noted that both the European Commission and the European Chemicals Agency are aware of industry concerns and have started to reflect on how to streamline and simplify the Authorisation process for specific areas where the Authorisation requirement might impose a disproportionate administrative burden on operators[21]. Administrative burdens have also been reduced for SMEs and additional measures are being studied and implemented for the REACH 2018 deadline. For example, ECHA is planning to offer IUCLID, the software used to submit the REACH registration dossiers, as a cloud service, from an ECHA-hosted and managed infrastructure. This will save SMEs resources, which will not have to install the software, organise backups and migrate their data in case of new releases. Moreover, it will enable the ECHA to provide integrated support and help functionalities to companies when preparing registration dossiers. It has been estimated that this measure may save over €11 million per year across the industry.

Stakeholders consulted for the assessment of the functioning of the legislative framework governing the risk management of chemicals (excluding REACH) (RPA et al, 2017) have indicated that this has had a positive impact on the functioning of the single market. A harmonised community-wide approach is considered to provide added value (and ensures a more consistent and coherent approach) compared to a regulatory system that operated at the national level. However, some discrepancies are still present at the Member State level:

- Differences across Member States in the acceptance of the use of different methods for the classification of mixtures;
- Differences in the willingness of Member State authorities to support harmonised classification dossiers under the Biocidal Products Regulation and Plant Protection Products Regulation; and
- Differences in approaches to and levels of enforcement, which work against achievement of the

[20] There may be a slow-down of production growth before the introduction of such policies, in anticipation of changes and the preparation of new operating conditions, but this tends to be followed by a rebound, resulting in no cumulative loss.
[21] Announced in the Communication of 18 June 2014 on "Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook".

single market and the establishment of a level playing field for companies.

The existence of platforms such as the Enforcement Forum at the ECHA, or the creation of EU-wide expert groups, such as the chemical expert group on toy safety, are viewed positively across the different stakeholders, as these enable both harmonisation of approaches and the sharing of expertise and resources.

3.2 PROTECTION OF HUMAN HEALTH AND THE ENVIRONMENT

Since the late 1960s, European countries have aimed to harmonise and implement legislation aiming to protect human health and the environment from the exposure to hazardous chemicals, while maintaining the free movement of substances, mixtures and articles and ultimately enhance the competitiveness and innovation of the EU industry.

Amec et al (ongoing) found that the EU chemical legislation avoided significant costs to human health and the environment. Restrictions of certain uses of hazardous substances and the application of binding and indicative occupational exposure limits have resulted in significant reductions in exposure to carcinogens: when considering exposure to a group of 13 carcinogens since 1995, the authors estimate a total number of cancer deaths avoided (now and in the future) that may be in the order of 1.4 million deaths across Europe. The value of the reduction of the exposure to chemicals that may damage the development of children's brains has been estimated to be in the order of €450 billion of avoided damage per year (in terms of higher life earnings potential).

Other chemicals are known to have adverse impacts for reproductive health as well as causing birth defects. It is estimated that the benefit to women's and men's reproductive capability owing to reduced exposure to phthalates is €7 billion and €6.7 billion respectively (from the period between 1996 and 2008) (Amec et al, ongoing). Furthermore, the cost of occupational skin disease which can be attributed to being exposed to chemical substances has been valued at around €2 billion between 2004 and 2013 (RPA et al, 2016).

At present, a topic of significant debate, particularly in Europe, is the impact of endocrine disrupting chemicals (EDCs) on human health. Research shows that exposure to EDCs can cause health effects such as infertility, cancer and birth defects, as well as metabolic disease. The annual societal cost to the EU for obesity and diabetes due to EDCs has been estimated between €8–19 billion (using conservative assumptions) and €18-29 billion (Amec et al, ongoing).

Amec et al (ongoing) reports the costs to the environment due to the emissions of hazardous chemicals as they have been valued in many studies. For example, the utility foregone by bird watchers in the EU, due to a decline in the bird-of-prey population (due to exposure to DDT) has been valued to be in the range of €4-12 million per year. Researchers have also conducted a high-level extrapolation to estimate the benefits across the EU of pesticides regulation, which has been valued as being between €15-50 billion per year. Furthermore, the water treatment costs saved owing to a reduction of pesticides in drinking water equate to €500 million per year across the EU.

Other costs associated with the aquatic environment include the presence of chemicals in water bodies causing declines in bio-populations such as fish and shellfish. There are two costs associated with this: firstly, there is the loss of economic income for the fishing industry and secondly, there is the loss ecological benefit. For example, tributyltin and tributyltin oxide have been linked to negative impacts on shellfish population. Regulation to ban these two chemicals led to the recovery of shellfish populations and an annual increase in revenue for the shellfish industry estimated to be between €4–19 million for the UK. It has also been estimated that the annual ecological benefits of this range from €15 million to €15 billion, a range which reflects the uncertainty surrounding the science of monetising the societal impacts of chemical exposures. Extrapolated across the EU, the estimated benefits would be €158 million-€126 billion per year.

RPA et al (2016) aimed to develop a system of indicators establishing and measuring the links between the action of chemical legislation and the reduction in the impacts on human health and the environment. Indicators were defined at three different levels of objectives (operational, specific and general), measuring the specific actions (deliverables) of the legislative mechanisms, the immediate effects of the legislation on the direct recipients (changes in exposure to chemical substances) and the ultimate consequences of the legislation beyond its direct interaction with recipients (changes in human health and environmental impacts). Although data on the positive impacts of the legislation on human health and the environment are not available EU-wide, biomonitoring data collected in Germany in the last two decades show that the legislation has played an important role in reducing the concentration of chemicals associated with adverse human health and environmental effects in human, animal, plant and soil samples. Moreover, evidence collected in Germany and the UK shows that the chemical legislation has been conducive to a strong reduction in occupational skin diseases and occupational asthma. The systematic collection and harmonisation of statistics on human health and the environment will contribute to a better understanding of the relationship between chemical consumption, chemical exposure, effects on human health and the environment and may, consequently, contribute to the supply and demand of less toxic chemical substances.

RPA et al (2017) aimed to identify and evaluate the impact and consequences of implementing the CLP Regulation and the interface with other related chemicals legislation, including other legislation governing hazard identification and communication and legislation establishing risk management measures linked to CLP. The authors concluded that the CLP Regulation is ensuring a high level of protection for human health and the environment with respect to the hazard classification of substances and mixtures. The Regulation provides the basis for identifying properties of concern, with this information then being used in communications (through safety data sheets and labels) to workers, downstream users and consumers of chemicals, thereby ensuring their safe use. Nevertheless, there are areas where the effectiveness of the legislation may require further consideration:

- Lack of clarity with respect to how some of the bridging principles within CLP as part of the classification of mixtures are to be applied;
- The potential value of including additional criteria into CLP for terrestrial toxicity and immunotoxicity, to improve the quality of the information available on these endpoints could be considered further.

There is a wide consensus among stakeholders that the lack of assessment for combination effects and multiple routes of exposure is an important deficit in ensuring a higher level of protection of human health and the environment, although they acknowledge that more research on the technical capacity to assess these is required. Stakeholders have also highlighted that the delay in determining appropriate criteria for endocrine disrupting chemicals, under some legislation, affects the functioning of the whole legislative framework. Some opportunities to improve hazard communication have also been identified.

In terms of ensuring the protection of human health and the environment, the findings of CSES et al (2015) confirm the conclusions of the 2012 REACH review process; namely, that the Authorisation and Restriction mechanisms are working and are ensuring that risks from Substances of Very High Concern (SVHC) are controlled and that, where suitable alternatives are economically and technically viable, that those substances are being replaced progressively.

Indeed, for around 50% of the 31 substances in Annex XIV[22], no Applications for Authorisation (AfA) have been received by ECHA and the latest application dates have passed. Moreover, some of the 28 applications received so far are so-called "bridging applications", meaning that the applicants are working on phasing out the substance from their processes/products, but need more time to fully

[22] At January 2017.

develop an alternative. On top of this, companies involved in an AfA usually improve their risk management measures to have the strongest arguments for the application.
Moreover, over 50% of the respondents, to the extensive survey launched in the context of the CSES et al (2015) study, reported having improved risk management procedures because of REACH, with another 39% reported having improved the management of environmental emissions and waste. Various studies have concluded that expenditure on occupational safety and health is an investment that "pays off" and calculated the Return on Prevention (ROP) to be 2.2 (Kohstall et al, 2013) or the Benefit-Cost Ratio to be between 1.04 and 2.70 (EC, 2011).

This brief overview of the benefits of the chemical legislation highlights the importance of further refining the current legislative framework, in order to further incentivise the development of safer alternatives to hazardous substances. The following Section explore a range of policy instruments to complement and supplement the action of command-and-control regulation in the chemical area, in particular with regard to their role in incentivising innovation.

4 INSTRUMENTS USED IN ENVIRONMENTAL POLICY

4.1 INTRODUCTION

The central message put forward by Porter and van der Linde (1995) is that "*the environmental-competitiveness debate has been framed incorrectly*"; it is a static view of environmental regulation whereby technology, products, processes and customer needs are fixed. The paradigm explored in this paper is that international competitiveness is dynamic and based on innovation. Previous studies of hundreds of industries worldwide show that those who are the most internationally competitive are those with the capacity to improve and innovate continually. The main argument of the authors is that "*properly designed environmental standards can trigger innovation that may partially or more than fully offset the costs of complying with them*".

An important aspect of environmental legislation is that it can expose resource inefficiencies and potential technological improvements. Regulations that collect and disseminate information such as this can raise corporate awareness and increase efficiency in industry, thereby boosting competitiveness. Regulation can put pressure on companies to change, motivating innovation and progress, while also levelling the playing field so that one company cannot opportunistically gain position by avoiding investments in the environment.

Concepts put forward by Porter and van der Linde that should be considered in the design of environmental regulation include:

1. Maximum opportunity for innovation should be created, leaving the approach to be taken up by industry, rather than to standard-setting authorities;
2. Regulations should foster continuous improvement, not favouring one form;
3. Regulations should leave as little room for uncertainty as possible. Making information available to all is a start;
4. Market incentives should be included, e.g. pollution taxes, tradeable permits.

The findings of the 2014 paper by the OECD on environmental policies and productivity reinforce the conclusions of Porter and van der Linde. The authors suggest that the introduction of more stringent environmental policies have had no negative effect on overall productivity growth. Prior to the introduction of such policies, a country's overall production growth slowed, perhaps due to the anticipation of change and the preparation of new operating conditions. This was followed by a rebound, resulting in no cumulative loss. Those firms that are most productive and technologically advanced saw a temporary boost in production due to their moves to take advantage of new, more environmentally friendly opportunities, resulting in them reaping the rewards of early innovation and creating a favourable market position for themselves.

The key policy message in this OECD paper is that "*more stringent environmental policies, when properly designed, can be introduced to benefit the environment without any loss in productivity*". Policies should be encouraging cleaner technologies and new business models that benefit both the economy and the environment. Governments should continue to design environmental policies with streamlined administrative procedures so as not to create barriers to business. The emphasis should be placed on flexible, market-based instruments such as taxes.

Table 4 proposes a categorisation of policy means that can be used in the context of the 7th EAP to complement the Command and Control policy measures already established in the chemical area (e.g. REACH, CLP, OSH legislation, the WFD and EQSD) and provide further incentives and support to

innovation.[23]

Table 4: Proposed categorisation of policy means

Type	Sub-type	Examples of current use
Economic instruments	Taxes and subsidies	Fertiliser taxation e.g. Denmark, Finland, Norway, Netherlands, Sweden Pesticide taxation e.g. Denmark, Finland, Norway, Sweden Chlorinated solvent taxation e.g. Denmark, Norway
	Payments	Deposit refund schemes for lead acid batteries, USA Payments for ecosystem services for water quality, UK
	Tradable rights	SO2 allowance trading scheme, USA CO2 emissions trading scheme, EU
	Public procurement	Municipal procurement of cleaning products, France Chemicals Action Plans of the cities of Gothenburg and Stockholm Central government sustainable procurement rules, UK
	Liability/insurance	Comprehensive Environmental Response Compensation Act, USA EU Environmental Liability Directive
Co-regulation	Covenants and negotiated agreements	Environmental Covenants, Netherlands Nanomaterials voluntary reporting, UK
Information based instruments	Targeted information provision	Children's health public campaign, Denmark REACHReady, UK
	Registration, labelling and certification	EU Ecolabel The Green Dot, EU Ecocert, global
	Naming and faming/ shaming	Bathing water interactive map, EU E-PRTR interactive map, EU Local Air Quality Network, UK
Civic and self-regulation	Voluntary regulation	Responsible Care, global VinylPlus, EU
	Civic regulation	Eagle Nickel Mine Community Environmental Monitoring Programme, USA Bucket Brigades, Global Community Monitor, USA
	Regulation by professions	Chartered membership of IChemE, global Chartered Environmentalist, UK/global
	Private corporate regulation	Boots Code of Conduct for Ethical Trading, global BASF Supplier Code of Conduct, global
	Self-regulation	ISO14001, global ISO 45001, global
Support and capacity building	Research and knowledge generation	EPA Green Chemistry funding, USA
	Demonstration projects/ knowledge diffusion	Small Business Technology Transfer (STTR) Program, USA Eco-Innovation Program Lighthouse Projects, Denmark National Demonstration Test Catchments Network, UK
	Network building and joint problem solving	European Technology Platform for Sustainable Chemistry (SusChem), EU ResearchGate, global
	Crowd-funded research	Experiment.com, USA Crowdcube, UK

Categories and sub-categories can be added as examples that do not fit the proposed categorisation are identified. The purpose is to maintain consistent definitions and stimulate ideas.

The following Section provides an overview of policy means that have been used to regulate and steer the economic activity in order to protect the environment and minimise the exposure to hazardous substances.

[23] Based on Taylor C., Pollard S., Rocks S., and Angus A., 2012, 'Selecting policy instruments for better environmental regulation: a critique and future research agenda.', Environmental Policy and Governance 22, no. 4.

4.2 ECONOMIC INSTRUMENTS

According to the World Health Organisation, "the common element of all economic instruments is that they effect change or influence behaviour through their impact on market signals"[24]. Economic instruments allow the internalization of externalities and facilitate the implementation of the "Polluters Pays Principle". According to Mazzanti and Zoboli (2005), specific economic instruments based on this principle can influence innovation, when the policies have impact on very complex industrial subsystems. In analyzing the effects of the End-of-Life Vehicles Directive (ELVD), they conclude that in order to generate a desired innovation path, two dimensions need to be considered in applying the incentives:

- Where to apply them in the production-to-waste chain;
- How to apply them, in terms of net cost allocation;

As these two factors will influence the way in which the incentive is transmitted, upward or downward, to other industries. According to Zoboli et al (2000), the ELVD has been a powerful stimulant of innovation in the car and car-related industries and brought forward ten innovative developments:

- Creation of special technical competences in car manufacturing companies;
- Creation of dismantling and recovery/recycling networks (contracted by car companies) with incremental innovation;
- Advances in design for dismantling;
- Advances in design for recycling;
- Adoption of life-cycle strategies;
- Material regime simplification in cars;
- Material competition and substitution;
- Advances in automotive plastic recycling;
- Research and development in innovative recovery technologies for automobile shredding residue, the most problematic element in ELV techniques;
- Co-operative research at the industrial level.

4.2.1 Taxes and subsidies

Taxes and subsidies alter the market prices of goods or services, thereby changing the quantities the market demands and supplies. Examples of taxes and subsidies applied in the context of chemicals policy include:

- **Fertiliser taxation** e.g. in Austria, Denmark, Finland, the Netherlands, Norway and Sweden. Söderholm (2009, p.41) found that these taxes have played a role in reducing fertiliser use, although as price responses have been low this has meant relatively small impacts in terms of quantity reductions. It should be noted that in Sweden, taxation on fertilisers were successfully used to steer farmers towards the adoption of fertilisers with a low content of cadmium.
- **Pesticide taxation** e.g. in Denmark, Finland, Norway and Sweden. Söderholm (2009, p. 48) found that most ex ante analyses of taxes on pesticides show that they can be an effective way of inducing reductions in use, although the design of the tax plays a role in determining the overall policy's effectiveness. For example, Denmark and Norway adopted different taxes according to the toxicity of the different pesticides, incentivising the adoption of lower risk pesticides. In general, the volume of pesticide used has decreased in those countries that have implemented taxes on pesticide use.
- **Chlorinated solvent taxation** in e.g. Denmark and Norway. Söderholm (2009, p. 51) found that the introduction of taxation on some chlorinated solvents has accompanied significant reductions

[24] http://www.who.int/heli/economics/econinstruments/en/

in consumption in Denmark and Norway, although this approach has not been widely adopted elsewhere.

4.2.2 Payments

Payments can be made conditionally to incentivise a particular activity, such as recycling products, or the provision of ecosystem services from an area of managed land. In the case of deposit-refund schemes, a tax on product consumption can be combined with a rebate payment when the product or its packaging is returned for recycling (Walls, 2011). Relevant examples of payments include:

- **Deposit-refund schemes for lead-acid batteries** e.g. in the USA. Walls (2011 p3) reports that 44 states in the USA have some kind of lead-acid battery deposit refund programme, and with widespread adoption the recycling rate has risen to 97%.
- **Payments for Ecosystem Services (PES)**, e.g. in the Fowey Catchment (Cornwall, UK), Defra has carried out a pilot study to test whether PES could be used to enhance water quality[25]. In 2012-13, a "reverse auction" was run, with South West Water as the single buyer. Farmers' bids of environmentally-improving capital investment projects were evaluated on a value-for-money basis.

4.2.3 Tradable rights

Rights (or permits) to emit pollutants (e.g. SO_2) or to consume resources (e.g. water) can be issued by a government, up to a capped total quantity of emissions or consumption. Owners of rights are then allowed to trade, establishing a market that, in theory, could lead to a cost-effective reduction in emissions or distribution of consumption. Relevant examples include:

- **SO_2 Allowance Trading Scheme, USA**: Schmalensee and Stavins (2012) report that this scheme has been seen as innovative and successful since its establishment in 1990, although they also report that recent court decisions and subsequent regulatory responses have led to the collapse of the US SO_2 market.
- **EU Emissions Trading Scheme**: The first and biggest international system for trading greenhouse gas emission allowances, covering more than 11,000 power stations and industrial plants in 31 countries and airlines[26].

4.2.4 Public procurement

Public authorities can seek to procure goods, services and works with a reduced environmental impact throughout their lifecycle when compared to those otherwise procured with the same primary function (EC, 2008).

- **Ville de Venelles, France:** In 2011, Venelles tendered for cleaning products with a reduced impact on human health and the environment for its schools. The tender included several requirements, referring both to eco-labels and other criteria, and asked for samples before awarding the contract. After testing the products under real-life conditions and considering the ideas of the cleaning personnel, a detailed analysis of the offers was done to decide on a supplier (EC, 2012).
- **The UK Department for Environment, Food and Rural Affairs (Defra), UK**, with help from government, industry and other stakeholders, has developed a set of mandatory standards that all UK Government Departments must follow when buying goods and services covered by the standard. The standards cover things like 'energy in use', 'water in use', 'resource efficiency' and

[25] Ecosystems Knowledge Network (no date): Payments for Ecosystem Services – West Country Research Pilot, available at: http://ecosystemsknowledge.net/resources/programmes/pes-pilots/fowey
[26] http://ec.europa.eu/clima/policies/ets/index_en.htm

'use of hazardous materials' (Defra, 2012).

- **Chemicals Action Plan, City of Gothenberg, Sweden[27]:** The purpose of the Chemicals Action Plan is to enable the city to run a professional and systematic approach to chemicals, and in so doing make a major contribution to creating a non-toxic environment. A Chemicals Advisory Board will guide the city's work, ensuring that measures in the plan are carried out, which include 1) administrations and companies document and report on the use of chemical products with mandatory labelling, 2) administration services and companies phase out hazardous substances in chemical products and 3) the Procurement Company, in cooperation with the Chemicals Advisory Board, draws up chemical requirements which must be used during procurement.
- **Chemicals Action Plan, Stockholm, Sweden[28]:** The Chemicals Action Plan presents a vision for the city's chemical strategy: "A non-toxic Stockholm in 2030 – world-class chemicals management". The Chemicals Action Plan presents a total of 43 actions divided into seven activity areas: 1) implementation support, including a Chemicals Centre, 2) information and dialogue, 3) procurement, pursuing the vision that "Articles and chemical products that are used in the City of Stockholm's operations do not contain any substances that pose a risk to humans or the environment", 4) materials for construction, 5) control and supervision, 6) handling of chemicals and 7) monitoring of environmental pollutants.
- **The project NonhazCity** (2016-2019) is financed by the European Regional Development Fund and aims to find innovative management solutions for minimising emissions of hazardous substances from urban areas in the Baltic Sea. Local administrations will be approached in order to develop appropriate strategies to phase out hazardous substances, introducing criteria on hazardous substances into public procurement practices.
- **The Mediterranean Action Plan by UNEP** aims to protect the Mediterranean Sea's marine environment by, among other initiatives, phasing out hazardous chemicals originating from human activities. One of the targets to be met by 2025 is to have the majority of the twenty-one Mediterranean countries committed to green and sustainable public procurement programmes[29].

4.2.5 Liability/insurance

Governments can assign liability for harm to people or the environment to businesses or individuals in law, and may require that they purchase insurance against this liability. Relevant examples include:

- **United States Comprehensive Environmental Response Compensation and Liability Act (CERCLA)**: Mintz (2012) reports that CERCLA has catalysed clean-up activities at many abandoned hazardous waste sites in the US and has provided an incentive for voluntary clean-up of contaminated sites by private entities, but notes challenges to effective enforcement.
- **EU Environmental Liability Directive:** Directive 2004/35/EC established a framework based on the polluter pays principle to prevent and remedy environmental damage. Transposition was completed in 2010. Work to assess effectiveness is ongoing[30].

4.3 CO-REGULATION

The 2003 Interinstitutional Agreement on Better Law-making[31] defines co-regulation as "the mechanism whereby a Community legislative act entrusts the attainment of the objectives defined by the legislative authority to parties which are recognised in the field (such as economic operators, the social partners, non-governmental organisations, or associations)". Under co-regulation therefore the

[27] City of Gothenberg Environment Administration (2014): http://goteborg.se/wps/wcm/connect/e135f577-361b-4b61-849d-ec87b4633ff8/140630-002--800-Kemikalieplanen_Engelska_FINAL.pdf?MOD=AJPERES
[28] Stockholm City Environment and Health Administration (2016): www.stockholm.se/PageFiles/1176228/engmar16webb.pdf
[29] https://wedocs.unep.org/rest/bitstreams/9737/retrieve
[30] http://ec.europa.eu/environment/legal/liability/
[31] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2003.321.01.0001.01.ENG

regulatory role is shared between government and industry, with the latter usually formulating a code of practice in consultation with the government, with breaches of the code sanctioned by industry rather than the government. However, according to OECD (2002), there is substantial risk of anti-competitive activities created by the industry regulators. In order to avoid such activities, the European Commission has developed some principles[32] to be followed in developing and implementing self- and co-regulation initiatives:

- Maximise the number of relevant participants;
- All parties should be involved in designing the actions;
- The objectives need to be clear and unambiguous and include targets and indicators;
- Actions need to be coherent with the EU and national laws;
- The initiatives need to be improved iteratively during the process;
- The initiatives need to be easily monitored by all the parties;
- All participants should be allowed to assess whether the initiative may be concluded, improved or replaced;
- Disputes should be solved in a timely manner;
- The participants should finance the initiative.

Co-regulation instruments have been used in particular to complement and supplement the laws regulating the digital market, but some examples are also present in the environmental area.

4.3.1 Covenants and negotiated agreements

Governments can negotiate agreements with target business sectors to achieve environmental objectives. Relevant examples include:

- **Covenants for environmental policy outcomes, Netherlands**: Bressers et al (2011) report that covenants negotiated by the Dutch government with multiple industry sectors are generally perceived to have been effective, finding that appropriate goal setting, attention to costs and finding ways of keeping focus and agreement among target groups, in addition to governmental pressure (e.g. the threat of regulation), have been key to their success.
- **Voluntary reporting to a nanomaterials observatory, UK**: RPA et al (2014) report that while there have been several voluntary initiatives in different countries to gather information about the nanomaterials market, and its potential associated risks, reporting on a voluntary basis has not achieved satisfactory level of information gathering or participation by industry.

4.4 INFORMATION BASED INSTRUMENTS

According to OECD (2002), information based instruments are the most widely used alternative approach to regulation in OECD member countries. These instruments target information asymmetries and try to empower businesses and citizens to adopt actions or make informed choices. Complete information on the market is key to stimulate innovation and, according to Stewart (2010), is one of the three dimensions that most affect the impact of regulation on innovation, with the other two dimensions being flexibility and stringency.

4.4.1 Targeted information provision

Governments and other stakeholders can provide information (e.g. guidance webpages) to enable businesses and citizens to make better-informed decisions about managing risks to human health or the environment. Relevant examples include:

[32] https://ec.europa.eu/digital-single-market/sites/digital-agenda/files/CoP%20-%20Principles%20for%20better%20self-%20and%20co-regulation.pdf

- **Public information campaigns on minimising risks associated with chemicals, Denmark:** The Danish EPA[33] conducts information campaigns to inform citizens of what they can do to minimise the risks associated with chemicals e.g. being aware of small children's heightened sensibility to endocrine disrupters or teenagers' excessive use of personal care products leading to allergies.
- **REACHReady, UK[34]:** REACHReady is a wholly-owned subsidiary of the Chemicals Industries Association that keeps subscribers informed of regulatory developments (e.g. for REACH, CLP and BPR) and can fulfil users' registration and authorisation needs.

4.4.2 Registration, labelling and certification

Schemes can be established by government or other stakeholders (e.g. industry groups) through which registered businesses label their products to indicate compliance with standards to users' for e.g. materials sourcing or production, or product properties. Relevant examples include:

- **EU Ecolabel, EU**[35]: The EU Ecolabel helps consumers identify products and services that have a reduced environmental impact. Companies can comply voluntarily with associated standards, against which their performance is checked by independent experts.
- **The Green Dot, EU**[36]: The Green Dot on product packaging indicates that a financial contribution has been paid to a qualified national packaging recovery organisation that has been set up in accordance with the principles defined in the European Packaging and Packaging Waste Directive 94/62 and respective national law.
- **Ecocert, Global**[37]: Ecocert is an inspection and certification body specialising in the certification of organic agricultural products, and certifies against technical criteria for a range of goods and services including natural and organic cosmetics, natural cleaning products, and inputs eligible for use in organic farming (fertilisers, phytosanitary products, etc.).
- The **Nordic Ecolabel**[38] and the **Blue Angel**[39] are ecolabels with criteria defined on four dimensions: environment, climate, health and performance. Manufacturers must use samples and documentation to prove that their products meet the criteria. The Nordic Ecolabel is coordinated by the Nordic Council of Ministers while the Blue Angel by The German Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety.
- **Chemical Footprint Project (CFP)**, **Global**[40]: The CFP is a system to measure overall corporate chemicals management developed by the Clean Production Action of the Lowell Center for Sustainable Production (University of Massachusetts) in co-operation with Pure Strategies. It is based on a 20 questions survey that is scored to a maximum of 100 points. The areas addressed are: management strategy (20 points), chemical inventory (30 points), footprint measurement (30 points), public disclosure and verification (20 points). The CFP defines a chemical footprint as the "*total mass of chemicals of concern in products sold by a company, used in its manufacturing operations and by its suppliers, and contained in packaging*".

4.4.3 Naming and faming/shaming

Governments and other stakeholders (e.g. NGOs, trade associations) can publicise environmental performance information of industry sectors, government bodies or individual businesses,

[33] http://eng.mst.dk/topics/chemicals/consumers--consumer-products/information-campaigns/
[34] http://www.reachready.co.uk/about_us.php
[35] http://ec.europa.eu/environment/ecolabel/
[36] http://www.pro-e.org/Green-Dot-General-Remarks.html
[37] http://www.ecocert.com/en
[38] http://www.nordic-ecolabel.org/
[39] https://www.blauer-engel.de
[40] https://www.chemicalfootprint.org/learn/faqs

incentivising better environmental behaviour to enhance or avoid damage to reputation. Relevant examples include:

- **Interactive map of the state of bathing waters, EU**[41]: The EEA maintains an interactive map showing bathing water quality at monitored sites across the EU. Member states are obliged to disseminate information42 on bathing quality to users.
- **Interactive map of E-PRTR facilities, EU**[43]: The EEA maintains an interactive map enabling citizens to find data on pollutant releases and transfers for regulated sites across the EU.
- **London Air Quality Network, UK**[44]: King's College London's Environmental Research Group publish a detailed map of air quality measurements allowing London's citizens to monitor current and average air pollution.

4.5 CIVIC AND SELF-REGULATION

As for co-regulation, self-regulation has been recognized by the OECD as an important instrument to complement and supplement CAC regulation. It can provide greater responsiveness and flexibility than CAC regulation but needs to adhere to the principles established by the Commission in order to avoid collusive behaviours.

4.5.1 Voluntary regulation

Groups of businesses, and potentially other stakeholders such as trade associations, NGOs and civil society groups, can agree on standards or objectives beyond those required by law to which businesses can voluntarily commit. With direct government involvement, voluntary regulation becomes a form of co-regulation. Relevant examples include:

- **Responsible Care, global**[45]: Commits participating companies, national chemical industry associations and their partners, to: continuously improve to avoid harm to people and the environment, efficient resource use, open performance reporting, consult with people, cooperate in the improvement of regulations and help and advice their supply chains.
- **VinylPlus, Voluntary Commitment of the PVC Industry**[46]**, EU**: The voluntary commitment of the European PVC industry, that sets objectives for controlled-loop management, organochlorine emissions, sustainable additives, sustainable energy use and sustainability awareness.

4.5.2 Civic regulation and monitoring

Local community groups, or other stakeholder groups such as environmental NGOs, can agree performance standards with particular firms, and may undertake monitoring of firm performance. Relevant examples include:

- **Eagle Nickel Mine Community Environmental Monitoring Programme, USA**[47]: Lundin Mining has established an independent environmental monitoring programme through an agreement with two local community groups. Monitoring results are shared with the public, and public forums enable stakeholders to propose additional monitoring.

[41] http://www.eea.europa.eu/themes/water/interactive/bathing/state-of-bathing-waters
[42] http://ec.europa.eu/environment/water/water-bathing/signs.htm
[43] http://prtr.ec.europa.eu/#/home
[44] http://www.londonair.org.uk/LondonAir/Default.aspx
[45] http://www.cefic.org/Responsible-Care/
[46] http://www.vinylplus.eu/resources/publications/voluntary-commitment-2
[47] http://eaglemine.com/approach/community/community-environmental-monitoring-program/ , http://swpcemp.org/about-us/

- **Bucket Brigades, Global Community Monitor, USA**[48]: In the mid-1990s Attorney Ed Masrey, who hired the now-famous Erin Brokovich, commissioned the design of a low cost device that communities could use to monitor air quality near industrial plants, which became known as a "bucket". Community groups using the bucket ("Bucket Brigades") have been active in 27 countries and reportedly have a proven track record of effectiveness in "forcing polluters and agencies to clean up their acts".
- **CITI-SENSE**[49] is a collaborative project co-funded by the European Union's Seventh Framework Programme with the aim of developing tools to involve citizens and local communities in the monitoring of air pollution. Among the most widely used tools, there are a personal air monitoring toolkit and web-pages and apps to visualise and download data.

Conrad and Hilchey[50] (2011) reviewed 10 years of literature on Community Based Monitoring, finding societal benefits of the approach to include the creation of environmental democracy and social capital, increased scientific literacy and inclusion in local issues, and time and money saving benefits to government.

4.5.3 Regulation by professions

Professional bodies can require that members attain certain skills or experience as conditions of membership, increasing the capability of those working in a given sector. Relevant examples include:

- **Chartered Membership of IChemE, global**[51]: The MIChemE qualification is awarded to individuals who have been assessed by the Institute of Chemical Engineers to have necessary knowledge and understanding and professional experience in chemical, biochemical, process and related areas of engineering across industry and academia.
- **Chartered Environmentalist, SocEnv, UK/global**[52]: The Society for the Environment awards CEnv status to professionals who have demonstrated a required level of knowledge and experience.

4.5.4 Private corporate regulation

Individual companies may define standards with which their suppliers are required to comply as part of their terms of business, which may propagate these standards along supply chains and internationally. Relevant examples include:

- **Boots Code of Conduct for Ethical Trading, global**[53]: Boots uses an in-house supplier assessment team and approved external suppliers to assess every Boots brand and exclusive product supplier against the Boots Code of Conduct for Ethical Trading, which includes environmental and health and safety commitments.
- **BASF Supplier Code of Conduct**[54]**:** BASF has defined environmental, social and corporate governance standards which they expect their suppliers to enact.

[48] http://www.gcmonitor.org/communities/start-a-bucket-brigade/history-of-the-bucket-brigade/
[49] http://cordis.europa.eu/result/rcn/175088_en.html
[50] Cathy Conrad and Krista G. Hilchey, 2011, 'A review of citizen science and community-based environmental monitoring: issues and opportunities', Environmental monitoring and assessment 176.
[51] http://www.icheme.org/membership/member.aspx
[52] http://www.socenv.org.uk/cenv/about-cenv/
[53] http://www.boots-uk.com/corporate_social_responsibility/marketplace/sustainable-supply-chains.aspx , http://www.boots-uk.com/Corporate_Social_Responsibility/media/App_Media/BUKCSR2013/Home/pdf/Boots_Code_of_Conduct_for_Ethical_Trading.pdf
[54] https://www.basf.com/en/company/about-us/suppliers-and-partners/download-center.html

4.5.5 Self-regulation

Businesses may independently adopt standards e.g. for environmental risk management or occupational health and safety, which may be externally verified. Relevant examples include:

- **ISO14001, global**[55]: Sets out criteria for an environmental management system against which certification can be assessed. There are more than 300,000 certifications in 171 countries.
- **ISO 45001, global**[56]**:** Currently under development, ISO 45001 will set out a framework for occupational health and safety at work. It will follow the same generic management system approaches such as ISO 14001.

4.6 SUPPORT AND CAPACITY BUILDING

The direct funding of research and actions aimed at the creation of business networks, stakeholders collaboration and shared knowledge platforms are the initiatives that the highest impact have on innovation (EC, 2015; Frontier Economics, 2014).

4.6.1 Research and knowledge generation

Governments and other actors can fund or undertake research to increase knowledge, to develop new substances, products or processes for example, or to increase understanding of health or environmental impacts of human activity. Relevant examples include:

- **EPA Green Chemistry Funding, USA**[57]: The US Environmental Protection Agency provides funding to academic researchers and small businesses for green chemistry, including through Science To Achieve Results (STAR) research grants.

4.6.2 Demonstration projects/knowledge diffusion

Governments and other actors can fund projects to demonstrate feasibility and raise awareness of new technologies or processes, which may help to create commercially viable business models:

- **Small Business Technology Transfer (STTR) Program, USA**[58]: The STTR aims to stimulate technological innovation, foster technology transfer through cooperative research and development between small businesses and research institutions, and increase private sector commercialisation of innovations derived from federal R&D.
- **Eco-Innovation Program Lighthouse Projects, Denmark**[59]: The Danish Ministry of Environment and Food has provided funding to support pioneering projects to test at full scale promising technologies in biorefining, water treatment, vehicle emissions reduction and built environment.
- **National Demonstration Test Catchments Network, UK**[60]**:** is a UK government-funded project designed to provide robust evidence on how diffuse pollution from agriculture can be cost-effectively controlled to improve and maintain water quality in rural river catchment areas.
- The **LIFE Programme** funded and keeps funding several chemicals related projects[61] aiming to demonstrate the feasibility of new technologies and increase awareness over the availability and efficiency of new approaches. An example is **LIFE REWATCH**, a demonstration project of an

[55] http://www.iso.org/iso/iso14000
[56] http://www.iso.org/iso/iso45001
[57] http://www.epa.gov/greenchemistry/funding-green-chemistry
[58] https://www.sbir.gov/about/about-sttr
[59] http://eng.ecoinnovation.dk/the-danish-eco-innovation-program/light-house-projects/
[60] http://www.demonstratingcatchmentmanagement.net/
[61] http://ec.europa.eu/environment/life/project/Projects/index.cfm?fuseaction=home.getProjects&themeID=27&projectList

innovative recycling scheme to increase the water efficiency in the petrochemical industry.

4.6.3 Network building and joint problem solving

Stakeholders including government can establish initiatives to help people exchange ideas and work together to solve problems, for example in the field of sustainable chemistry. Relevant examples include:

- **European Technology Platform for Sustainable Chemistry (SusChem), EU**[62]: SusChem is the European Technology Platform[63] (ETP) for sustainable chemistry. It is an industry-led stakeholder organisation that develops long-term research and innovation agendas, and holds stakeholder meetings and brokerage events to increase collaboration between parties in the chemicals industry value chain.
- **ResearchGate, global**[64]**:** Founded in 2008, ResearchGate is a social networking site for scientists and researchers to share papers, ask and answer questions and to find collaborators.

4.6.4 Crowd-funded research

Research teams can raise money to fund their research through "crowd-funding" typically small contributions from a large number of contributors. Relevant examples include:

- **Experiment.com, USA**[65]: A for-profit company that allows members of the public to donate funding to researchers who have submitted funding requests, and charges an 8% platform processing fee on projects that successfully meet their funding target.
- **Crowdcube, UK**[66]: Provides a platform through which members of the public can invest in business ideas, as equity or mini-bonds.

[62] http://www.suschem.org/
[63] http://ec.europa.eu/research/innovation-union/index_en.cfm?pg=etp#whatare
[64] https://www.researchgate.net/
[65] https://experiment.com/discover/chemistry
[66] https://www.crowdcube.com/how-crowdcube-works

5 AVAILABLE TOOLS TO ADDRESS GAPS AND DEFICITS

5.1 GAPS AND DEFICITS

The following gaps and deficits have been identified on the basis of the literature review, of the issues highlighted during the NTE workshop and of the results of the online surveys (it should be noted that different stakeholder groups have diverging opinions; what is regarded as a deficit by one stakeholder group, may be considered an incentive by another stakeholder group):

1. Unsatisfactory synergies between chemical policies;
2. Lack of (eco)toxicological information for low volume production substances;
3. Lack of information on chemicals in articles;
4. Relatively high administrative burden of EU legislation (especially on SMEs), causing the diversion of resources from innovation;
5. Lack of appropriate and strategic use of EU funding in supporting transformative technologies with strong innovative potential and added value for manufactured products and services;
6. Funding available for innovation projects does not meet the ambition of industrial scale projects, mainly due to scattering of support over calls and topics across a large range;
7. Lack of support or encouragement for co-operation within and/or between sectors (e.g. between large businesses and SMEs; between industry and academia);
8. Insufficient capacity to attract foreign investment to enable innovation;
9. Inadequacy of the academic curricula: most of the chemistry curricula across universities in Europe provide for limited training in toxicology and ecotoxicology and only few universities offer courses on green chemistry;
10. Contradictory regulatory signals to investments in innovation.

5.2 REASONS FOR GAPS AND DEFICITS

Some of the gaps and deficits listed above have also been identified in the other sub-studies. Others refer to the wider context of innovation in the EU.

Although substances manufactured or imported in quantities between one tonne and one hundred tonnes per year per manufacturer or per importer will have to be registered by June 2018, the information requirements for these low-volume substances do not cover all end-points. Moreover, substances manufactured or imported in quantities below one tonne per year do not have to comply with any registration information requirements. The lack of information on the uses and presence of hazardous chemicals in articles prevents informed choices and affects the efficiency of any prioritisation strategy for the purposes of substitution by downstream users.

These gaps in information contribute in the imperfect synergies between the different chemical legislative acts, with the ultimate effect of a limited or inefficient internalisation of human health and environmental costs by the chemical or product manufacturers. For example, chemicals regulated by both the REACH Regulation and the Water Framework Directive may leak from products during their life cycle or during the waste stage. However, the costs to clean up such pollution is borne by the wastewater treatment companies and drinking water suppliers and, ultimately, by the citizens.

The imperfect synergies between the different chemical legislative acts may impact also on innovation, with companies, especially SMEs, having to divert resources from research and development to regulatory compliance activities.

The lack of a legislative framework that clearly reward sustainable choices aiming to develop a non-toxic environment, such as the substitution of hazardous chemicals, and that penalise instead non-

sustainable practices, may undermine the confidence of industry stakeholders to invest in green innovation. During the workshop, some stakeholders indicated that the granting of authorisation for the uses of substances in applications, for which safer alternatives were available, is a regulatory signal that may stifle, rather than reward, innovation. Others pointed to the inability of regulation in dealing with cases of regrettable substitution, where substances are substituted with other substances with similar hazard properties or of equal concern.

The European framework to support innovation may benefit from enhanced co-operation between geographical areas and sectors. Many downstream users would like to manufacture and put safer products not containing hazardous substances on the market, but they face two major problems:

- Lack of communication with their chemical providers;
- Lack of adequate expertise and the inability in finding alternative providers of sustainable alternatives.

Moreover, SMEs willing to engage in green innovation may lack the adequate market power to require safer substances to their chemical providers or may lack the resources to find and switch to an alternative provider.

Another aspect that can have important impacts on the competitiveness of European businesses and on their capacity to innovate is the way trade is regulated with EU partnering countries. Free trade agreements (FTAs) are essential for maintaining the competitiveness of the European industry. The inclusion of environmental standards in the FTAs between the EU and third countries first happened in 1999, with the signing of the EU-South Africa Trade, Development and Co-operation Agreement. This was the first deal providing for a separate article on the environment. However, its provisions were not legally binding and did not envisioned penalties. This approach drastically changed with the new generation of FTAs, including chapters with legally binding provisions on sustainable development. The EU currently prefers a soft approach to the enforcement of environmental standards. Their effectiveness in ensuring a high protection of the environment and of the civil society in third countries and in guaranteeing that the strict environment standards imposed on EU businesses cannot be played down by businesses in the partnering countries cannot be fully established and should be subject to closer scrutiny, in particular with regard to the chemical policy.[67]

5.3 POSSIBLE RESPONSES

The gaps and deficits have been identified by Member States competent authorities, ECHA, the European Commission and other stakeholders. These have also suggested possible measures to address these problems. The catalogue of identified responses, presented below, is a comprehensive inventory of all possible measures identified during the study. Further assessment will be needed in the context of the better regulation agenda, should any of the activities in the catalogue be considered by the Commission.

Through a literature review and stakeholders' consultation, we identified the following possible responses, presented by type of instrument:

Strengthening and streamlining existing legislation:

1. Increase information requirements for low production volume substances;
2. Impose an automatic restriction on imported articles containing authorised substances;
3. Extend the available time to identify and move to sustainable alternatives;

[67] https://www.wto.org/english/tratop_e/envir_e/envir_req_e.htm and http://governanceinnovation.org/wordpress/wp-content/uploads/2015/11/PB_Postnikov_final.pdf

4. Shorten product safety assessment processes by public authorities (e.g. product approval for aviation or medical devices);
5. Refuse authorisations for the use of Annex XIV substances for which alternatives are available on the market;
6. Co-ordinate substitution initiatives across member states around prioritised chemicals of concern;
7. When regulating a substance, consider systematically the application of grouping strategies;
8. Further reduce the administrative burden for SMEs (e.g. more time to comply with the legislation, lower fees);
9. Improve access to markets through trade agreements to facilitate investment opportunities, but balance the rights of corporations with the protection of human health and the environment;
10. Improving intellectual property rights protection;

Economic instruments:

11. Reward/incentivise sustainable substitution (e.g. VAT reduction);
12. Promote taxation of hazardous substances among Member States;
13. Enhance government green procurement programmes, considering the functional substitution of hazardous chemicals.

Information based instruments:

14. Develop an EU-level substance-regulation navigator, including implemented and upcoming international and national legislation by substance/application;
15. Develop tools to track hazardous chemicals in articles;
16. Enhance the available databases with information on alternatives;

Support and capacity building:

17. Fund further research into chemical product life cycle risk assessment;
18. Raise awareness on the benefits of – and to stimulate market demand for - safer alternatives;
19. Enhance supply chain collaboration and engagement through, e.g. shared performance testing and evaluation and the creation of demonstration sites;
20. Promote circular economy business models (e.g. chemical leasing);
21. Develop ECHA and Member State Competent Authorities' capacity to support substitution;
22. Facilitate public-private investment partnerships to support research into safer alternatives and for the provision of technical support to SMEs, on technical feasibility of alternatives in particular;
23. Create an expert knowledge platform to support authorities and industry with substitution initiatives;
24. Raise awareness about functional substitution (rather than chemical-by-chemical substitution);
25. Create a system for consistent definitions, classification and characterisation of functions of chemicals;
26. Encourage the design of chemical alternatives in accordance with the green chemistry principles by creating academic curricula and by funding green chemistry;
27. Develop rapid and efficient (high-throughput) quantitative screening tools combining hazard, exposure and, possibly, life cycle impacts to avoid burden shifting and regrettable substitution;
28. Develop and encourage the adoption of environmental labelling communicating the chemical safety performance to customers/consumers;
29. In the NTE strategy, discuss how Key Enabling Technologies may provide support to solving the challenges and to achieve the desired objectives;
30. Improving access to markets through trade agreements to facilitate investment opportunities;
31. Investing in KETs-related skills in Europe e.g. through partnerships between industry and education providers;

Enforcement:

32. Dedicate more resources to enforcement of every aspect of the chemical legislation;

Monitoring:

33. Encourage initiatives such as the chemical footprint project;
34. Enhance chemical monitoring programmes.

5.4 INTERVENTION INSTRUMENTS

For each gap, one or more responses have been identified. Some of these responses may address several gaps and deficits, others would need to be combined in order to effectively fill the gap. Some of these measures may be implemented in the short (1 or 2 years) or medium term (3 to 5 years), while others would need a longer time span (over 5 years) because it would likely involve new legislation or amendments to the current legislative framework.

Table 5 (at the end of section 6) qualifies and discusses each idea in brief.

6 CONCLUSIONS

Through the review of literature, the discussions over the issues highlighted at the NTE workshop and the results of the online survey, certain gaps and deficits have been identified in the context of innovation and competitiveness in the EU chemicals industry. Some of the issues are linked to innovation and competitiveness directly, such as the high administrative burden of the regulation for SMEs, which is diverting their resources away from innovation.

Several suggestions have been received from the stakeholders on how to address the issues associated with innovation and competitiveness. With regard to possible amendments of the existing legislation (strengthening and streamlining), suggestions go from increasing the information requirements for low production volume substances to granting more time to SMEs to comply with the legislation. The increase in information requirement would benefit the research of safer alternatives; however, SMEs are already struggling with the high costs associated with testing the substances and/or the purchase of letters of access, in particular those SMEs with a high number of substances of low production volume in their portfolio (e.g. dyes, essential oils). Additional time would allow for better planning within each company and for more and better collaboration within the consortia for registering substances. Some stakeholders also suggested extending the available time to identify and move to sustainable alternatives, as there are groups of chemicals for which finding safer alternatives with similar performances is problematic and requires considerable amounts of resources (e.g. perfluorinated chemicals). The co-ordination of the international and national initiatives around the theme of substitution of hazardous substances would guarantee a better use of the resources, in particular around the prioritized chemicals of concern. Moreover, regulatory action when possible should be on chemical groups of concern, in order to avoid regrettable substitutions.

When negotiating trade agreements, the European Union should ensure that the strict environment standards imposed on EU businesses cannot be played down by businesses in the partnering countries, as a major concern among European businesses is that articles manufactured in extra-EU countries and exported to the EU do not have to pass the same level of scrutiny of articles produced in EU countries.

Economic instruments are powerful tools to stimulate innovation through their impact on market signals. Taxes have been successfully used in Scandinavian countries to incentivize the adoption of less hazardous pesticides and innovative approaches to pesticides use and management. The European Commission should encourage the discussion among Member States authorities on the opportunity of imposing taxes over the production and/or consumption of hazardous substances. Public procurement is another economic instrument that can be used in support of innovation, but procurers should avoid favouring low cost solutions versus new technologies and solutions that may bring longer-term benefits. This may happen because procurers are not aware of the existence of new and better solutions. The creation of a platform to foster dialogue between innovative solutions providers and procurers, as well as the linkage between public procurement and public policy objectives (such as the development of a non-toxic environment), may prevent these short-comings. Such a platform should be implemented at European level, in order to avoid the fragmentation of the demand into too small individual procurements that would not provide adequate incentives for companies to develop innovation. In this process, it is important to pay particular attention to the barriers that SMEs, often creators of innovative solutions, face when participating in public procurement tenders.

The provision of funding and technical support to companies, in particular SMEs, through the establishment of public-private long-term investment partnerships for the development of innovative green products and services (e.g. via the LIFE program) and the commitment of purchasing those solutions by the procurers may facilitate the invention of new approaches to solving the environmental and public health problems related to the use of chemical substances. Enhanced supply chain collaboration and engagement through, e.g. shared performance testing and evaluation of safer alternatives and the creation of demonstration sites, may also be beneficial to the efficient use of

public and private resources.

Other information based instruments that may greatly contribute to the strategy for a non-toxic environment are, for example, public awareness campaigns on the risks of hazardous substances in products, such as the ones carried out in Denmark. A complementary instrument is the development of environmental labelling communicating the chemical safety performance of products to consumers. These tools would stimulate market demand for safer alternatives. In addition, the European Commission may flank UNIDO and the governments of Austria, Germany and Switzerland in the promotion of the chemical leasing business model, which has proved to support companies in achieving great economic and environmental gains.

At the same time of offering resources to the private sector and of increasing awareness among consumers, the competences of the public authorities should also be developed, so to enhance their capacity to support the assessment of alternatives and their awareness of the concept of functional substitution. A possible initiative could be the creation of an expert knowledge platform within the remit of ECHA.

Some stakeholders referred that academic curricula are inadequate to provide the right skills required for the development of green solutions, as chemists and chemical engineers have limited training in toxicology. The Commission may promote the inclusion of green chemistry in the traditional chemistry curriculum.

More funding is needed on the research of rapid and efficient (high-throughput) quantitative screening tools combining hazard, exposure and, possibly, life cycle impacts to avoid burden shifting and cases of regrettable substitutions. More resources are also needed for the enforcement of the current chemical legislation, as companies, in order to commit to innovation investments, need to be sure that their market is protected from the unfair competition of cheaper, but less safe, products.

More in general, the Commission should consider how the Key Enabling Technologies and the policies for their promotion can be linked to the objectives of the strategy for a non-toxic environment.

Table 5: Responses identified

Gap / Deficit	Reason for Gap/Deficit	Identified Responses	Qualification	Discussion
Unsatisfactory synergies between chemical policies	Complex legislative framework	e.12. Promote taxation of hazardous substances among member states	Short-medium term Economic instruments	The promotion of substitution would eliminate the problems at the source rather than requiring end-of-pipe controls by different sectorial legislation.
		e.06. Co-ordinate substitution initiatives across member states around prioritised chemicals of concern	Short-medium term Streamlining legislation	
		e.07. When regulating a substance, consider systematically the application of grouping strategies	Short term Streamlining legislation	
Gaps in (eco)toxicological, bioaccumulation and environmental degradation information	Limited information requirements Inadequate quality of the registration dossiers submitted	e.01. Increase information requirements for low production volume substances	Medium term Strengthening of existing legislation	Low production volume substances may prove to be a good pool of potential alternatives and the availability of information would enable robust comparative risk analyses.
		e.26. Encourage the design of chemical alternatives in accordance of the green chemistry principles by creating academia curricula and funding green chemistry;	Medium-long term Support and capacity building	
Information gaps on chemicals in articles	Lack of reporting requirements for information on the toxic content of substances in materials and articles to authorities and in the supply chains, information on functionalities of substances in materials is regarded as confidential. Lack of structured and accessible information on	e.15. Develop tools to track hazardous chemicals in articles	Short-medium term Information based instrument	This would increase the availability of information to all actors, allowing for better risk assessment and management, better prioritisation of regulatory activities and may encourage substitution. The creation of a market demand would generate a bottom-up pressure on chemicals manufacturers to communicate the presence of hazardous substances in articles.
		e.33. Encourage initiatives such as the chemical footprint project	Medium term Co-regulation	
		e.18. Raise awareness on the benefits of – and stimulate market demand for - safer alternatives	Short-medium term Information based instrument	

Gap / Deficit	Reason for Gap/Deficit	Identified Responses	Qualification	Discussion
	toxic substances in materials and articles.	e.24. Raise awareness over functional substitution (rather than chemical-by-chemical substitution);	Short-medium term Support and capacity building	
		e. 25. Create a system for consistent definitions, classification and characterisation of functions of chemicals	Short-medium term Support and capacity building	
Administrative burden	Complex legislative requirements	e.08. Reduce the administrative burden for SMEs (e.g. more time to comply with the legislation, lower fees)	Medium term Streamlining legislation	Apart from a direct support by, for example, further lower fees for SMEs, all other initiatives would contribute in easing the administrative burden. More efficient grouping of substances would help in saving companies' resources.
		e.27. Develop rapid and efficient (high-throughput) quantitative screening tools combining hazard, exposure and, possibly, life cycle impacts to avoid burden shifting and regrettable substitution	Medium term Support and capacity building	
		e.22. Facilitate public-private investment partnerships for supporting research into safer alternatives and for the provision of technical support to SMEs, in particular on technical feasibility of alternatives	Short-medium term Support and capacity building	
		e.14. Develop an EU-level substance-regulation navigator, including implemented and upcoming international and national legislation by substance/application;	Medium term Information-based instruments Short-medium term Support and capacity building	
		e.15. Develop tools to track		

Gap / Deficit	Reason for Gap/Deficit	Identified Responses	Qualification	Discussion
		hazardous chemicals in articles;		
		e.16. Enhance the available databases with information on alternatives		
		e.17. Fund further research into chemical product life cycle risk assessment		
		e.19. Enhance supply chain collaboration and engagement through, e.g. shared performance testing and evaluation and the creation of demonstration sites;		
Lack of appropriate and strategic use of EU funding in supporting transformative technologies with strong innovative potential and added value for manufactured products and services		e.31. Investing in KETs-related skills in Europe e.g. through partnerships between industry and education providers	Medium-long term Economic instruments Support and capacity building	It is fundamental to develop high-skilled workforce and to discuss the suitability of KETs in supporting the development of the strategy for the NTE
		e.22. Facilitate public-private investment partnerships for supporting research into safer alternatives and for the provision of technical support to SMEs, in particular on technical feasibility of alternatives		
Funding available for innovation projects does not meet the ambition of industrial scale projects, mainly due to scattering of support over calls and topics across a large range		e.22. Facilitate public-private investment partnerships for supporting research into safer alternatives and for the provision of technical support to SMEs, in particular on technical feasibility of alternatives	Medium term Support and capacity building Long term Economic instruments	Trade deals and financial partnerships are crucial to the development of ambitious projects. However, it is important that the protection of human health and the environment are not used as negotiable elements
		e.30. Improving access to markets through trade agreements to facilitate		

Gap / Deficit	Reason for Gap/Deficit	Identified Responses	Qualification	Discussion
		investment opportunities		
Lack of support or encouragement for co-operation within and/or between sectors (e.g. between large businesses and SMEs; between industry and academia)		e.06. Co-ordinate substitution initiatives across member states around prioritised chemicals of concern	Medium term Strengthening and streamlining existing legislation	The co-ordination of resources dedicated to substitution and the provision of support in establishing collaboration is functional to the engagement of companies, especially SMEs
		e.23. Create an expert knowledge platform to support authorities and industry with substitution initiatives;	Medium term Support and capacity building	
		e.20. Promote circular economy business models (e.g. chemical leasing);	Short-medium term Support and capacity building	
Insufficient capacity to attract foreign investment to enable innovation		e.31. Investing in KETs-related skills in Europe e.g. through partnerships between industry and education providers	Medium-long term Economic instruments Support and capacity building	Higher protection of innovation and a high skilled workforce are prerequisite for the attraction of foreign investment.
		e.22. Facilitate public-private investment partnerships for supporting research into safer alternatives and for the provision of technical support to SMEs, in particular on technical feasibility of alternatives		
		e.10. Improving intellectual property rights protection	Strengthening and streamlining existing legislation	
Lack of skilled European workforce		e.31. Investing in KETs-related skills in Europe e.g. through partnerships between industry and education providers	Medium-long term Economic instruments Support and capacity building	Co-operation between companies and academia is key for the engagement of young people in science and engineering.
Regulatory signals to investments in innovation		e.02. Impose an automatic restriction on imported articles containing authorised	Short-medium term	These initiatives would help manufacturers in developing alternatives and downstream users in

Gap / Deficit	Reason for Gap/Deficit	Identified Responses	Qualification	Discussion
		substances	Information based instrument Short-medium term Information based instrument Short-medium term Support and capacity building	searching for alternatives.
		e.03. Extend the available time to identify and move to sustainable alternatives;		
		e.04. Shorten product safety assessment processes by public authorities (e.g. product approval for aviation or medical devices);		
		e.05. Refuse authorisations for the use of Annex XIV substances for which alternatives are available on the market;		
		e.11. Reward/incentivise sustainable substitution (e.g. VAT reduction);	Short-medium term Economic instruments	
		e.12. Promote taxation of hazardous substances among member states		
		13. Enhance government green procurement programmes, considering the functional substitution of hazardous chemicals.		

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European Commission

Study for the strategy for a non-toxic environment of the 7th EAP

Sub-study f: Programme on new,

non-/less toxic substances

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August 2017

This sub-study report has been prepared by Antonia Reihlen of Ökopol.

The views expressed herein are those of the consultants alone and do not necessarily represent the official views of the European Commission.

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ABSTRACT

This sub-study analyses the needs and options to foster the development of new, non-/less toxic substances. It includes an assessment of existing policy programmes, including R&D funding, supporting green or sustainable substance development and an analysis of related barriers and drivers.

The analysis of existing activities shows that no programmes specifically supporting the development of new, non-/less toxic substances exist, albeit the US EPA and individual Member States carry out individual activities, however with a broader scope, i.e. fostering sustainable use of chemicals.

The main barriers to substance development identified are: lack of contacts between supply and demand, confidentiality, time to market and resource needs, general resistance to change and fear of change-over costs, complexity of supply chains and a lack of research funding. The main drivers identified are legal pressure and consumer demands, as well as competitiveness (new functionalities, less toxic solutions).

An EU programme specifically addressing the development of new, non-/less toxic substances would support the implementation of the Non-Toxic Environment Strategy by increasing the supply of alternatives for the use of toxic substances. Support actions of the programme should consist of integrating the 'Non-toxics issue' into all EU policies, including in R&D funding instruments, providing opportunities for stakeholders to make contacts and overcome supply-chain barriers, supporting education and training at all levels of the supply chain and in universities, as well as general awareness raising on the benefits of less toxic substances. Any (additional) actions supporting substitution would also drive new, non-/less toxic substances development.

EXECUTIVE SUMMARY

This sub-study analyses the needs to implement, at the Commission level, a specific 'Programme on the development of new, non-/less toxic substances' (EU Programme) that should support the provision of alternatives to the use of toxic substances, thereby contributing to achieving a non-toxic environment.

The report identifies current barriers and disincentives to the production and use of new, non-/less toxic substances from literature review and stakeholder discussions, which the potential EU Programme should help to overcome. The EU Programme is understood as a broader set of measures improving the overall conditions for new, non-/less toxic substances development. Therefore, the analysis of and needs for support identified are not limited to funding activities but include various aspects. The sub-study closely relates to the sub-study on substitution and the sub-study on innovation and competitiveness that form part of the project report, too.

A potential EU Programme should generally strengthen the supply of substances with (more) favourable properties for human health and the environment than those they should replace. This includes properties that enable safe and efficient recycling, while meeting the technical needs of the users.

Non-toxic or less toxic substances can be regarded as a sub-set of 'green chemicals' and 'sustainable chemicals'. While the concept of green chemicals also addresses, among others, resource efficiency and optimizing chemical synthesis in addition to the reduction of (eco-)toxicity, the concept of sustainable chemicals additionally includes social and economic aspects of chemicals production and use.

The assessment of existing programmes supporting new, non-/less toxic substance development includes programmes that address green and sustainable chemistry. This acknowledges the fact that many industry actors already take an integrated perspective to substance and product development, i.e. use sustainability indicators or criteria to guide their business decisions.

In order to structure the identification of needs to support the process of new, non-/less toxic substance development, three distinct steps in this innovation process are identified as posing specific challenges, which would not exist or to a lower extent for the use of existing alternatives in substitution. These are:

- identification of technical requirements to new, non-/less toxic substances (application, end-of-life properties, specific technical functionality) and of business /research partners
- identification of future legal requirements or certification needs potentially guiding the substance design and
- actual substance (*in-silico*) design process, which should take account of the legal and technical demands and requirements as well as avoiding toxicity of the new substance.

No existing programmes that specifically support the development of new, non-/less toxic substances could be identified. However, several programmes and initiatives exist, in the United States in particular, to foster the use of green or sustainable chemistry, among others by supporting substitution in general. Some EU Member States implement related activities. The lack of strong programmes supporting new, non-/less substances development can be explained by the fact that publicly funded research is increasingly organised to fulfil societal (sustainability) needs and hence addresses larger contexts and research clusters. Consequently, rather than supporting specific substance development as such, existing programmes embed these activities into larger research and innovation areas.

Several stakeholder networks exist which, among others, work on the (improvement of the conditions for) innovation via the development of new, non-/less toxic substances. One example is the Green

Chemistry and Commerce Council, a US-based network of academics, companies and legislators, which, among others, has outlined a strategy to promote green chemistry in general. At the EU level, the platform 'SusChem' is a prominent example of such networks, which has sub-organisations in different Member States.
From the literature review and stakeholder discussions, barriers to the R&D of new, non-/less toxic substances were identified, which cannot, however, be prioritised with regards to their relevance, due to lack of substantiating data on the actual impacts on R&D. Furthermore, most literature addresses barriers to substitution without differentiating whether and how they (also) relate to substitution with new substances rather than existing ones.

The main barriers identified, which are regarded as being relevant for the R&D process on new, non-/less toxic substances can be summarized as follows:

- conflicts from increased transparency needs of users and the protection of confidential business information;
- researchers of new substances do not know the needs (companies in demand, types of substances and applications);
- companies wanting to use a new, non-/less toxic substance have difficulties identifying a partner to conduct the development work with;
- research and development of new substances needs time;
- administrative and financial burdens as well as registration process of new substances (in competition to existing ones)
- the need for new infrastructure for the design and production;
- fear of hidden costs and resource needs for changes to new products;
- fragmented demands due to complexities of the supply chains;
- general resistance to change;
- different messages from policy, science, supply chain, etc.;
- difficulties in expressing benefits in terms of cost savings due to quantification and focus on prices rather than costs;
- lack of funding;
- lack of trained and well- educated workforce.

Feedback from the stakeholder workshop, conducted in the context of this project, mainly support these findings from the literature. No ranking of relevance of these aspects was possible. It was mentioned, however, that research funding and the existing research infrastructure would not be of highest priority for action, although more support from EU R&D would be useful. Substance design tools were named as 'sufficient', however with a need for improvement with regard to coverage and quality of individual tools.

The stakeholders at the NTE Workshop identified the following factors as main barriers to R&D on new, non-/less toxic substances:

- insufficient (legal and market) incentives for new substance development;
- lack of contacts between substance developers and users of these substances as well as opportunities and platforms for experience exchange;
- lack of a basic overall understanding of toxicity aspects and how these could be integrated in substance design by all concerned actors;
- low 'interdisciplinary understanding', lack of education and training;
- missing specific funding opportunities;
- low overall awareness of benefits of non-/less toxic substances.

The main drivers for the development of new, non-/less toxic substances identified from literature also relate to substitution in general. Overall, consumer demand and regulatory pressure are identified as the core drivers for green chemistry innovation, with an overall agreement from literature and stakeholder feedback that the incentives posed by regulation outweigh the barriers that could arise

from requirements to assess and register new chemicals before marketing. Additional drivers include competitive advantages from new, innovative products and avoiding business risks, such as scandals, insurance costs, etc. The opportunity to develop new or more efficient functionalities/materials, such as could be the case from the use of nanomaterials is another, important driver of new substances development.
The use of waste as feedstock was analysed with a view to the opportunities to link the development of non-toxic or less toxic substances to related R&D activities. It is concluded that related research mainly focuses on exchanging the feedstock for chemicals production. Aspects of the (eco-) toxicity of the products are of low relevance, as the main aim of related projects is to lessen dependency on raw materials from other countries while obtaining the same product as if virgin materials are used. Consequently, little incentives for the development of new, non-/less toxic substances are expected from this area and the topic was not further elaborated.

Drawing conclusions from the internet research, literature review, stakeholder interviews and the NTE stakeholder workshop in June 2016, an EU programme supporting research and development of new, non-/less toxic substances could help achieving a non-toxic environment by providing alternatives to toxic substances. While the programme should include elements that increase available research and development funding, other aspects of improving the overall 'environment' in relation to providing guidance at policy level, raising awareness, increasing education, enabling networking and fostering substitution appear of equally high relevance.

It seems important to view the development of new, non-/less toxic substances in context and differentiate two principle cases: larger innovations at material level, where broader contexts are addressed and research and development of specific substances in specific applications. While the former is currently covered by the EU research and innovation programmes, like Horizon 2020, the smaller scale research happens at company level and less public funding appears to be granted (and demanded). In both cases, new, non-toxic or less toxic substance development is not an end in itself, but instead functions as an enabling factor in the context of a larger undertaking.

Several proposals and recommendations on how to overcome barriers to the development of new, non-/less toxic substances and their use, and to strengthen respective drivers, were identified from the literature and stakeholder inputs. These could be grouped into two types of responses:

- Response 1: Strategic actions to integrate 'new, non-/less toxic substance development' in all EU policies and to improve the overall regulatory and economic frame for related R&D; and
- Response 2: Enabling actors to better implement R&D on new, non-/less toxic substances by awareness raising, enabling networking and supporting training and education.

To guide all actors on the direction of innovation, the EU Commission could develop a Communication that:

- outlines the roadmap to phasing out (eco-)toxic substances,
- describes the needs and opportunities to foster the development of new, non-/less toxic substances across policies and activities, and
- highlights priority research areas for new substance development based on the priority substitution needs as well as synergies and interlinks with other societal challenges.

The EU Commission could initiate reviewing policies in order to reduce regulatory burdens and include more drivers for the development and use of non-/less toxic substances. Additionally, 'toxicity aspects' as a horizontal requirement could be included or further emphasized in all of the research and innovation activities funded by the Commission. A separate R&D programme supporting the development of new, non-/less toxic substances to fulfil the (priority) substitution needs would provide further incentives in this regard and would need further assessment of what are the priorities for substitution (i.e. which substances/substance groups, which applications etc.).

Approaches enabling all actors to more efficiently innovate towards new, non-/less toxic substances could include several actions, starting with the identification of needs for training and education, the facilitation of information and methods-exchange between training institutions or the publication of best practice examples of 'green chemistry education'.
Supporting networking activities of all actors would be another action that could be incentivized or further supported by the EU Commission, e.g. via web platforms or conferences. Finally, funding for R&D in the field of new, non-/less toxic substance development could be provided, for the development or improvement of substance design and hazard prediction tools in particular.

Key findings on new, non-toxic substances development

The problem

- A non-toxic environment implies that toxic substances are replaced with safer alternatives. Existing substances and non-chemical solutions are not always suitable alternatives and new solutions may be required;
- Barriers to the development of new, non-toxic substances include fears of costs, a lock-in in the current production situation, the potential need to establish new relationships with suppliers/customers, a lack of experience in cooperating on issues of substitution and substance development and uncertainty about the outcome of the development process and the future market opportunities for the new, non-toxic substances;
- Contextual factors that hamper the development of new, non-toxic substances include a lack of clear development goals at policy level (i.e. definition of non-toxic substances), missing inter and transdisciplinary cooperation in science and at the corporate level, a generally hesitant business environment regarding "green chemistry" and a lack of awareness and education;
- Research and innovation programmes exist which integrate the development of new, non-toxic substances as an option to achieve larger solutions to societal problems at the Member State and EU level. However, research programmes that specifically address the development of new, non-toxic substances at smaller scale, i.e. for specific applications, are largely unavailable.

Gaps and inconsistencies in current policy

- The need to develop new, non-toxic substances is not integrated as horizontal issue in all EU policies and research programmes;
- Although substitution of hazardous substances is discussed since a long time, little emphasis has been placed on supporting the related development of new, non-toxic substances and creating a favourable business environment, e.g. with view to replace restricted substances; hence, an EU research area or strategy specifically targeting new, non-toxic substances development is needed.
- A strategy, implementation instruments and networks to raise awareness about the benefits of using non-toxic substances and building related capacities in companies, academia and the general education system should be considered; such measures are still lacking at EU level (including providing support to Member States).

ABBREVIATIONS USED

CEFIC	European Chemicals Industry Association
CIEL	Center for International Environmental Law
CMR	Carcinogenic, Mutagenic, Reprotoxic
EAP	Environment Action Plan
EC	European Commission
ELINCS	European List of New Chemical Substances
EINECs	European Inventory of Existing Chemical Substances
EPA	Environmental Protection Agency
ERA	European Research Area
EU	European Union
EuMat	European Engineering Materials and Technologies
FET	Future and Emerging Technologies
FP	Framework Programme
GC3	Green Chemistry and Commerce Council
LEIT	Leadership in Emerging and Industrial Technologies
MoE	Ministry of the Environment
NCER	National Center for Environmental Research
NGO	Non-Governmental Organisation
NOTES	Non-toxic Environment Strategy
NTE	Non-toxic environment
OECD	Organisation for Economic Cooperation and Development
PBT/vPvB	Persistent, Bioaccumulative and Toxic /very Persistent, very Bioaccumulative
PPP	Private Public Partnership
PPORD	Product and Process Oriented Research and Development
(Q)SAR	(quantitative) structure activity relationships
R&D	Research and Development
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SAICM	Strategic Approach on International Chemicals Management
SME	Small and medium sized enterprise
SPIRE	Sustainable Process Industry through Research and Energy efficiency
SusChem	Sustainable Chemistry
UBA	German Federal Environment Agency (*Umweltbundesamt*)
UN	United Nations
UNEP	United Nations Environmental Programme
US	United States
WHO	World Health Organisation

1 INTRODUCTION

The aim of sub-study f is to assess the need and potential options to develop an EU Programme on new, non-/less toxic substances that should support the achievement of a non-toxic environment.

It is acknowledged that existing substances, materials and processes could prove as valid and less or non-toxic solution to the use of toxic substances. Although also this area of identifying research and development deserves support, this sub-study merely addresses the aspect of developing new substances.

In this report, information is compiled on the status quo:

- regarding policy support in similar programmes, however with a broader scope than 'only' development of new, non-/less toxic substances, i.e. on the development and use of Green Chemistry or Sustainable Chemistry, and
- of individual activities and measures implemented at different levels and by different actors, such as governments in the EU Member States or in non-EU countries, companies, research networks, or non-governmental organisations (NGOs).

Furthermore, literature on barriers and incentives to the implementation of Green Chemistry was analysed and stakeholders were consulted via interviews and as part of the Non-Toxic Environment Workshop (NTE workshop) conducted in June 2016.

Based on the status quo description and the identification of barriers and incentives to the development of new, non-toxic or less toxic substances, options for the EU to act are extracted and described that could constitute different elements of an EU programme.

In the following, and throughout the sub-study report, the term less toxic substances is used to facilitate readability. While 'no toxicity' is the goal for orienting activities, 'only' a decrease in toxicity (less toxic) may be achievable and desirable. Hence, the term 'less toxic' includes both inherently non-toxic substances (if possible) and less toxic substances than those in use, both of which will result in an overall decrease in the toxicity of substances on the market.

1.1 PROBLEM TARGETED

The implementation of a non-toxic environment strategy (NOTES) obviously requires the eventual phase-out of the use of toxic substances in mixtures, articles and processes. Key drivers to substitution are regulatory pressure, e.g. from use restrictions, product authorization or the duty to communicate on substances in products and articles, as well as market demands for less toxic products (c.f. sub-study a on substitution or sub-study b on non-toxic articles and material cycles).

The phase-out of substances is only possible if suitable alternatives are available that ensure the respective functionality remains on the market[1]. Replacement of a toxic substance could occur by different means, including with different processes, materials or services. In case of chemical alternatives, a substitute could be selected from the existing substances or the development of a new substance could be started. In the optimal case, the research and development would result in a non-toxic substance that fulfils the functions and requirements of the originally used, toxic substance. Finally, the new, non-toxic substance should have properties enabling safe and efficient waste

[1] In exceptional cases, products, processes or services including or requiring the use of the toxic lack benefits and should not be maintained on the market.

treatment as a contribution to implementing a circular economy.
The cases of phthalates and of poly- and perfluorinated chemicals shows that the replacement of a toxic substance with (similar) existing substances may be 'regrettable', as similar (eco-)toxicities may be linked to them, and that it may be difficult to find alternatives from the portfolio of existing substances in the market. These cases are strong triggers for the development of new, non-/less toxic substances. However, these activities may take time and, as is evident for the fluoro-chemistry, may require different substances for different applications of a toxic substance. In some cases, it may be necessary to consider entirely different technologies, in particular where the molecular structure required for a particular technical function is directly linked to toxic properties, as shown in the example of persistence (c.f. also the sub-study d on persistent chemicals).

In addition, substances may be developed to fulfil a particular (new, innovative) function in a larger context. This has been occurring of late in the area of nanomaterials, where material scientists have improved the technical functionalities of e.g. plastics by incorporating carbon nanotubes and have developed new, functionalized packaging materials etc. Here, the development of new substances, which may or may not be less or non-toxic, is driven by the aim of developing a new functionality, a new material or significantly improving the quality of existing materials rather than only replacing a substance without achieving different functionalities.

The (current and) future overall demand for new, non-/less toxic substances can hardly be estimated due to several reasons, such as:

- It is not fully clear in which applications substances are used, which are deemed for substitution, due to an overall lack of knowledge on the use of substances;
- It cannot be judged to which extent non-chemical solutions or existing substances are feasible alternatives to the use of toxic substances and, vice versa, if the pressure to identify new molecules will increase as no feasible alternatives are on the market;
- The rate of substance development, whether as a possible alternative or as a development to create new materials or product innovations, which could be judged e.g. by the number of non-phase in substances under REACH is not a good indicator for the need of substances, as they only show the successfully finalized development processes;
- Substance development is an innovation activity and all actors are careful about publishing needs and offers in this regard;
- The statements of different actors are not pointing towards the same direction regarding the needs for support on the research and development of new, non-/less toxic substances.

Consequently, if and how large the demand for new, non-/less toxic substances actually is cannot be quantified. However, with view to the fact that approximately 60% of all existing chemicals are classified as hazardous for human health (and additional ones for the environment), a potential demand of a large scale is expected, if a non-toxic environment should be achieved.

Key aspects to be addressed in the area of designing new, non-/less toxic substances relate to:

- bringing those actors who are able to design new, non-toxic or less toxic substances together with those, who need either to substitute a toxic substance or who would like to develop new materials, products or functions;
- further developing methods and tools for *in-silico* design and hazard prediction, as well as educating scientists and technologists who can work with and interpret them;
- providing funding opportunities to academics and companies;
- improving the overall research and business environment paying more attention to and placing emphasis on the low toxicity of substances in a horizontal approach; this could trigger additional needs for substance development, in particular where they are addressed in EU funded research and innovation projects, for instance.

The EU Research and Innovation Programmes cover a wide range of domains addressing different scientific, economic and societal challenges. There is no specific theme for the development of new, non-/less toxic substances, but this issue is covered by projects funded under different themes, notably LEIT-NMPB (Leadership in Enabling and Industrial Technologies, Nanotechnologies, advanced Materials, advanced manufacturing and Processing and Biotechnology). Activities address the whole innovation chain with technology readiness levels spanning the crucial ranges from medium levels to high levels preceding mass production. They are based on research and innovation agendas defined by industry and business, together with the research community, and have a strong focus on leveraging private sector investment.

The large EU R&I programmes, such as Horizon 2020, provide funding opportunities for multinational research networks developing large-scale innovations and development processes. Projects targeting the development of new, non-/less toxic substances to replace toxic ones may fit into the category of eligible projects. This could be the case if they do not concern any of the currently prioritised societal challenges or if they do not have large-scale impacts across a sector but 'only' for individual products. They may not be regarded as 'innovative enough', e.g. if they involve incremental improvements rather than systematic changes, or they may not need a large research community to be involved. Nevertheless, these projects may considerably contribute to a decrease in production, use, emissions and exposures to toxic substances and hence be a valuable contribution to the non-toxic environment. Consequently, there is a funding gap.

1.2 FOCUS OF THE SUB-STUDY FOR THE NON-TOXIC ENVIRONMENT STRATEGY

Sub-study f focuses on the identification of needs and opportunities to increase (scientific) research and development on new, non-toxic and less toxic substances and analyses barriers and disincentives to their production and use. Issues relating to the general context of substitution and commercialisation of substances are part of sub-study a, on substitution and grouping.

It is not in the remit of this sub-study to define the understanding of 'non-toxic substances'. However, the understanding of the term in this sub-study is outlined in Section 2.1.1.

The EU Programme is understood as a set of instruments, tools and measures that support any of the actors developing new, non-/less toxic substances in overcoming barriers and challenges in their work. In addition, it should include activities improving the overall scientific and business environment in relation to the use of less toxic substances.

1.3 CONTEXT OF THE R&D PROGRAMME ON NEW, NON-/LESS TOXIC SUBSTANCES

The two aspects new substances should fulfil – absence of or significantly reduced toxicity and properties supporting safe and efficient waste treatment - are part of the wider concepts of green chemistry and sustainable chemistry.

The term 'green chemistry' was introduced by Paul Anastas and John Warner in the late 1990s. It was, and still is, defined by the majority of actors and in most related publications according to the '12 principles of green chemistry'[2]. These principles include, in addition to a decrease in the toxicity of products as well as a decrease in the toxicity and the amount of wastes from the manufacturing processes, aspects such as improved efficiency of the production process, reduction in resource use and emissions of greenhouse gases, or improved installation safety. Consequently, the concept of green chemistry relates to a number of environmental, health and safety aspects in the production and

[2] American Chemical Society, April 2016.

use of chemicals in general.

Green chemistry can be viewed as part of the wider concept of sustainable chemistry, which evolved with the global sustainability goals. Apart from the principles of green chemistry, the concept of sustainable chemistry also includes economic and social aspects of the production and use of chemicals.

The German Federal Environment Agency (UBA) and the OECD have developed a concept that represents the common understanding of sustainable chemistry.[3] Rather than being a fixed goal, sustainability is understood as an improvement process, with different aspects and criteria that should provide orientation about the direction in which innovation should move. How sustainability is interpreted in practice depends on the actors applying the concept and the question they aim to answer; the tools and approaches require operationalisation of the general goals of reduced environmental impact, contribution to social improvement and economic balance.

Although there are clearly differences between the concept of green chemistry and sustainable chemistry, the two terms are frequently used synonymously.

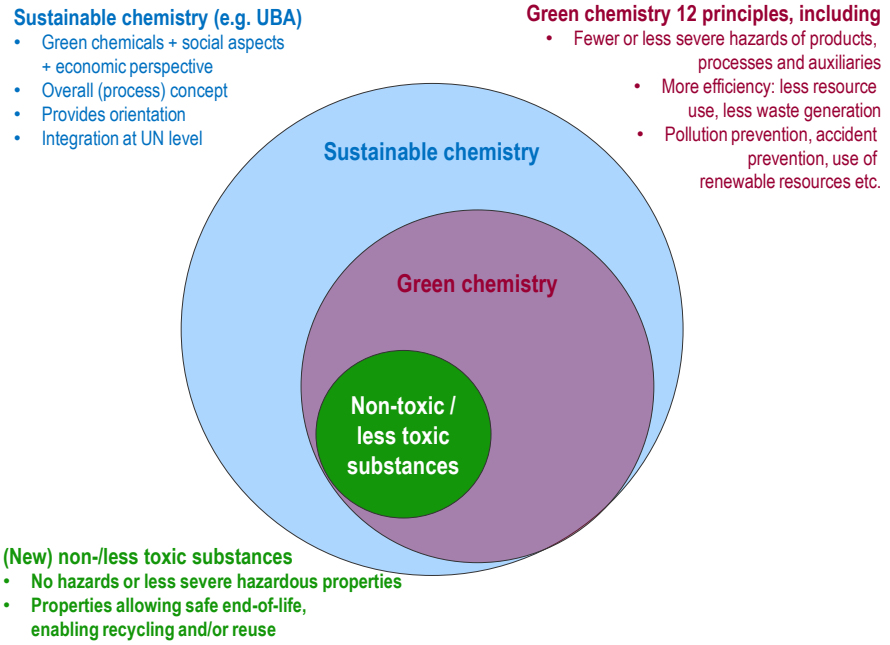
At the workshop organised by the EU chemicals industry association (CEFIC) to provide input to the NTE project at an early stage, the presentation by Clariant, among others, showed that companies normally do not view the aspect of 'non-toxic substances' or 'less toxic chemicals' in isolation but as a part of a wide range of improvement areas for their portfolio. Clariant stated that they consider the 12 principles of green chemistry as well as several economic and social factors in the analysis of how their product portfolio could be improved. Hence, it is noted that an isolated view on toxicity is not compatible with current trends in assessment and performance evaluation, as well as innovation and development work in companies and policies.

At the stakeholder workshop in June, several participants also stressed that an EU Programme on less on non-toxic or less toxic substances should not only focus on identifying alternatives to toxic substances. Instead, it should widen the focus and a) strengthen thinking about which functionalities need to be achieved rather than which substances need to be substituted and b) to focus on non-chemical alternatives.[4] While considering these two as important aspects of substitution, they are not covered in this sub-study.

The recycling of waste chemicals through their use as feedstock in the production of other chemicals is an additional aspect included in the analysis of this sub-study. Although relevant to the concepts of green chemistry and sustainable chemistry, it is analysed mainly to identify synergies to foster the development of green chemicals. Figure 1 illustrates how the development of new, non-/less toxic substances is embedded in the 12 principles of green chemistry and the even wider concept of sustainable chemistry.

[3] Umweltbundesamt, viewed April 2016.
[4] The sub-study on substitution considers this aspect.

Figure 1: Embedding of non-/less toxic substances in the landscape of chemicals concepts



1.4 AIMS OF THE SUB-STUDY F

The aims of sub-study f, as outlined in the terms of reference of this project, are to:

- give an overview of existing programmes and individual measures supporting new, non-/less toxic substance development, including a brief analysis of the level of related investments;
- describe instruments and approaches to promote the development of new, non-/less toxic substances;
- identify the need for and the potential scope of a respective R&D Programme in the EU and how it could be integrated in and complement ongoing activities;
- outline potential elements of an R&D Programme on new, non-/less toxic substances in the EU;
- describe the added value of a potential EU Programme on the development of new, non-/less toxic substances.

2 OVERVIEW OF THE STATE OF PLAY OF THE SUB-STUDY AREA

2.1 DEFINITIONS AND CONCEPTS

2.1.1 Definition of non-/less toxic substances[5]

At the NTE stakeholder workshop in June, the participants stressed the need to define the term 'non-toxic substance' as used in the 'Non-Toxic Environment Strategy' as well as in the context of new substance development. This would be needed to give guidance to substance developers and signals to the target what should be achieved by the market, i.e. which substance properties should be avoided (as a minimum) and which properties could be desirable. It was also common understanding that the definition might change over time to take account of progress in phasing-out of toxic substances or of new scientific knowledge on (eco-)toxicity. The workshop participants identified the definition of 'non-toxic substance' as (also) a political issue and did not conclude on it further.

It can be regarded to be common understanding that 'non-toxic substances' are considered substances that at least have no properties of (very high) concern, as defined by REACH Art. 57:

- Carcinogenic, mutagenic and reprotoxic (CMR), persistent, bioaccumulative and toxic /very persistent and very bioaccumulative (PBT/vPvB);
- Properties of similar concern, commonly understood as including at least endocrine disruption and respiratory sensitisation.

In addition, scientists increasingly discuss developmental neurotoxicity as a threat to the overall health of the human population, due to the serious effects they could have on brain development[6]. Furthermore, highly sensitising and immunotoxic substances may be included in the definition of a non-toxic substance. Another type of substance that could be considered are 'persistent, mobile and toxic' (PMT) substances, which can spread rapidly and irreversibly, thus have the characteristics of becoming planetary boundary threats.

Whether the concept of non-toxic substances should cover very persistent substances may be subject to discussion (c.f. sub-study d). At the NTE stakeholder workshop, persistence was highlighted as a property that needs to be viewed with care.

Whereas persistence is an important functionality for many technical application and might be desirable for substances handled in closed systems and where a long lifetime is intended (e.g. in cooling liquids), it should be avoided for all substances that might be released and reach humans and/or the environment. In the best case, a substance would be stable (persistent) during its use and any potential recycling and recovery, but non-persistent when released into the environment. Scientists stated that there are options to design substances that change their persistence depending on 'outside' conditions, e.g. pH value.
It was also noted that containment of chemicals or materials in the technosphere has proven very difficult over time and considering the waste life-stage. Hence, it appears plausible and precautionary to assume all substances are eventually released to the eco-sphere, unless they are destroyed before (non-persistent).

Overall, the definition of 'non-toxic substances' is regarded as a dynamic concept, which should be reviewed regularly and updated to take account of progress made and new scientific information on

[5] In the following, the term „less toxic substances' is understood as including non-toxic substances a primary goal as well as substances that are less toxic than the toxic substances they should replace.
[6] C.f. for example the recently published consensus statement derived from a study. Project TENDR, 2016.

properties posing threats to human health or the environment.

Other than the definition of 'absence of hazards' (c.f. above), the target to be reached does not have to be changed over time. However, the following proposal needs concretisation. As an overall goal for the use of substances, the following aspects were identified as being the most relevant long-term goals at the NTE workshop's break-out group. Substances on the market are:

- able to satisfy and balance societal needs;
- safe in their uses;
- 'gone' after their use.

2.1.2 Understanding of the term 'programme'

The sub-study should draw conclusions, among others, on potential elements of an EU programme on the development of new, non-/less toxic substances. Therefore, we will briefly outline the understanding of the term 'programme' of this study.

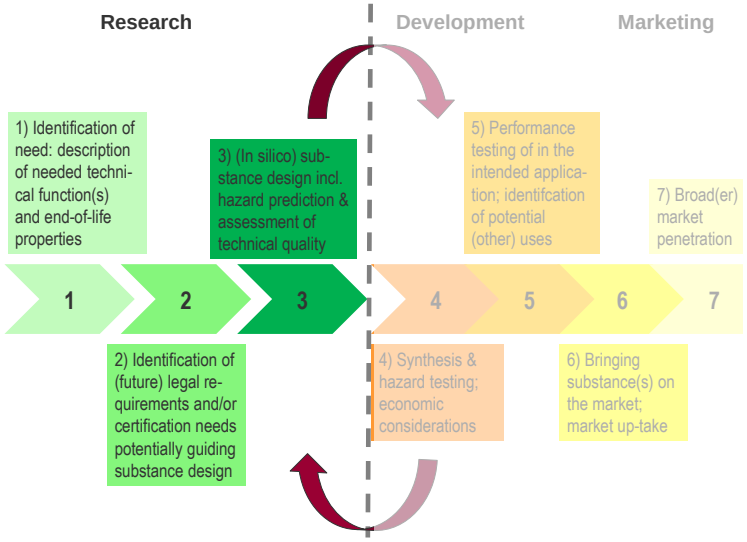
A 'programme' is considered to be a set of measures that contribute to the same overall objective and are interlinked. A programme is developed together with the relevant stakeholders. It defines the roles and responsibilities of the actors involved and focal action areas. It should also include a system to monitor progress against the objectives (and potentially more specific, defined, targets). These aspects are described in an overarching programme document.

2.1.3 Model of the substance development process

We structure the identification of needs for an EU Programme on the development of new, non-/less toxic substances according to a model of the substance development process. The model was introduced and discussed at the NTE stakeholder workshop in June 2016 and was revised afterwards according to the input received. Figure 2 illustrates the model as discussed in the break-out group of the workshop, with slight amendments.

According to stakeholder feedback, the activities in an EU programme should focus on the steps 1 to3 in Figure 1, because only these are specific to new substance design. Steps 4 and 5 would relate to the development process and steps 6 to 7 to the actual marketing. These four steps rather depict 'regular business' of companies and are similar for any substitution activity. However, there are interactions between the phases as challenges in development or marketing might influence substance design and the substance design largely determines development and marketing strategies.

Figure 2: Steps in the development of new substances



As indicated in the workshop, the first three steps are the core focus of this sub-study, while development and marketing challenges and opportunities are considered as factors influencing the former to varying degrees. Consequently, the EU programme should include activities that support actors in identifying the needs for new substance and provide the necessary tools and instruments for (*in-silico*) substance design, while at the same time creating a favourable business environment (marketing) and overcoming structural challenges in substance development, such as production infrastructure, economic risks etc.

2.2 EXISTING PROGRAMMES ON NEW (SUSTAINABLE) SUBSTANCE DEVELOPMENT

Existing programmes that support 'green' or 'sustainable chemistry' were identified via an internet search, screening web-pages of the UN, the OECD and the environment ministries of various countries.[7] While some organisations conduct activities, like awareness raising or explaining the concept of green or sustainable chemistry, such as the UNEP or the OECD, other institutions or programmes become more actively involved in the actual development, marketing and use of such substances. The latter could be research institutions, companies, technology platforms or funding institutions/programmes that more directly interact with the market. In the following section, we describe what actors or activities we have identified at the global, regional and national levels.

2.2.1 Global level

The United Nations Environment Programme (UNEP)[8] and the Strategic Approach on International Chemicals Management (SAICM)[9] mostly address issues related to the sound management of, and communication on, chemicals. Whereas the reduction of negative impacts from the production and use of chemicals is the core goal of SAICM, the development of 'green chemicals' and related research and development actions are not explicitly mentioned in the implementing documents. Hence, no respective programme supporting the development of new, non-/less toxic substances exists at the UN level. There are no indications of relevant individual activities directly related to SAICM

[7] Individual activities by government actors related to green or sustainable chemistry but not integrated into a GCP are not considered here, but are described in section 2.9.
[8] UNEP, http://www.unep.org/chemicalsandwaste/.
[9] SAICM, http://www.saicm.org/index.php?ql=h&content=home.

implementation that should be taken into account in the sub-study. However, the overall goal of SAICM can be regarded as a driver for substitution and therefore indirectly to the development of new, non-toxic substances.

2.2.2 Organization for Economic Cooperation and Development (OECD)

The OECD maintains a website[10] on sustainable chemistry including a 'Sustainable Chemistry Platform' and the possibility to download OECD publications related to sustainable chemistry. The platform provides links to other websites. It states that the OECD's work focuses on the identification of drivers for 'sustainable chemistry' and innovation. Documents and links are partly outdated and the webpage appears to be maintained very infrequently. Consequently, the OECD is not an active player in the field of green or sustainable chemistry, neither by raising the issue prominently nor by actively influencing market supply.

The OECD coordinates and carries out activities in the area of development and making accessible hazard prediction tools and hazard testing of chemicals. The former activities are relevant for substance design in order to screen potential new substances for undesirable hazards.

2.2.3 United States

2.2.3.1 Federal level – the United States Environmental Protection Agency (US EPA)

The US EPA and its federal partners (i.e. federal research institutes and authorities) do not embed its activities on 'green chemistry' into an overall programme framework. However, the many actions implemented do form a programme and are arranged in such a way that they complement each other and create synergies in the implementation.

In 2014, a proposal for a national 'Sustainable Chemistry Research and Development Programme' was introduced to the US Senate. It was referred to a committee and no further actions are reported on it.[11] The bill defines sustainable chemistry as follows:

> *'The term 'sustainable chemistry' means the design, development, demonstration, and commercialization of high quality chemicals and materials, chemical processes and products, and engineering and manufacturing processes that eliminate or reduce chemical risks to benefit human health and the environment across the chemical lifecycle, to the highest extent practicable'*

The programme should coordinate and promote all of the national efforts related to the development and use of sustainable chemicals. The proposed bill foresees the establishment of an interagency working group to manage the programme, which is supported by an advisory group composed of independent experts from all relevant stakeholder groups. It also suggests a study to identify the status quo on sustainable chemistry research, based upon which a national strategy should be elaborated. The act furthermore includes requirements for the national agencies' budgeting and reporting on achieving the programme's goals.

The topic 'green chemistry' constitutes a priority work area of the US Environmental Protection Agency and it runs a respective website[12], which includes basic information on the understanding of green chemistry and the EPA's research activities, the annually granted Green Chemistry Challenge Award and links to literature and tools in support of green chemistry.

The EPA's national research is structured in accordance with the Chemical Safety for Sustainability

[10] OECD, http://www.oecd.org/chemicalsafety/risk-management/sustainablechemistry.htm.
[11] US Congress, 2014.
[12] US Environmental Protection Agency, *Green chemistry.*

Strategic Research Action Plan 2016 – 2019[13] and includes several topics relevant to the development of green chemicals[14]:

- development of (computational) methods to assess and predict chemical hazards;
- provision of data for risk assessment of new materials;
- improvement of assessment methods of life cycle risks;
- development of tools to support the design of sustainable substances;
- promotion of tools and information to identify the sustainability of chemicals;
- supporting other institutions in their activities to promote and develop green chemicals.

The EPA funds academic research related to green chemistry via its National Center for Environmental Research (NCER). It also provides grants to individual researchers (fellowship programmes). In addition, two funding programmes for innovative activities or technologies exist for small and medium sized enterprises (SMEs). These are not specific to green chemistry but cover environmentally friendly innovations in general.[15]

2.2.3.2 State level – the example of Washington

Washington is an example of a federal state that maintains its own Green Chemistry Programme. The Department of Ecology manages the programme and has it on its website.[16] The department offers support to companies, e.g. regarding hazard and risk assessment of chemicals, provides general information on green chemistry, such as webinars, case studies on the use of less hazardous chemicals and links to other information as well as annually puts up an award for 'Safer Chemistry Champions'.

Under the leadership of the Department of Ecology, a roadmap for green chemistry was established[17]. The Roadmap is based on an analysis of existing activities and actors in the field and discussions at a dedicated roundtable. It describes the process of initialising a Green Chemistry Programme, starting with a phase of awareness-raising and capacity-building and continuing with the development of the actual programme and its implementation. A Green Chemistry Center was established, which works to integrate Green Chemistry into education and training and to identify and create green chemical solutions. The centre maintains a network of actors from industry, governments, non-governmental organizations and academia. It publishes a newsletter and organizes webinars and conferences.

In other federal states, such as California, Connecticut, Michigan or Maine, so-called 'Green Chemistry Initiatives' exist, which mainly consist of legislation on particular products (e.g. children products, cosmetics) or substances (e.g. flame retardants). They do not comprise particular programmes to promote the development of new, green chemicals. They are frequently accompanied by information and tools for e.g. alternatives assessment, hazard information databases or links to 'design for environment' programmes, e.g. by the US EPA. Green chemistry programmes mainly aimed at promoting research for new green substances or respective collaboration centres do not appear to exist in other states than Washington.

2.2.3.3 Stakeholders

The Green Chemistry and Commerce Council (GC3) is a US-based network for companies that aims at promoting the use of Green Chemistry and implements relevant activities. Among others, it

[13] US EPA, 2015.
[14] Other aspects relate to more efficient risk assessment of existing chemicals via computational methods, the improvement of tools by which to assess the lifecycle risks of chemicals or e.g. the assessment of alternatives.
[15] US Environmental Protection Agency, *Small business innovation research program*.
[16] State of Washington, Department of Ecology, *Green chemistry.*
[17] Washington State Department of Ecology, 2013.

published an 'Agenda to Mainstream Green Chemistry'[18] outlining strategies and specific actions in this regard. Although the GC3 does not focus on the development of new green substances, the overall approach and some of the action areas are relevant.
The Agenda to Mainstream Green Chemistry was developed and agreed among the members of the GC3; hence involving those actors that are actually developing new green chemicals. It includes a definition of green chemistry:

> *'Green chemistry is the design of chemical products and processes that reduce or eliminate the use and generation of hazardous substances throughout their lifecycles: design, manufacture, use, and end of life'.*

2.2.4 Other, non-EU countries

Scientists and companies all over the world involve in the research and development of green and sustainable chemistry. Frequently, they organise their work in industry and/or academic networks or platforms at national or regional level. However, government policies and programmes supporting these activities in a structured and overarching manner are rare. No specific policy programmes supporting the (national or regional actors in) research and development of 'green' or 'sustainable' chemistry have
been identified in Australia, Canada, Japan, India, Russia and China.[19] Little information on the government projects or activities were identified in these countries.

Apparently, in Brazil no government green chemistry programme exists[20], but some related initiatives were identified in the Brazilian research community; however, they focus on the use of renewables as energy sources and raw materials. A proposal for a roadmap to foster research and development in green chemistry was published and is stated to be implemented in Brazil (Chemical Watch (2011) and Correa *et al.* (2013)).

2.3 THE EUROPEAN UNION'S RESEARCH AND INNOVATION FUNDING

2.3.1 The 7th framework programme for research and technological development

Prior to the implementation of Horizon 2020, EU research and innovation support was partly covered in the framework programmes for research and technological development (FP). In the 7th FP, approximately 150 projects in the area of environment and health were funded between 2007 and 2016.

In a report by the World Health Organisation (WHO)[21], some key figures on the research activities are provided, among others it is pointed out that the topic nanotechnologies, materials and new production technologies were more prioritised in the 7th FP than in earlier research programmes. Related activities included research on risks and risk assessment methods from nanomaterials, alternative toxicology testing for chemicals (i.e. non-animal test methods) and work on food contaminants. The authors state that 'environmental chemicals' and 'nanomaterials' had received the highest funding of all work on environmental stressors. Another statistic included in the report shows that end-point related research

[18] Green Chemistry and Commerce Council, 2015.
[19] The following web-sites were searched for indications of green chemistry programmes: Australian government, Department of the Environment and Energy, home; Government of Canada, *Federal sustainable development strategy;* Government of Japan, Ministry of the Environment, *In focus;* Government of India, Ministry of Environment, Forest and Climate change, *Home;* Ministry of Natural Resources and Environment of the Russian Federation, *Home;* Ministry of Environmental Protection, People's Republic of China, *Home.*
[20] Minstério do Meio Ambiente, *Segurança química*.
[21] WHO, 2015.

was funded, e.g. on genotoxicity, carcinogenicity and ecotoxicological effects. The statistics do not point out which of these projects include a development of new, non-/less toxic substances as alternatives to the studied environmental stressors.

A EU report[22] providing summaries of the research projects funded under the 7th FP area of health and environment shows that none of the projects in the area of 'chemical risks' deals with the development of new, non-/less toxic substances. Instead, projects focus on alternative methods to animal testing, the development of hazard prediction methods, databases for hazard and risk information as well as risk assessment methods. The same applies to the research area 'Safety of Nanomaterials', within the health and environment funding, where methods and tools for the extraction, detection, identification and hazard and risk assessment of nanomaterials mainly have been the focus.

An overview and short descriptions of projects on nanotechnologies and nanoscience funded under the 6th and 7th FP is published as pdf-version of a mapping portal[23]. According thereto, around 200 'nano-projects' were funded under the programme area 'key enabling technologies' in FP6 and FP7. These projects are differentiated by the portal into projects supporting policymaking and projects for particular applications. The later are separated into research on nanomedicine; energy and environment; electronics, information and communication technologies; agro-food; industrial applications, nanomaterials, textiles security. Whether or not in these projects new, non-/less toxic substances were developed could not be analysed; however, it is assumed that this occurred to a significant extent as many of these projects appear to aim at providing innovative materials with new functionalities. Unfortunately, an assessment or the innovation activities including the development of new substances and an evaluation of whether or not they are non-toxic or less toxic and in how far this has been considered in these projects does not exist.

A report analysing patenting activities under the 7th FP[24] provides several perspectives on the nature of patents that can be related to the projects of the FP. However, it is not possible to identify from the report if any of the patents relate to newly developed substances (with less toxic characteristics). In addition, the report specifies that patents are not a comprehensive indicator of new product development, as not all new developments are patented. According to the Commission Communication on the evaluation of the 7th FP[25], 1,700 patents are related to studies conducted under the research programme.

2.3.2 Horizon 2020

Horizon 2020 is the EU research and innovation programme aimed to support the implementation of the EUs economic, environmental and societal goals and making it competitive on the global market. Other research and innovation programmes, such as the European Research Area (ERA) or the LIFE+ programme complement Horizon 2020.
Funding under Horizon 2020 is organised in multi-annual work programmes prepared by the Commission and involving stakeholder consultations via different advisory groups. The work programmes are separated into thematic sections. The following research areas are regarded as being particularly relevant for the funding of those projects involving the development of new, non-/less toxic substances:

- Excellent Science with the topic of 'future and emerging technologies';
- Industrial leadership with the topic of 'Nanotechnologies, Advanced Materials, Advanced Manufacturing and Processing, and Biotechnology';

[22] European Commission, 2014.
[23] European Commission, n.d.
[24] European Commission, 2015.
[25] European Commission, 2016.

- Societal changes with the topic of 'Climate Action, Environment, Resource Efficiency and Raw Materials'.

Unfortunately, no statistics and comprehensive overview of the content of funded projects or the nature of innovations (i.e. development of new substances) is available from the Horizon 2020 website. The Cordis website allows searching for research projects but a detailed assessment of projects funded under the 'Leadership in Enabling and Industrial Technologies' (LEIT) programme regarding the extent to which new, non-/less toxic substances were developed is impossible, as it requires extensive resources. Therefore, instead we have assessed the description of some calls in the current Horizon 2020 work programmes regarding how the development of new, non-/less toxic substances is addressed.

2.3.2.1 Future and emerging technologies (FET)

In the 2016-2017 work programme on future and emerging technologies (FET) one important funding are is 'open research'. Projects need to meet several conditions to qualify for funding, which are specified in the separate calls under the FET topic. These include that research should contribute to a larger, radical technological innovation. We cannot deduce from the work programme if new substances' development would be included in the definition of 'a radically new technology'.

Under the FET topic 'Open coordination and support actions', activities to disseminate research results and support experience exchange are financed. Under the area 'innovation launchpad', continuing support to innovative projects in the phase of marketing new products is covered and the call 'FET pro-active' includes sub-topics under which R&D for new, non-/less toxic substances could be covered, such as the area 4: 'New technologies for energy and functional materials'. Finally, the area 'FET flagships' addresses large scale research initiatives aiming at transformation with regards to a particular goal.

Research and development of new, non-/less toxic substances could fit under the topic of future and emerging technologies of Horizon 2020 because research topics are not limited. However, substance development for a particular purpose or application, e.g. with the aim of providing an alternative to a toxic substance and not addressing a larger innovation, is unlikely to accord to the level of ambition highlighted under the programme objectives and the conditions listed in individual calls.

2.3.2.2 Climate action, environment, resource efficiency and raw materials

The topic area 'Climate action, environment, resource efficiency and raw materials' implements research activities under the Europe 2020 Strategy on 'Smart, Sustainable and Inclusive Growth' and is stated to be driven by and oriented towards main societal challenges. This area is expected to consume around 60% of Horizon 2020's budget with the share of climate related actions being 35% of this. The Horizon 2020 website does not provide any information on how the development of new, non-toxic substances is considered under this topic.

The work programme 2016-2017 covers the research call 'greening economy'. In this call, actions on resource efficiency, green and competitive economy are being prioritized, which relate, among others, to the EU 7th Environment Action Plan (EAP). According to the summary text of the call, research eligible for funding should concern systemic innovations which include the 'adoption of a challenge-driven, solutions-oriented research and innovation strategy that crosses disciplinary boundaries and involves co-creation of knowledge and co-delivery of outcomes with economic, industrial and research actors, public authorities and/or civil society.' A work focus on avoiding the use of toxic substances or promoting the development of new, non-/less toxic substances is not included, despite

the high priority given to the topic in the EU's 7th EAP.

In 2012, the EU Commission decided on a strategy concerning bioeconomy[26], which is due for review and updating in 2017. Among others, the strategy should support the EU in securing food supply, in preventing the depletion of natural resources and in decreasing environmental pressures, including from the use of energy and on the climate. Furthermore, the EU's dependency on fossil fuels should be reduced.

The bioeconomy strategy links to R&D on new, non-/less toxic substances in two aspects: The use of bio-based products, defined as products derived from biological materials, is expected to result in improved functionalities and characteristics, including a lower toxicity. Bio-based processes could be alternatives to processes involving the use of toxic substances.
The description of the research area does not explicitly mention a reduced toxicity of bio-based products (as compared to those they should replace) or (reduced) emissions of (less) toxic substances from bio-based processes as an explicit goal or aspect to consider.

2.3.2.3 Key Enabling Technologies

The area of 'Key Enabling Technologies' is the most likely of all Horizon 2020 research areas to address the development of new, non-/less toxic substances. It focuses on four technologies: nanotechnologies, advanced materials, advanced production technologies and biotechnology. These areas are assumed to be crucial to maintaining a competitive position in the EU.

While research on nanotechnologies and advanced materials may involve the development of new substances (at nanoscale), biotechnologies and changed processing may result in lower emissions of (less) toxic substances as a side effect.

The overarching aim, in this research area is also the increase of competitiveness of EU industries, with a view to resource and energy efficiency and the use of non-fossil materials in particular, which is emphasized as being the (most) important goals of the programme area.

Several calls with various sub-topics are foreseen in the 2016-2017 work programme covering among others the construction sectors, information and communication technologies, biotechnologies, within which the development of new, non-/less toxic substances could occur. Toxicity as a characteristic to consider in the project design and outcomes is, however, stressed only in very few of the sub-calls in the current work programme.

While the development of new, non-/less toxic substances may be covered under this research area, as nanomaterials per se are frequently new substances, the requirement that funding projects should concern an enabling technology might be the main obstacle in research on new, non-/less toxic substances fitting under this heading.

2.3.2.4 Overall suitability of EU research funding

The EU invests considerable amounts of financing in research and development activities. Apart from the large framework programmes, which merged into Horizon 2020, additional, smaller programmes, such as the ERA exist. The research programmes aim to support the EU in remaining /becoming a sustainable, competitive economy.

From screening the directly available documentation of activities in the FP7 and Horizon 2020, it is

[26] EUROPEAN COMMISSION, Directorate-General for Research and Innovation, 'Innovating for Sustainable Growth - A Bioeconomy for Europe', 2012, available at: http://ec.europa.eu/research/bioeconomy/index.cfm?pg=policy&lib=strategy.

concluded that the toxicity of chemicals used in products, processes or services is in principle considered in research actions via a general requirement to assess and manage the research impacts, including potential risks.

However, it is understood from the overview descriptions and some exemplary work programmes of Horizon 2020 that the development of new, non-/less toxic substances is not an explicit focus. While it is likely that projects on technological innovations (partly) include developments of new substances, in the area of nanomaterials at least, it is unclear from the documentation of project results to which extent this occurs and whether or not they are 'non-/less toxic'.

Overall, EU research intends to support meeting the global societal challenges, including climate change and increasing resource efficiency. The reduction of the toxic load in humans, the environment and the technosphere are not listed as a 'societal challenge' and, therefore, do not trigger any specific work programmes.
The Horizon 2020 eligibility criteria regarding the level of innovation and the size of the problem to be tackled, as well as the partly defined transnational and interdisciplinary approaches of projects, could prevent access to financing for companies who 'only' want to innovate via substituting one substance by another.

Consequently, it is concluded that there is room for improvement and that an EU programme specifically addressing the development of new, non-/less toxic substances, regardless of whether within or in addition to Horizon 2020, could be of significant added value and would not double any of the existing research activities. In addition, further mechanisms to built-in project elements identifying needs for and potentially implementing new, non-/less toxic substance development could be considered.

2.4 EU MEMBER STATES

Whereas in many EU Member States the Ministries of Environment (MoE) have specific departments dedicated to chemicals or chemical policy to fulfil regulatory tasks and obligations, no accompanying larger scale programmes to specifically promote the development of new, non-/less toxic substances beyond the regulatory work could be identified, although individual activities exist (c.f. below). An exception is the field of nanomaterials, where for example awareness raising and dialogue projects are initiated by the governments.

One example of a framing activity is the German National Dialogue on Nanomaterials[27], which the German government initiated in 2006 with the aim of providing a platform for stakeholders to discuss risks and opportunities of the new technology with a view to a sustainable development. The 'Nano-Commission' published two reports of its work (2006 – 2008 and 2010 – 2013). The Commission's work is continued in a new format as topic-related 2-day stakeholder workshops on a half-year basis.

Another example is the National Action Plan on Nanomaterials in Austria[28], which structures the government's related work, including involvement of stakeholders via a commission and other forms of dialogue. It also outlines scientific R&D priorities to identify uses and potential risks from nanomaterials. The action plan included measures to promote Austria's strengths in the field of nanotechnologies, fostering research on environmental health and safety and supporting stakeholder dialogue and public awareness-raising.

Another example of ongoing activities in the Member States is the 'International Sustainable

[27] Bundesministerium für Umwelt, Naturschutz, Bau und Reaktorsicherheit, *Der NanoDialog der Bundesregierung*
[28] Nanoinformationsportal, *ÖNAP*.

Chemistry Collaborative Centre' (ISC3). The ISC3 aims to bundle and network actors working on sustainable chemistry, further promoting, developing and implementing the concept of sustainable chemistry internationally. Furthermore, specific research and activities are envisaged, making the ISC3 a focal point for sustainable chemistry. The Center is due for opening in 2017 and supports ongoing efforts of the German policy makers and environmental administration, including on the implementation of SAICM.

The German Federal Environment Agency has commissioned several projects in the sustainable chemistry areas, such as on instruments to measure the sustainability of chemicals and to promote chemical leasing.

In addition, national research funding may be targeted, among others, to promoting science on sustainable and green chemistry. An example is the Danish National Research Council, which funds the Center for Sustainable and Green Chemistry, an institution supporting with fundamental concepts on establishing a new, (non-toxic) chemistry based on renewable resources. Other initiatives, e.g. investigating 'cleaner production' technologies, such as the use of biocatalysis in chemical synthesis exist, e.g. the programme Greenchem at the University of Lund, Sweden. As a side effect from optimised processing, substances may include less impurities leading to less toxicity.

Consequently, there are activities in the EU Member States that aim at promoting the use of sustainable chemistry in general and, among others, the use of less or non-toxic substances. However, comprehensive programmes targeted to supporting the R&D and the use of new, non-/less toxic substances could not be identified.

Research is increasingly organised and funded according to clusters of societal needs or clusters related to particular fields of innovation, both in the EU and in the Member States. Consequently, scientific research and development is not organised according to 'traditional' or newly oriented basic sciences but rather follows a transdisciplinary approach. Given this, the development of new green chemicals is not explicitly subject to research programmes, but may be included in larger innovation projects. Again, nanomaterials, which are frequently new substances, are an exemption as their development may be subject to individual research programmes, such as at the EU level[29].

According to a recent literature review by Dichiarante, V. *et al.* (2015), the majority of scientific publications on green chemistry research focuses on process optimisation and catalysis. Most articles deal with organic chemicals or the processing/production of organic chemicals. A survey conducted in 2004 among experts is cited, which indicated a need for support in the field of computer-aided molecular design. The authors assume that this is due to the fact that the development of the new substances and designing it according to technical and societal needs it the basis for all further innovation and development work.

2.5 CONCLUSIONS ON EXISTING PROGRAMMES ON NEW, NON-/LESS TOXIC SUBSTANCES

Apart from the activities of the US EPA, no consistent or strategic governmental policy framework to promote the development and use of 'green' or 'sustainable' chemistry solutions have been identified at the level of international organisations, non-EU countries or the EU Member States. However, relevant activities, including the promotion of substance development in general exist and are, in addition, likely to be integrated in R&D (funding) programmes.

At the EU level, the development of new, non-/less toxic substances is covered as an aspect that is

[29] European Commission, 2013.

integrated into different research programmes, in particular the 'leadership in enabling and industrial technologies'. However, Horizon 2020 does not define a specific work focus in this regard, apart from funding nanotechnology research. Furthermore, the conditions defining eligibility of projects might be very demanding for substance developers that are not embedded in larger innovation projects.

Therefore, a specific research area on the development of new, non-/less toxic substances or, more broadly, 'sustainable chemistry', would complement existing research programmes and provide opportunities for targeted research funding to develop new, non-/less toxic substances as alternatives to the use of toxic substances. This could also support steering the substance development towards substitution priorities, e.g. regarding particular substances or substance groups or applications with high exposure potentials.

2.6 BARRIERS TO THE DEVELOPMENT OF NEW, NON-/LESS TOXIC SUBSTANCES

Literature on barriers to, and opportunities for, the development of new, non-/less toxic substances was analysed in order to identify which potential actions, by a related EU Programme would help overcome the barriers and to strengthen the opportunities.

It should be noted that barriers to changing chemical supply in general, e.g. from the fossil-based resources to renewables, are not addressed, as they do not directly relate to the aim of toxicity reduction and pose other challenges (e.g. competition on land use with other uses).

In general, few publications address barriers to and opportunities for the development of new, non-/less toxic substances specifically. Some publications on substitution in general include a perspective on the option to use new, non-/less toxic substances as alternatives and what barriers need to be overcome in these cases. Any drivers and barriers identified for substitution would also apply to the specific activity of new substance design, unless it is conducted in the context of an entirely new application or material development. In this regard, the analysis of barriers can be seen as comprising a sub-set of issues identified in sub-study a on substitution as well as of sub-study e on innovation and competitiveness. These three aspects need to be viewed together in order to identify optimal solutions for a non-toxic environment, i.e. the phase out of the use of toxic substances as far as feasible.

The most advanced sector in designing new substances is pharmaceuticals. The approach of *in-silico* design of new active substances rather than synthesising a high number of potential derivatives and assessing their effects is increasingly used. This allows targeted modifications of structures, among others, to ensure these substances do not remain in the environment but are biodegraded.[30]

Fennelly and associates[31] identify several obstacles for the implementation of green chemistry. These mainly relate to the interaction in supply chains and although they are not specific, they are applicable to the process of developing new substances. The barriers described are listed in the following with the barriers at the top of the list being the most specific to new substance development and those in the later bullet points being barriers to substitution in general and, hence, are also applicable to R&D on new, non-/less toxic substances:

- conflicts between increased transparency needs of users (more certainty about what they are doing) and the protection of confidential business information;

[30] C.f. for example the approach 'benign by design', which aims at optimising the persistence of substances, so as to have the necessary stability of substances to carry out their function (in the body) but to be easily and quickly degraded in the environment, if possible to full mineralisation. Lederer *et al.*, 'Putting benign by design into practice-novel concepts for green and sustainable pharmacy: Designing green drug derivatives by non-targeted synthesis and screening for biodegradability', in *Sustainable Chemistry and Pharmacy* 2 (2015) 31–36.
[31] Fennelly and associates, 2015.

- green chemistry suppliers do not know those in need, companies in demand of green chemistry hesitate to contact suppliers beyond existing supply chains;
- burden from the process of registering a new product on the market /regulation for placing new substances on the market, including the need to development analytical methods and standards;
- fear of hidden costs and resource needs for changes to new products;
- lack of a common definition of 'green' chemicals in the specific supply chain;
- fragmented demand due to complexities of the supply chains (one manufacturer - many clients, one retailer - many products);
- resistance to change in supply chains with regards to actors and products; any innovation must compete with existing infrastructure;
- confusion on what are the best (better) solutions due to different messages from policy, science, supply chain etc.;
- fear of regrettable substitution;
- difficulties to express benefits in terms of cost savings due to quantification and focus on prices rather than costs;
- imbalance in supply and demand, low rate of commitment between suppliers and users.

Obviously, but something which is not explicitly mentioned in the report, the development of new, non-/less toxic substances takes time, which may be another reason why actors chose to look for existing alternatives, rather than developing new ones, in particular where regulatory requirements include short transition periods.

The report 'An Agenda to Mainstream Green Chemistry'[32] identifies that the development of green chemistry innovations is a key barrier to green chemistry implementation; i.e. it indicates that the supply of new, non-/less toxic substances lags behind the demand. The lack of respective innovation is regarded as being due to financial challenges, difficulties in getting clear market signals about the potential uptake of new, safer alternatives as well as path dependence in supply chains affecting the ability to adapt to changes. Further potential barriers are seen in the lack of funding opportunities for green chemistry innovations as well as regulatory uncertainty regarding options for placing new substances on the market. The authors identify a strong need for education and training at all levels to overcome a lack of awareness and competence, and approaches to stop the externalisation of health and environmental costs in public evaluation of policies and practices in order to illustrate true costing of products and processes. A last barrier mentioned is the lack of indicators to measure whether a change signifies a move in the direction of green chemistry or not.

R.E. Engler [33] identifies the following barriers to sustainable chemistry in general (not focusing on substance design):
- (anticipated) availability, costs or performance of (new) technology;
- needs for technical qualification (internal or regarding standards);
- change-over cost or business risk;
- regulatory notification/registration/approval; and
- a general hesitation to apply 'green' technologies.

He concludes that barriers (and drivers) for green chemistry are equal in all regions of the world and that regulatory barriers apply to any new technology, regardless of whether it is green/sustainable or not. However, where data requirements exist for marketing substances, a more level playing field exists if these apply equally to existing and new substances, hence indirectly supporting the development of new substances as compared to regions, where data requirements exist only for new substances.

[32] Green Chemistry and Commerce Council, 2015.
[33] Engler R.E, 2016.

One of the reasons to introduce REACH in the EU was to eliminate this discrimination between new and existing substances with regards to market access. While the legislation prior to REACH did not require placers on the market to provide information on existing substances[34], extensive information had to be provided for new substances before their placement on the market.

Since the registration of non-phase-in substances under REACH came into force (app. 10 years), 1,567 non-phase-in substances were registered.[35] Statistically, this amounts to app. 195 new substances brought to the market.

The European List of New Chemical Substances (ELINCs) includes approximately 5,400 substances notified between September 1981 and 2008. In addition, notifications that could not be concluded before REACH are included in the REACH statistics as NONS registrations, of which 3,790 were claimed (i.e. a registration number taken). This amounts to a total of approximately 9,200 newly marketed substances within 26 years; i.e. on average 350 per year. This indicates that the development of new substances has decreased since the implementation of REACH.
This analysis should be regarded as very rough and simplified and it should be borne in mind that resources of substance manufacturers were reallocated from R&D to registration activities[36].

An OECD report[37] on the role of governments in green chemistry innovations is based on a survey among company representatives active in the field. The respondents indicated a great potential for growth in green chemistry and highlighted an increasing level of cooperation, including with government agencies in research and information exchange. Challenges are posed by risks and uncertainties related to investments into new technologies and markets.

The participants in the NTE workshop's break-out group were of the opinion that there is no significant lack of tools by which to predict hazards and/or design new substances. An example mentioned is the QSAR toolbox by OECD/ECHA. Stakeholders stated that these tools are available, although some of them are of too a low quality and/or too expensive (for SMEs to afford) and would benefit from improvements regarding their predictability, completeness and applicability. It was not discussed in detail if these tools are sufficiently applicable and fit for purpose if molecules from a (bio-based) chemistry should be assessed.

Overall, stakeholders did not see a lack of tools as a significant obstacle to substance development. This is partly reflected in the written feedback received after the workshop, where the lack of tools for hazard prediction and substance design was evaluated as of low priority with regards to existing gaps and deficits. This is, however, contradicted by the considerably high priority given to activities to improve these tools and implementing respective activities. Furthermore, the working group and feedback from stakeholders might not represent the entire community of scientists and companies that (want to) develop new substances.

Likewise, the availability of research funding for the development of new, non-/less toxic substance was not ranked as a significant gap; in contrast, several actors stated that sufficient funding programmes exist and provide resources, including to SMEs as parts of larger consortia. However, several participants mentioned that the 'freedom of research' is limited by the availability of funding not directly related to marketing a final (innovative) product. Opportunities such as provided by the European Research Council that select projects identified as 'pioneers' and qualify for excellent science should therefore be increased, potentially with a focus, however, on the development of new,

[34] Substances listed in the European Inventory of Existing Chemical Substances (EINECS).
[35] ECHA registration statistics (https://echa.europa.eu/regulations/reach/registration/registration-statistics), viewed November 2016. This number includes actually new substances, as well as 'existing' substances, which have not been pre-registered. However, it is likely that the latter case is infrequent.
[36] EU Commission, 2015.
[37] OECD, 2012.

non-/less toxic substances to direct related R&D activities. It was stated important that research could work on a 'trial and error' basis to develop actually new solutions, rather than (only) incremental improvements. On the other hand, directing research towards providing solutions to societal challenges ensures that public money is being spent for the overall welfare of society and ensures that forces are joined and synergies are created.

The written feedback on research funding is difficult to interpret, because it was identified as a significant gap (second highest priority), whereas the corresponding responses of providing research funding was ranked with a comparatively low priority.

It was discussed at the Stakeholder Workshop that chemicals production is 'locked-in' in the traditional manufacturing processes and facilities as well as the raw materials it uses since a very long time. The comparatively low degree of flexibility in production combined with a business model of selling chemicals rather than solutions would hinder innovation and the development of new, non-/less toxic substances.

In addition, and forming another perspective on the infrastructure for new, non-/less toxic substances development, a lack of education of chemists and chemical engineers in green chemistry was emphasised as important obstacle.
There is a significant correlation between the results from the literature review and the feedback from the stakeholders, identifying the following issues as main challenges/barriers to new, non-/less toxic substance development:

- There are insufficient (legal and market) incentives for new substance development; under the current conditions new, non-/less toxic substances bear many risks as compared to the use of hazardous substances or as compared to substitution with a less, but still hazardous substance. Incentives could include:
  - Regulation has been identified as main innovation driver, e.g. in the latest EU innovation surveys;
  - Economic instruments such as fees and taxes enhancing the need to phase out the use of toxic substances;
  - Methods to internalise external costs of using toxic substances, in order to make new, non-/less toxic substance development more attractive;
  - Instruments like patent rules, awards and market pull instruments to support introduction of new, non-/less toxic substances.
- Actors developing new, non-/less toxic substances and their potential users have insufficient opportunities to make contact. Therefore, it is challenging to change existing, traditional supply chains or to initiate new, non-/less toxic substance development in a particular application. In addition, actors within the scientific and research community should have more opportunities for exchanging information and experience;
- New, non-/less toxic substance development is an interdisciplinary task. Due to a lack of a basic overall understanding of toxicity and how it could be integrated in substance design by all of the actors concerned, the R&D work is less efficient and successful than it is assumed that it could be;
- The overall awareness of benefits of non-/less toxic substances is regarded as low.

2.7 DRIVERS OF R&D OF NEW, NON-/LESS TOXIC SUBSTANCES

The report 'An Agenda to Mainstream Green Chemistry'[38] identifies consumer demand and regulatory pressure as core drivers for green chemistry innovation in general and the related demand for new

[38] Green Chemistry and Commerce Council, 2015.

solutions. Overall, both literature as well as the stakeholder feedback suggest that the incentives posed by regulation outweigh the barriers that could arise from requirements to assess and register new chemicals before marketing. Whereas barriers only occur from chemicals legislation (testing costs, administrative efforts for registration etc.), drivers stem from different legislation, including environmental and workers' protection legislation.

Additional drivers include competitive advantages from new, innovative products and avoiding business risks, such as scandals, insurance costs, etc.

In his presentation at the Global Business Summit 2016, Engler[39] mentioned the following drivers for the implementation of green chemistry, which also relate to aspects of sustainable chemistry in general:

- cost savings, e.g. through waste reduction, treatment reduction, energy savings, worker safety, reduced capital investment;
- unique performance or properties;
- regulatory pressure;
- consensus standards (e.g. ISO, ASTM);
- feedstock security;
- accident prevention;
- liability concerns;
- encourage investment;
- employee recruiting, engagement, retention.

A recent notice by Chemical Watch[40] quotes John Warner (co-founder of the 12 principles of green chemistry) and David Constable (Director of the American Chemical Society's Green Chemistry Institute) saying that regulation would hinder innovation, as industry invests resources in fighting new regulation rather than in developing new, non-/less toxic substances. They state that REACH has only pushed the production of hazardous chemicals to Asia rather than promoting their phase-out. In contrast, the notice quotes the NGOs ChemSec and Centre for International Environmental Law (CIEL), which argue that stricter laws (restrictions and authorisation) do help to bring safer chemicals to the market.

In the report for CIEL, Baskut T.[41] analysed patent filings after a scientific opinion on phthalates was published and the EU Commission recommended that Member States adopt measures preventing children's exposure to phthalates in 1998. He identified a significant increase in patents both for alternative substances to phthalates and alternative solutions that would not need the use of softeners at all. The second case analysed concerns related to CFCs, which, after legislation on ozone depleting substances was passed and continuously made stricter, also stimulated inventions to replace the use of CFCs with less toxic alternatives. Furthermore, it is stated that a clear (legal) direction, according to which chemical properties are to be avoided, is necessary to ensure that new chemicals are actually less toxic than those they replace.

Baskut argues that stricter legislation and economic instruments proved to be useful in making new substances more competitive compared to existing ones, which benefit from economies of scale. This particularly relates to the implementation of the 'polluter pays principle' and taxation of the use of hazardous substances, which directly relates to the degree of hazard and would be a means to internalise external costs from the use of toxic substances.

[39] Engler R.E., 2016.
[40] Stringer, L., 2016.
[41] Baskut T., 2013.

Baskut T. also highlights the importance of information availability on toxic properties in the identification of substances that should be replaced by less hazardous alternatives. He stresses that confidentiality should not apply to substance property information.

Green Budget Europe[42] published a note on the Danish taxation of PVC and phthalates, which was introduced in 2000 and aimed at initiating a reduction in the use of PVC and substitution of phthalates. It requires tax-paying for any products (including imported articles) containing more than 10% PVC and differentiates tax rates according to product types. Phthalate-free PVC is taxed at approximately half the rate of phthalate-containing PVC. The tax is described as successful because it has reduced the use of phthalates by one third and lead to substitution of classified phthalates by non-classified ones.

Schulte, P.A. *et al.*[43] state that green chemistry should include considerations of workers' protection early in the design and selection of chemicals. This would correspond to the hierarchy of measures for workers' protection and has the potential of significantly reducing workers' exposure both during substance manufacture, as well as during formulation and use of mixtures. Parenthetically, the objective of improving workers' protection could be an important driver for green chemistry solutions. The authors also advise involving workers in implementation processes of green chemistry solutions.

The SusChem 'Vision for 2025 and beyond'[44] outlines that the EU chemical industry needs support in order to develop innovations and foster competitiveness of EU industry. They see problems of current R&D work, among others, in the lack of R&D funding and a less positive image of chemistry in general which may be a cause of decreasing numbers of chemistry students.
One of the visions is that working at the molecular scale, e.g. by targeted substance design, would yield new products with improved properties, including fewer and/or less severe hazards. This includes increased use of nanotechnologies and biotechnology, which is also believed to improve material efficiency, better use of wastes as feedstock and would result in less (hazardous) waste. However, the production of substances with fewer or less severe hazards is not explicitly mentioned as a goal or vision of the platform (although it can be assumed to be implied in many areas, such as the development of new materials).

The OECD report[45] on the role of governments in green chemistry innovations identifies regulatory requirements and product standards as key factors driving investment decisions.

Nanomaterials
A number of publications from different perspectives and actors highlight the potential of nanomaterials as an innovation area eliciting high expectations regarding more sustainable solutions to existing challenges, such as the publications by Iavicoli, I. *et al.*[46], Senjen, R.[47] or the OECD[48]. These expectations mainly relate to improved or new technical properties and resource savings, e.g. due to the weight reduction of materials and products. The expectation of new materials with novel properties that could fulfil functions in technical applications for which no solutions exist or where quality could be significantly improved, including through a reduced use of resources or longer product lifetimes, are a key driver in the development of nanomaterials. Barriers to nanomaterial development are uncertainties regarding the potential health and environmental risks from nanomaterials, a lack of methods for their identification and the scepticism of (parts of society) regarding the use of nanomaterials in general. The latter is stated to be reflected in supply chain requests for 'nanomaterial-free' products.

[42] Green Budget Europe, *Briefings, publications.*
[43] Schulte *et al.*, 2013.
[44] SusChem, 2016.
[45] OECD, 2012.
[46] Iavicoli, I. *et al.*, 2014.
[47] Senjen R., 2009.
[48] OECD, 2013.

Due to their small size, nanomaterials may have different hazardous properties than the substances at microscale. Hazards were assessed at the international level for a number of substances by the OECD[49] and, for example, in the context of REACH registrations. At the EU level, the NanoSafety Cluster[50] is dedicated to safety research for nanomaterials. In recent reports, opportunities to predict nanomaterials' hazards using grouping and read-across approaches are discussed, which could be used in the development of nanomaterials and early assessments[51].

Under the EU research and innovation programme Horizon 2020, several projects are funded that deal with the development of (production lines of) nanomaterials that should provide new or improved functionalities. Hence, the particular technology 'nano' is promoted as a research area that appears to have resulted in considerable (positive) innovations.

In the German National Stakeholder Dialogue on Nanomaterials[52], the aspect of safety of nanomaterials was discussed several times. All industry participants and associations, regardless of their size and sector, confirmed that risk assessment is an integral part of their R&D. Nanotechnologies have been discussed at the very beginning of their (intended) use in the market. The high public awareness of potential risks motivated companies to include hazard prediction actions as well as risk assessments to exclude nanomaterials, which are not likely to get acceptance on the market (i.e. cause high risks).

Nevertheless, a study showed that of the total amount of investments done in the development of nanomaterials, only a few percent were allocated to characterising and evaluating their hazards[53].
At the NTE workshop, regulation was found to be the most relevant driver for the development of new, non-/less toxic substances (as opposed to substitution with existing substances), with a functionality not being available in the market (i.e. there is no alternative) or the development of new approaches to solving a particular challenge. More favourable patent rules and/or easier market access for new, non-/less toxic substances were discussed as being supportive but not a sufficient incentive to trigger their respective substance development.

Some participants mentioned that for the substance producers, any change taking place 'anyway' in the production lines could be an opportunity to consider including a new substance in the portfolio.

2.8 PUBLIC PRIVATE PARTNERSHIPS TO FOSTER GREEN CHEMISTRY

Existing public private partnerships (PPP) appear to focus mainly on the use of renewable resources, increasing resource efficiency and decreasing environmental impacts in the field of waste generation, climate gas emissions etc., in order to achieve sustainability goals.

The PPP 'Sustainable Process Industry through Resource and Energy Efficiency (SPIRE)[54]', for example, aims at reducing energy use and consumption of non-renewable resources compared to the current levels. Reduction of the toxicity of products is not in the focus of the program.

The European Technology Platform SusChem[55], and the respective national platforms, is an example of a PPP with the aim of promoting R&D in sustainable chemistry. The cooperation is characterised as

[49] OECD, *Sponsorship programme for the testing of manufactured nanomaterials*.
[50] NanoSafety Cluster, *About the NanoSafety Cluster*.
[51] For example Oomen *et al.*, 2015.
[52] Bundesministerium für Umwelt, Naturschutz, Bau und Reaktorsicherheit, *Der NanoDialog der Bundesregierung*.
[53] EEA, 2013.
[54] SPIRE, *Sustainable Process Industry through Resource and Energy Efficiency*.
[55] SusChem, *Welcome*.

fruitful by its organisers and necessary to join forces and effectively and efficiently promote innovation.[56]

There are several examples of PPPs established to conduct research and innovation in the field of green chemistry, such as:

- The public private partnership 'Bio-based Industries', which uses EU research funding (Horizon 2020) in conjunction with private investments (at a ~1:3 ratio) to further develop technologies and products from renewable resources.[57]
- The Netherlands Organisation for Scientific Research (NWO) under the Ministry of Education, Culture and Science. Among others, it funds research from an 'Innovation Fund Chemistry – LIFT'[58] for university researchers that cooperate with at least one private company.

In their report 'Making the Business and Economic Case for Safer Chemistry', Trucost[59] shows that sales of 'safer chemicals' are increasing whereas the market for conventional products has remained stable. Consequently, they expect economic benefits from green chemistry innovations, with these trends being likely to continue in the future.

An important reason for hesitation in investing in green chemistry is seen in a lack of communication of success stories and related low awareness of overall benefits, including for society (enhanced by the fact that societal costs of toxic chemicals are not quantified and communicated). Furthermore, more fundraising potential could be spurred on if existing co-operations were better supported and if supply chains further aligned their interests and capacities. An analysis of shareholder and NGO activities shows that there is a strong demand for policies to phase-out the use of the most hazardous substances (and replace them with safer alternatives).
Overall, stakeholders generally consider PPPs useful to:

- leverage financing for research and development projects;
- ensure that research and development is oriented towards fulfilling societal goals;
- support uptake of innovations in the market;
- foster health and safety research alongside product innovations; and
- join forces to achieve progress in sustainable development.

2.9 ADDITIONAL INFORMATION FROM STAKEHOLDER INTERVIEWS

Some stakeholders were interviewed to identify which particular support is helpful to foster the design of new, non-toxic substances[60].

The stakeholders confirmed that in most cases, market actors in need of a new, non-/less toxic substance (due to the lack of an existing alternative) initiate R&D. However, if possible they would normally prefer the use of existing substances, because of lower R&D costs, the possibility to test a substance in its application and a higher certainty of knowledge on substance properties as well as a good overview of its supply. The lack of opportunities and networks for suppliers and users to meet virtually or in reality (e.g. conferences, round tables etc.) would hamper the initiation of corresponding actions.

[56] Euractive, *Sustainable chemistry: at the forefront of European innovation*.
[57] Bio-based Industries, *Home.*
[58] NWO, *Innovation Fund Chemistry – LIFT*.
[59] Trucost, 2015.
[60] Joel Tickner, University of Massachusetts, Christopher Blum, German Federal Environment Agency, Klaus Kümmerer, Leuphana University Lüneburg, Several officials from US EPA.

It was mentioned that prejudgements about the high costs and low quality of green chemistry solutions still prevail, creating a potentially cautious or negative business climate towards green chemistry. They stressed a need for awareness-raising, publication of good practice examples on the use of new, non-toxic/less toxic substances and a demand for more/better education and training of all actors involved.
Finally, few incentives to invest in the development of new, green substances were said to exist. This regards the lack of clear regulatory signals on (future) restrictions and substance properties that should be phased out, as well as the existence of standards and certification procedures that hinder changes in product design. Interestingly, the development of more favourable patent rules and exemptions from legal obligations for research and development were not viewed as of high priority for action.

According to stakeholders, the development and use of new, non-/less toxic substances would mainly need:

- Clear guidance from regulation and the market on which substance properties should be phased out (i.e. a definition of 'non-toxic'), clear signals on the phase-out goals (consistent authorisation decisions) and guidelines on when hazard and when risk would be a decision criterion;
- Proper planning and clarification of demands regarding a new, non-toxic substance, including on its technical performance, future legal requirements, standards and certification procedures;
- Networking opportunities for all actors, in particular among those companies that provide and need new, non-/less toxic substances;
- Promotion of any kind of partnerships, e.g. between different companies, between academia and companies, between public authorities and companies, etc.;
- Education and training:
  - Of all actors on the benefits of new, non-/less toxic substances and how to overcome barriers, e.g. via publication of best practice examples;
  - Of researchers and substance designers within their own profession and to enable understanding of the others' work to facilitate a common understanding (e.g. training chemists in basic toxicology or toxicologists in basic chemical engineering);
- Creation of incentives to develop new, non-/less toxic substances, e.g. through green chemistry awards, tax reductions, facilitated market access, market restrictions.

Over the course of interviews, it was explained that the design process '*in-silico*' of new substances is comparatively new and requires a high level of expertise. However, tools are available and could be used after relevant training. Furthermore, the prediction of hazardous properties and linking the substance design to avoiding (eco-)toxicologically hazardous properties are partly new scientific disciplines. Models for hazard prediction would be available, but not for all relevant endpoints and would need improvement.[61] An overview of coverage and the quality of existing hazard prediction models is missing.

In relation to the possibilities to include hazard considerations early into the substance development process, the following needs can be derived from the statements of the interviewees:

- education and training on the design of new, non-/less toxic substances—including on '*in-silico*' and hazard prediction tools—should be promoted;
- work in transdisciplinary teams should be increased to integrate diverse knowledge on substance properties and technical functions early on in the decision-making on substance design;
- networks should be established to combine expertise of different actors in the development of new, non-toxic substances.

[61] Prediction models for physical-chemical properties, mutagenicity and genotoxicity were stated to be well developed. Models for ecotoxicity, bioaccumulation, biodegradation and endocrine disruption were found insufficient.

2.10 USING WASTE AS FEEDSTOCK

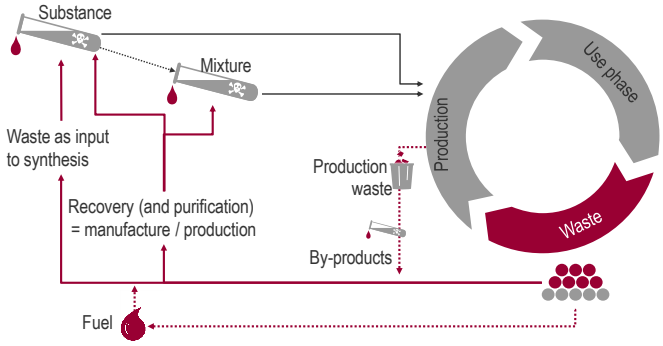
In addition to the goal of developing new, non-/less toxic substances, the EU programme could include aspects of using waste as feedstock in chemicals production to possibly attract more resources and actors involved therein. In addition, this could provide a link to the policy aim of closing materials cycles/circular economy.

The use of waste as feedstock could regard:

- the synthesis of substances from wastes;
- the recovery/extraction of substances from waste materials and their reuse in a new production cycle (potentially after purification);
- the extraction of mixtures from waste materials and entering them into the production cycle (after purification);
- the use of wastes as fuel or energy source for chemicals production.

Figure 3 illustrates the four cases.

Figure 3: Use of waste as feedstock in chemicals production



This aspect was not discussed in detail at the NTE stakeholder workshop. However, in general all participants agreed that:

- efficient use of raw materials, decreasing toxicity and amounts of wastes in the production and use of chemicals are in line with the concept of sustainable chemistry;
- the type of input materials is not likely to (significantly) change the properties of the resulting product (except as impurities) because the same substance should be produced as if virgin materials are used;
- the issue of using waste as feedstock could be considered as vehicle to integrate the topic of developing non-/less toxic substances in existing research programmes.

In addition, the use of waste as feedstock may require different steps in the production of a chemical. A result of this may be that the amount and types of intermediates and by-products as well as impurities of the manufactured substance or mixture changes, which could cause lower (or higher) emissions of toxic substances. This is currently not addressed in detail in the research on waste as feedstock and does not appear to be a priority issue.

Lin, C.S.K. *et al.*[62] give an overview of case studies and activities to use food waste as input material for the production of fuels and chemicals. Food wastes are a valuable input material given their content of organic materials and the high amounts available. Technologies involve the extraction of substances as well as transformation via thermochemical processes (biofuels). However, whether or

[62] Lin, C.S.K. *et al.*, 2013.

not the use of food wastes as feedstock would result in lower emissions of hazardous substances is not part of the current research.

Koutinas, A.A. *et al.*[63] identify biotechnological processes/fermentation as an important option for future production of chemicals from wastes and industrial by-products. The potential of using wastes and applying specifically tailored biological processes are highlighted, i.e. the focus is set on the principles of waste reduction. Whether or not these technologies, and the use of wastes and chemical by-products, would influence the quality and toxicity of the final products and processing emissions is not mentioned.

As in these two examples, literature on the use of waste as feedstock to chemicals production focuses on reducing (organic) wastes and saving input materials. Accordingly, the use of waste as feedstock is (currently) not identified as having a clear relationship to the non-toxic environment.

Several sub-topics on the use of waste as feedstock for the production of secondary materials are covered under Horizon 2020, by research on 'climate, environment, resource efficiency and raw materials'. The aim of these projects is, among others, to decrease the EU's dependency on other regions in obtaining their raw materials. Priority appears to be given to the supply of critical raw materials, including minerals and metals. The focus of research on the use of waste as feedstock focus on resource savings and do not appear to link to toxicity of input or output materials.

[63] Koutinas, A.A. *et al.*, 2014.

3 GAPS AND DEFICITS

3.1 OVERVIEW

Drawing conclusions from the internet research, literature review, stakeholder interviews and the NTE stakeholder workshop in June 2016, significant challenges to the development of new, non/less toxic[64] substances exist and drivers are comparatively weak.

Assuming that regulatory pressure for substitution will increase, among others, due to the implementation of the strategy for a non-toxic environment, the need for safer alternatives will also increase. Stimulation of research on new, non-/less toxic substances may be a logical consequence thereof. However, it is doubted that market forces and creating a demand for new, non-/less toxic substances will be sufficient to satisfy the needs.

The design of benign substances (which are also suitable for the circular economy, in particular where they are destined to stay in articles), should therefore be further enhanced by public programmes, including at EU level, to achieve the societal challenge of a non-toxic environment.

At present, it appears that research funding at the EU level is not fully suitable for projects targeting the development of new, non-/less toxic alternatives to the use of hazardous substances. This is expected at least for those projects that do not address a global challenge in addition to the 'toxic load' and/or which do not involve multidisciplinary, international research teams but are rather targeted to a replacement of a particular toxic substance in a particular application. Furthermore, it seems that the reduction exposure to toxic substances is integrated consistently and focussed as a horizontal approach in all research calls.

Which priority the non-toxic environment should have in relation to other societal challenges, like climate change or resource efficiency, is a political decision. Similarly, the degree to which policy makers interfere in the 'freedom of research' by directing it via the goals of any activity they fund may be a more general discussion at policy level and relate to the level at which the problem is defined that should be solved by research and development projects. However, if the replacement of toxic substances by new, non-/less toxic substances should be promoted, prioritising the topic as a global challenge and creating a separate programme may be useful.

Overcoming challenges from the identified deficits requires targeted actions, possibly in form of an EU programme on the development of new, non-/less toxic substances. The following gaps and deficits were identified:

- Lack of **awareness, education and training** on the possibilities to design (and use) new, non-/less toxic substances at all levels, for example:
  - Company (product) managers are insufficiently aware of benefits of green/sustainable chemistry and have little knowledge on how to identify suppliers, or experience in defining needs;
  - Cooperation in transdisciplinary teams developing new, non-/less toxic substances suffers from a lack of basic understanding between researchers from different disciplines;
  - Chemists lack education and training on how to use available tools, such as for substance *in-silico* design or hazard prediction.
- Lack of **incentives to develop new, non-/less toxic substances and considerable barriers**, e.g. due to:

[64] In the following, the term less toxic substances is used, integrating both the options that a substance is inherently not toxic or that it is 'only' less toxic than the substance it should replace.

- Regulatory uncertainty on the phase-out of substances with hazardous properties, as the current signals from the authorisation procedure are ambiguous (no denial of authorisation) and restrictions are patchy. This results in uncertainties about potential future markets for a new substance.
- Lack of guidance towards the goals of substance development (i.e. which properties should be avoided, which are to be targeted, also with regards to the waste stage of substances);
- Few market incentives and strong competition from existing substances, which are available at low cost (among other factors due to a lack of internalisation of environmental costs and path-dependence relating to existing production equipment) and carry less risk (hazards and market shares are known);
- Few or no market advantages from the use of new, non-/ less toxic substances, e.g. via exemptions from legislation during R&D, patent rules, etc.
- The need to change production equipment, if new substances need to be supplied.

- Lack of **networking opportunities:**
  - For suppliers and potential users of new, non-/less toxic substances to meet and identify cooperation opportunities ('market platforms' outside traditional supply chains);
  - For researchers to exchange information and experience in new, non-/less toxic substance development and to identify cooperation opportunities;
  - For companies using new, non-/less toxic substances to exchange best practices and experience;
  - For all stakeholders to increase awareness.
- Lack of **suitable research funding,** either related to basic research that could inquire new approaches and qualitative changes in the supply of new, non-/ less toxic substances or related to specific, smaller scale research on the development of alternatives to the use of toxic substances, which are not related to larger technology changes.

In addition, all factors hampering the substitution of hazardous substances influence the need for, and readiness to initiate and conduct, the development of new, non-/less toxic substances.

In the discussions at the NTE workshop, the participants in the break-out group stressed that the current culture in substance design should change in order to achieve the goals of having only substances on the market that are safe during use and do not cause any problems during disposal. In particular, the integration of hazard prediction and respective design criteria excluding certain toxic properties from the beginning of the development process were pointed out as a new and necessary mind-set.

Apart from the gaps and deficits identified, an EU R&D programme on new, non-toxic substances would need to have defined goals, indicators for success and related tools to monitor progress as well as an organisation overseeing the implementation of possible activities. These elements that usually pertain to any policy programme are not discussed in detail.

3.2 IDENTIFIED RESPONSES

The gaps and deficits identified in current policy are not new. Member States and stakeholders have, to a smaller or larger extent, identified the gaps and have developed or are developing measures to address the gaps. The catalogue of identified responses listed below, comprises a listing of existing measures practiced in Member States and/or by other stakeholders as well as measures described in the reviewed literature.

A number of ongoing processes within the Commission are currently assessing the performance of chemicals legislation. These include the fitness check of all chemicals legislation except REACH and the REACH review, which are both due in 2017. To achieve consistency between these processes and the non-toxic environment study, the relevant results of this study will be used within those processes.

The catalogue of identified responses in this study is a comprehensive inventory of all possible measures identified during the work of this study. Further assessment will be needed in the context of the better regulation agenda should any of the activities in the catalogue be considered by the Commission to address the gaps or deficits.

Several proposals and recommendations on how to overcome barriers to the development of new, non-/less toxic substances and their use and to strengthen respective drivers were identified from the literature. These could be grouped into two types of responses to the gaps and deficits:

- Response 1: Strategic actions to integrate 'new, non-/less toxic substance development' in all EU policies, including research funding, and to improve the overall regulatory and economic frame for related R&D by:
  - (Further/enhanced) integration of the issue of 'non-/less toxic substances' in all relevant policy areas, research and innovation funding schemes and projects, technology support or publications etc.;
  - Providing orientation on the direction of new substance development with clear signals from legislation on desirable and undesirable substance properties via respective risk management measures and policy statements;
  - Increasing the importance of the non-toxic environment as a global challenge and considering the implementation of a separate research area, aimed at providing alternatives to the use of toxic substances;
  - Lowering regulatory burdens for the development of new, non-/less toxic substances, e.g. regarding approval procedures, registration, authorisation, notification etc. and increasing regulatory burdens for the use of toxic substances;
  - Creating economic incentives by decreasing costs for the development and use of new, non-/less toxic substances *inter alia* via taxes or reduced fees, favourable patent rules etc. and by increasing the costs for (the use of) existing, toxic substances, among others by internalising environmental and health costs, taxes etc.
- Response 2: Enabling actors to better implement R&D on new, non-/less toxic substances this group of identified responses consists of the following actions:
  - Overall awareness-raising of all actors on (the benefits of using) new, non-/less toxic substances, including communication and campaigns on green and sustainable chemistry and substitution, and increasing (commercial and consumer) market demand for non-toxic products;
  - Increasing competences and capacities for new, non-/less toxic substances development through education of the workforce and scientists at all levels;
  - Enhancing collaboration of all actors active in the field (stable, comprehensive, structured and long-term cooperation of all stakeholders);
  - Creation of specific research funding instruments targeting new, non-/less toxic substances development conducted in smaller scale projects than being covered by e.g. Horizon 2020;
  - Promoting the use of legislation and economic instruments in the Member States to increase investments into R&D on new, non-/less toxic substances.

In the following sections, tables are provided listing the different responses identified to support R&D on new, non-/less toxic substances. It is specified for each response, to the closure of which type of gap it could contribute and whether it could be implemented in the short-term, mid-term and long-term. Finally, a brief characterisation of the type of response and why it is useful is provided.

It should be noted that the responses listed only relate to the EU Commission or the Member States. It is expected that the most important incentives for R&D on new, non-/less toxic substance development come from industry, e.g. by starting substitution activities and initiating research on new, safer alternatives.

3.3 RESPONSES RELATING TO POLICY INTEGRATION REGARDING THE ISSUE OF SUPPORTING THE DEVELOPMENT OF NEW, NON-/LESS TOXIC SUBSTANCES

Table 1: Responses identified related to policy integration

Gap /deficit	Reason for gap/deficit	#	Identified responses	Qualification	Discussion
Lack of awareness and low priority on the topic of new, non-/less toxic substance development in the EC in general	Lower priority compared to other challenges	1	Development of a Commission communication on the need to consider across policies and activities if the development of new, non-/less toxic substances could be supported or incentivised. The communication could raise general awareness and outline priority areas where policies could take up instruments and tools to enhance R&D. The communication could also highlight the goal of the non-toxic environment as another horizontal challenge to society. It could point out direction to R&D (i.e. what type of substances and/or materials should be targeted and which properties would be regarded as 'non-toxic') thereby providing orientation and guidance.	Short term, information, orientation and guidance	The option would create an overall framework for policy integration, send clear signals on the relevance of R&D and provide directions for all policy economic and societal actors
		2	Each DG and their units assess what incentives they could provide and/or how barriers could be reduced for R&D on new, non-/less toxic substances: ■ Include the non-toxic environment as a policy goal /societal challenge to be tackled; ■ Identify legislation that discourages R&D on new, non-/less toxic substances, lower disincentives and increase incentives; ■ Identify actions to motivate more consideration of R&D on new, non-/less toxic substances.	Mid-term, EC internal review and different resulting actions	The option would raise awareness and trigger specific actions to strengthen legal drivers, weaken barriers and increase the overall weight of the issue in policymaking.
R&D does not sufficiently include priorities for R&D of new, non-/less toxic substances	Lower priority compared to other challenges	3	Integration of new, non-/less toxic substance design in R&D and R&I funding programmes ■ In evaluations of R&D programmes and their results, the development of new, non-/less toxic substances is explicitly addressed ■ Include rules in existing programmes that encourage assessment and discussion of whether the development of new, non-/less toxic substances could (also)be addressed in an application, e.g. to substitute toxic substances or innovate at a larger scale ■ The awards of research grants could include criteria related to the development of new, non-/less toxic substances; ■ Projects on resource efficiency of use of waste etc. should have an obligatory component assessing substitution opportunities and whether or not new, non-/less toxic substances could be developed; ■ Research strengthening consideration of toxicity in life cycle assessment should be promoted (operationalisation and weighting against other criteria); ■ An assessment of impacts of R&D projects on the use of toxic substances and/or the opportunities to develop new, non-/less toxic	Short-term, information collection, integration in R&D funding	Enhances the understanding that chemicals as a horizontal issue need to be considered in R&D of all areas, increases awareness, directs funding to projects supporting non-toxic innovations, improves information basis on toxic substance use, promotes consideration of toxicity aspects in LCAs, promotes interdisciplinary teamwork

Gap /deficit	Reason for gap/deficit	#	Identified responses	Qualification	Discussion
			substances could be made obligatory.		
Current R&D funding does not fully answer the needs of developing safer alternatives for toxic substances in particular applications	EU R&D funding focuses on other societal challenges; research funding requires high degree of innovation, which might and rather addresses large consortia	4	Identify, which programmes are suitable to fund R&D on new, non-/less toxic substances (e.g. LIFE +) and develop a respective guiding brochure Assess, if additional programmes should be implemented, e.g. as research topic under Horizon 2020 or under other schemes, like ERA etc. Develop research programme, if relevant	Mid-term, information collection and provision, gap analysis, implementation	Pointing out funding opportunities in existing instruments, in particular to SMEs could increase new, non-toxic substance development. From the current study, it cannot be sufficiently well derived, if there is a significant need for funding and/or if this type of R&D should have higher priority to support the NOTES
The implementation of authorisations and restrictions does not fully exploit the potential as regulatory driver for new, non-/less toxic substances development	Regulation and underlying policy priorities were set on other aspects /challenges than phase-out of hazardous substances and replacement by new, non-toxic substances	5	Authorisation decisions should increase pressure for phase-out (i.e. no granting of authorisations where feasible (e.g. DEHP, HBCD)). This would indicate market potentials for new, non-toxic substances and create more predictability.	Short-term, legal implementation	Strengthens regulatory pressure for substitution and development of safer alternatives, prevents ambiguous signals to the market.
		6	Restrictions could apply to substance groups rather than individual substances (decreases the likelihood of existing substances being used as alternative) Restrictions could apply to broader product groups, extending potential markets for new, non-toxic substances.	Mid-term, regulatory	Grouping could decrease the attractiveness of existing alternatives. A broadened product scope might increase potential markets for new, non-/less toxic alternatives (more applications) and make R&D more attractive
Regulatory burdens related to the development of new, non-/less toxic substances are too high	Up to now, regulation is equal for new and existing substances, no priority yet on positively discriminating (new,) non-/less toxic substances, yet. Toxic substances use not in the focus of standards setting.	7	Identify significance of current burdens and extend or revise R&D exemptions, where feasible, not increasing risks and supporting R&D on new, non-/less toxic substances	Mid-term, regulatory, to be addressed under relevant legislation	Decrease administrative burdens /costs for R&D
		8	Identify if the concept of 'low risk products' applied in plant protection and biocidal product legislation could apply in other legal fields, too (i.e. lower burdens for products containing substances fulfilling specific hazard criteria). Incentives/lower burdens include requiring fewer resources for authorisation applications, quicker processing of applications, longer duration of authorisations.	Mid-term, regulatory, to be addressed under relevant legislation	Easier market access for non-/less toxic substances /mixtures containing these, based on proven favourable properties
		9	Revise standards regarding unnecessary burdens for R&D on new, non-/less toxic substances Technology standards may prevent re-design of mixtures and articles; this would also discourage related substance development.	Mid-term, implementation	Potential barriers to market access and /or risks related to denial of market access could be reduced
Too few	Up to now,	10	Develop patent rules favouring new, non-toxic substances, e.g. lower fees,	Mid-term,	Marketing barriers could be

Gap /deficit	Reason for gap/deficit	#	Identified responses	Qualification	Discussion
incentives to invest in R&D	regulation was equal for new and existing substances, no positive discrimination on (new,) non-toxic substances. (Further) promoting phase-out at MS level is hardly implemented.		longer patent duration.	implementation	decreased and potential profits increased, thereby making R&D more attractive
		11	Develop compensation schemes for investments, which do not payoff (non-fault failures to place safer alternatives on the market).	Mid-term, economic	Risks of failure and related costs would be carried (partly) by society, this would have to be accompanied by criteria and routines for proper implementation and prevention of misuse
		12	Motivate Member States to implement taxation schemes for hazardous substances to internalise external costs for the use of toxic substances. Tax breaks could be provided for companies using (new), non-toxic substances.	Mid-term, economic	This could create /increase markets for new, non-/less toxic substances and decrease differences in costs for new and existing substances.
		13	Develop a label 'toxic–free' or 'innovative product due to content of newly developed, non-toxic substance'.	Mid-term, implementation	Promote marketing on new, non-/less toxic substances, support market actors in choosing non-/less toxic substances
Existing (toxic) substances don't reflect their true costs	External costs are not born by the companies (polluter does not pay).	14	Develop schemes that require companies to internalise external costs.	Mid-term, economic	Creating a more level playing field regarding prices /costs of substances would increase the competitiveness of new, non-/less toxic substances and make this option more attractive to companies considering substitution.

3.3.1 Empowering actors to improve new, non-/less toxic substance development

3.3.1.1 Education, training and awareness-raising

Education, training and awareness-raising actions by the Commission could aim at increasing their own activities and incentivising related actions in the Member States and in EU institutions (e.g. scientific committees, agencies, and the JRC). For example, the Commission could seek opportunities to integrate R&D on new, non-/less toxic substance into existing (staff) training programmes.

Another approach would be to launch actions or projects that would deliver materials and tools that could be provided to support teachers at all levels (scholars to professionals), such as lecturing building blocks, experiments, exercises, etc.

Grants could be given to professors to establish new research areas and Ph.D. schools within universities and technical (engineering) schools, possibly in collaboration with business interested in innovation. This could form the basis for developing student courses for bachelor, master and PhD level. In connection with the development of new chemistry, it should be assured that analytical monitoring methods are developed to make it possible to determine future occurrence, hazards and health impacts of the new chemicals

This could be accompanied with an awareness-raising or communication that the topic 'development of new, non-/less toxic substances' be integrated in all of the relevant curricula and specific courses or seminars of scientists and engineers, including toxicologists and ecotoxicologists. Education and training of company managers, procurement personnel and others involved in the decision on which products are manufactured or used could support market uptake and demand for less toxic substances, as well as lower barriers to R&D investments. Education of scientific and technological staff should support innovation capacity. The conduction of these activities by other actors could be stimulated or supported by providing funding – e.g. under the Horizon 2020 or European Research Area.

Examples of existing activities
Discussions of and approaches to education and training are primarily identified in the United States and in relation to the concept of green chemistry. Recommendations from an early stakeholder workshop on the topic[65] appear to be implemented in several universities with chemistry education. Awareness-raising campaigns are also part of many national activities (e.g. at the EPA), or state government policy, where green chemistry is a priority policy area. Existing practices include databases with teaching materials, teachers' networks and student awards.

In the EU, green chemistry or sustainable chemistry teaching appears to be less explicit in the academic context, although some universities offer respective specifications for chemists and chemical engineers. The extent to which 'green chemistry' or 'sustainable chemistry' is integrated into other (scientific) education could not be assessed.[66]

General awareness-raising campaigns on green chemistry or the use of new, non-/less toxic substances by national public authorities could not be identified. However, EU and national institutions as well as stakeholders conduct specific campaigns on substitution, e.g. in relation to workers' protection.

[65] Anastas *et al.*, 2007.
[66] An internet research was performed using English, German and French key words but did not show clear results in this regard. Several Member States might have education programmes on sustainable chemistry in the different natural sciences studies but this was challenging to identify due to the high number of universities, as well as to websites being in national languages.

Table 2: Responses identified related to education, training and awareness raising

Gap	Reason for gap/deficit	#	Identified responses	Qualification	Discussion
There is a lack of overview of existing activities	Education and training on new, non-/less toxic substances (development) is a horizontal issue and only in a few cases a separate activity. Therefore, no monitoring or statistics exist.	15	Collect information on ongoing education and training activities on the development of new, non-/less toxic substances in the Member States as well as in the Commission institutions, e.g. via surveys and/or a dedicated study. Assess the status quo at all stages of education, including scholar, university education and professional training. Identify priority areas, where too little education and training is provided and/or where a demand exists for more knowledgeable staff.	Mid-term, information collection	A better and more detailed picture of training and education needs, e.g. needs for qualified workforce is necessary. Needs and offer on training and education as a basis to decide what specifically should be implemented /supported to strengthen the workforce
		16	Organise information and experience exchange between businesses and educational institutions to identify specific needs for professionals to support and initiate the development of new, non-/less toxic substances.	Mid-term, information and awareness	
Lack of awareness in teaching institutions	R&D on and the use of (new), non-/less toxic substances is not a high priority and challenging to teach due to inherent interdisciplinarity	17	Awareness raising at relevant teaching and training institutions on the development and use of new, non-/less toxic substances for innovation and sustainable development, including demonstrating benefits and opportunities as well as the related legal context.	Mid-term, information and awareness	The option should increase the awareness level via multipliers conducting training and education already.
Lack of opportunities for experience exchange	Teachers and trainers are not aware of each other, no initiative to network has been started. Topic has low priority /awareness in relevant institutions	18	Creation of an EU-wide education network to support teachers and enable sharing of materials and tools for teaching green chemistry or sustainable chemistry for all education levels.	Mid-term, information and awareness	The activity should support information and experience exchange to increase efficiency and spread best practices
		19	Organisation of conferences for education and training institutions to support integration of green chemistry in curricula of all relevant disciplines.	Information and awareness	This response should raise awareness and enable exchange on how R&D on new, non-/less toxic substances can be integrated in current education and training.
General lack of information on benefits of using new, non-/less toxic substances	Low priority of topic, complex issue that cannot be easily discussed.	20	Development and publication of best practice examples of the use of new, non-toxic or less toxic substances, including societal benefits, to raise awareness and create a favourable business environment.	Information and awareness	The action should increase the number of businesses and researchers considering new substance development as a viable solution, including through demonstrating benefits

3.3.1.2 Networking of actors

The aim of networking activities would be to foster the demand for and the supply of new, non-/less toxic substances. This means, in particular, providing structural support for establishing contacts between green substance designers/suppliers and those actors who are in need of solutions requiring the development of new, non-/less toxic substances. This may be challenging, as new business relationships beyond existing supply chains are necessary and particularly relevant for SMEs.

In addition, networking should enhance cooperation and knowledge transfer within the expert community, supporting the development of new, non-/less toxic substances in general and cooperation on specific aspects in particular, such as finding partners for research projects. This includes bringing together experts from different disciplines, such as toxicology and ecotoxicology, engineering, process and product design, etc.

Examples of existing activities
Several examples of networking and cooperation exist in the field of research and (technology) development, some of them are introduced in the following:

SusChem[67], a European Technology Platform for Sustainable Chemistry was created in 2004 as a joint initiative between several chemical umbrella organisations, such CEFIC or the German Society of Chemistry. SusChem, like other EU technology platforms are co-funded by the EU and have an important role as an external advisory forum in the development of the research agenda under Horizon 2020. Several national Technology Platforms are 'members' of the EU SusChem Platform.

The aim of SusChem is to foster and to inspire EU-wide research in sustainable chemistry with a focus on resource efficiency, water, raw materials, smart cities, enabling technologies and education. The development of new, non-/less hazardous substances is not an explicit priority area, according to the overall mission statement. However, the idea of an internet platform organising common research and development activities appears a promising approach leading to synergies, efficient use of resources and ensuring knowledge is distributed between different institutions.

COST is a European framework (not only EU Member States) aimed at supporting cooperation and networking of researchers and other actors, including policymakers and society. This should foster joint idea development and facilitate information exchange, also between policymakers and NGOs. Networking activities within projects qualifying as COST actions are supported with funding, whereas the direct research is not eligible for funding. COST complements research actions and programmes of the EU and in other European countries.

In the US, a network of so-called 'Manufacturing Extension Partnerships' exists, which aims at enhancing productivity and technological performance of US enterprises, including on green innovations.[68] The MEP is organized by the National Institute of Standards and Technology (NIST). It has local offices in all federal states, which are established in cooperation between the Federal Government (NIST) and different public and private partners, including universities, enterprises and non-profit organisations.

The MEP offices provide technical and organisational advice and specifically target SMEs. Support ranges from the provision of advice on workforce management to consultation on optimising technical processes as well as on sustainability, research and innovation.

Funding is stated to be shared among the government and private organisations, i.e. the infrastructure

[67] SusChem, *Home.*
[68] NIST, n.d., *Hollings manufacturing extension partnerships.*

is supported by public funding whereas individual activities and support actions are financed by enterprises and other sources, including research funds. According to its website, and statements by US representatives, the network is very successful in supporting enterprises and the return is much higher than the State's investments in enterprises[69].

With its funding of several technology platforms, such as SusChem, Advanced Engineering Materials and Technologies (EuMat) or Manufuture, the EU contributes to the networking of relevant actors and stakeholders for industrial materials and technologies. In addition, most research projects should include networking activities with other, related projects by default. Consequently, the EU already supports experience exchange of research it is funding.

However, experience exchange and networking of actors not involved in the EU funded research projects but innovating at smaller scale are not normally included in these activities, except where they are members of national technology platforms that are linked to those active at EU level.

Consequently, and in order to support smaller scale, specific development of new, non-/less toxic substances, the EU could support the networking of actors by providing infrastructure (web space, contact persons, potentially coordinators in agencies) and further integrating these actors. Responses to the gap in networking and experience exchange are provided in the next table.

[69] 'As a public/private partnership, MEP delivers a high return on investment to taxpayers. For every one dollar of federal investment, the MEP generates $17 in new sales growth and $24 in new client investment. This translates into $2.3 billion in new sales annually. For every $1,900 of federal investment, MEP creates or retains one manufacturing job. Since 1988, MEP has worked with 86,620 manufacturers, leading to $96.4 billion in sales and $15.7 billion in cost savings, and it has helped create and retain more than 797,994 jobs.'; http://www.nist.gov/mep/about/index.cfm; viewed 07.04.2016.

Table 3: Responses identified related to networking of actors

Gap	Reason for gap/deficit	#	Identified response	Qualification	Discussion
Lack of networking opportunities for potential suppliers and users of new, non-/less toxic substances	Unclear, who should best take the initiative, confidentiality may hinder cooperation, lack of resources, diverse companies and actors which could /should be involved	21	Provide a web platform for companies to post their needs/offers related to developing new, non-/less toxic substances e.g. in the context of substitution or for larger product innovations	Short-term, information	This should help overcoming problems in matching demand and (R&D) supply. This was identified as crucial by many actors
		22	Make existing networks, e.g. on sustainable chemistry, aware of the importance of R&D on new, non-/less toxic substances development.	Short-term, awareness and information	General awareness raising and promotion of new substance development to replace substances of concern.
		23	Provide information on how to meet potential suppliers/customers via relevant agencies (e.g. ECHA discussing potential authorisation applications/Member States).	Short-term, information	Use of the authorities' knowledge on producers /researchers of alternatives to support matching demand and (R&D) supply
Lack of networking opportunities for substance developers	Apart from nanomaterials development, no 'research community' on new, non-/less toxic substances, lack of resources	24	(Provide funding for the) organisation of conferences on new, non-/less toxic substance development.	Short-term, information	Facilitates spreading of best practices and innovation ideas in the research and market communities
		25	Make existing scientific networks, aware of the importance of R&D on new, non-/less toxic substance development.	Short-term, information and awareness	This option should increase interest in the scientific community to contribute to the development of new, non-/less toxic substances

3.3.2 Additional promotion and funding of R&D

The first section of this chapter discussed how R&D promotion and funding on new, non-/less toxic substances should ideally be (further) integrated into existing funding programmes, such as Horizon 2020, LIFE or national R&D programmes. In addition, a separate funding instrument specifically targeting smaller scale research on new, non-/less toxic substances, e.g. in the context of substitution, could be implemented. Finally, it would support the research community if, for example, the elaboration and improvement of tools for (*in-silico*) substance design and hazard prediction could be fostered.

The use of *in-silico* tools appears most advanced in the area of pharmaceuticals; a transfer of experience and an assessment of whether or not, and which, tools could also be used in other applications would be useful. These tools might be adapted to incorporate new functionalities, such as an option to consider specific technical performance of substances.

The identification of hazards to human health and the environment is a crucial step in the design of new, non-/less toxic substances. The earlier the identification of (potential) hazards takes place in the substance design phase, the better this can be taken into account in deciding on and steering the innovation direction. Consequently, there is a need for tools that can reliably predict potential hazards early on in the design phase; i.e. before an actual synthesis takes place (based on information on chemical structures, computational methods/(Q)SARs))[70].

The wide range of tools supporting the comparison of alternatives to hazardous chemicals and/or to assess economic and technical feasibility of substitution are not considered in R&D programmes for new, non-/less toxic substances, as they contribute to facilitating substitution but do not target the substance design phase.

Existing activities
Methods and tools to predict a substance's hazardous properties early in the design phase (i.e. before actual synthesis) can only be based on models and approaches such as (Q)SARs, read-across categories or other computational models, e.g. based on mode of actions.

The literature review on such tools shows that several activities are ongoing, related to all methods of hazard prediction and that many of these aim to improve or develop computational methods and models by which to predict hazards without (new) testing. Research on testing methods also could contribute to model development, as testing results would feed into the overall information basis underlying the development—or supporting the verification—of models.

Overall, considerable progress is being made in hazard prediction for all of the available methods, but existing models are regarded as still being insufficient for regulatory (and potentially also scientific) purposes. For example, (Q)SARs are stated to be available for all classification endpoints; however, they do not cover all of the possible substances (limited applicability domain) and are less reliable than, e.g. animal tests. For complex effects in particular, such as repeated dose toxicity, modelling and hazard prediction based on molecular structure and substance (physical-chemical), properties may remain a challenge for a long time to come.

Large research programmes are ongoing in the EU[71] and the US[72] with the aim of developing new

[70] Although supporting the hazard assessment of new, green substances, the improvement of testing methods for chemicals are not regarded as specific to green chemistry. They are therefore not regarded as in the scope of a GCP programme. An exception is research and development on (in vitro) methods that aim at developing predictive models based on chemical structure.
[71] EUTOXRISK, *An Integrated European 'Flagship' Program Driving Mechanism-based Toxicity Testing and Risk Assessment for the 21st Century*.

hazard prediction approaches based on adverse outcome pathways and modelling as well as in vitro methods, all of which would support the design of new, non-/less toxic substances. In addition, there are software tools being developed[73] that enable the use of existing information for hazard prediction via computational methods.

Research is also ongoing on individual approaches to link the physical chemical properties of substances to their toxicity or to develop intelligent testing strategies for example.[74] These also include specific efforts for efficient hazard identification of nanomaterials.

[72] US EPA, *Toxicology Testing in the 21st Century (Tox21)*.
[73] E.g. CEFIC's ambit tool, available at http://ambit.sourceforge.net/.
[74] E.g. Schug *et al.*, 2013 and Kostas *et al.*, 2015.

Table 4: Responses identified related to additional R&D funding

Gap	Reason for gaps /deficits	#	Identified responses	Qualification	Discussion
Hazard prediction tools need improvement	Tools do not cover all relevant hazards /substance types, quality and usability can be increased	26	Contract study to assess gaps and improvement needs for hazard prediction tools.	Short-term, information gathering	These activities should identify the bottlenecks in hazard prediction, in order to design targeted research calls to close existing gaps in the availability and functionality of hazard prediction tools.
		27	Discuss priorities to improve hazard prediction tools with experts and stakeholders (e.g. public consultation, conferences etc.).	Short-term, information gathering	
		28	Launch call for proposals to close the identified gaps via improvement/development of new related tools (project funding).	Short-term, implementation	
		29	Support (international) networking of researchers on (computational) hazard prediction methods, involve in the work at OECD level.	Short-term, information	Create synergies and enable experience exchange to facilitate the development of better hazard prediction tools that can be used in *in-silico* substance design
		30	Launch EU-wide (or global) platform to consolidate knowledge on hazard prediction methods and create a knowledge resource. Identify if existing platforms, such as created in SEURAT for potential synergies/interlinkages.	Short-term, implementation	Supporting experience exchange and information as well as making available of existing hazard prediction tools
In-silico design tools need improvement	According to stakeholders, the tools are not of sufficient quality (some are) and could be developed to meet specific needs /for specific uses.	31	Assess and publish the status quo of existing tools; gaps and deficits in relation to the ability to design new, non-/less toxic substances for any application (e.g. technical chemicals, plant protection products).	Short-term, information gathering	Feedback on the need for (better) design tools was mixed and the situation unclear. These measures should identify and describe in detail any gaps in tools and incentivise their development, where necessary
		32	Set priorities on improvement needs/needs to support the development of additional tools involving relevant stakeholders.	Short-term, implementation	
		33	Identify training and education needs on the use of tools; assess possibilities to support respective train-the-trainers programmes.	Short-term, implementation	This should enable more actors to use available tools and to involve in new, non-toxic substance development.

3.4 THE USE OF WASTES AS FEEDSTOCK TO CHEMICALS PRODUCTION

Activities on the use of waste as feedstock may be interesting for two reasons:

- The use of wastes as feedstock could affect the use and emissions of toxic substances:
  - Replace toxic virgin materials resulting in a use reduction of toxic substances and/or;
  - Produce less toxic products (differences in impurities and hence in (eco-)toxicity due to input materials and/or differences in processing) and/or;
  - Changes in the amount of emissions of toxic substances (differences in processing).
- Projects assessing the use of wastes as feedstock could be connected to new, non-/less toxic substances development and reducing toxic substance emission, i.e. triggering innovations to generate different products, with less toxic properties. Potential synergies involve raising awareness and integrating the topic of 'non-/less toxic substance development' into overall funding policies.

A literature research on the use of wastes as feedstock to chemicals production has identified a considerable amount of activities. Waste streams rich in organic carbon, such as plastics or food wastes, are considered as a valuable resource, which could be used to produce chemicals either via extraction or by synthetic reactions. Among the latter, biotechnological processes appear to be the most promising option to obtain new chemicals. Research also seems to be oriented towards the production of commodities rather than towards specialty chemicals, i.e. biofuels, acids, polymers etc. are the main products described in the publications. Some examples of related publications are provided in the following paragraphs.

Lin *et al.*[75] give an overview of case studies and activities to use food waste as input material for the production of fuels and chemicals. Food wastes are a valuable input material given their content of organic materials and the high amounts available. Technologies involve extraction of substances as well as transformation via thermochemical processes (biofuels). However, whether or not the use of food wastes as feedstock would result in lower emissions of hazardous substances is not part of the research.

Koutinas, A.A. *et al.*[76] identify biotechnological processes/fermentation as an important option for future production of chemicals from wastes and industrial by-products. The potential of using wastes and applying specifically tailored biological processes are highlighted; i.e. focus is set on the principles of waste reduction. Whether or not these technologies and the use of wastes and chemical by-products would influence the quality and toxicity of the final products and processing emissions is not mentioned.

Xiangqing, J. *et al.*[77] describe a catalytic process using polyethylenes as feedstock to produce fuels and waxes. The two-staged process requires low energy (catalysis). Due to the specificity of the process, purer products are obtained compared to other recycling processes of polyethylenes. This may result in less toxic products and process emissions, but this matter is not explicitly discussed by the authors.

No scientific research has been identified, up to now, on the change in toxicity of the final product, the by-products or emissions from processes using waste as input material. Therefore, it is not possible to judge if these activities are linked to reduced or eliminated toxic substances and, therefore, could contribute to a non-toxic environment. The research priority in the field of using waste as feedstock is clearly set on resource saving and decreasing the dependency on fossil fuels as well as resources from outside the EU. Integrating aspects of the emission or production of new, non-toxic substances in these

[75] Lin, C.S.K. *et al.*, 2013.
[76] Koutinas, A.A. *et al.*, 2014.
[77] Xiangqing, J. *et al.*, 2016.

projects is not evaluated as being helpful, given that other priorities are followed. However, integrating a perspective of monitoring the changes in toxicity both on the side of input and output materials could widen the perspective on costs and benefits of using waste as feedstock and increase awareness on the issue. No specific responses were identified in this respect.

4 AVAILABLE TOOLS TO RESPOND TO GAPS AND DEFICITS

The development of new, non-/less toxic substances is an important element of a Non-Toxic Environment Strategy because it supports a) the phase-out of toxic substances by providing safer alternatives and b) the development of (new) materials or processes that could avoid the use of toxic materials as part of larger innovations.

At present, and using the methods applied in this sub-study (literature research, targeted interviews and stakeholder workshop), it is difficult to judge the current and future demand for new, non-/less toxic substances development. However, assuming policy trends moving towards the phase-out of toxic substances, and with a view to the continuous specialisation and innovation regarding new materials and processes it seems important and forward-looking in supporting and further developing competences and capacities in the EU research community on the development of new, non-/less toxic substances. A further development of capacities and competences inside the companies using chemicals, as well as in capacity building, training and educational institutions, is of equal importance to ensuring market uptake and the availability of a well-trained workforce.

Dedicated programmes for supporting research and the development of new, non-/less toxic substances do not exist at the global, regional or national levels, except the 'Green Chemistry Initiative' by the US EPA. The EU funding programmes do not explicitly target the development of new, non-/less toxic substances to replace toxic ones; however, there are related programmes in the area of (nano-)material innovations. Several institutions as well as stakeholder organisations are working on elements related to and supporting the development of new, non-/less toxic substances, such as building up pressure for the substitution of toxic substances, awareness raising, research and the development on design and hazard prediction tools etc.

Specific barriers to the development of new, non-/less toxic substances are a lack of contacts between the supply and the demand side, as new relations outside traditional supply chains need to be established. In addition, the development of new, non-/less toxic substances poses considerable business risks, including development costs, risk of decreased performance of the new products, low acceptance on the market etc., which appear to frequently outweigh the potential benefits of reducing the content and emissions of toxic substances from products and processes. Finally, it is challenging for new, non-/less toxic substances to compete with existing substances, of which hazards and costs are known and which are available without a time lag. Consequently, any 'programme' to enhance the development of new, non-/less toxic substances should respond to the barriers identified and strengthen any drivers and benefits of new substance development.

In this regard, several types of responses to the gaps and deficits are identified:

- (Further) integration into EC policies and activities as well as awareness raising on the needs and the opportunities to develop new, non-/less toxic substances in all relevant directorates of the EU;
- Review of existing legislation and its implementation regarding barriers to new, non-/less toxic substances development and how they could be decreased as well as which elements strengthening related R&D could be further elaborated;
- (Further) integration of aspects related to the substitution of toxic substances and the development of new, non-/less toxic alternatives in all EU funding policies and consideration of establishing a funding programme specifically addressing the need to develop safer alternatives as replacement for toxic substances;
- Implementation of measures at EU or Member State level to decrease the discrimination of new, non-/less toxic substances against existing ones, regarding prices by integrating external costs and using economic instruments like taxes and fees;
- Education and training of scientists, engineers and other relevant staff on the benefits and options to develop new, non-/less toxic substances as alternatives or in the context of product and process

innovations;

- General awareness raising on the toxic load and options to reduce it by developing new, non-toxic substances;
- Increase of information and experience exchange between researchers, companies and policy makers as well as teachers and trainers create synergies and spread best practices;
- Provision of additional, specific funding for research supporting the development of new, non-/less toxic substances by providing new and improved tools;
- Provision of research funding at 'small scale' to specifically support the development of new, non-/less toxic substances to replace toxic substances in particular applications.
- Development of indicators and monitoring instruments to evaluate policies and research funding with regard to the availability of (new) non-/less toxic substances on the market, e.g. by production and use volumes.

Overall, the societal challenge of a continuously increasing use of chemicals and an increased exposure level of humans and the environment currently has a lower priority than other challenges, such as climate change and resource efficiency. This results in a lower priority of substance development for R&D.

An EU programme on the development of new, non-/less toxic substances should be weaved into existing activities and could, to a large extent , consist of integrating and/or highlighting the option and opportunities of developing new, non-/less toxic substances. However, a separate programme would have be a stronger incentive for substance development.

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Study for the strategy for a non-toxic environment of the 7th EAP

Sub-study g: Early Warning Systems for emerging chemical risks

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ABBREVIATIONS USED

AF	Advisory Forum
ANSES	Agence Nationale de Sécurité Sanitaire
BEUC	European Consumer Association, Bureau Européen des Unions de Consommateurs
Bfr	Federal Institute for Risk Assessment
BVL	Federal Office on Consumer Protection and Food Safety (Germany)
CAD	Chemical Agents Directive
CEI	Centres for Epidemiology and Animal Health Centres for Emerging Issues
CEPA	Canadian Environmental Protection Act
CEPROSS	Communication of Occupational Diseases, Social Security
CESES	Consumer Exposure, Skin Effects and Surveillance
CIS	Common Implementation Strategy of the Water Framework Directive
CLP	Classification, Labelling and Packaging of substances and mixtures
CMR	Carcinogenic, Mutagenic or Reprotoxic
COEH	Centre for Occupational and Environmental Health
CPSC	Consumer Product Safety Commission
CRL	Community Reference Laboratory
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
CTGB	Board for the Authorisation of Plant Protection Products and Biocides in the Netherlands
DMEL	Derived-Minimum-Effect-Level
DNEL	Derived-No-Effect-Level
EAP	Environment Action Programme
EASIS	Endocrine Active Substances Information System
EC	European Commission
ECDC	European Centre for Disease Control
ECETOC	European Centre for Ecotoxicity and Toxicity of Chemicals
ECHA	European CHemicals Agency
ED	Endocrine Disruptor
EEA	European Environment Agency
EFSA	European Food Safety Authority
EMEA	European Medicines Agency
EMM	European Media Monitor
EMPODAT	Emerging Pollutant DATabase
EMRISK	Emerging Risks Unit at the EFSA
EPIDERM	European Prevention Initiative for Dermatological Malignancies
EQS	Environmental Quality Standards
EREN	Emerging Risk Exchange Network
ESCO	EFSA Scientific Cooperation Working Group
EFTA	European Free Trade Association
EU	European Union
EU-OSHA	European Agency for Occupational Safety and Health Administration
EU-RAR	European Risk Assessment Report
EUROSTAT	European Union statistical office
EVESCAP	Valoración de sospecha de cáncer professional
EWG	Environmental Working Group
EWS	Early Warning System
EXPOCAST™	US-EPA research programme: Exposure Science for Prioritisation and Toxicity Testing
FAO	Food Agricultural Organization of the United Nations

GAST	Le Groupe d'Alerte en Santé Travail
GIEWS	Global Information and Early Warning System on food and agriculture
GOARN	Global Outbreak and Alert and Response Network
GPHIN	Global Public Health Intelligence Network system
GPSD	General Product Safety Directive
HSE	Health Safety Environment
I&M	Ministry of Infrastructure and the Environment (the Netherlands)
IGZ	Inspectie voor de Gezondheidszorg/Health Care Inspectorate
IIDB	Industrial Injuries Disablement Benefit
ILO	International Labour Organization
INAIL	National Institute for Insurance against Accidents at Work (Italy)
INFOSCAN	International Food Safety Authorities Network
IPCheM	Information Platform for Chemical Monitoring
JRC	Joined Research Centre
LOQ	Limit of Quantification
KWR	Watercycle Research Institute
MALPROF	Italian system for recording and surveillance of work-related diseases under INAIL
MEC	Measured Environmental Concentration
MODERNET	Monitoring trends in Occupational Diseases and tracing new or Emerging Risks
MSDS	Material Safety Data Sheet
MTR	Maximaal Toelaatbaar Risiconiveau (MPC, Dutch Maximum Permissible Concentration)
MW	Molecular Weight
NCOD	Netherlands Centre for Occupational Disease
NERCs	New and/or Emerging Risks of Chemicals
NGO	Non-Governmental Organisation
NIOSH	National Institute for Occupational Safety and Health
NORMAN	Network of reference laboratories, research centres and related organisations for monitoring of emerging environmental substances
NVIC	Nationaal Vergiftigingen Informatie Centrum/Dutch National Poisons Information Centre
NVWA	Netherlands Food and Consumer Product Safety Authority
OccWatch	Occupational diseases sentinel clinical Watch system project
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
OPRA	Occupational Physicians Reporting Activity
OSPAR	Oslo and Paris Conventions for the North Atlantic marine environment
PANOTRASTSS	Incidence and prevalence of occupational diseases in Spain
PBDEs	Poly Brominated Diphenyl Ethers
PBT	Persistent, Bioaccumulative and Toxic
PFCs	Perfluorinated Chemicals
PNEC	Predicted-No-Effect Concentration
QSAR	Quantitative Structure-Activity Relationship
RAPEX	Rapid Alert System for dangerous non-food products
RASFF	Rapid Alert System for Food and Feed
RAS-BICHAT	Rapid Alert System for Biological and Chemical Attacks and Threats
REACH	Registration, Evaluation, Authorisation and restriction of Chemicals
RIDDOR	Reporting of Injuries, Diseases, and Dangerous Occurrences Regulations
RIVM	National Institute of Public Health and Environment (the Netherlands)
RNV3P	National Occupational Diseases Surveillance and Prevention Network (France)
RWS	Rijkswaterstaat
SCCP	Scientific Committee on Consumer Products
SCCS	Scientific Committee on Consumer Safety
SCENIHR	Scientific Committee on Emerging and Newly Identified Health

	Risks
SCER	Scientific Committee for Emerging Risks
SCHER	Scientific Committee on Health and Environmental Risks
SCHEER	Scientific Committee on Health, Environmental and Emerging Risks
SCOEL	The Scientific Committee on Occupational Exposure Limits
SIGNAAL	Signalering Nieuwe Arbeidsgerelateerde Aandoeningen Loket/Signaling New Occupational Diseases Counter
StaCG-ER	Stakeholders Consultative Group on Emerging Risks
SVHC	Substance of Very High Concern
SWORD	Surveillance of Work Related and occupational lung Disease
SZW	Ministry of Social Affairs and Employment (the Netherlands)
SUE	Serious Undesired Event
TERA	Toxicology Excellence for Risk Assessment
THOR	The Health and Occupation Research
TRA	Targeted Risk Assessment
UN	United Nations
US-EPA	United States Environmental Protection Agency
US-FDA	Food and Drug Administration of the United States
vPvB	very Persistent and very Bioaccumulative
VWS	Ministry of Health, Welfare and Sport (the Netherlands)
WHO	World Health Organization
WFD	Water Framework Directive

ABSTRACT

This report describes the current methodologies for finding new and/or emerging risks (NERCs) for the protection of workers, consumers and the environment. The key goal here is the identification of a generally applicable methodology to finding NERCs for each of these three protection groups. The feasibility of such a universal approach must also be addressed, in light of the differences in the discovery and evaluation of NERC signals.

The systems that exist at present depend highly upon observed and documented signals relating to occurrence of effects and potential exposure, the so-called "effect based" or "disease first" systems. Some systems contain elements that can be used to proactively identify possible NERCs, based on a proper risk assessment, the so-called "exposure first" methods.

The analysis of existing national and international tools and methods, developed and in operation for the early identification of new or upcoming chemical threats, identified several reasons why existing approaches are not completely satisfactory and why greater effort at the European Union level is needed.

The continuous effort of screening and filtering signals is essential to early identification, but a labor-intensive process needs input from experts, which is not organized and coordinated at an international level.

An international platform, working continuously on the identification of chemical threats and in the application of different approaches for collecting these signals appears to be lacking. In general, there is a need for greater cooperation and exchange of information at the EU level on NERCs. An overall integral approach covering identification, finding further evidence, and proposing appropriate risk management measures at the EU level is needed in order to facilitate progress towards a non-toxic environment, but seems to be missing. However, there are various initiatives in the areas of early identification, data collection, and the management of chemical threats at the national and international levels that could possibly connect to the establishment of an early warning system.

EXECUTIVE SUMMARY

Chemicals regulation in the European Union aims at the safe use of chemicals and protecting man and the environment through predicting the hazardous properties and by limiting exposure through risk management measures. Despite the various kinds of legislation, numerous well-documented cases exist of extensive damage to health and environment caused by the production and use of chemicals. Furthermore, it often takes a long time for societal institutions to pick up on these warning signals, and even longer for them to react.

For example, 10 of the 15 *Late Lessons from Early Warnings* identified by the European Environment Agency are directly linked to chemicals with hazardous properties (i.e. benzene, asbestos, PCBs, halocarbons, DES, antimicrobials, MTBE, PFAS, TBT, EDCs). Half of those cases highlighted issues caused by the persistent nature of chemicals (i.e. PCBs, halocarbons, MTBE, PFAS and TBT), several emphasized the additional risks induced by the cumulative effect of hazardous substances (i.e. PCBs, halocarbons, MTBE, TBT, EDCs), and two underlined the impacts of late lessons on vulnerable groups (i.e. PCBs, EDCs). Furthermore, instances are highlighted in which years or decades spanned before regulatory intervention.

This illustrates that the early identification of chemical threats to human health and to the environment is of great importance in taking timely measures to reduce or to eliminate the risk of hazardous compounds.

The aim of early warning systems is to identify, as early as possible, those chemicals that might potentially be hazardous and cause adverse effects, as well as to identify those situations in which exposures to substances could lead to harm to humans or to the environment. Early identification allows for appropriate actions to protect man and the environment to be undertaken earlier and can be of great value in achieving a high level of public safety and environmental protection. Early identification provides more time for further investigation or the implementation of measures to prevent or control issues of concern. In this way, an early warning system could facilitate progress towards a non-toxic environment.

Further, a systematic approach for the early identification of chemical threats could contribute to identifying gaps in existing legislation, as well as in data and knowledge, and could support enforcement authorities. Developing an earlyresponse system for detecting and tackling approaching chemical threats to human health and the environment should however be regarded as a complementary action, a kind of safety net, though and not as an alternative instrument to replace current legislation.

A variety of tools, methods and activities have been drawn up, developed or initiated for the early identification of new or upcoming chemical threats for the protection of workers, consumers and the environment. These tools and methods are commonly known as Early Warning Systems (EWS) or Rapid Response Systems (RRS).

This study provides an overview of existing national and international tools and methods as well as an analysis of the systems for the early identification of new or upcoming chemical threats.

Early warning systems considered

Important aspects to consider when establishing an early warning system include the definition of new and/or emerging risks (NERCs) and the system's specific aim. This pre-defines what the system will be able to do and sets the boundaries to the kind of information to use and the output to generate.

A variety of terms and definitions have been used, such as new risk, emerging risk, emerging issue,

emerging pollutant, emerging substance, and contaminant of emerging concern. These can be grouped into three main categories: (i) newly created risk; (ii) newly identified risk; or (iii) increasing risk becoming widely known or established. Examples of the last category includes combined and cumulative exposure to chemicals as well as low dose and long term effects on health and environment. These issues are considered as major challenges, not sufficiently managed by current policy, while concerns and attention to them is growing.

A review of currently available methodologies and systems have identified various components that will be required in order to develop an operational warning system for the EU, one aimed at proactively identifying new and emerging risks of chemicals. In general, the phases presented below have been identified. An EU early-warning system should first be able to filter signals from the media, scientific literature, and experts and to evaluate those signals. This could also include screening and monitoring data. The second step should be to check if the signal has been identified previously and if actions or regulatory measures have already been implemented and if so deemed sufficient. A third step, based on target-specific criteria, would include the gathering of additional exposure, hazard and policy data regarding these risks for discussion by experts. Subsequently, the data could be translated into a risk score, thereby prioritizing newly identified risks of chemicals and finally defining the risk management options (RMO) required and/or identifying the most suitable actor to address the risk.

In-depth analysis of existing systems

In general, two basic methods can be distinguished. The proactive "exposure first" method would aim to identify possible new and emerging chemical risks (NERCs) based on physical, chemical, and toxicological properties of a substance and/or the (altered) exposure resulting from the use of a substance, taking technological and societal developments into account. The second method is the "disease first method" (or "effect first method"). This is a reactive method that tries to identify environmental and health effects of NERCs as soon as possible. The "disease first" method is complementary to the "exposure first method".

Environment

Only two operational systems were identified that aim both at the identification and management of new or emerging risks of chemicals (NERCS) for the environment – the NORMAN network (2016) and the NERC system operated by the RIVM. Both non-institutionalized systems are currently operational in the EU and are discussed in greater detail below. In addition, a more general approach to the identification and prioritization of emerging issues is presented.

NORMAN is a network of reference laboratories, research centers and related organizations for the monitoring of emerging substances. It systematically collects monitoring data and information on the effects and the hazardous properties of substances. Based on this information, the substances are assigned to priority action categories. A set of criteria is used for the allocation of emerging substances to these clearly pre-defined categories and their subsequent prioritization. The ultimate aim is that substances are selected to be put on the Watchlist of the Water Framework Directive 2000/60/EC. The list of substances to be considered for prioritization is established through expert consultation and chemical analytical methods. An example of the latter is non-target screening; a method aiming at a broad detection and identification of chemicals that is not directed to a specific set of chemicals. Action is taken when there is clear evidence of actual environmental effects. The method could, therefore, be characterized as "effects first".

The system operated by the RIVM uses online media monitoring, expert consultation and non-target screening for the identification of new or emerging risks. A hazard and exposure based approach is used to provide further evidence on the possible risk and derive a risk score in order to prioritize. A variety of information sources are used to provide information on the possible exposure and hazardous properties of the potential new or emerging chemicals identified. Highly prioritized chemicals can, then, be proposed for a risk management option analysis under REACH for instance. Based on this analysis, the most suitable risk management measure within REACH or other legislation would be determined. The method allows to identify substances and undertake action before an effect occurs, for instance based on identified hazardous properties, as well as to identify substances with clear environmental effects, based on observed effects or exceedance of quality standards, resulting from the evaluation of monitoring data. This system uses the "disease first" method, complementary to the "exposure first method".

Thirdly, the work done by the Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR) is largely based on expert consultation. Two parallel and complementary approaches may be used to identify emerging issues: (i) a proactive approach that requires 'brain storming' sessions to identify the emerging issues of principal concern followed by the introduction of procedures to detect and characterize their development; (ii) and a more reactive approach based on the identification of indicators of change and the monitoring of these to detect emerging issues.

SCENHIR proposes a decision tree approach (algorithm) for the identification and prioritization of NERCS, based on qualitative criteria such as uniqueness, soundness, and scale of severity.

Workers

In relation to chemicals at the workplace, proactive "exposure first" methods aim to identify possible NERCs, based on a proper risk assessment. However, for most substances the necessary information to use deductive reasoning is lacking. This holds especially true for toxicological information regarding the routes of exposure that are important for workers, i.e. inhalation and dermal exposure (most available toxicological information is for oral exposure). Therefore, an inductive way of reasoning is needed to identify and handle substances that have a negative impact on worker's health; i.e. "the disease first" method. This inductive way of reasoning works from observations (cases of diseased workers) toward generalizations and theories. The "disease first" method is used, for instance, in pharmacovigilance. Drugs are tested thoroughly prior to their introduction onto the market, but the identification and evaluation of negative health effects reported after their introduction onto the market is still needed.

Considering the "disease first" method, there are systems based on expert forecasts. One review consists of an overview of more than 40 (potential) NERCs for workers reported over the last few decades using several data sources. A method for prioritization of these NERCs is presented in Palmen and Verbist (2015). As part of the current sub-study, a survey was carried out among European countries to get an overview of existing early warning systems for workers. This revealed three different methods within the "disease first method" category:

- 'clinical watch system' for the collection of spontaneous reported cases in Europe;
- databases that may be used for epidemiological research on possible relationships between occupation and/or exposure to substances and health effects (e.g. occupational cancer);
- biomarkers for exposure and/or biomarkers for biological effects that can be used to detect NERCs.

One limitation of such a system can be the long response time between exposure and observed effects. This can be addressed partly by detection of more sensitive effects or end-points by using for instance biomarkers.

No typical system using the "exposure first" method has been identified for workers.

Consumers
Several systems or organizations, which deal with new and emerging risks of chemicals in food or consumer products (toys, cosmetics and household cleaning products), were found to be of potential use for the possible layout of a future EU-wide, sector-specific early warning system for consumer protection.

The systems that exist at present highly depend on observed and documented signals relating to occurrence of effects and potential exposure. Cosmetovigilance systems such as the European Cosmetovigilance and the Dutch Consumer Exposure Skin Effects and Surveillance and the national poison centers provide valuable information on the epidemiology of adverse effects, intoxications and poisoning incidents that can be used to pick up a signal and to take measures.

The EU-wide Rapid Alert System for dangerous non-food products (RAPEX) enables quick exchange of information about dangerous products found. The reports in RAPEX deal mainly with the failure of compliance with regulations, thus mainly regulated products and chemicals. In a sense, this system is pro-active as it aims to prevent harmful effect resulting from product failure or products not being compliant.

The European Food Safety Authority (EFSA) seems, so far, to have the most advanced early warning system regarding food related consumer exposure. This EWS is aimed at proactively identifying a (re)emerging hazard and, consequently, preventing the presence of this hazard from giving rise to a risk by taking preventive measures. Trends in indicator values and a variety of information sources such as monitoring and scientific data are combined and evaluated to identify an emerging risk within a network of experts. The key characteristic of this system is that it is anticipatory, rather than responsive. It is different from rapid alert systems such as the Rapid Alert System for Food and Feed (RASFF) where notifications are triggered by controls or consumer complaints.

Conclusions
Several approaches can be taken to pick up signals, such as online media monitoring and expert consultation or registration systems for the collection, evaluation and systematic monitoring of spontaneous reports of undesirable events. The systems that exist at present highly depend on observed and on documented signals relating to occurrence of effects and potential exposure, the so-called "effect based" or "disease first" systems. Some systems contain elements that can be used to

proactively identify possible NERCs, based on a proper risk assessment, the so-called "exposure first" methods.

Many data sources are already available that can be used to provide further evidence for the selection or prioritization of potential new or emerging risks related to chemical substances. The selection of suitable approaches for picking up signals and prioritization should be based on effectiveness and efficiency. Generating an overview on existing data sources, their availability, accessibility, and their usefulness would be essential to establishing an EWS. Subsequently, the data would have to be made accessible through a central database. A quantitative risk based procedure, based on hazard assessment and exposure assessment, is common in the field of risk assessment of chemicals for human health and the environment. An alternative way to identify or prioritize new or emerging risks, such as those proposed by SCENIHR, is based on identifying possible NERCs, based on qualitative criteria.

Investigating and identifying appropriate risk management options, followed by communication of the risks identified and the proposed measures are essential to managing the observed risks. It appears that the component covering risk communication is not always well covered in existing systems, meaning that there is limited or no information about a communication plan directed at decision makers and enforcement authorities or notice to define the actions on how to communicate the results obtained. The need to develop a communication plan (including by whom and how) should, therefore, be addressed in the development of an early warning system in particular. Building an overview of current environmental legislation and the risk management options they provide, including the competent authorities, is the first step in formulating a communication plan.

Due to the many differences that exist between the fields of environmental, consumer, and worker protection and the differences between and within Member States on how signals on new and emerging risks are collected, processed and interpreted, it may not be feasible at this moment in time to create a single system covering all the three fields. The overall advice, therefore, would be to utilize existing systems as much as possible and to try to make interconnections and facilitate communication at the Member State and European levels. The basic building blocks and steps as described above can be used as a starting point to establish a European early warning system for identifying chemical threats to human health and the environment.

There are several reasons why existing approaches are insufficient and effort at the European Union level is needed. From the analysis of existing national and international tools and methods developed and operated for the early identification of new or upcoming chemical threats it is concluded that the continuous effort on screening and filtering of signals is essential for early identification, but thislabor-intensive process also needs input from experts at the national level, which is currently not organized and coordinated at the EU or international level. Furthermore, it will always be hard to establish a causal link between exposure to chemicals and, for example, diseases. One issue relating to this is the limitations of epidemiology, meaning that a harmful effect must often be rather drastic and widespread in order to be detectable. There is often a lack of information due to the absence of relevant hazard data as well as the absence of exposure and use information. Therefore, it is important to identify all of the useful sources of information and databases that are available, and to centralize this information as much as possible in order to come to an effective and efficient procedure for the evaluation of the signals collected and identifying new or emerging risk of chemical.

An EU or international platform, working continuously on the identification of chemical threats and applying different approaches for collecting these signals appears to be lacking. In general, there is need for more cooperation and exchange of information at the EU level on NERCs. An overall integral approach, covering identification, finding further evidence, and proposing appropriate risk management measures at the EU level is needed in order to facilitate progress towards a non-toxic environment, but currently seems to be missing. However, at the national, EU and international levels, there are various initiatives in the area of early identification, data collection, and in the management

of chemical threats that could possibly connect well to the establishment of an early warning system.

1 INTRODUCTION

Chemicals regulation in the European Union aims at the safe use of chemicals and protecting man and the environment through predicting the hazardous properties and by limiting exposure through risk management measures. Despite the various kinds of legislation, numerous well-documented cases exist of extensive damage to health and environment caused by the production and use of chemicals. Furthermore, it often takes a long time for societal institutions to pick up on these warning signals, and even longer for them to react.

For example, 10 of the 15 *Late Lessons from Early Warnings* identified by the European Environment Agency (EEA, 2002 and 2013) are directly linked to chemicals with hazardous properties (i.e. benzene, asbestos, PCBs, halocarbons, DES, antimicrobials, MTBE, PFAS, TBT, EDCs). Half of those cases highlighted issues caused by the persistent nature of chemicals (i.e. PCBs, halocarbons, MTBE, PFAS and TBT), several emphasized the additional risks induced by the cumulative effect of hazardous substances (i.e. PCBs, halocarbons, MTBE, TBT, EDCs), and two underlined the impacts of late lessons on vulnerable groups (i.e. PCBs, EDCs). Furthermore, instances are highlighted in which years or decades spanned before regulatory intervention.

Therefore, the early identification of chemical threats to human health and to the environment is of great importance in taking timely measures to prevent, reduce or to eliminate the risk of hazardous compounds.

This interim report describes the current methodologies in finding new and/or emerging risks (NERCs) for the protection of workers, consumers and the environment. A key goal is the identification of a generally applicable methodology to finding NERCs for each of these three protection groups. In light of the differences in the finding and evaluation of NERC signals, the feasibility of such a universal approach must also be addressed.

A range of tools, methods and activities have been drawn up, developed or initiated for the early identification of new or forthcoming chemical threats. These tools and methods are commonly known as early warning systems (EWS) or Rapid Response Systems (RRS). The report presents key findings from the literature review of the existing projects and studies on Early Warning Systems for anticipated chemical threats, together with the outcomes of the Workshop 'Strategy for a non-toxic environment' held in Brussels on 8/9 June 2016.

The study on existing early warning methods and systems intends to provide:

- An overview of existing projects and studies in the area of EWS that could be of use in the development of an EWS for chemical risks;
- Insight into the different aspects for consideration in establishing an EWS for chemical risks, including components that already exist or would need to be developed;
- An overview and discussion of the remaining gaps and deficits in respect of such an an EWS;
- An overview of possible improvements and options for the set-up of a useful EWS.

Problem Statement

Despite the various kinds of chemicals legislation in the EU, numerous well-documented cases exist of extensive damage to health and environment caused by the production and use of chemicals. Furthermore, it often takes a long time for societal institutions to pick up on these warning signals, and even longer for them to react. Therefore, the early identification of chemical threats to human health and to the environment is of great importance in taking timely measures to prevent, reduce or to eliminate the risk of hazardous compounds.

Problem Statement

Developing an early response system for detecting and tackling approaching chemical threats to human health and the environment should be regarded as a complementary action, a kind of safety net, and not as an alternative instrument to replace current legislation.
The aim of an EWS is to identify; as early as possible, those chemicals that may be hazardous and cause adverse effects. Early identification of emerging issues can be very valuable in maintaining a high level of public safety and environmental protection. Early identification provides more time for investigation or the implementation of appropriate measures to prevent or control the issues of concern. A systematic approach for the early identification of chemical threats could also contribute to identifying gaps in existing legislation, as well as data and knowledge gaps, or to informing enforcement authorities or other stakeholders of the acquired information to . In this way, an EWS could facilitate progress towards a non-toxic environment.

An EWS should take a systematic, proactive approach and aim to provide additional evidence, insight into the appropriate risk management options, and communicating this information to the relevant authorities or other stakeholders to enable them to act voluntarily or proactively.

2 OVERVIEW OF THE STATUS QUO

2.1 DEFINITION AND SCOPE OF AN EARLY WARNING SYSTEM

Two critical aspects to consider when establishing, organising, and operating an EWS are: (a) the definition of new and/or emerging risks and (b) the system's specific aim or aims. This pre-defines the scope of the system, i.e. what it will be able to do, as well as setting limits on the kinds of information used and the outputs generated.

Those working in the area of EWS (e.g. European Food Safety Authority (EFSA) 2009 and 2014a; U.S. Environmental Protection Agency (US-EPA), 2008; Network of reference laboratories, research centres and related organisations for monitoring of emerging environmental substances (NORMAN Network), 2016 and Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), 2009) use a variety of terms and definitions, such as new risk, emerging risk, emerging issue, emerging pollutant, emerging substance, and contaminant of emerging concern. These can be grouped into three main categories:

- Newly created risk;
- Newly identified risk;
- Increasing risk or risks becoming widely known or established.

The typologies of NERCs used in this study were adapted from the European Agency for Safety and Health at Work (EU-OSHA) [EU-OSHA, 2009]. These are presented in Table 1 below.

Table 1: Typologies of new and emerging risks of chemicals

New risks	Emerging Risks
• Risk caused by new types of substances on the market, new processes, new technologies, new types of workplaces, new types of exposure routing; social or organisational change; environmental changes. • An issue is newly considered as a risk due to a change in social or public perceptions. • New scientific knowledge allows a longstanding issue to be identified as a risk.	• Number of hazards leading to the risk is growing. • Likelihood of exposure to the hazard leading to the risk is increasing, (e.g. exposure degree and/or the number of people exposed). • Effect of the hazard on the environment, the health of workers or consumers is worsening. • More information on an issue becomes available.

This study focuses on the risks posed by chemicals to human health and the environment. The kinds of chemicals covered are used as, or in, industrial chemicals, biocides, pesticides, food and feed additives, cosmetics, medicines, metabolites, and by-products (e.g. from combustion and material (dust) generated by high energy treatment of solids substrates). The different environmental compartments affected are air, water and soil. Human exposure might occur via the environment, consumer products, food, and exposure to chemicals at the workplace.

2.2 GENERAL APPROACH OF AN EARLY WARNING METHODOLOGY

Based on the existing methods and tools developed by the Food Agricultural Organization of the United Nations (FAO, 2006), Dulio and von der Ohe (2013), SCENIHR, 2009 and the National Institude of Public Health and the Environment in the Netherlands (RIVM, Hogendoorn, 2014 and Palmen, 2016) the following five steps of an EWS can generally be identified (see Figure 1 below). These steps are further explained in the sections below.

Figure 1: Steps involved in an EWS

The first step, picking up signals, involves searching and tracing information on new or emerging chemical risks and their possible related effects, using various sources (e.g. scientific literature, news sites, websites, electronic databases and stakeholder networks). For risks to humans (workers or consumers), epidemiological research and case reports are also valuable sources of information. While clear criteria help the process of filtering out relevant signals, initial expert assessment is an essential factor in the signal evaluation process (Palmen, 2016 and Hogendoorn, 2014).

The next step is to check if the signal has been identified previously and, if so, whether actions or regulatory measures have already been implemented. This could lead to an immediate follow-up action, such as informing enforcement or inspection authorities, depending on the kind of signal. If the identified concern is already sufficiently covered and there is no need for further enforcement actions, additional information collection and prioritisation is considered unnecessary.

During the next step, 'signal strengthening', additional evidence should be obtained, including expert consultation, in order to assess the causality between the chemical exposure and the harmful effect.

A 'prioritisation of risks' then follows, in which an indication of the severity of the risk will be provided based on the information obtained during the 'strengthening of signals'. The prioritisation step will result in a list of potential NERCs requiring a follow-up procedure.

Finally, follow-up measures are defined, including derivation of a safety limit (e.g. Scientific Committee on Occupational Exposure Limits (SCOEL) for worker risks) and actions to be taken, for example under Registration, Evaluation, Authorisation and restriction of Chemicals (REACH) or Classification, Labelling and Packaging of substances and mixtures (CLP) legislation, e.g. authorisation, restriction, or harmonised classification and labelling) or by making use of, or adapting, other relevant legislation.

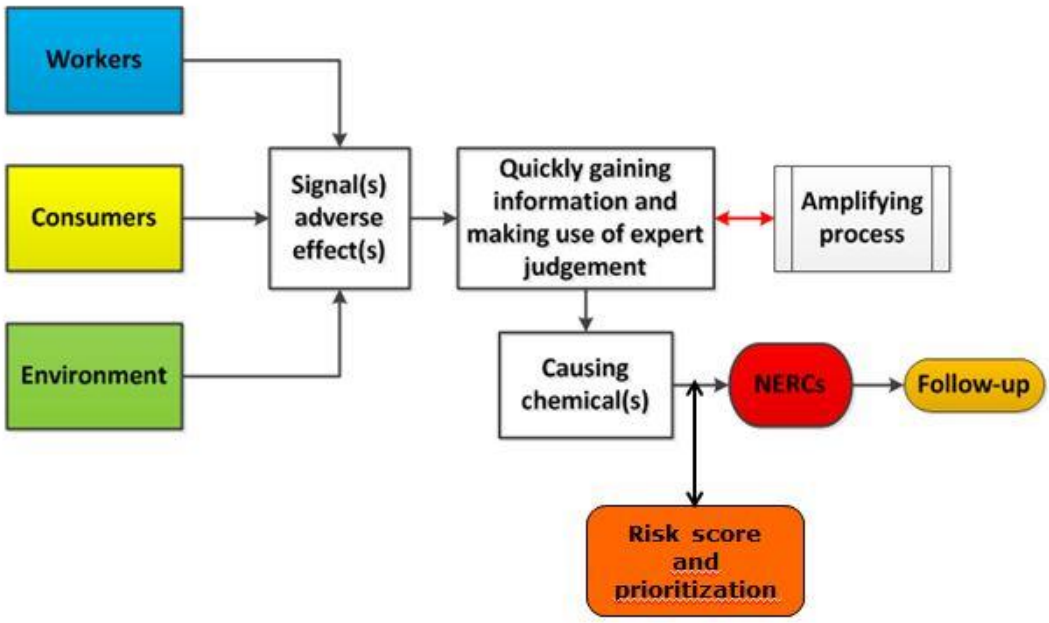
2.2.1 Detecting signals

For each protection target (the environment, consumers, workers), the first crucial step is to pick up signals on new or emerging threats posed by chemicals, then finding and collecting relevant information on the potential NERC. For workers and consumers, this requirement focuses on the collection of data on adverse health outcomes related to exposure from various sources, thus providing an overview of chemical stressors. Based on this data, well-known chemical stressors may be identified, for instance in new types of products, as well as new chemical risks, i.e. new hazardous properties previously undiscovered or not associated with a particular substance.

In practice, the process of identifying NERCs varies slightly for each protection target. For workers, the identification process of a NERC is usually triggered when an adverse health effect is observed in workers and there is a likely causal relationship with specific chemicals at the workplace. In the case of consumers, the identification of a NERC is often based on the collection of information on an adverse human health effect caused by exposure to consumer products containing a variety of substances, which might eventually lead to the identification of the chemical(s) causing the adverse effect. For the environment, the identification of a NERC is usually severely hindered by the presence of numerous other compounds with highly fluctuating concentrations. This makes it very difficult to determine causality between an observed adverse effect and a single target chemical (NERC). The same is true for humans indirectly exposed via the environment (air, drinking water and food). This reactive approach – the so-called 'disease first' method – tries to identify environmental and health effects of NERCs as soon as possible after an adverse effect has been reported. The proactive 'exposure first' method, by contrast, would aim to identify possible new and emerging chemical risks (NERCs) based on all physical/chemical/toxicological properties of a substance or the (altered) use of a substance, taking technological and societal developments into account. It is important to be aware of the differences in routing and evaluation in the identification of a NERC and these are further described in Chapter 3 of this report. After the collection of data, an evaluation and/or expert judgement will be necessary in order to identify NERCs that require a follow-up action to reduce or eliminate the risk.

A general scheme for the identification and evaluation of signals of possible NERCs for the three target protection groups is illustrated in Figure 2 (Hogendoorn, 2014).

Figure 2: General scheme for the tracing and evaluation of NERCs



Several methods or tools are used to pick up or generate signals, such as foresight approaches, monitoring and sampling, citizen science, and online media monitoring (Science for Environmental Policy, 2016). Some of the methods are briefly outlined below, providing an overview of the different possibilities rather than an indepth analysis of their efficiency and effectiveness.

Foresight approaches are, essentially, expert consultations, where a team of specialists and academics works together to identify important future threats, such as the Delphi method (systematically developing expert consensus on future developments and events). Also in this category is scenario planning, which can usefully be combined with the Delphi method to detect emerging risks. Scenario planning is about describing potential future challenges and is not a prediction of what will happen in the future. Another approach is horizon-scanning; this aims to spot signals, watch trends and make sense of the future. This includes, for example, forecasting trends in the use of new chemicals and new applications of chemicals based on the development of new technologies.

Monitoring and sampling covers several techniques, such as chemical analysis of the known chemicals in the environment in order to keep track of changes. Another technique is non-target screening, used to detect chemicals that are not covered by the standard monitoring programmes. It is a method for the identification of environmental pollutants without having to first identify the compounds of interest. Methods like bioassays and biomonitoring identify the biological activity of chemicals or monitor and link specific chemicals to measured effects in (living) organisms in order to identify chemicals of concern. An example of a biomonitoring programme is the European Human Biomonitoring Initiative – HBM4EU (EC, 2017)

Citizen science or community-based monitoring uses the community to detect certain kinds of information, e.g. environmental hazards (air concentration of pollutants), weather information (precipitation, temperature), information on the occurrence of animals and plants (invasive species, bird counting, etc.). Citizen science uses modern technology like smart phones, such as in the iSPEX-project (iSPEX-EU, 2016) and internet communities such as Observation International, 2016 or the UK Environmental Observation Network (UKOEF, 2017). This information can be collected at an higher level (European Union) using national focal points and national reference centres, as in the case of the European Environment Information and Observation Network (EEA, 2016)

Screening online media - such as online news, scientific publications and social networks - by applying software that uses algorithms and structured search terms for picking up relevant signals that can also give an indication of a new or emerging risk. A variety of public tools exist, e.g. the European Media Monitor (EMM, 2016), or the International Biosecurity Intelligence System (IBIS, 2016), while commercial tools such as HowardsHome Monitoring and Coosto are available to screen digital media on the internet.

2.2.2 Signal strengthening and priority setting

'Signal strengthening' aims to collect additional evidence, including expert consultation, to assess the causality between the chemical exposure and the reported harmful effect. Evidence requires both information on exposure and hazardous properties of chemicals, or the discovery of similar cases. In view of the 'exposure first' method, there is no link with observed effects at that point in time. Nonetheless, the aim is to find evidence of possible adverse effects or hazardous properties of the chemical in question.

A 'prioritisation of risks' then follows, in which an indication of the severity of the risk is given, based on the information obtained. The prioritisation step will result in a list of potential NERCs requiring a follow-up procedure. In practice, the causality assessment and prioritisation are simultaneous and complementary processes.

Several different approaches are used to rank the relevance of a potential chemical of concern. In general, a risk-based approach is applied, using various kinds of information on the exposure and hazards of that particular chemical. The information used in prioritisation depends on the availability and accessibility of data, as well as the amount of effort required to generate specific data, such as measured and modelled exposure concentrations or Quantitative Structure-Activity Relationship (QSAR) estimates for hazardous properties. Ranking of the potential risk can be carried out by applying exposure or hazard categories (high, medium or low) to the data obtained. (Hogendoorn, 2014; Palmen and Verbist, 2015; Schuur and Traas, 2012; ECHA, 2010 and 2014; Ohe et al., 2011; Dulio and von der Ohe, 2013; Kuzmanović, et al., 2015; Mitchel et al., 2013; Guillén et al., 2012). An inventory of potential data that can be used for prioritisation purposes is therefore particularly important. Each parameter must be assessed: both the data source and its availability should be indicated, together with the actions and amount of effort needed to gather or generate specific type of information.

Several potential data sources and platforms have been considered here, such as IPChem (2016), NORMAN network databases (NORMAN, 2016), EASIS (2016), EXPOCAST™ program (Egeghy et al. 2011; Mitchell et al. 2013; Wambaugh et al. 2013) and the MODERNET network (Palmen, 2016). Some of these are solely data sources, some address data gathering, risk assessment, and prioritisation, others tend to be used for the early identification of new and emerging chemical risks.

Table 2 provides a short overview of the data on hazards, exposure and risks that might be used in the prioritisation of new and emerging chemicals. Different types of data can be used for both signal strengthening and prioritisation, e.g. measured data, data based on modelling or statistical methods, and data based on expert judgement. By its nature, each type of data has a degree of uncertainty, and this must be reflected in scoring or characterising the potential risks that have been identified. In setting up its EWS and prioritising NERCs (Hogendoorn, 2014), RIVM applied a qualitative indicator to the degree of uncertainty.

Table 1: Overview of potential data sources that can be applied in prioritisation

Description	Data Source	Degree of uncertainty
Hazard		
Environmental and occupational quality standards, limit values etc.	Legislation (Water Framework Directive (WFD), Air Quality Directive, etc.)	Low
Predicted no effect concentration, no observed effect levels, etc.	REACH registration data	Medium
Hazardous properties	C&L notification and REACH registration database at ECHA, EASIS database. PBT assessments	Low
QSAR based assessment of hazardous properties	QSAR models/software	High
Hazard scores and prediction of potentials or mode of action based on QSARS and models	QSAR models/software	High/Indicative
Exposure		
Measured concentrations	NORMAN databases, IPChem, national databases	Low/Medium
Production volumes	REACH registration database at ECHA	Low/Medium[1]
Modelled worker exposures (inhalation and dermal)	ECETOC-TRA, Stoffenmanager, Advanced Reach Tool (ART), and others	Medium/High
Modelled concentrations based on emissions and used volumes	SOLUTIONS project	Medium/High
Exposure categories (environmental release categories, process categories, etc.)	ECHA registration database	Indicative[2]
Risk		

Description	Data Source	Degree of uncertainty
Measured data case by case, accidents		Low
Epidemiology		Low-High
Modelled results from risk assessments	Risk assessment reports, chemical safety assessments (CSA), REACH registrations	Medium/High

[1] The exact production volumes are not publicly available but are usually provided in ranges. Class widths generally cover a factor of 10: 1-10; 10- 100; 100-1,000, etc.
[2] The exact share of the different uses of the total (production) volume is unknown; main use should be identified, with broad exposure categories.

2.2.3 Follow-up actions and communication

In the final step, (see Figure 1 and 2) after identifying and determining a NERC, follow-up actions have to be indicated, including possible risk management measures and a communication strategy. For example, the REACH Regulation includes some possible risk management measures which could be utilised to address an identified risk.

For a quick and appropriate response, an EWS should ideally pre-define or inventory the possible risk management measures to be triggered, e.g. by identifying the types of chemicals to be covered (industrial chemicals, biocides, cosmetics, etc.), the relevant risks (safety or health related), the pieces of legislation that address these risks and the risk management options within each piece of legislation (restriction, authorisation, enforcement, etc.). Finally, each measure should also identify the appropriate authorities to be informed.

3 LITERATURE REVIEW

A literature review was carried out of the existing projects and studies on EWS for anticipated chemical threats in order to gain an insight into those that might prove to be useful in the development of an EWS and to provide an overview on the different aspects to be considered in such a system, including those components that already exist or those that would need to be developed. The review was also designed to ascertain the remaining gaps and deficits that would impact on the establishment of an EWS, as well as an overview of the improvements needed and the viability of setting-up a useful EWS.

In order to extract information in a consistent and useful way, the literature selected was evaluated through the checklist shown in the text box below.

Questionnaire for reference

1. *What is the name of the system /registry/instrument?*
2. *What is the goal of the system/method/instrument/ methodology/ database?*
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?*
4. *Which organisation collects the information on possible (new and emerging) risks?*
5. *Which language is used in the system?*
6. *Is it available publicly or not?*
    a. *Scale (national, EU, intercontinental)*
    b. *Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics, etc.)*
7. *What definition is used for new or emerging risks?*
8. *In which way are signals on possible (new and emerging) risks collected?*
    a. *Automated procedure, expert judgement, expert panels, internet communication platforms*
    b. *Type of sources consulted (newsletters, databases, digital media, scientific papers, symposia, etc.)*
9. *Are possible (new and emerging) risks collected in some way (national database)? How is the registration done?*
10. *How is the first report of a possible (new and emerging) risk evaluated and what criteria are used to evaluate reported signals?*
    a. *Level at which automated procedures, expert judgement, manual work, is needed*
11. *Who evaluates the first report of a possible (new and emerging) risks?*
12. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body? Which evaluating bodies are in contact?*
13. *How does the evaluation and start/set-up of follow up for a possible (new and emerging) risk take place?*
14. *What were the costs involved in the set-up of the system? What does the maintenance of the system cost?*

The individual responses for the systems examined in this way are presented in Appendix 1, which also includes an interview with the Dutch National Poisons Information Centre (NVIC), using the same questionnaire. The following three sections discuss the results of the review for each of the relevant policy areas.

3.1 EARLY WARNING SYSTEMS FOR ENVIRONMENTAL PROTECTION

The literature review revealed only two operational systems that aim to both identify and manage new or emerging risks of chemicals (NERCs) for the environment: the NORMAN network (2016)[1] and the NERC system operated by the RIVM (Hogendoorn, 2014). Both systems are currently operational within the EU and are discussed in more detail below. A more general approach to the identification and prioritisation of emerging issues (SCENIHR, 2009) is included, as are the screening and prioritisation approaches of ECHA and Member State authorities under REACH, and which cover the environment, public health and occupational health.

The NORMAN network is a non-profit association of all interested stakeholders in the field of emerging substances. The goal of the NORMAN network is to enhance the exchange of information on emerging environmental substances. It encourages the validation and harmonisation of common measurement methods and monitoring tools to better meet the requirements of risk assessors and risk managers. The NORMAN network (2016) distinguishes between emerging pollutants and emerging substances. 'Emerging substances' can be defined as substances that have been detected in the environment but which are currently not included in routine monitoring programmes at EU level and whose fate, behaviour and (eco)toxicological effects are not well understood. 'Emerging pollutants' can be defined as pollutants that are currently not included in routine monitoring programmes at the European level and which may be candidates for future regulation, following research into their (eco)toxicity, potential health effects and public perception, and analysis of monitoring data on their occurrence in the various environmental compartments. According to the NORMAN network, emerging pollutants are any substances introduced into the environment that adversely affect the usefulness of a resource or the health of humans, animals, or ecosystems. In that sense, emerging substances are potentially emerging pollutants but which lack sufficient information to either address them as pollutants or deal with them through existing regulations.

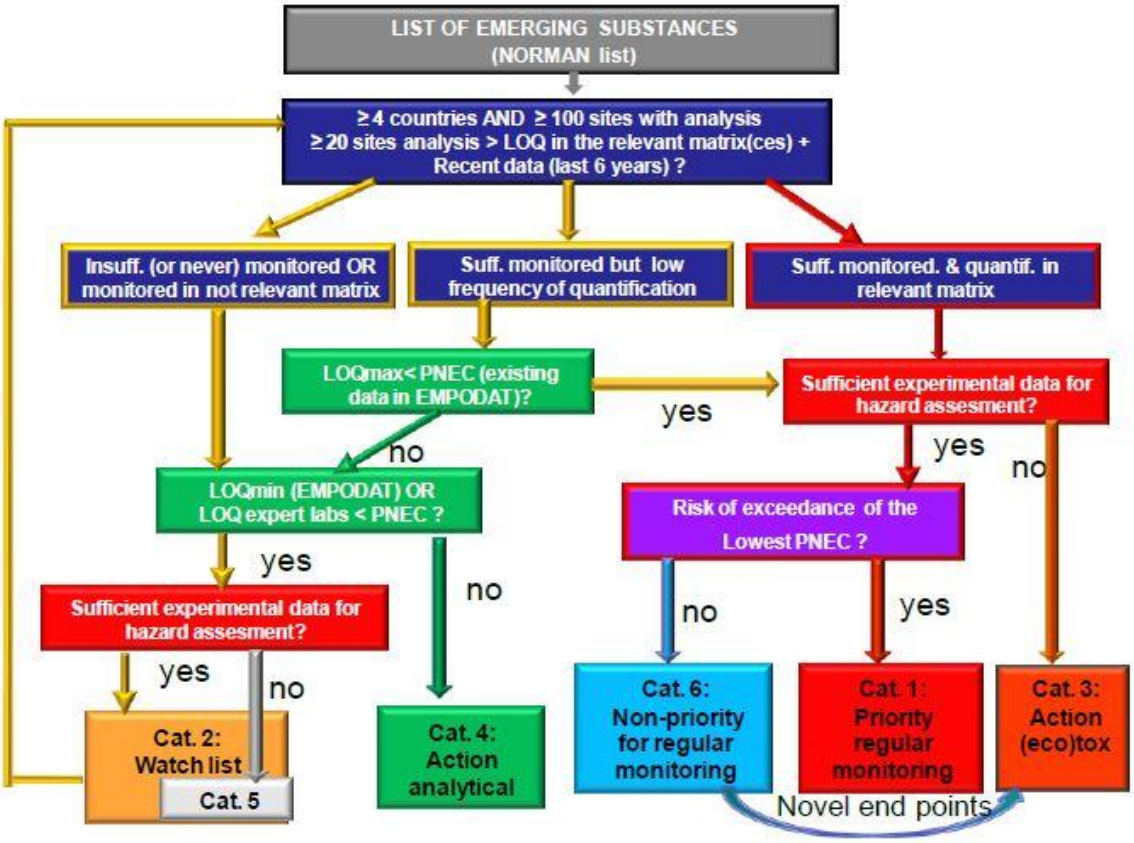
To-date, the activities of the NORMAN network have chiefly addressed the requirements of the WFD. Identified and prioritised chemicals are proposed as candidate substances for the EU Watch List of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council (Article 8 of Directive 2013/39/EU).

The NORMAN network systematically collects monitoring data and information on the effects and the hazardous properties of these substances in EMPODAT, a database of geo-referenced monitoring or occurrence data on emerging substances. Based on this information, the substances are assigned to priority action categories by the NORMAN Prioritisation Working Group, which is co-ordinated by INERIS (France) and comprises experts from national authorities, industry and consultancies

The NORMAN network procedure for the classification of emerging substances is shown in Figure 3, along with the steps to be followed.

[1] http://www.norman-network.net/

Figure 1: Norman network approach on finding NERCs in water



The list of emerging substances (NORMAN list) is compiled through expert consultation and then augmented with substances identified from other NORMAN working group activities, such as the working group on effect-directed analysis for hazardous pollutants identification, the working group on non-target screening, and the working group on biomonitoring (bioassays and biomarkers).

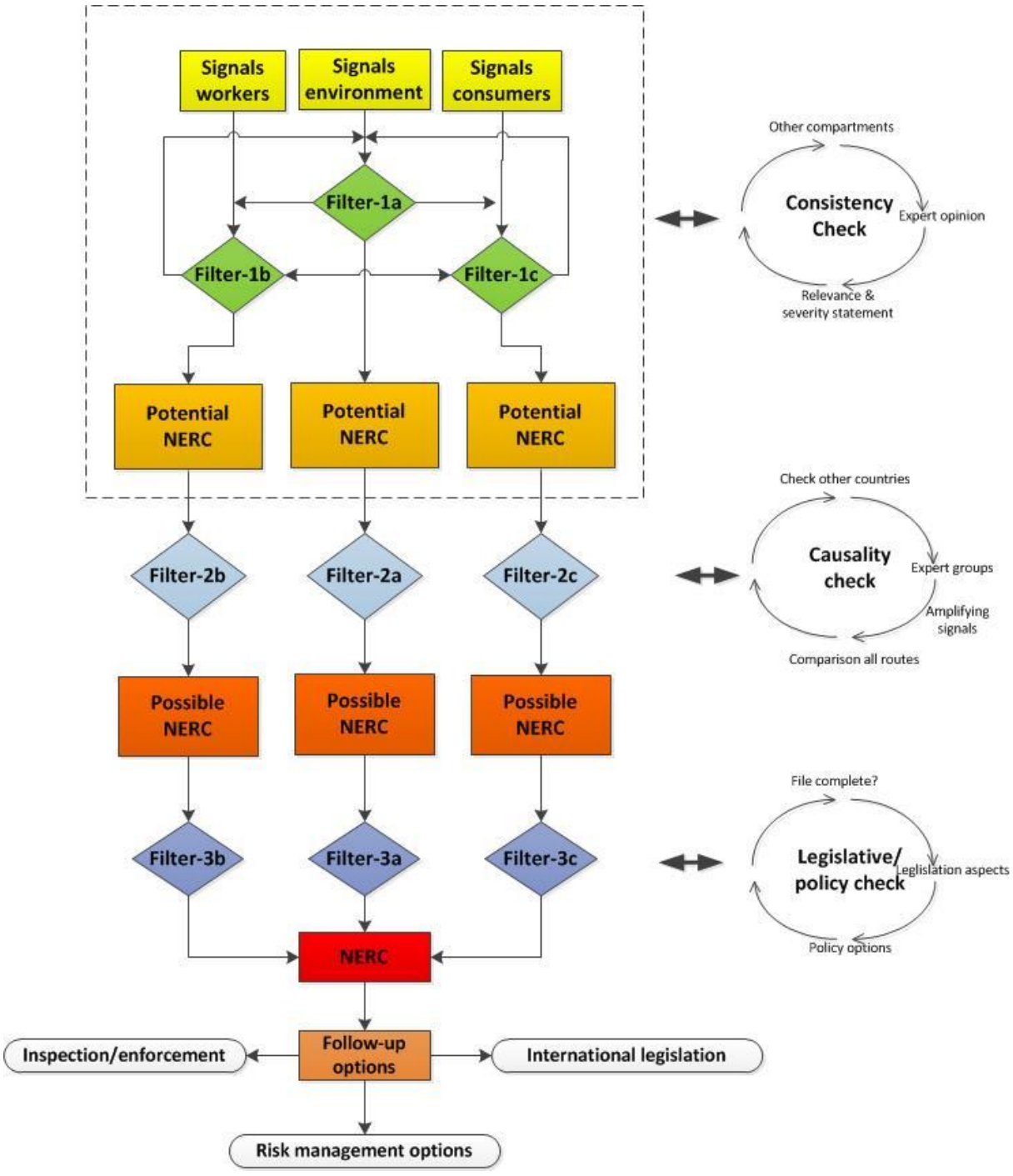
A set of criteria is used for the allocation of emerging substances to clearly pre-defined categories (e.g. substances for which there is not yet sufficient information about their toxicity, substances for which there is evidence of hazard but analytical performance is not yet satisfactory, etc.), and their subsequent prioritisation.

The criteria employed are frequency of occurrence, exceeding environmental quality standards (EQS), and hazard information. The information needed for prioritisation is collected in the EMPODAT database, and a high degree of manual work and expert judgement is necessary for the prioritisation process.

The RIVM study (Hogendoorn, 2014) presents methodologies for finding and prioritising NERCs for each protection group i.e. consumers, workers and the environment. It also suggests measures to reduce exposure to the selected NERCs in the short-term. Although there are methodological similarities in the identification of NERCs for each protection goal, the complexity and route of exposure of NERCs requires different approaches to identification and risk management in each case. The separate pathways for each protection goal are illustrated in Figure 4, which shows the approach, the steps involved, and the process of linking information. The common features are at the level of methodology. Common and different types of sources are explored for signalling (e.g. scientific literature, news sites, websites, electronic databases, stakeholder networks) and for gathering and

evaluating information, involving international networks of experts to assess the causality between the chemical exposure and the effect. The approaches for worker and consumer-related NERCs will be discussed in Chapters 3.2 and 3.3 of this report.

Figure 2: Schematic of the approach to the tracing of NERCs (Hogendoorn, 2014)



The NERC system operated by the RIVM is not aimed at any specific piece of legislation in the field of chemicals. The focus for the environment - until now - has been the aquatic environment.

The system operated by the RIVM (Hogendoorn, 2014) uses online media monitoring, expert consultation and non-target screening for the identification of new or emerging risks. The European Media Monitor (EMM, 2016) is used to screen digital media by applying a specific set of search terms. In addition to the EMM, a weekly newsletter is generated by using HowardHome Monitoring to screen online news sites and scientific literature. A web-based expert platform has been set-up to facilitate discussion and information exchange on new and emerging risks, as well as new analytical techniques or tracing them. Two projects have been carried out, applying non-target screening for the identification of new or emerging chemicals in the aquatic compartment. A substantial set of substances was identified as potential new or emerging chemicals (Kolkman and ter Laak 2012; Sjerps et al, 2015).

To derive a risk score for prioritisation, Hogendoorn (2014) uses a hazard and exposure based approach. Various sources provide information on the possible exposure and hazardous properties of the new or emerging chemicals in question. The information used ranges from environmental monitoring data to proxies for potential exposure, such as use-based exposure categories and production volume. Identification of hazardous properties is based on existing EQS or no effect levels, the classification of substances as carcinogenic, mutagenic, and reprotoxic (CMR), ED, or an assessment of these properties based on QSARs when no other information is available.

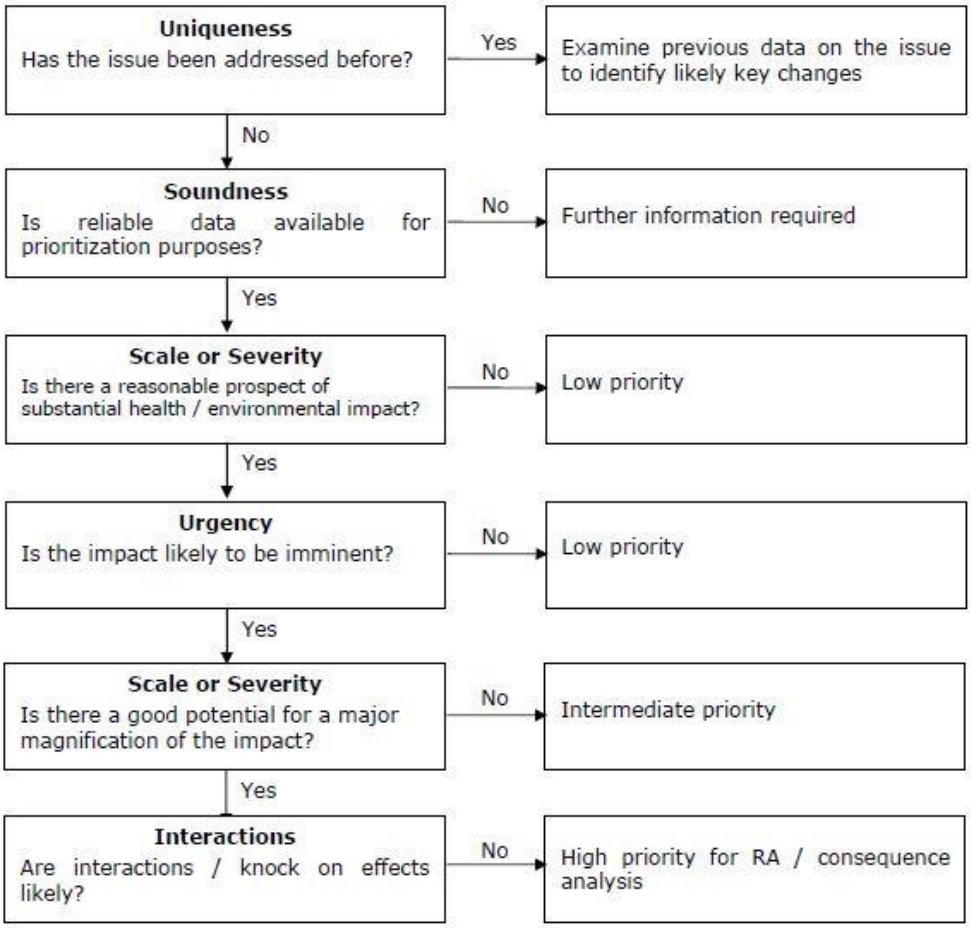
Some highly prioritised new or emerging chemicals were proposed for a risk management analysis under REACH. Based on this analysis, the most suitable risk management measures within REACH (substance evaluation, restriction, authorisation or harmonised classification and labelling), were determined and further REACH activities and processes initiated.

The SCENIHR provides opinions on emerging or newly-identified health and environmental risks and on broad, complex or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other Community risk assessment bodies. The work done by the committee is largely based on expert consultation and foresight approaches. A position paper on emerging issues and the role of the committee (SCENIHR, 2009) recognised two parallel and complementary approaches to identifying emerging issues:

- A proactive approach by the SCENIHR. This requires ‘brainstorming’ sessions to identify the emerging issues of principal concern, followed by the introduction of procedures to detect and characterise their development; and
- A more reactive approach based on the identification of indicators of change and their subsequent monitoring in order to detect emerging issues.

The SCENIHR proposed a decision tree approach (algorithm) for the identification and prioritisation of NERCs, as shown in Figure 5.

Figure 3: Proposed algorithm for identifying priorities (SCENIHR, 2009)



The weighting of these criteria indicates that a health/environmental impact perspective is prioritised in dealing with these issues, while final prioritisation by the Commission may be influenced by political factors such as socioeconomic considerations and public concern. While this decision tree approach is designed to be easy to use, it inevitably prioritises some criteria over others. This may be a problem if the data for a particular decision point are inadequate. As experience is gained in its use, it may require further development.

ECHA works together with the European Commission (EC) and the Member States for the safety of human health and the environment by identifying the needs for EU-wide regulatory risk management. The Member States or ECHA (at the request of the Commission) initiate the identification of substances of potential concern. To this end, ECHA and the Member State competent authorities have developed a common screening approach to systematically screen available information for substances in the REACH registration dossiers (and other databases) and to identify substances for the different REACH and CLP processes such as substance evaluation, authorisation and restriction (ECHA, 2015). To focus the work under different REACH and CLP processes, the substances that matter most must be identified, including those substances for which further information is needed to draw conclusions on the hazards or risks they might pose, as well as substances for which further regulatory action should be considered. Part of the regulatory process is risk management option analysis (RMOA). The purpose of RMOA is to assist with a decision on whether or not further regulatory risk management activities are required for a substance, as well as to identify the most appropriate instrument to address a given concern. A Member State or ECHA (at the request of the Commission) can carry out this case-

by-case analysis. Although RMOA is an important step, it is not part of the processes defined in the legislation.
Substances of concern are mainly those meeting the criteria for inherent properties (Article 57) and the information according to Article 58(3), as set out in the REACH Regulation. Groups of substances included are CMRs, sensitisers, PBTs, very Persistent, very Bioacumulative (vPvBs), ED, or substances of equivalent concern. The screening or prioritisation processes are used to identify and investigate substance-specific (and dossiers-specific) information, in order to make a preliminary assessment on how to proceed. The focus is mainly on the criteria/properties defined in Article 57, together with the criteria defined in Article 58 (3) relating to the use of a substance, such as market volume, wide dispersion, and professional and industrial use (EC, 2013 and ECHA, 2014). Comparing their structural similarity to substances on REACH's Candidate List is one way to identify new or emerging chemical substances. Inherently hazardous properties other than those explicitly mentioned in Article 57 can also be included to address equivalent concern.

The primary goal is to identify and regulate substances of very high concern (SVHC) covered by the REACH regulation. REACH, however, does not include all uses of chemicals but, rather, addresses mostly industrial chemicals (including cosmetics) with a volume of one tonne or more, placed on the market in the EU. Many kinds of chemicals regulated by other legislation fall outside the scope of REACH, such as medicines, pesticides, biocides, food and feed additives and others. To some extent, new or emerging risks can be identified and dealt with under REACH, despite the focus on those substances registered, and the hazardous properties defined, under the REACH Regulation.

ECHA and Member States carry out collaborate screening for substances of potential concern, and this process has many hallmarks of a system to identify and prioritise NERCs. It aims to find substances of potential concern for both human health (consumers and workers) and the environment. REACH, however, does not cover all chemical uses, and its regulatory processes focus on specific hazardous properties and registered substances. There is less focus on the identification of new uses of chemicals, newly identified hazardous properties of chemicals, or using monitoring data as a primary source to identify chemicals of concern,. REACH has generated a large amount of useful data on uses and hazardous properties of chemicals, as well as prompting the development of useful screening and prioritisation methods and tools to streamline regulatory processes.

3.2 EARLY WARNING SYSTEMS FOR WORKER HEALTH AND SAFETY

The literature review includes six systems applicable to workers (see Appendix 1). Three of these are expert forecast systems (EU-OSHA, 2009; EU-OSHA, 2013; SCENIHR, 2014) and can be regarded as methods at a higher level, since the expert forecast is prompted professionals in the field (e.g. physicians, occupational hygienists). One review consists of a summary of more than 40 (potential) NERCs for workers reported in recent decades, using several data sources (Palmen et al, 2013). A method for prioritisation of these NERCs is presented in Palmen and Verbist (2015). As part of the current study on a strategy for a non-toxic environment, European countries were surveyed on their existing early warning systems for workers (Palmen, 2016).

All workers are entitled to work in environments where chemical exposure-related risks to their health and safety are properly controlled. Palmen et al. (2013) describe the chemical legislation relevant for workers. According to the legislation, every employer whose workers may be exposed to chemicals must carry out and keep a relevant risk assessment. The employer must take the necessary preventative measures identified in this assessment, and risks must be eliminated or reduced to a minimum in line with the hierarchy of prevention measures. However, despite all regulations, workers still suffer detrimental health effects from occupational exposure to chemicals.

In an ideal situation, all chemical hazards associated with a substance would be known prior to it being placed on the market, in order to prevent negative health impacts for workers as a consequence of chemical exposure at the workplace. This implies that all toxicological information is available for a substance, including oral, inhalation and dermal exposure. In this scenario, *deductive reasoning* could be used to link a reported health effect to occupational exposure. This proactive approach is called the '*exposure first' method*[2]. It aims to identify possible new and emerging chemical risks (NERCs) based on all physical/chemical/toxicological properties of a substance or the (altered) use of a substance, taking technological and societal developments into account. No such 'exposure first' system is typically used for workers.

For most substances, the information needed to use deductive reasoning is lacking. This is especially true of toxicological information in respect of the routes of exposure for workers, i.e. inhalation and dermal exposure (most toxicological information is available for oral exposure). *Inductive reasoning* is therefore needed to identify and handle substances that have a negative impact on worker's health, i.e. the *'disease first'* method. This inductive type of reasoning starts with observations of diseased workers and moves towards generalisations and theories. The 'disease first'method is reactive, and tries to identify health effects of NERCs as soon as possible in order to prevent additional cases. The 'disease first' method complements the 'exposure first' method and is used in pharmacovigilance. While drugs are tested thoroughly prior to their introduction on the market, negative side effects are often found following their introduction, necessitating the ongoing identification and evaluation of any negative health effects.

The 'disease first' approach requires the use of several complementary methods. Active detection via health surveillance, active literature search using text mining, and secondary analysis of other sources should all be used to identify new and emerging risks, as should clinical watch systems[3] and databases with information on exposure and health effects (Palmen et al., 2013).

A good example of a 'disease first'method is the expert forecast of NERCs by EU-OSHA (EU-OSHA, 2009). In this study, the Delphi method[4] was used to identify NERCs highlighted by experts (see Figure 6). Six literature reviews explored the main emerging risks in greater depth, particularly those singled out by the forecast in terms of context, workers at risk, health and safety outcomes, and prevention. This forecast gives an overview of the most important issues, according to the experts. These experts need on-the-ground information from practitioners, those who actually see patients, as well as seeking out data from the literature (reported cases, toxicological and epidemiological research). This type of 'disease first'method is, again, an example of a higher-level method, since the experts in the Delphi study do not have direct contact with professionals in the field who actually pick up the first signals.

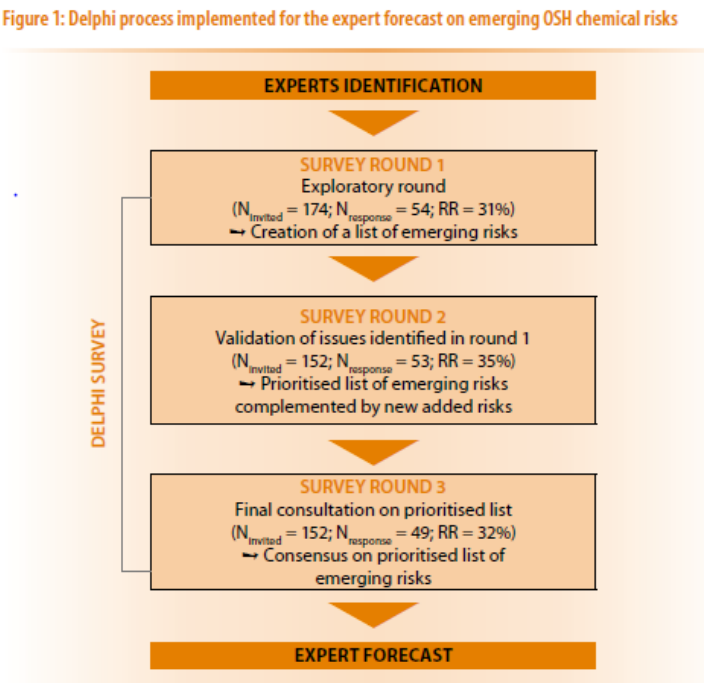
Looking ahead to the role played by NERCs in green jobs, EU-OSHA (2013) has identified the key technological innovations that may be introduced in green jobs over the next 10 years, both those which may lead to new and emerging risks in the workplace, and those that may have a positive impact on workers' safety and health. These health and safety aspects were defined by experts, based on scenario building. This method may improve knowledge about key technological innovations, thereby leading to the discovery of NERCs.

[2] Personal communication: https://www.slideshare.net/secret/jz0hzKYaVXRUhc

[3] Clinical watch system: sentinel surveillance systems in occupational health involve the ongoing and rapid identification of sentinel health events (cases and their corresponding occupational risks) for the purposes of follow-up and for developing statistical trends (available at: http://occmed.oxfordjournals.org/content/65/8/611.full.pdf+html).

[4] Delphi method: a methodology used widely to create foresight information on topics for which only uncertain or incomplete knowledge is presently available. There are several variations of the Delphi method, all of which are based on an iteration process with at least two survey rounds in which the results of the previous rounds are fed back and submitted to the experts for re-evaluation a second time. The feedback process ensures that the experts are aware of the views of other experts and gives them the opportunity to revise their first evaluation. At the same time, it avoids group pressure, which could lead to experts withholding their true opinions and thus distort the results.

Figure 4: Delphi method used by EU-OSHA to identify NERCs (EU-OSHA, 2009)



In addition to the literature review and as part of the current study on a strategy on a non-toxic environment, a survey was carried out by Palmen (2016) on EWS employed to detect NERCs in Europe based on the 'disease first' method. The main findings are presented below.

Contact persons of all European countries (see Appendix 2) were asked to complete a questionnaire on EWS (see Appendix 3), gathering information on:

- The existence of one or more '*clinical watch systems*' for the collection of spontaneous reported cases in Europe;
- The existence of *databases* that may be used for epidemiological research on possible relationships between occupation and/or exposure to substances and health effects (e.g. occupational cancer);
- *Biomarkers* for exposure and/or biomarkers for biological effects that can be used to detect NERCs.

The completed questionnaires were analysed both qualitatively and quantitatively, and the answers were compiled qualitatively. Frequencies were presented, where applicable. The first draft of the survey was submitted to the respondents and revised where necessary.

Clinical watch systems

In the occupational safety and health context, European countries typically use the reactive, 'disease first' method to identify NERCs. Of the 51 European countries, 23 responded, seven of which reported having five clinical watch systems that were specifically designed to detect NERCs:

- The United-Kingdom and Ireland founded the THOR network, which is an abbreviation of 'The Health and Occupation Research' network. It comprises several other networks:
  - OPRA: Occupational Physicians Reporting Activity;
  - EPIDERM: reporting scheme for occupational skin disease;
  - SWORD: surveillance of work-related and occupational lung disease;

    - THOR-GP: reporting scheme for general practitioners with training in occupational medicine.
- France has three clinical watch systems:
    - RNV3P: National Occupational Diseases Surveillance and Prevention Network;
    - GAST: occupational health warning groups;
    - OccWatch: occupational diseases sentinel clinical watch system project.
- The Netherlands created the SIGNAAL tool together with Belgium.
- Italy has the MALPROF system for the recording and surveillance of work-related diseases.
- At the regional level, there are many initiatives in Spain. One such example is in the Asturias region, where a system (EVESCAP) is specifically designed to detect and register occupational cancer. It includes an evaluation system and a specific cancer register. The Navarre region has a sentinel clinical watch system for occupational diseases in general, and is considered a reference point in Spain (García López, 2011). An overview of Spanish systems is shown in Appendix III.

In addition to these clinical watch systems, there are systems that are not specifically designed to detect NERCs but which can be used for that reason:

- Belgium: Fund Occupational Diseases.
- Bulgaria: Occupational disease register.
- Denmark: Erhvervssygdomsregistret; Doctors and dentists must submit a notification if they learn or suspect that a patient's injury is related to his job.
- Finland: Register of occupational safety and health administration.
- Hungary: Mandatory reporting and registration system of occupational diseases.
- Latvia: National Registry of Occupational Diseases of Republic of Latvia.
- Norway: Registry of work-related diseases.
- Spain: At a national level, CEPROSS (for occupational diseases on the official list approved by Royal Decree) and PANOTRASTSS ('annexed' to the previous list to register non-traumatic health effects that could be considered occupational diseases in the future).
- Sweden: Doctors' reporting of illness, according to AFS 2005:6, § 11.
- Switzerland: Statutory Health Surveillance organised by Swiss Accident Insurance Fund (Suva).

The Czech Republic's National Institute of Occupational health is preparing a sentinel clinical watch system, to be launched in the near future.

In six countries, the Labour Inspectorate *collects possible NERCs*, especially in the northern countries (see Table 3). Research organisations (n=6) also carry out this task and are particularly important as they organise and analyse those clinical watch systems that are designed to detect NERCs . Finally, insurance funds (n=5) are also important institutions in collecting possible NERCs.

Table 2: Overview of organisations collecting possible NERCs (countries with clinical watch systems designed to detect NERCs are printed in bold)

Type of institute	Country	Additional information
National Institute of Occupational Health	Czech Republic (under construction)	---
	Hungary	Office of the Chief Medical Officer – Department of Occupational Health
Government	**Spain**	Most of the existing regional systems are dependent on the REGIONAL GOVERNMENTS
Labour Inspectorate	Finland	--
	Norway	--
	Sweden	SWEA
	Denmark	Working Environment Authority
	Latvia	--

Type of institute	Country	Additional information
	Italy	--
Research organisations	**UK**	Centre of Occupational and Environmental Health (COEH), University of Manchester
	Belgium	SIGNAAL, hosted by the University of Leuven: Centre for Environment and Health
	The Netherlands	SIGNAAL, hosted by the Netherlands Center for Occupational Diseases; Part of Coronel Institute on Work and Health, AMC, University of Amsterdam
	Ireland	Physician epidemiological reporting schemes funded by the Labour Inspectorate HAS (Ireland)
	Latvia	The Centre of Occupational and Radiological Medicine of Pauls Stradins University hospital (Centre)
	France	RNV3P (ANSES): French Agency for Food, Environmental and Occupational Health & Safety
		GAST (InVS): Institute for Public Health Surveillance[5]
		OccWatch: MODERNET network (Monitoring Occupational Diseases and Emerging Risks New Network)
Insurance funds	Switzerland	Swiss Accident Insurance Fund (SUVA)
	Belgium	Fund of Occupational Diseases
	Bulgaria	National Social Insurance Institute (Bulgaria)
	Spain	At a NATIONAL level: Ministry of Labour. Secretary of State for Social Security (CEPROSS and PANOTRASTSS)
	Italy	INAIL (National Institute for Insurance against Accidents at Work) – MALPROF system
Others	Denmark	National Board of Industrial Injuries

Occupational physicians, medical specialists, and general practitioners can report possible NERCs to almost all of the clinical watch systems. Only occupational physicians can report in the Latvian and Belgian 'SIGNAAL' system, while, in Denmark, dentists can also report. Industrial hygienists can report in the Swiss, Latvian, and French systems (GAST and OccWatch). Employers and trade union delegates can report in the Danish and French (GAST) systems. Self-reporting of workers is also allowed in the Danish, French (GAST), Latvian and Swiss systems.

The *evaluation of possible NERCs* is usually carried out by a group of experts, the exact composition of which depends on the reporting system itself. Research institutes play an important role in the evaluation of most of the reporting systems, but the Labour Inspectorate and insurance funds are also frequently mentioned as an evaluating organisation.

Cases reported in a clinical watch system must be evaluated with the aim of establishing whether or not the reported case really is a new risk, and whether this signal can be strengthened by finding additional cases. Literature searches are a common way to investigate if the reported case was already

[5] In VS will become the (French) National Agency for Public Health in 2016.

known in the past. It often happens, therefore, that risks that were known in the past are no longer common knowledge among professionals. Communication between experts is often used to build knowledge on the causal relationship between exposure and the reported health effect, and to find additional cases to strengthen that causal relationship. The way in which a first report will be evaluated depends on the individual clinical watch system.

Table 4 gives an overview of the clinical watch systems and the ways in which a new possible risk will be evaluated. It shows that communication between experts is the chief means of evaluating new cases. An expert group is associated with all clinical watch systems, with the exception of the Italian MALPROF system. However, this system reports evaluating a patient's work history, which may mean that an industrial hygienist checks the historical exposure of a case and communicates with the physician.

Literature searches are also mentioned by most clinical watch systems as a means of evaluating cases. With the exception of the Bulgarian, French (GAST) and Latvian systems, all others perform a literature search. In the Belgian (Fund of Occupational Diseases) system, literature searches are performed at the request of the commissions within the fund.

Table 3: Evaluation of a first report of a possible NERC

Country	Literature search	Communication between experts	Remarks
Belgium	Yes (SIGNAAL) No/yes (Fund of Occupational Diseases)	Yes (SIGNAAL and Fund of Occupational Diseases)	
Bulgaria	No	Yes	
Czech Republic	Yes (under construction)	Yes (under construction)	Physical examination by specialist
Denmark	No answer	No answer	
Finland	Yes	Yes	
France	Yes (RNV3P, OccWatch) No (GAST)	Yes (RNV3P, OccWatch, GAST)	
Hungary	Yes	Yes	
Ireland	Yes	Yes	QSAR structural analysis if and as appropriate
Italy	Yes	No	Patient's work history
Latvia	No	Yes	
The Netherlands	Yes	Yes	
Norway	Yes	Yes	
Spain	At a National level: Yes (CEPROSS and PANOTRASTSS) At a Regional level: NAVARRE: Yes	At a National level: Yes (CEPROSS and PANOTRASTSS) At a Regional level: NAVARRE: Yes	
Sweden	Yes	Yes	
Switzerland	Yes	Yes	
UK	Yes	Yes	

Most clinical watch systems inform the reporter or notifier of the outcome of the evaluation. However, in the Spanish national system, reporters or notifiers are not always informed, nor is any communication reported by the Belgian Fund of Occupational Diseases, Finland or Italy. The most common means of communication between the reporter/notifier and the evaluating body of the clinical watch system is by email/website or in a written letter. The French RNV3P system has an elaborate reporting system, comprising several steps leading from the clinicians within the RNV3P network to an international alert.

The follow-up of a possible NERC is, in most instances, undertaken by a national and/or international expert group. In some instances, communication takes place within an expert group of an insurance

company (i.e. Switzerland and Denmark). The Labour Inspectorate may also play a role in some countries (the UK and Norway).

Most clinical watch systems that are designed to detect NERCs *collect/report them in a database*. This includes the UK and Ireland system (THOR), the French RNV3P, GAST and OccWatch systems, and the Italian MALPROF system. The Dutch and Belgian SIGNAAL tool reports the cases and their outcomes via the website and collects them in a database. Cases in the Latvian National Registry of occupational diseases are collected in a database of occupational disease, occupational health risk factors, and exposure data. Bulgaria and Denmark also have national databases of cases, while Spain has regional databases.

Databases:

Data mining of case report notification registries in databases is a valuable tool for generating hypotheses on possible NERCs and for epidemiological research. Relationships between health effects and exposure and/or occupation can effectively (being both objective and replicable) be studied, especially when exposure data are incorporated into the database. An overview of the names of the databases and their managing organisations is presented in Table 5. Several of the databases mentioned are based on the clinical watch systems described earlier:

- THOR system of the UK and Ireland.
- French RNV3P database of ANSES.

However, other databases could also be used for (epidemiological) research on work-related health effects. The organisations managing these databases are diverse (i.e. occupational health providers, institutes of occupational health, Labour Inspectorates, and insurance funds). Experts groups are linked to the databases to investigate possible NERCs, and dissemination of this information takes place via international papers and symposia, reports, and websites.

Table 4: An overview of databases and their managing organisations

Country	Name of database	Organisation
Belgium	■ Precube ■ Claims of Fund of Occupational Diseases	Occupational health provider IDEWE Fund of Occupational Diseases
Finland	Finnish Institute of Occupational Health's register of occupational diseases	Finnish Institute of Occupational Health
France	RNV3P	French Agency for Food, Environmental and Occupational Health & Safety (ANSES)
Hungary	■ Register of occupational diseases, ■ Register of reported infectious diseases, infections and epidemics	Office of the Chief Medical Officer – Department of Occupational Health (former Hungarian Institute of Occupational Health)
Ireland	The Health and Occupation Research (THOR) network	THOR: Centre of Occupational and Environmental Health (COEH), University of Manchester
Latvia	National Registry of Occupational diseases of the Republic of Latvia	The Centre of Occupational and Radiological Medicine of Paula Stradins University Hospital
Netherlands	■ National notification and registration system ■ Sentinel surveillance system for the notification of occupation diseases ■ National Cancer Registry	Netherlands Centre for Occupational Diseases, Coronel Institute on Work and Health, AMC, University of Amsterdam Netherlands Comprehensive Cancer Organisation (IKNL)
Norway	Registry of work-related diseases	Labour Inspectorate
Switzerland	■ Statistikpool der Sammelstelle für die Statistik der Unfallversicherungen (SSUV) ■ Future Radar	■ SSUV: Swiss Accident Insurance Fund (Suva) and Sammelstelle für die Statistik der Unfallversicherungen UVG ■ SUVA: Swiss Accident Insurance Fund
Spain	National level: ■ CEPROSS	National level: ■ PANOTRASTSS & CEPROSS: Secretary of

Country	Name of database	Organisation
	■ PANOTRASTSS ■ Tumour registry or Cancer registries (Population registries and Hospital registries) Regional level: Database from the Navarre Occupational Health Surveillance Programme	State for social security, Spanish Ministry of labour. ■ Tumour registry or Cancer registries: Departments of Health of the Local/Regional Governments Regional level: Navarre: Institute of Public and Occupational Health of Navarre (ISPLN). Government of Navarre
UK	■ The Health and Occupation Research (THOR) network ■ Industrial Injuries Disablement Benefit (IIDB) Scheme ■ Reporting of Injuries, Diseases, and Dangerous Occurrences Regulations (RIDDOR) ■ Others e.g. HSE's register on pesticides	■ THOR: Centre of Occupational and Environmental Health (COEH), University of Manchester ■ IIDB: Department of Work and Pensions ■ RIDDOR: The UK Health and Safety Executive (HSE)

Biomarkers

Biological monitoring of exposure assesses health risk through the evaluation of the internal dose of a substance or its metabolite(s), using biomarkers for exposure (Lauwerys and Hoet, 2010). It can be used to determine total exposure (oral, inhalation, dermal) to substances. Biological monitoring of effects by using biomarkers for effects must be clearly distinguished from biomarkers for exposure. While the latter attempt to detect unhealthy exposure conditions, biomarkers of effect evaluate health status and aims to identify individuals with early signs of adverse health effects (Lauwerys and Hoet, 2010). Biomarkers for biological effects may also be an indication of early health effects leading to occupational disease. This prospective method is useful, given that a causal relationship between the level of exposure and possible health effects is easier to demonstrate.

In many countries, occupational health services and research institutions play an important role in promoting the use of biomarkers for the identification of NERCs.

Only a few countries have declared that they regularly use biomarkers specifically for the identification of NERCs (Czech Republic, Romania, and Latvia). In Romania, the use of biomarkers for early biological effects caused by carcinogens and ionising radiation has been legally established. The Czech Republic uses inflammation and oxidative stress markers to measure exposure to nanoparticles. Several countries only use biomarkers specifically for the identification of NERCs in research projects (i.e., Belgium, Denmark, France and Germany). Most countries, however, do not use biomarkers specifically to detect NERCs.

Finland, Norway, Latvia and Hungary compiles the results of biomonitoring of NERCs in a database. In Norway, the EXPO database collects voluntary reporting of all types of exposures, and is maintained by the National Institute of Occupational Safety and Health. In Hungary, there is a 'Register of excessive exposures' to arsenic, benzene, cadmium, chromium and nickel. Data within normal values are not collected.

The follow up of possible NERCs is very varied. In Finland, Hungary and Italy, the decision is made by national or local expert groups. In Latvia, the University of Riga Stradin is responsible. In Luxemburg and the Netherlands, occupational health services are obliged to further investigate occupational risk exposure and health surveillance. The insurance fund Suva is responsible for follow up in Switzerland, while the Labour Inspectorate is responsible in Norway. No follow up is reported by Bulgaria, Czech Republic, or Romania.

3.3 EARLY WARNING SYSTEMS FOR CONSUMERS

The literature review makes reference to 15 EWS for consumers (see Appendix 1 for a partial summary). Consumer exposure to chemicals via various consumer products is divided into two main categories: food and non-food products (e.g. personal care products, toys, cleaning and home maintenance items). There are several European systems that deal with the identification of new and emerging risks of chemicals in food or consumer products: EMRISK by the European Food Safety Authority (EFSA), the European Cosmetovigilance, and the Rapid Alert System for dangerous non-food products (RAPEX). In addition, there are several local organisations with systems in place, such as the Dutch Consumer Exposure Skin Effects and Surveillance (CESES), the Norwegian Cosmetovigilance system, the Dutch Poisons Information Centre (NVIC), and the Dutch New and Emerging Risks of Chemicals (NERCs) for consumer products. These were found to be potentially useful in setting out a possible future EU-wide, sector-specific EWS for consumer protection.

3.3.1 Food

The EFSA, via the EMRISK project (EFSA, 2006), has developed a procedure to handle indicators and information sources and create an effective and efficient EWS (See Figure 7). Emerging risks can be the result of many factors, such as changing consumption patterns, new processes, and increased levels of pollutants. EMRISK consists of a set of key indicators, together with the information sources and networks of (issue and sectoral) experts and electronic scanning systems at its disposal. An **indicator** or **priority issue** (Figure 7) is comprised of a focused selection of parameters that can be measured/calculated qualitatively and/or quantitatively. Indicators may be directly related to the food chain or may be connected to it via one or several indirect links. Choosing the most relevant set of indicators and their data sources is an essential step in ensuring a functional emerging risk identification system. A **signal** is identified as a temporal or spatial trend in an indicator value. This signal, or combination of several signals, may indicate an emerging risk. This signal or emerging issue can be defined as one that has very recently been identified and merits further investigation, and for which the information collected is still too limited to assess whether or not it meets the requirements of an emerging risk. Thus, emerging issues are identified at the beginning of the emerging risk identification process, as topics that merit further investigation and additional data collection (EFSA, 2012). According to the definition adopted by the Scientific Committee of EFSA in 2007, 'a [food and feed-related] emerging risk to human, animal and/or plant health is understood as a risk resulting from a newly identified hazard (chemical or biological) to which a significant exposure may occur or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard' (EFSA, 2007).

This EWS aims to **proactively** identify a (re-)emerging hazard and prevent its presence from giving rise to a risk. A key characteristic of this system is that it is anticipatory rather than responsive. Rapid alert systems such as the Rapid Alert System for Food and Feed (RASFF) are mainly **reactive**, with notifications triggered by: 1) European Economic Area border controls (over half of the notifications), 2) official control of the internal market (30% of notifications), 3) consumer complaints (3% of notifications), 4) company notifying the outcome of their own check (13% of notifications), or 5) a food poisoning incident (2% of notifications) (EFSA, 2015). Finally, this EWS takes preventative measures, thus combining both proactive and reactive measures to identify potential (re-)emerging risks. The well-known hazards that are presently controlled are excluded.

1. Identification of data sources and data collection for food-related priority issues by EFSA
There are four main types of data sources to be considered: (i) 'soft', including those generated by the media and literature; (ii) 'regulatory', including data from rapid alert systems and compulsory reporting/monitoring of foodborne illness; (iii) 'scientific', including published papers, proceedings, research findings and documented reports; and (iv) 'expert judgement' (EFSA, 2009).

i. Soft data from web monitoring systems

Among the many systems in place that can be used to retrieve so-called soft data (e.g. news from the media), the Europe Media Monitoring (EMM) of the Joint Research Centre (JRC) and the Global Public Health Intelligence Network (GPHIN) system of the Public Health Agency of Canada were considered by the Scientific Committee for Emerging Risks (SCER) and the EFSA Scientific Cooperation (ESCO) Working Group (WG) on Emerging Risks liaise the Emerging Risk Exchange Network (EREN), to be among those most likely to be relevant and accessible.

ii. Regulatory data

Regulatory data include information that can be retrieved from official bodies at a Community, national or international level, such as:

a. Rapid Alert System for Food and Feed RASFF (EFSA, 2015);
b. Rapid Alert System for Biological and Chemical Attacks and Threats (RAS-BICHAT) (Dekker-Bellamy, 2004);
c. Monitoring of parameters via EUROSTAT (EUROSTAT, 2016) (e.g. the report 'From farm to fork') (EUROSTAR, 2011);
d. WHO's Global Outbreak and Alert and Response Network (GOARN, which complements and supports the existing WHO networks, includes a Chemical Alert and Response component (WHO GOARN, 2016);
e. FAO's Global Information and Early Warning System (GIEWS) on food and agriculture (FAO GIEWS, 2016);
f. International Food Safety Authorities Network (INFOSCAN), launched by the WHO to promote the exchange of food safety information and to improve collaboration among national and international food safety authorities (WHO INFSCAN, 2016);
g. Pathfinder is a scanning tool for electronic surveillance that has been adapted for the Centres for Epidemiology and Animal Health Centres for Emerging Issues (CEI) in the U.S. (Kopral, 2004);
h. Horizon scans performed by the JRC in collaboration with the Emerging Risks Unit and the Support to External Security Unit (EU Science Hub, 2016).

iii. Scientific data from research

Scientific research is one of the most reliable sources of information for the identification of emerging risks. There are well-established search methods for the retrieval of such findings once they have been published in journals or proceedings (e.g. Pubmed), but the time delay to publication is generally considerable. It would be worthwhile to develop a procedure to make such findings available to emerging risk evaluators more quickly. The present reluctance of experts/scientists to reveal preliminary findings and forward them as signals in an EWS is expected to be overcome by establishing an environment in which confidentiality is guaranteed by the EFSA.

Through DG-Research, the EC has the capacity to initiate, consolidate, and sustain the further research needed on emerging risks. Knowledge of the research generated at several JRC and Community Reference Laboratories (CRLs) can provide a considerable amount of information with regard to emerging risks (EFSA, 2009*)*.

iv. Expert network and judgement

a. EFSA has many internal and external expert networks for the identification of priority issues. The Scientific Committee for Emerging Risks (SCER) and the EFSA Scientific Cooperation (ESCO) Working Group (WG) on Emerging Risks liaise with the Emerging Risk Exchange Network (EREN), which is the principal body for exchanging information on emerging risks to food and feed safety between the EFSA, Member States, the Commission, EU agencies, and international organisations. This network of professionals is currently composed of delegates from 21 Member States and Norway, designated through the Advisory Forum (AF), as well as observers from the EC, EU pre-accession countries (Former Yugoslav Republic of Macedonia, Serbia, Turkey), the Food and Drug Administration of the USA (FDA), and the FAO.

The main objectives of the EREN are: (i) to facilitate the exchange of information and expertise on emerging risks in the fields of food and feed safety, human, animal and plant health; (ii) to promote the coordination of activities and the development and implementation of joint research projects; and (iii) to build support and commitment among Member States for the emerging risk identification activities of the EFSA.

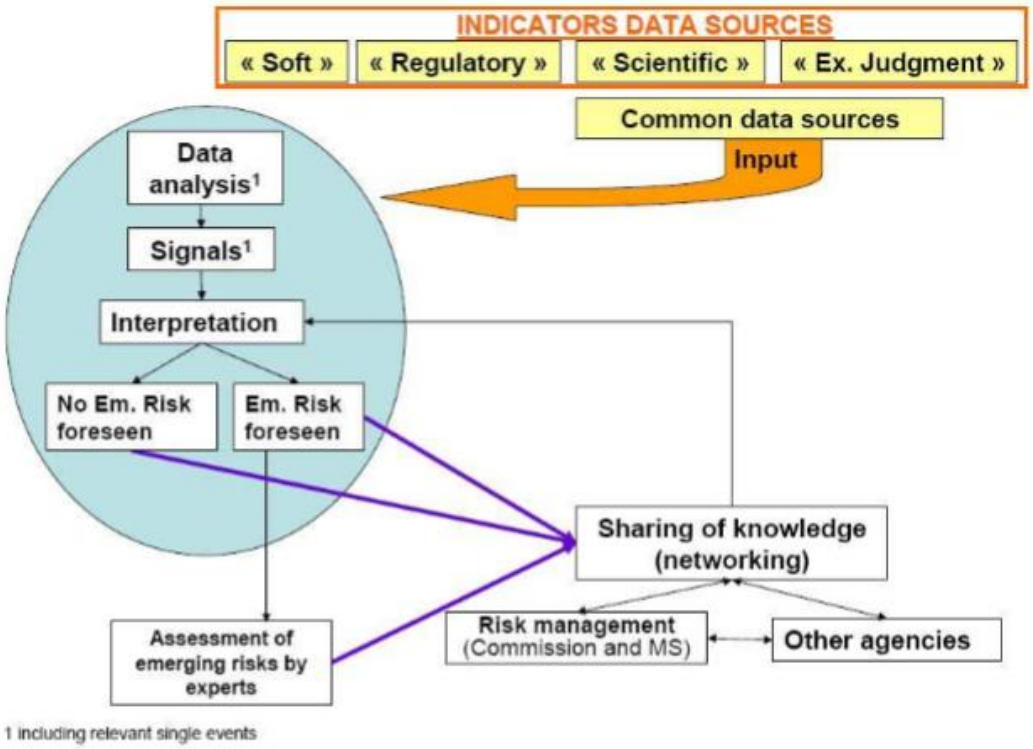
b. Cooperation with the three non-food scientific committees of the Commission via the Scientific Committee on Consumer Products (SCCP), the Scientific Committee on Health and Environmental Risks (SCHER), and the SCENIHR, provides considerable assistance to EFSA in respect of early identification of emerging risks which may impact on food safety aspects of the food/feed production chains.
c. Other EU agencies, such as the European Medicines Agency (EMEA), the European Centre for Disease Control (ECDC), the European Environmental Agency (EEA), and the European Chemicals Agency (ECHA) are potential partners for EFSA in the identification of emerging risks affecting food/feed production chains, and of future food safety-related risks originating from these operations.
d. The Stakeholders Consultative Group on emerging risks (StaCG-ER) provides information on emerging risk identification under three headings: (i) current methods; (ii) data sources and tools; and (iii) future procedures to be developed. Emerging risk identification issues were indicated as part of the daily activities in the food and feed sector organisations, mainly undertaken through regular monitoring of various data sources by expert groups, combined with information received through the organisations' networks.

EFSA is now populating a chemical hazards database to store summary hazard data from EFSA's chemical risk assessments in food and feed. The database – which aims to map the hazard data as extracted from the EFSA's opinions, statements, and conclusions – describes the following features: chemical identification, document descriptors, hazard identification, and hazard characterisation/risk characterisation. Notably, the database focuses on hazard data. The repository includes data extracted from opinions and statements adopted by a number of EFSA panels (EFSA, 2014a,b).

2. Identification of priority issues for food by EFSA
The following criteria were used to identify indicators or priority issues:

- *Measurable.* For (semi-) quantitative indicators: is it possible to establish a threshold or range so that a major change in the indicator can either be too low, too high or out of range? For qualitative indicators: is it possible to value the outcome as negative or positive, absent or present, or simply as a yes or no?
- *Interpretable.* Is it possible to detect trends and make an assessment based on those trends observed?
- *Directness.* It is estimated that the shorter the distance between indicator and emerging hazard, the higher the probability that the indicator will provide a valid signal for emergence. It follows that if the distance is long (between indicator and emerging hazard), the probability that the indicator is valid will be lower (or the number of false positives is likely to be higher).
- *Potential impact.* Is the emerging hazard which can be proactively identified by this indicator estimated to cause serious harm to animal or public health, or is there a high likelihood of it spreading?
- *Comprehensive.* Is the indicator generic or a specific? Generic indicators are preferred by the EFSA EMRISK Working Group.
- *Discriminatory.* The list of indicators sometimes contains overlapping indicators, i.e. that mean more or less the same and provide the same information. This 'discriminating' criterion has been added to prevent the occurrence of duplication or overlap. However, the comparison requires a knowledge of the other indicators, thus this criterion should be seen as a final quality check (EFSA, 2006).

Figure 5: General procedure for the identification of emerging risks (adapted from EFSA, 2009)



3. Final evaluation and identification of emerging risks for food

The most sensitive indicators within the context of the host environment are selected using the ranking system based on the following criteria: interpretable, comprehensive, directness and potential impact. Directness and potential impact are considered to be more important than the criteria of interpretable and comprehensive and, accordingly, receive a weight factor of two. All criteria are scaled from 1 to 5 (very low, low, medium, high, very high), with a maximum score of 30 for any single indicator. The scoring shows a few equally important indicators, enabling the determination of a top five or top 10, depending on the threshold level to be set. Urgency factors are also considered, according to expert judgement.

The interpretation of the signal values are evaluated according to:

a) *Urgency*: this refers to the speed with which assessment actions should be taken, in view of the alert value assigned to the feature of every single signal. The higher the urgency factor the more speed should be given to risk assessment actions in this approach.
b) *Importance*: this reflects the fact that the signals are not all equally important. There are several reasons to grade a signal with a higher importance factor, such as the number of sources that lead to the signal, the reliability of the sources, and the potential impact. This ranking of the signals must be carefully carried out because of its impact when the different weight factors are combined.
c) *Relationship*: this accounts for the relationship that can exist between signals. Obviously, the weighting of signal relationships should be performed by a multi-disciplinary scientific group, i.e. expert opinions and historic evidence are expected to be the main factors contributing to this weighting (EFSA, 2006).

The EREN[6] meets twice a year with three sessions per meeting. The first session is dedicated to presentations and discussion of new potential emerging issues; the second is dedicated to discussion of new information on previously raised issues; and the third is dedicated to updating the network on the EFSA and Member State activities and developments in the area of emerging risks, such as upcoming projects, survey results, and outcomes of scientific conferences. Between the meetings, members have the opportunity to comment and to provide further information on the emerging issues.

Before each meeting, each member fills out a standard form (Appendix 4) and provides input on:

i. Any additional background information important for the evaluation of the issue;
ii. Limitations of the analysis/study;
iii. Toxicological information of this (or similar) agents/compounds;
iv. Legal and institutional aspects.

The main evaluation criteria for discussion are the expert's view on whether or not the possible emerging issue is a new driver, new hazard, new or increased exposure, or if it involves a new susceptible group.

Experts are also asked for their opinion with regard to:

i. the *soundness* of the given sources of information;
ii. the *severity* of the health effects, such as morbidity and/or mortality;
iii. the *imminence* of the potential hazard
    a. how soon it is estimated that the potential hazard will manifest in the food, feed, environment; or
    b. how soon is it estimated that this health risk will manifest in the population;
iv. the *scale* (magnitude) of the emerging issue
    a. number of people and Member States potentially exposed.

Finally, each expert provides their views on the actions needed from the EFSA to address the potential emerging issue(s), providing a statement on whether the EFSA should:

1. Continue to monitor the issue;
2. Undertake a review of this issue, with the aim of publishing a report;
3. Begin a project to generate data on this issue (e.g. outsourcing);
4. Initiate a risk assessment;
5. Consult other bodies (e.g. the Stakeholder consultative group).

A consensus on the necessary actions, if any, is established at the end of each EREN meeting. A weight-of-evidence and consensus approach is used for the evaluation and identification of NERCs in food.

3.3.2 Non-food consumer products

Non-food consumer products include a wide-range of items such as cosmetics and other personal care products, toys, cleaning and home maintenance items. Unlike with food, EWSs for non-food consumer products are still in development. For cosmetics, there are two established post-market surveillance

[6] This network of professionals currently comprises delegates from 21 Member States and Norway, - designated through the AF - and observers from the EC, EU pre-accession countries (Former Yugoslav Republic of Macedonia, Serbia, Turkey), the FDA and the FAO. The main objectives of the Network are: (i) to facilitate the exchange of information and expertise on emerging risks in the fields of food and feed safety, human, animal and plant health; (ii) to promote the coordination of activities and the development and implementation of joint research projects; and (iii) to build support and commitment among Member States for the emerging risk identification activities of EFSA.

systems: the European Cosmetovigilance and the Dutch Consumer Exposure Skin Effects and Surveillance (CESES). The Rapid Alert System for dangerous non-food products (RAPEX) enables the quick exchange of information between 31 European countries and the EC about dangerous non-food products that pose a risk to the health and safety of consumers. The Dutch National Poisons Information Centre (NVIC) publishes yearly reports summarising the incidence of acute poisonings related to the misuse of consumer products in the Netherlands, where an EWS for the identification of NERCs for consumers is also under development.

3.3.2.1 EU cosmetovigilance

Cosmetovigilance is defined by the collection, evaluation and monitoring of spontaneous reports of undesirable events observed during, or after, normal or reasonably foreseeable use of a given cosmetic product. Together with other tools, cosmetovigilance contributes to post-market surveillance. The Cosmetics Regulation (EC Regulation No. 1223/2009 on cosmetic products) defines undesirable events as 'adverse reactions for human health attributable to the normal or reasonably foreseeable use of a cosmetic product'. Serious undesirable effects are defined as 'undesirable effects which result in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death'. In these definitions, 'serious' refers to the intensity (severity) of the effect (mild, moderate or severe), whiles 'seriousness' refers to the patient/event outcome or action. Here, a causality assessment is used to provide a basis for a common understanding and uniform approach to the performance of causality assessments for serious undesirable events from cosmetic products (Figure 8) (EC, 2012). According to Article 23 of the Cosmetics Regulation, all responsible persons and distributors have the legal obligation to report all serious undesired effects to the competent authorities of the relevant Member Statse. Consumers, or attending medical professionals, can inform the producer, importer, distributor or public authorities about the undesired effect. The person that receives the information must make a causality assessment and submit the case report (via a harmonised notification form) to the competent authorities. The German Federal Office on Consumer Protection and Food Safety (BVL) gathers all of the cases in the EU (Butschke et al., 2016).

Until May 2016, there were a total of 680 cases of Serious Undesired Effects (SUEs) from 23 Member States shared within the EU, with hair dyes and skincare products having the most frequently reported SUEs. The majority of SUEs (80%) were reported in the head area, particularly to the skin of the face (Butschke et al., 2016).

Figure 6: Decision tree for the identification of SUEs in cosmetic products (adapted from EC, 2012)

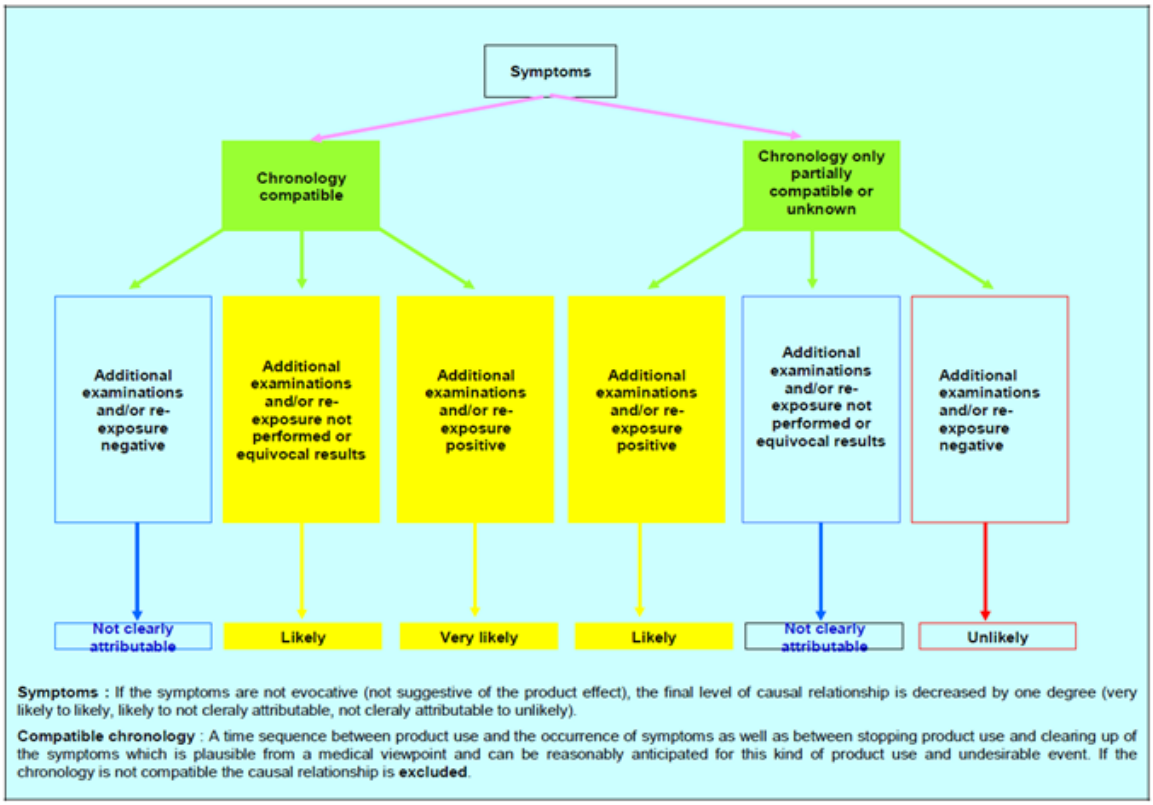


Table 5: National contact points for the reporting of (serious) undesirable effects via EU cosmetovigilance

Country	Institution
Austria	Federal Ministry of Health and Women's Affairs
Belgium	Ministry of Health
Bulgaria	Ministry of Health
Cyprus	Ministry of Health
Czech Republic	Ministry of Health of the Czech Republic
Denmark	Danish Environmental Protection Agency
Germany	Federal Office of Consumer Product and Food Safety
Estonia	Health Authority
Greece	National Organisation for Medicines
Spain	Spanish Agency of Medicines and Health Products
Finland	Finnish Safety and Chemicals Agency (Tukes)
France	French National Agency for Medicines and Health Product Safety
Croatia	Ministry of Health
Hungary	National Food and Nutrition Science Institute
Ireland	Health Products Regulatory Authority
Italy	Ministry of Health
Lithuania	Public Health Centre
Luxemburg	Ministry of Health
Latvia	Ministry of Health
Malta	Malta Competition and Consumer Affairs Authority (MCCAA)
Netherlands	The Netherlands Food and Consumer Product Safety Authority
Norway	Norwegian Food Safety Authority
Poland	State Sanitary Inspection
Portugal	National Authority of Medicines and Health Products
Romania	Ministry of Health
Slovakia	Public Health Authority
Slovenia	Chemicals Office of the Republic of Slovenia
Sweden	Medical Products Agency

Country	Institution
UK	Department for Business, Innovation and Skills

3.3.2.2 Dutch Consumer Exposure Skin Effects and Surveillance (CESES)

CESES monitors undesirable reactions attributed to cosmetic products. These monitoring data are used to gain insight into the incidence and prevalence of undesirable reactions to cosmetics and to assist in the identification of the products and product ingredients that are responsible for these reactions. Within CESES, an undesirable reaction is defined as any adverse effect attributed to the use of cosmetics under reasonably foreseeable conditions. General practitioners, dermatologists, and consumers in the Netherlands complete questionnaires on reported undesirable effects from cosmetics. Dermatologists carry out patch tests and, where necessary, tests with specific batch ingredients of the associated cosmetic product. A website and a public notification system are available for consumers to report undesirable effects (http://www.cosmeticaklachten.nl/). An assessment of the causality between undesirable reactions and cosmetic products is conducted by senior dermatologists, based on the outcomes of the patch test with the European Baseline series and the cosmetic product and batch-specific ingredients of the cosmetic product. In respect of the outcomes of the patch test with the European Baseline series, only relevant cosmetic allergens are taken into account for causality assessment (Salverda-Nijhof et al. 2011a, 2011b; De Wit-Bos et al. 2012, 2014a, 2014b; Woutersen and Bakker, 2015a). In 2015, the dermatologists who reported undesirable reactions came from six participating dermatological centres. These included five academic hospitals (Erasmus MC, UMCU, VUMC, LUMC and UMCG) and a peripheral hospital (Van Weel-Bethesda Hospital). Two other participating centres (Deventer Hospital and the Centrum voor Huid en Arbeid in Arnhem) did not report any finalised cases in 2015. The sensitivity of CESES can be improved by increasing the number of reports and participating dermatologists, either nationally or internationally, and by the addition of dermal reactions to other specific products such as tattoos and tattoo aftercare products, which are known to sometimes cause (severe) allergic reactions, but for which there is currently no monitoring system (Woutersen and Bakker, 2015a).

3.3.2.3 Norwegian cosmetovigilance system

The Norwegian Food Safety Authority has established a cosmetovigilance system to detect undesirable effects of cosmetic products. Since the implementation of Regulation 27 February 2008 No. 219 on the obligation of health personnel to report suspected adverse effects of cosmetics and body care products, doctors, dentists, health visitors, pharmacists and other health personnel are obliged to report undesirable effects of cosmetics. The Norwegian Institute of Public Health registers and assesses the reported undesirable effects on behalf of the Norwegian Food Safety Authority and received 105 such reports in 2014 (National Market Surveillance Programme, 2015, Norway). A new online application for consumers was launched on May 26, 2015, enabling consumers to report any undesirable effects of cosmetics directly, without seeing health personnel. The Norwegian Food Safety Authority provides information on substances in consumer products such as cosmetics via a website (www.erdetfarlig.no) operated by the Norwegian Environment Agency (National Market Surveillance Programme, 2016, Norway).

3.3.2.4 The Rapid Alert System for dangerous non-food products (RAPEX)

RAPEX is a database of information, compiled by Member State national authorities and held by the EC, on dangerous products found and the measures taken. RAPEX enables the quick exchange of information between 31 European countries and the EC about dangerous non-food products that pose a risk to the health and safety of consumers. The information may come from producers or distributors who voluntarily organise recalls of the products they have found to pose a risk to consumer health. Most notifications are the result of enforcement programmes from national enforcement agencies, often in response to existing or new restrictions. A list of (dangerous) products, describing the risks

they pose and the measures taken, is published online every week. Other countries may find the same product in their national markets and add extra information and/or measures to prevent further sales of the dangerous product. All of this information is circulated within this European network of authorities from 31 countries (EC, 2016). The reports in RAPEX deal mainly with failure of compliance with regulations (GPSD, REACH, Cosmetic Products Regulation, etc.).

3.3.2.5 Dutch National Poisons Information Centre (NVIC)

The NVIC publishes annual reports summarising the incidence of acute poisonings in the Netherlands from consumer products such as household products, do-it-yourself products, cosmetics, and toys, as well as medicines (NVIC, 2015). The task of the NVIC is to supply information on acute poisoning incidents to those professionals working in the field. All activities of the NVIC are relevant to the signalling of emerging risks. Of particular importance is the 24/7 information line that provides access to medical healthcare personnel. Each year, there are about 44,000 inquiries, all of which provide valuable information on the epidemiology of intoxications and poisoning incidents, and this information is stored in the Toxicological Information and Knowledge Bank (Netherlands Toxicologische Informatie & Kennisdatabank, TIK). All calls for information are collected, making it possible sometimes to pick up a signal. For example, the emerging risk of biting or swallowing a new type of detergent product - liquid capsules - was picked up in this way.

3.3.2.6 Dutch New or Emerging Risk of Chemicals (NERCs) early warning system

The methodology for identifying NERCs for consumers is under development and the system is presently at a stage where a data collection system and *database* (worksheet) have been generated by the RIVM. Starting with signal collection, the following information sources are screened for a link between chemicals in consumer products and health effects:

- *Literature search*, including international government reports (Danish Environmental Protection Agency, the German BfR, Health Canada), *internet searches* including Dutch and international media reports, and *database searches* including ChemicalWatch.com and RAPEX weekly report listings.
- *Network* via reports from the Dutch Poison Information Centre (NVIC).
- *Consumer complaints* about undesirable skin effects of cosmetics, through the dermatologist-assessed CESES programme.

The *database* (worksheet) contains chemicals in consumer products, together with their reported adverse effects. All information relevant for the identification of consumer risks, as well as additional data on types of exposure and consumer product details, is collated. This includes the severity of the effect as a result of product exposure, whether the end user is a part of a sensitive group like children and/or whether the product is widely used, creating a high probability of exposure. Product categories are assigned to discriminate between the different types of products and to better define various types of exposures. For instance, the category of 'cosmetics' contains products used daily, while household products contain products used generally on a weekly or monthly basis. Another important category is 'toys' because the end-user is a sensitive group of consumers (i.e. children). In addition, a chemical category for the identification of important groups of chemicals (phthalates in plastics, flame retardants in textiles or parabens in cosmetics) has also been added. The chemical categorisation is useful because in many instances regulation applies to groups of chemicals and allows for the identification of those products that are most likely to result in the highest consumer exposure, or groups of chemicals with a high hazard potential (i.e. CMRs and respiratory sensitising compounds) (Hogendoorn, 2014).

The *evaluation of potential NERCs* should be performed by a group of national and/or international experts. There are various *prioritisation methodologies* or tools that could be used by experts to rank

chemicals in non-food consumer products on the basis of risk (defined as a combination of hazardous properties of a chemical and its exposure) (Schuur and Traas, 2011 (for chemicals in REACH and CLP); Nijkamp et al. 2014 (for textiles); Woutersen et al., 2015b (for consumer products), or more broadly (including environment or life cycles), such as in the systems described by Mitchell et al. (2013) and Wambaugh et al. (2013)).

In 2015, RIVM collected 92 signals for consumers and these were prioritised according to their classification, potency and exposure information. In the first-tier analysis, a worst-case scenario approach was taken. Classification information was obtained from the ECHA database, with priorities assigned: highest priority was given to carcinogenic and mutagenic substances, followed by reprotoxic substances, then respiratory sensitising substances and, finally, the lowest priority was given to dermal sensitising substances. No weight differences were applied within each category. Non-threshold effects received a higher priority than threshold effects. Potency information was obtained from the ECHA database, with the lowest derived-no effect level (DNEL) or derived minimal effect level (DMEL) applied. Scoring was assigned according to Woutersen et al.'s system (2015), i.e. the product of the exposure estimation, usage/consumption and frequency of use. The exposure estimation, usage/consumption and frequency of use parameters were derived by Woutersen et al., (2015) from the European Centre for Ecotoxicity and Toxicity of Chemicals (ECETOC) Targeted Risk Assessment (TRA) tool that calculates the risk of exposure from substances to consumers. In each case, the highest exposure score associated with the product or article category of the signal was used. Finally, a priority (risk) score was obtained by adding the hazard to the exposure score. A second-tier approach is needed to move from default exposure scores to more product-specific scores within each product or article category. A national and international expert group is currently being established to refine the evaluation and prioritisation of potential NERCs for consumers.

3.3.2.7 Other relevant approaches/reporting systems

Goldsmith et al. (2014) developed a consumer ingredients database for chemical exposure screening and prioritization, using product Material Safety Data Sheets (MSDSs), publicly provided by a large retailer, and which contain 1,797 unique chemicals mapped onto 8,921 consumer products. While this tool is not necessarily intended for the identification of new and/or emerging risks, it has enabled the development of a mechanism for prioritisation based on the possibility of exposure to chemicals. For instance, the identification of chemicals present at high concentrations and across multiple consumer products and use categories that hold high exposure potential.

3.3.2.7.1 Databases and scientific reports

Data mining in databases and scientific reports on the topic of potential NERCs is useful to establish relationships between health effects and exposure. Table 7 presents a list of useful sources.

Table 6: An overview of additional useful sources of NERCs for non-food consumer products

Country	Name of database	Organisation
Denmark	Consumer surveys	Danish EPA
Germany	Product safety reports	Federal Institute for Risk Assessment (BfR)
Europe	Scientific opinions on consumer safety	Scientific Committee on Consumer Safety (SCCS)
Europe	Scientific opinions on emerging risks	Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)
Europe	Flagship campaign publications	BEUC: The European Consumer Association
Canada	Consumer product recalls and publications	Health Canada
USA	EWG's Skin Deep® Database	Environmental Working Group (EWG)
USA	Kids Chemical Safety publications	Toxicology Excellence for Risk Assessment (TERA)
USA	Recalls and product safety reports	Consumer Product Safety Commission (CPSC)
Australia	Consumer product recalls and publications	Australian Competition and Consumer Commission

4 OVERVIEW OF EARLY WARNING SYSTEMS

This chapter draws conclusions for each of the three compartments, i.e. environment, workers, and consumers. Based on the studies reviewed, three mechanisms were considered to be most relevant for consumer protection and food safety, with a further four identified for environment, and two for worker health and safety. The last section here provides an overall summary of the review.

4.1 ENVIRONMENT

Two operational systems aim to identify and manage new and emerging risks of chemicals for the environment, one run by the NORMAN network and one by the Dutch RIVM.

There are several approaches used to pick up signals, such as online media monitoring and expert consultation. While non-targeted and effect-directed analysis would provide valuable input, these are still under development. However, useful results from these methods of chemical analysis should be expected in the near future. Online monitoring is an efficient approach for picking up signals as it can be automised to a large degree, but then requires continuous evaluation efforts by experts. In terms of signal strengthening, there are many data sources that can be used to provide further evidence for the selection or prioritisation of potential new or emerging risks related to chemical substances. An important issue is how to deal with data gaps. The NORMAN methodology takes a practical approach by applying different pre-defined prioritisation categories. There is, however, a need to generate an overview of the data sources available and their availability, accessibility, and usefulness, in light of the specific aims of the EWS. A risk-based procedure, based on hazard assessment and exposure assessment, is common in the field of risk assessment of chemicals for human health and the environment. Suitable approaches for prioritisation should be selected based on their effectiveness and efficiency. To begin with, a simple risk-based scoring methodology (such as that provided by Hogendoorn (2014)), could be applied for the quantification of the potential risk of an identified chemical of concern. The main effort lies in gathering the data rather than in scoring and prioritisation, which can be automised for the most part. There are also alternative ways to evaluate new or emerging risks, such as those proposed by the SCENIHR committee.

Investigating appropriate risk management options, together with communication of the risks identified and the measures proposed, are essential to managing the observed risks. From the literature and systems studied, it appears that there has been given little attention to risk communication, meaning that there is little information on a communication plan or actions defined on sharing the results obtained in most cases. NORMAN (2016) and ECHA (2014 and 2015) elaborated this to some extend. A communication plan is considered to be a key requirement in the development of an EWS. Building an overview of current environmental legislation and the risk management options they provide, including the relevant competent authorities, should be the first step in formulating a communication plan.

4.2 WORKERS

There are two types of EWS for workers, i.e. the proactive 'exposure first' method and the reactive 'disease first' method.

Proactive 'exposure first' method: This tries to identify possible NERCs through proper risk assessment. In order to do this, however, a complete picture is needed of the hazardous properties of a substance and the (altered) use and exposure to the substance. In an ideal situation, all health hazards

of a substance would be known, taking into account all exposure routes, and an extensive exposure assessment would be available to make a risk assessment. However, for most agents currently used in the workplace, this essential information is lacking or incomplete. A new EU initiative (HAZCHEM@WORK[7]) to create a database and develop a model to estimate occupational exposure may help to improve this situation.

Work-related exposures and diseases remain an issue and need to be detected as early as possible to both treat and prevent new cases (the 'disease first' method).

Reactive 'disease first' method: This tries to identify the health effects of NERCs as soon as possible by identifying cases through clinical watch systems and research on databases containing information on job/exposure and health effects. An overview of (possible) NERCS was provided by Palmen et al. (2013) using this method. The first signs of disease which may be related to exposure to substances must be evaluated for their causal relationship. In Palmen and Verbist (2015), these (possible) NERCs were prioritised, and checked for their inclusion in existing legal frameworks.

The expert forecasts of NERCs are another type of'"disease first'method. The Delphi method is used to identify emerging occupational safety and health chemical risks identified by experts in the EU-OSHA expert forecast (EU-OSHA, 2009). The main emerging risks were singled out in an expert forecast examining context, workers at risk, health and safety outcomes, and prevention in greater depth. This forecast provided an overview of important issues, according to the experts. In their foresight study on the role of NERCs in green jobs, EU-OSHA (2013) identified the key technological innovations that may be introduced in green jobs over the next 10 years, and used scenario building to define the important health and safety aspects. SCENIHR (2014) have made a position statement on NERCs for submission to the EC, pointing to the NERCs with the potential to impact significantly on human health and /or the environment in the future. The identification of these NERCs was largely based on expert judgement.

4.3 CONSUMERS NON-FOOD AND FOOD

There are two different types of EWS to identify new or emerging risks of chemicals for consumers, i.e. to identify chemicals in food and chemicals in non-food consumer products.

For signal identification and evaluation, the currently available systems are heavily dependent on observed and documented signals relating to occurrence and potential exposure. Only the cosmetovigilance systems include observed effects, which are mostly related to skin effects. The EU cosmetovigilance reporting system is just recently beginning to gather all the SUEs from all European countries (Butscher et al. (2016)). This includes reports from the Dutch CESES and Norwegian cosmetovigilance system. Based on the inventory undertaken in this study, the EFSA's EMRISK seems thus far to represent the most advanced EWS for consumers. Generally, EWS are 'data hungry' and require sophisticated search and filtering strategies. While the exposure-based prioritisation research studies analysed here (including Mitchell et al. (2013), Wambaugh et al. (2013), and Goldfield et al. (2014)) are the most advanced, they do not have a direct link to effects present among the general (consumer) population. Other systems, not necessarily intended for the identification of new and/or emerging risks, report the development of a prioritisation mechanism based on the possibility of exposure or failure to meet European regulation, such as those reports in RAPEX.

The development of risk management options, together with communication of the identified risk and the proposed measures for its management, remain challenging for consumers. The fact that consumer product legislation is compartmentalised remains an obstacle, as it falls under many different pieces of

[7] http://www.hazchematwork.eu/

legislation (e.g. REACH, the General Food Law Regulation, the GPSD, the Cosmetics Regulation, the Textile and Clothing Regulation, the Toy Safety Directive, etc.), each of which is overseen by different authorities (EFSA, ECHA, SCCS). In addition, each branch has its own type of 'surveillance system' (EMRISK for food; RAPEX for non-food consumer products; EU cosmetovigilance for cosmetics). Although it is unrealistic to converge food and non-food EWS, it might be useful to generate a unified EWS for non-food consumer products. This might be useful both in more effective identification of potential new or emerging risks of chemicals and in the communication of potential risk management options.

4.4 SUMMARY

The most relevant systems are briefly summarised below:

- **Environment**
  - NORMAN (Dulio and von der Ohe (2013); NORMAN network (2016)).
  - NERC-system (RIVM, Hogendoorn, 2014).
- **General**
  - SCENIHR Committee (SCENIHR, 2009 and 2014).
  - REACH regulatory processes (screening and SVHC prioritisation: ECHA, 2014 and 2015).
- **Workers**
  - Reactive'"disease first' method (Palmen (2016))
    - Clinical watch systems (MODERNET, UK and Ireland (THOR network), France (RNV3P, GAST, OccWatch), the Netherlands and Belgium (Signaal), Italy (MALFPROF) and Spain (regional systems);
    - Databases on exposure and health effects;
    - Biomarkers: mainly by research organisations.
  - Reactive 'disease first' method by EU-OSHA (EU-OSHA (2009 and 2013)).
- **Consumers - food and non-food**
  - *Food*
    - EMRISK (EFSA 2006, 2014a, 2014b, 2015, Altieri 2014).
  - *Non-food*
    - CESES, Dutch Consumer Exposure Skin Effects and Surveillance *(*Salverda-Nijhof et al. 2011a, 2011b; De Wit-Bos et al. 2014a, 2014b; Woutersen and Bakker, 2015);
    - Dutch NERCs EWS (Hogendoorn, 2014).

Table 8 presents the EWS identified for each policy area, according to the four main elements of an EWS, i.e., emerging risk signal identification, signal strengthening, signal prioritisation and follow-up actions (risk management options and communication).

Table 7: Relevant mechanisms identified for specific and general policy areas, where early warnings of chemical risks are considered particularly important: (i) environmental protection; (ii) occupational health and safety; and (iii) consumer protection, including food safety; (iv) general

Mechanisms	Emerging risk signal identification	Causality assessment	Emerging risk signal prioritisation	Follow-up risk management and communication
Consumers and food				
EMRISK *(EFSA 2006, 2014, 2015)*	Expert consultations (Delphi method)	Identification of data sources and data collection (monitoring, stakeholder, expert consultation)	Based on EFSA's emerging risk definition and ad-hoc criteria Specific *Emerging Risks Unit*	EMRISK Unit and Scientific Committee WG: evaluate and provide recommendations on emerging issues*
CESES	Monitoring reports of undesirable events by GPs, dermatologists, and consumer questionnaires	Evaluation through questionnaires and patch tests by senior dermatologists	Only relevant cosmetic allergens are taken into account for causality assessment	Informing national enforcement authorities
NERC-system *(Hogendoorn, 2014)*	Monitoring of online media, literature, RAPEX, and reports from Dutch cosmetovigilance (CESES) and from Dutch NVIC	Evaluation of signal according to severity, including classification, potency and exposure information	Risk-based: exposure and hazard scoring	Identification of appropriate risk management options, with focus on REACH Informing members of appropriate REACH committees of identified concerns
Workers				
Reactive 'disease first' method (THOR, RNV3P, GAST, OccWatch, Signaal, MALPROF, Spanish regional systems) *(Palmen, 2015, 2016)*	Stakeholder consultation: Labour Inspectorates, research organisations and insurance funds, medical doctors, industrial hygienists, occupational nurses, employers, trade unions and workers	Via clinical watch systems which all have at their disposal an expert group and the availability of databases for epidemiological research	Impact analysis based on the severity of the effect on health (impact) and the evidence of occurrence (likelihood).	Informing decision makers, REACH committees, Labour associations, medical officers, and enforcement authorities, professional societies on occupational health and safety
Reactive 'disease first' method EU-OSHA *(EU-OSHA (2009 and 2013))*	Expert forecasts (Delphi method)	Stakeholder, expert consultation for identification key technological innovations. Health and safety aspects defined by experts, based on scenario building	Experts assessed future new and emerging risks in the workplace, or key changes leading to **positive impacts** on workers' safety and health	EC
Environment				

Mechanisms	Emerging risk signal identification	Causality assessment	Emerging risk signal prioritisation	Follow-up risk management and communication
NERC system *(Hogendoorn, 2014)*	Online media and literature monitoring; non target screening, expert consultation via online platform for expert exchange	Different selection criteria are defined to address relevance or plausibility for the environment (aquatic compartment)	Risk-based: exposure and hazard scoring	Identification of appropriate risk management options, with focus on REACH Informing members of appropriate REACH committees of identified concerns
NORMAN *(Dulio and von der Ohe (2013)*	Expert consultation, (possibility of non-target screening and biomonitoring are being explored)	Expert judgement, scientific literature	Risk-based: exposure and hazard scoring defining different outcome categories based on data richness	Prioritised substances will be proposed as candidates for the WFD's watch-list of chemicals
General				
SCENIHR committee *(SCENIHR, 2009 and 2014)*	Expert consultation	Expert consultation A proactive approach based on 'brainstorming' sessions on emerging risks, followed by procedures to detect and characterise their development. Reactive approach based on the prior identification of indicators of change and the monitoring of these to detect emerging issues	Decision tree approach using an algorithm for identifying priorities. Matrix system approach using a scoring/weighting system for different criteria, such as uniqueness, soundness, scale, urgency, severity, interactions	EU Commission Services
REACH regulatory processes carried out by ECHA and EU Member States (screening program and SVHC prioritisation)	Screening of registered substances for certain hazardous properties, specific types of use and market volume. Other signals might also trigger the REACH regulatory processes	Differs case by case, scientific literature, monitoring data, outcomes of epidemiological research etc.	Risk-based: exposure and hazard scoring	Identification of appropriate risk management options within the REACH and CLP Regulations, such as authorisation, restrictions, substance evaluation and harmonised classification

* Some recent examples include: risk assessment of chemical mixtures, providing a roadmap for a strategy across ESFA's risk assessment of chemical hazards, follow-up on specific cases, bee health and the impact of multiple stressors

5 POTENTIAL TO SET-UP AN EU-WIDE EWS

Several ideas are outlined here on setting up an EU-wide EWS for the identification of new or emerging risks of chemicals to the different target groups (environment, workers, and consumers). These are drawn from the workshop 'Strategy for a non-toxic environment' held on 8/9 June 2016 in Brussels, which discussed the data gaps identified (Appendix 5) and ideas for improvement (Appendix 6), as well as relevant information from the literature evaluated in this study.

5.1 WHAT IS NEEDED TO ADVANCE NERCS FOR THE ENVIRONMENT?

The next steps in establishing a system for the early identification of chemical threats for the environment are described below.

While it is expected that the identification and evaluation of signals or the plausibility check (i.e. the evaluation of the likelihood that a first signal is a NERC, followed by checking existing regulations and measures) will be done at Member State level by an expert national group, this could also be effective if organised at EU level. Various EU authorities have gained experience in the area of the identification of chemical threats, such as EFSA (through its EREN), SCHEER, and the screening on potential chemicals of concern by ECHA. Irrespective of its owner, this should have a uniform approach, therefore requiring the establishment of a working procedure defining the goals, providing clear definitions of emerging chemical threats, and defining selection criteria or a plausibility check procedure. This could be done collaboratively by national and international experts (NORMAN network), together with advisory committees such as SCHEER.

Different sources providing signals on emerging chemicals should be explored further. Some experience has been gained with online media monitoring (Hogendoorn, 2014) and expert consultation through scenario building (SCENIHR), and a lot of progress is being made in the field of non-targeted analysis, biomonitoring and effect-directed analysis. The NORMAN network is very active in these areas and would provide an excellent platform to investigate how the results from these research fields might be linked to an EWS methodology, and explore what is needed to further process these signals.

Current work on EWS for the environment has focused on the water compartment. Possibilities for the other compartments (air and soil) should also be considered.

A platform is needed to provide easy access to all data sources relevant for causality assessment, as well as the supplementary data expanding the evidence on chemicals of concern. The first requirement is an overview of the kinds of data needed and the sources available. Several institutions have significant experience in this area, such as the JRC, ECHA and the EEA. The IPCHeM portal, as a current platform for chemical monitoring data, has the potential to be extended to host data on hazardous physical and chemical properties, as well as uses and and other exposure information.

The work on causality assessment and evidence collection would be best centralised at EU level through national and international expert groups. This approach would also seem the most appropriate for the work on assigning appropriate risk management measures, facilitated in a similar way to existing international advisory committees such as SCHEER, or working groups such as those organised within the NORMAN network. Follow-up actions could be delegated to the national experts who then inform the relevant stakeholders, or to the EC.

Finally, assigning appropriate risk management measures requires an overview of the relevant environmental legislation and its instruments, in order to facilitate an examination of the different options available. Once appropriate risk management measures have been determined, follow-up

actions should be defined and communicated to the relevant stakeholders.

5.2 WHAT IS NEEDED TO ADVANCE WORK-RELATED NERCS?

Once a possible (new and/or emerging) work-related health risk has been identified by the methods described above, it is crucial that it is discussed amongst an (international) expert group, who will evaluate the possibility of a causal relationship between the exposure and the reported health effect, and the need for additional research or further evidence. In the survey described in Section 3.2, the respondents were asked to identify 'How to bring the possible (new and emerging) work-related health risks further'.

Their responses are given below:

- The availability of expertise centres in every country, both to study whether or not the NERC is associated with work, and also so that patients can consult with occupational experts (both on exposure and health effects).
- Establish an *international* platform of specialists on work-related health effects and occupational diseases, such as that of the MODERNET network. Communication between the specialists in the MODERNET network takes place through scientific meetings in which cases and research are presented and discussed. In addition, MODERNET's online tool, OccWatch, is used to discuss cases and to strengthen the evidence of a causal relationship between exposure/work and the health effect by finding similar cases in other countries. Further development of the MODERNET network was raised by several of the survey respondents.
- Establishment of a group of experts on work-related and occupational diseases, financed by the EU. This group could be organised in a manner similar to the Scientific Committee on Occupational Exposure Limits (SCOEL). It could work to identify the diseases needing further evaluation (e.g. cancers), consider how such evaluation should be carried out, agree the research required to find the necessary evidence, and develop coordination mechanisms to ensure efficient research and evaluation (EU, 2013).
- Establishment of a European tripartite expert group on work-related and occupational diseases, comprising government, unions and employers' associations.
- Discussions within and among existing international advisory committees, such as SCENIHR, European Union of Medical Specialists, OCCUSTAT[8], etc.
- Regular meetings between (national) institutes for health and safety.
- Discussions during international conferences.

5.3 WHAT IS NEEDED TO ADVANCE CONSUMER-RELATED NERCS?

Signal identification remains a major challenge for the identification of NERCs for consumer products, both food and non-food.

Food:
EMRISK (EFSA's EWS) is the chief body for food risk within Europe, and it should ensure the availability of experts/expertise, as well as supporting Member States to properly document each reported case.

- Support the availability of experts/expertise in all European countries.
- Ensure that all countries comply with their reporting obligations to the Rapid Alert System for Food and Feed (RASFF) and the Rapid Alert System for Biological and Chemical Attacks and

[8] OCCUSTAT: Expert group on occupational diseases statistics founded by the European Commission and EU-OSHA.

Threats (RAS-BICHAT).

Non-food:
Non-food consumer products comprise a wide range of products, each composed of a mixture of chemicals; finding a causal link between a (serious) undesirable effect and a chemical is therefore extremely challenging. Joint national and/or international signalling platforms, such as the Dutch CESES and the EU cosmetovigilance are of the utmost importance.

The following recommendations address improvements to the identification of consumer-related NERCs.

Cosmetics:

- Increase the number of reports for (serious) undesired effects (SUEs): national projects such as CESES in the Netherlands are key to the timely identification of SUEs from substances in cosmetics but efforts need to ensure that there are more participating dermatologists (either nationally or internationally) to document and report all SUEs within Europe.
- Expanding the range of products within the EU cosmetovigilance: dermal reactions to other specific products (e.g. tattoos and tattoo aftercare products) should be included in the EU cosmetovigilance. There have been (severe) allergic reactions associated with tattoo inks, but there is no established monitoring system for the identification of these potential NERCs.

Non-cosmetics:

- A consumer product monitoring or notification system for other non-cosmetic consumer products is needed, such that consumers can self-report health complaints from non-cosmetic consumer product use, such as textiles. Consumer awareness and an easy-to-use national platform for consumer complaints are necessary, for example through a web-based system or an app.

General recommendations for all non-food consumer products:

- Knowledge sharing via regular meetings between (national) health institutes dealing with consumer product safety and/or discussions during international conferences.
- A long-term goal would be to establish an EU monitoring/notification platform for all non-food consumer products. This would facilitate the identification of NERCs for consumers.

For signal evaluation and NERC identification:
Food:

- Continued collaboration and support between SCER and the EFSA Scientific Cooperation (ESCO) Working Group (WG) on Emerging Risks, with the EREN, Member States, the Commission, EU agencies and international organisations.

Non-food:

- Close collaboration between national and international experts and advisory committees (e.g. SCCS, SCHEER, the GPSD committee) is key for timely signal evaluation and establishment of a causal relationship between exposure and health effects.
- Establishment of national and international expert groups for consumer product safety evaluation and refinement of the prioritisation methodology.

6 CONCLUSIONS

This section provides the final conclusions and recommendations on setting up an EWS. While ideally, a single EWS should exist, this is neither feasible nor practical, in light of the substantial differences between environmental, consumer and worker protection, and between and within Member States on collection, processing and interpretation of new and emerging risks. A more practical approach, therefore, would be to continue to use existing systems while facilitating effective interconnections and communication at Member State and European level (see Table 9 for more details of this proposal). Such a system would take as its starting point the basic building components and steps (see Figure 1) for each of the protection goals , i.e. workers, consumers and the environment.

6.1 GENERAL CONCLUSIONS

Several approaches are used to pick up signals, such as online media monitoring and expert consultation, or registration systems for the collection, evaluation and systematic monitoring of spontaneous reports of undesirable events. Current systems depend heavily on observed and documented signals relating to occurrence of effects and potential exposure, the so-called 'effect-based' or 'disease first' systems. By contrast, other systems contain elements that can be used to proactively identify possible NERCs, based on a proper risk assessment, the so-called 'exposure first' method.

Many existing data sources can be used to provide further evidence for the selection or prioritisation of potential new or emerging risks related to chemical substances. The selection of suitable approaches for picking up signals and prioritisation should be based on effectiveness and efficiency. Gaining an overview of existing data sources, their availability, accessibility, and usefulness would be essential in establishing an EWS. Subsequently, the data would need to be made widely accessible, through a central database. A quantitative risk-based procedure, based on hazard and exposure assessment, is common in the field of risk assessment of chemicals for human health and the environment. An alternative means of identifying or prioritising new or emerging risks would be based on qualitative criteria, such as that proposed by SCENIHR.

Investigating appropriate risk management options, communicating the risks identified, and identifying measures are essential to managing the observed risks. Communication of risk is not always well-executed, meaning that there is little information on a communication plan for decision makers and enforcement authorities, nor on the actions for communicating the results obtained. The need to develop a communication plan (where, how and to whom) should, therefore, receive particular attention in the development of an EWS. Building an overview of current environmental legislation and the risk management options provided by each - including the competent authorities - is the first step in formulating a communication plan.

Many differences exist between the fields of environmental, consumer and worker protection, as well as between and within Member States, on the collection, processing and interpretation of signals on new and emerging risks, making it difficult at present to create a single system covering all three disparate fields. A more practical approach would be to use existing systems as much as possible and to focus on creating more effective interconnections and facilitating communication at Member State and European level. The basic building components and steps from Figure 11 could be taken as a starting point to establish a European EWS for identifying chemical threats to human health and the environment.

Three expert groups would be needed, one at national level and two at European level. The picking up and evaluation of signals (plausibility and causality check) would be best coordinated at Member State

level. At the European level, one expert group should be assigned to discuss possible causal relationships between exposure and effect, with a second providing advice on risk management measure to the relevant authority, under the auspices of one of the EC's Directorate-Generals. This second group would provide an opportunity for stakeholders from society (i.e. unions, insurers, industry, NGOs, regulators and professional associations) to participate. At the EU level this work could be undertaken by existing working groups and committees, or by newly established groups with a focus on the identification and management of new and emerging risks of chemicals.

Analysis of the existing national and international tools and methods for the early identification of new or anticipated chemical threats suggests that existing approaches are insufficient, with greater efforts needed at EU level.

While the continuous work to screen and filter signals is essential for early identification, it is labour intensive and requires input from experts at the national level, which is not organised or coordinated at the EU or international level.

In addition, establishing a causal link between exposure to chemicals and, for example, diseases, will remain difficult. A related issue is the limitations of epidemiology, meaning that a harmful effect must often be rather drastic and widespread before it is detected. There is often a lack of information, due to the absence of relevant hazard data and the absence of details on exposure and use. It is important, therefore, to identify all of the databases and other useful sources of information, and to centralise this information as much as possible, in order to establish an effective and efficient procedure to evaluate signals and identify new or emerging risks from chemicals.

There is currently no coordinate approach covering the different steps needed for the identification and management of chemical risks at the EU level . This highlights a broader need for more cooperation and exchange of information on NERCs at EU level. At the national and international level, various existing initiatives in the area of early identification and management of chemical threats could provide the basis for more comprehensive and coordinated work.

6.2 IMPROVEMENT OPPORTUNITIES

Picking up signals is an important task for every expert in the field. Amplification, evaluation of signals, confirmation checks against existing regulations and measures, and plausibility checks (i.e. evaluation of the likelihood that a first signal is a NERC), should be carried out at national level by an expert group. These researchers should form an international network of scientists to improve the entire process of detecting and establishing NERCs. For workers, such a network already exists (MODERNET). Such a group of national experts should preferably meet regularly, e.g. twice per year, to discuss the signals noted. In practice this would mean that each Member State has three or four expert groups, one for each compartment (environment, workers, consumers - food and consumers - non-food). Each group should comprise experts with relevant professional backgrounds. For workers, a suitable composition might consist of occupational physicians, clinical specialists, medical researchers, toxicologists, exposure scientists and epidemiologists. For consumers, the experts could include researchers, product designers, exposure scientists, chemists, toxicologists and risk assessors. For the environment, the group might comprise environmental scientists, ecotoxicologists, exposure scientists, modellers and risk assessors.

The outcome of the signals picked up by experts at Member State level and discussed with an international network, would then be communicated to the relevant EU agency or entity, who will further process the signals through EU expert groups. At a European level, two types of expert groups are needed: one for experts and scientists, aiming to establish a causal relationship between exposure and effect (e.g. an 'Institutionalised MODERNET'); and a second under a Directorate-General, where

stakeholders from society (e.g. trade unions, insurances companies, industry, NGO's, regulators and professional societies) also have the opportunity to participate. The aim of this group would be to provide advice directly to the authorities concerned, i.e., one of the EC's Directorate–Generals (See Table 9).

Throughout the entire process, a high degree of communication is essential to remain up-to-date during each step of the process. Therefore, a European NERC database to track the current status of a signal, the contact organisation (ECHA/EFSA/EEA/MS), etc. could be established. Such a database would facilitate overall NERC documentation, registration and communication (for example, through a website). It could also be used to trigger signal evaluations for other compartments. The database should feature a search mechanism for signals, chemicals and products, like that of the RAPEX system. A publicly available website would offer the advantage of speeding up substitutions for certain products by the industry in question.

Table 8: Proposal for setting up and organising a European EWS

Compartment	MEMBER STATE LEVEL 					EU LEVEL 		
Worker	Pick up and evaluation of signals			National expert groups		EU-OSHA (EU expert group)	Signal strengthening, causality assessment and prioritisation	International integrated NERCs groups (biennial)
	National systems, including expert groups	Communication within MODERNET network	National focal points of EU-OSHA				'Institutionalised MODERNET'	
	Conformity check						Risk score and prioritisation of risks	
	Existing regulations and measures in place						Follow up actions and communication (see Section 2.4)	
	Plausibility check						'Institutionalised MODERNET' / DG Employment	
Consumer	Pick up and evaluation of signals			National Expert groups		EFSA (food) and Commission (non-food) (EU expert group)	Signal strengthening and causality assessment	
	Food		Non-food				Risk score and prioritisation of risks	
	National systems / EFSA working groups (EREN)		National cosmetics groups, (such as CESES in NL) / Consumer safety network				Food: EFSA / Non-food: GPSD committee/SCCS	
	Conformity check						Follow-up	
	Existing regulations and measures in place						DG Growth / DG Environment / DG Sante	
	Plausibility check							
Environment	Pick up and evaluation of signals			National expert groups		EEA (EU expert group)	Signal strengthening and causality assessment Risk score and prioritisation of risks	
	National systems	NORMAN network					Water Directors meeting and CIS Chemicals working group, SCHEER	
	Conformity check						Follow-up	
	Existing regulations and measures in place						DG Environment	
	Plausibility check							

One of the study questions was the cost of a possible European EWS. Some indication of cost can be drawn based on implementation of the proposal in Table 9, although estimates are only possible for the national and international expert group meetings. As picking up first signals is generally carried out by professionals in the field, these costs are not included in the calculation below. For the expert groups, a difference is assumed between the cost to each Member State and to the EU. The cost estimate is partly based on RIVM experiences within the MODERNET network (Palmen et al., 2013; Hogendoorn, 2014; Palmen et al., 2015 and 2016).

For the national expert groups, the following assumptions are made:

- The national expert groups will consist of 10 people per group for each of workers, consumers and the environment, each group meeting twice per year for one full day, incurring personnel costs of 60 working days to attend the meetings.
- One person per compartment will prepare both meetings, with 10 preparation days needed per meeting, requiring a total of 30 working days.
- Meeting outcomes will be processed by two people, each working one day per week for the full year (as a continuous process). At two days per week, this amounts to eight days per month and 80 working days per year, assuming an effective working time of 10 months per year.
- In estimating total costs, an average working day is taken as eight hours, with an hourly rate of EUR 90.

This corresponds to an annual cost of:

- Expert group meetings: 60 days * 8 hours * EUR 90 = EUR 43,200 per year.
- Meeting preparation: 30 days * 8 hours * EUR 90 = EUR 21,600 per year.
- Continuous work: 80 days * 8 hours * EUR 90 = EUR 57,600 per year.

The total, therefore, is EUR 122,400 per year per Member State. These are labour costs, excluding travel, accommodation, costs related to the venue, and requipment/facilities' costs.

For the EU scientific expert groups, the following assumptions are made:

- They meet twice every year for two days, with the advisory group meeting for one day each year.
- Each Member State should be equally represented, with at least one person per Member State. Stakeholders will participate in the meeting on an ad-hoc basis, depending on the case(s) being discussed.

Participation in this meeting will cost EUR 720 per expert per day (8 hours * EUR 90), creating a cost of EUR 3,600 per Member State to attend all meetings each year. When 28 experts are invited, the meeting itself will cost EUR 100,800 for each area of interest, excluding travel, accommodation, costs related to the venue and facilities, and participation of ad-hoc stakeholders.

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APPENDIX 1. QUESTIONNAIRES FOR LITERATURE REVIEW

See separate document.

APPENDIX 2. OVERVIEW OF COUNTRIES AND THEIR ORGANIZATIONS

Country[9]	Organisation approached to fill in the questionnaire
Albania	Inspektorati Shteteror i Punes dhe Sherbimeve Shoqerore
Albania	MODERNET*
Andorra	Ministry of Health and Welfare
Armenia	Ministry of Health
Armenia	Ministry of Nature Protection of the Republic of Armenia
Azerbaijan	THE MINISTRY OF LABOUR AND SOCIAL PROTECTION OF POPULATION OF THE REPUBLIC OF AZERBAIJAN
Azerbaijan	State Labour Inspectorate
Austria	Unfallverhütung und Berufskrankheitenbekämpfung Allgemeine Unfallversicheringsanstalt
Austria	Arbeitsinspektion
Belarus	Ministry of Labour and Social Protection Republic of Belarus
Belgium	KU Leuven
Belgium	Federale Overheidsdienst Werkgelegenheid, Arbeid en Sociaal Overleg
Bosnia and Herzegovina	Ministry of Civil Affairs of Bosnia and Herzegovina
Bosnia and Herzegovina	Ministry of Health and Social Welfare of Republika Srpska
Bosnia and Herzegovina	MODERNET*
Bulgaria	National Centre of Public Health and Analysis
Croatia	University of Zagreb, School of Medicine
Cyprus	Department of Labour Inspection, Ministry of Labour, Welfare and Social Insurance
Cyprus	World Health Organization
Cyprus	Ministry of Health
Czech Republic	Charles University, Faculty of Medicine, Prague
Czech Republic	National Institute of Public Health
Denmark	National Research Centre for the Working Environment
Denmark	National Centre for the Working Environment
Denmark	Danish Working Environment Authority
Estonia	Department of Public Health, fFculty of Medicine, University of Tartu
Estonia	North Estonia Medical Centre Foundation
Finland	Finnish Institute of Occupational Health
Finland	Local Tapiola General Mutual Insurance Company
Finland	Ministry of Social Affairs and Health
France	ANSES
France	Eurogip
Germany	Deutsche Gesetzliche Unfallsversicherung (DGUV)
Germany	Gesellschaft für Versicheriungswissenschaft und -gestaltung e.V
Georgia	Ministry of Labour, Health and Social Affairs
Greece	Social Insurance Services of the Ministry of Labour and Social Insurance
Greece	Centre Hellenic Institute for Occupational Health and Safety
Hungary	Ministry for National Economy - Department of Labour Inspection

[9] An overview of the status of these European countries is available at: http://europa.eu/about-eu/countries/index_en.htm

Country[9]	Organisation approached to fill in the questionnaire
Hungary	Ministry of Human Resources
Hungary	Office of the Chief Medical Officer - OTH, Department of Occupational Health
Iceland	Focal point EU-OSHA
Iceland	MODERNET*
Iceland	Ministry of Welfare
Ireland	MC Member Ireland
Ireland	Health and Safety Authority
Italy	Istituto Nazionale per l'Assicurazione contro gli Infortuni sul Lavoro (INAIL)
Italy	MODERNET*
Kazakhstan	Centre of Health Management
Kazakhstan	The Centre for Healthcare Management
Kosovo	Ministry of Labour and Social Welfare Labour Inspectorate
Latvia	Pauls Stradins Clinical University Hospital
Latvia	Centre of Occupational and Radiological Medicine
Liechtenstein	Amt für Volkwirtschaft
Lithuania	Occupational Health Centre, Institute of Hygiene
Luxembourg	Inspection du Travail et des Mines
Luxembourg	Ministry of Health
Luxembourg	Service de santé au travail multisectoriel
Macedonia	MODERNET*
Malta	Director at Department of Health Information and Research
Moldova	Ministry of Health
Monaco	Directorate of Health and Social Work
Montenegro	Administration for Inspection Affairs
Montenegro	Ministry of Health
Netherlands	RIVM; National Institute of Public Health and Environment
Netherlands	NCOD / Coronel institute on Work and Health
Netherlands	ASRI; hogeschool voor sociale zekerheid
Netherlands	Foundation learning and developing occupational health; instituut klinische arbeidsgeneeskunde
Norway	National Institute of Occupational Health (STAMI)
Norway	Arbeidstilsynet
Norway	Stami; statens arbeidsmiljoinstitutt
Poland	Nofer Institute of Occupational Medicine (NIOM)
Portugal	National School of Public Health, Lisbon
Romania	National Institute of Public Health Romania
Russia	Ministry of Labour
San Marino	Institute for Health and Social Welfare
Serbia	Ministry of Labour, Employment, Veterans and Social Policy
Serbia	MODERNET*
Slovakia	Comenius University Bratislava; Department of Occupational Medicine and Toxicology in Bratislava
Slovakia	Pavol Jozef Šafárik University in Košice
Slovenia	Institute of Occupational Safety
Slovenia	University, Department of Occupational Medicine and Clinical Toxicology
Spain	University of Zaragoza, Departement of Occupational Medicine, Forensic Science

Country[9]	Organisation approached to fill in the questionnaire
	and Toxicology
Spain	Parc de Salut, Barcelona
Sweden	Institute of Environmental Medicine (IMM)
Sweden	Arbetsmiljöverket (Swedish Work Environment Authority, SWEA)
Switzerland	Institute of Social and Preventative Medicine, University of Lausanne
Switzerland	SUVA, insurance plus
Turkey	Calisma ve Sosyal Guvenlik Bakanligi
UK	University of Manchester, Centre for Occupational and Environmental Health
Ukraine	National O. Bohomolets Medical University, Department of Industrial Hygiene and Occupational Diseases
Vatican City	Facoltà di Medicina e chirurgia (Faculty of Medicine and Surgery)

APPENDIX 3. QUESTIONNAIRE 'EARLY WARNING SYSTEMS'

The first six months of the year 2016 the Netherlands will be the chair of the European Union. During that period, the Dutch Ministry of Socials Affairs and Employment (SZW) will organise an international conference on how to ban work-related cancer in the EU. The main purpose of this conference is to address policy agenda setting points for the years to come. The RIVM is asked to prepare the scientific substantiation for some of the themes. One of the themes is the availability and use of 'early warning systems' to identify and evaluate NERCs leading to occupational cancer, so that substances and/or processes will be identified and measures can be taken by policymakers to control exposure. The preparation of the conference will be done in close cooperation with other EU stakeholders to establish a solid basis and level playing field to agree on the agenda points to be set at the end of the conference.

Early warning systems are important to detect new or emerging work related health effects, including occupational cancer. The novelty of the use of early warning systems is to use signals from the field, such as cases or clusters of cancers suspicious to be related with occupational exposure. Obviously occupational health specialists (occupational physicians, lung specialists, dermatologists, industrial hygienists etc.) need to be on the alert on the occurrence of any possible work related cancers. These cancers may be a consequence of a known hazard or substance, but also of an unknown hazard of a known substance, through new use of a substance leading to an unknown risk (e.g. inhalation exposure instead of oral exposure), or even a completely new substance. Since new hazards may be rare or present after long latency, European collaboration is of great importance to detect and streamline these signals as was already recognised by WHO: http://www.who.int/occupational_health/activities/occupational_work_diseases/en/.

It is not the intention to create a harmonised or uniform approach, but to use the existing systems and share the results. So, the aim is to create an overview of existing 'early warning systems' in the different EU countries and share the outcomes of the analyses made by scientists. In any case, the identification of emerging risks requires the use of several complementary methods. In the end, an international group of experts may be needed in order to discuss the information, and make a decision on the work related risk of the substance or process to cause cancer.

In preparation of the conference, RIVM would like to make an inventory of 'early warning systems' already existing in the member states. Underneath you find a description of the systems we are looking for (clinical watch systems, databases for data mining, use of biomarkers in health surveillance etc.). We kindly request you to inform us about any system in your country that can be looked upon as 'early warning system' by completing the questionnaire. The results will be analyzed and published before the start of the conference.

In addition, we ask you to provide us with names of policy makers that should be invited to the conference according to you.

'Clinical watch systems':
The collection of 'spontaneous reported cases' is a very important source of information for the identification of NERCs. It is especially effective in cases of rare, serious health effects with a low incidence rate. The reporter or notifier suspects a relationship between the health effect and exposure to chemicals and/or an occupation. It is an effective, relatively inexpensive method that covers the whole working population. Drawbacks of this method are dependence on the willingness to notify (underreporting) and the need for further research on a possible causal relationship. The case reports need to be collected in a database and analyzed by experts.

Questions related to the existence of a clinical watch system:

Are you aware of any type of clinical watch system to identify possible (new and emerging) work-related health risks in your country?	❒ Yes ❒ No
If yes, please answer the next questions: *In case there are more than one clinical watch systems, please copy this table*.	
What is the name of the system /registry/instrument aimed at identifying possible (new and emerging) work-related health risks: …….	
Which organization collects the possible (new and emerging) work-related health risks?	❒ national institute of occupational health ❒ Labour Inspectorate ❒ fund occupational diseases ❒ occupational health providers ❒ other, which…… ……
Who can report possible (new and emerging) work-related health risks?	❒ occupational physician ❒ medical specialist ❒ general practitioner ❒ industrial hygienist ❒ worker ❒ other; who…… ……..
Who evaluates a first report of a possible (new and emerging) work-related health risks?	❒ the national institute of occupational health ❒ fund occupational diseases ❒ other; who…… ……...
How is a first report of a possible (new and emerging) work-related health risks evaluated?	❒ literature search on historical reporting ❒ communication between experts ❒ other, how? …… …….
Will the reporter or notifier be informed on the process and the outcome of his report?	❒ yes ❒ no
Are possible (new and emerging) work-related health risks collected in a (national) database?	❒ yes ❒ no If yes, please give the name:…… …….. ……
How does the communication of a (new and emerging) work related health risk between the reporter/notifier and the evaluating body take place?	❒ via the web ❒ on paper ❒ other; …… …….
How does the follow up of a possible (new and emerging) work-related health risks take place?	❒ no follow-up ❒ national expert group ❒ international expert group ❒ if so, which one? …….

'Databases'

Data mining, in databases of case report notification registries, is a valuable tool for epidemiological research. Relationships between health effects and exposure and/or occupation can effectively (objectively and reproducibly) be studied, especially when exposure data are incorporated in the database. This type of research results in the formation of a hypothesis. Further research is necessary to investigate a possible causal relationship between the exposure and the health effect.

Questions related to the existence of a (national) database on (new and emerging) work-related health risks:

Does your country have (a) database(s) that allow research between work – exposure to substances – health effects?	❒ Yes ❒ No
If so, please give the name(s)…… …… …… …… ……..	
If so, please answer the next questions *In case there are more than one (national) databases, please copy this table*	
Which organization(s) manage and maintain(s) the database(s)?	❒ not applicable ❒ please identify…… …… …… ……
Does research on identification of (new and emerging) work-related health risks take place?	❒ yes ❒ no
Is the database available for other research/researchers?	❒ yes ❒ no
Is an expert group on (new and emerging) work-related health risks available, discussing the causality between exposure and health effect?	❒ yes ❒ no
How will research results be disseminated?	❒ not applicable ❒ international papers ❒ international symposia ❒ other, please specify… …… …… ……..

Use of biomarkers in health surveillance

The active detection of health effects via health surveillance of workers is a valuable tool. Biomarkers for exposure can be used to determine total (oral, inhalation, dermal) exposure to substances. Biomarkers for biological effects may be an indication of early health effects leading to occupational disease. This prospective method is useful since a causal relationship between the level of exposure and possible health effects is easier to prove.

Are you aware of any type of health surveillance using biomarkers in your country to identify possible (new and emerging) work-related health risks?	❒ Yes ❒ No ❒ If so, which ?..... ……..
If so, which biomarkers *for identifying carcinogens or mutagens* are used, and for which (group of) substances?	…… …… ……..
Which organization takes the initiative to measure biomarkers for (new and emerging) work-related health risks	❒ research institutes ❒ occupational health services ❒ private parties ❒ general practitioners ❒ other; who……. ……..
Are the results of the biomarkers collected in a for research available (national) database?	❒ yes ❒ no If yes, please give the name:…… ……..
How does the follow up of possible (new and emerging) work-related health risks take place?	❒ no follow up ❒ national expert group ❒ international expert group ❒ if so, which one? ……. …….

APPENDIX 4. EFSA'S STANDARD TEMPLATE FOR THE DISCUSSION OF EMERGING ISSUES IN FOOD

Annex A – Template for a Briefing Note on Emerging Issues

BRIEFING NOTE ON EMERGING ISSUES[2]

Lasty updated by SCER on DD MM YYYY

Presented to EREN MTG on DD MM YYYY

The scope of this briefing note is to present emerging issues to EREN. EREN is requested to (i) evaluate the relevance of the issue presented and (ii) facilitate the exchange of any relevant information. The information provided in this briefing note is not comprehensive and is intended as a quick summary and a point of departure.

Title and ID

Description of the issue

Include a short description of the issue, mentioning the hazard under evaluation (e.g. which virus, bacteria, parasite, chemical, driver etc). Use the following criteria to explain why EMRISK considers this an emerging issue. Evaluation criteria to be considered include at least one of the three criteria listed below.

Additional supporting information

Provide any additional background information you believe is important in order to support the evaluation of the issue. For example:

Any additional information on the source of information (scientific or grey literature, inputs from AF, EFSA's Units, Experts, surveillance systems…);

Limitations of the analysis/study;

Toxicological information of this (or similar) agents/compounds;

Any other information you believe is important.

Has this related to any other issues already discussed in EMRISK monitoring meetings.

Legal and institutional aspects

Report the results of a basic search for EFSA risk assessment or action, and Commission documents or legislation on the subject.

EVALUATION

Main criteria

Driver: *(e.g. is this a new driver?)*

New hazard: *(e.g. Has a new hazard been identified? If so, which one and how?)*

[2] "*Emerging issues*" are identified at the beginning of the Emerging Risk Identification process as issues that may merit further investigation and additional data collection. Emerging issues can include specific issues (*e.g.* specific chemical substance or a pathogen), as well as general issues such as drivers of change (*e.g.* climate change). Risk management issues resulting from a lack of compliance with existing regulations should be excluded.

The information provided in this briefing note is not comprehensive and is intended as a quick summary and a point of departure.

New or increased exposure: *(e.g. Has a possible exposure through food/feed to the new hazard been identified?)*

New susceptible group: *(e.g. Has a new vulnerable group been identified?)*

Other qualifying criteria*: In addition, the following criteria can be addressed if you have information readily available*

Soundness: *(e.g. What is the reliability of sources of information? e.g. peer-reviewed journals)*

Severity: *(e.g. What could be the severity of the health effects in terms of morbidity and/or mortality?)*

Imminence: *(e.g. how soon it is estimated that the potential hazard will manifest in the food, feed, environment? How soon is it estimated that this health risk will manifest in the population?)*

Scale: *(e.g. number of people and Member States potentially exposed?)will IT, e.g. days, months, years)*

Conclusions: *Enter a brief summary of the reasoning that led to identify this as an emerging issue.*

Questions for EREN

Have you already identified this issue before? ☐ Yes ☐ No ☐ Not sure

Do you have any additional information/data on this issue? ☐ Yes ☐ No ☐ Not sure

Do you believe that this is an emerging issue? ☐ Yes ☐ No ☐ Not sure

Should EREN start exchanging information on the issue? ☐ Yes ☐ No ☐ Not sure

[*other*]

EREN Comments: _____

EREN recommendations (*examples*)

1. EFSA should keep monitor the issue.
2. EFSA should start a review of this issue aiming at publishing a report.
3. EFSA should start a project to generate data on this issue (e.g. outsourcing).
4. EFSA should start a risk assessment.
5. EFSA should consult other bodies (e.g. the Stakeholder consultative group).
6. [*other*]

REFERENCES

APPENDIX 5. GAPS AND DEFICITS IDENTIFIED

From both the literature, and the feedback gathered through 'Strategy for a non-toxic environment' workshop, the following gaps and deficits have been identified:

Signalling

- The screening and filtering of signals is a labour intensive process. When the purpose of an EWS is to quickly pick up on an effect on consumers, workers or the environment, and to help to prevent escalation, then continuous effort is needed for signal processing.

Signal strengthening

- One general concern for both health and environment, is the time lag between exposure and adverse effects. It is universally accepted that it is difficult to establish a causal link between exposure to chemicals and, for example, diseases. This stems partly from the limitations of epidemiology, where a harmful effect must often be rather drastic and widespread in order to be detected. In addition, exposure information is often lacking in epidemiological studies.
- The review of risk assessment procedures in current EWS raises questions about their effectiveness, particularly in cases where an identified risk still remains unclear after the signal strengthening and prioritisation procedures.
- During the prioritisation phase of cases, a lack of information often prevented the determination of at an appropriate score. This gap can stem from the absence of human or environmental health-based quality standards and other relevant hazard data, the absence of exposure and use information, or other types of information which form part of the checks during the identification of NERCs. It is important to understand how to:
  - Identify all of the useful sources of information and databases available and centralise this information as much as possible.
  - Establish an effective and efficient procedure for the evaluation of collected signals and identification of new or emerging risk of chemicals.
  - Deal with data gaps and uncertainty in NERC assessments.
  - Modify the existing exposure and risk assessment procedures by incorporating additional and more specific toxicological end-points, in order to trace adverse effects in a timely manner.

Organisational

- The identification of possible NERCs for workers is difficult in several countries, which experience problems in funding their expertise centres to assess and study incidences of work-related health effects among workers.
- While there are several EWS in Europe for workers, there is no international platform on work-related health effects and occupational diseases.
- In general, there is need for more cooperation and exchange of information on NERCs at the EU level.
- No system that interlinks all areas of focus has been identified by this study. The possibility of linking the approaches for assessment of risk to workers, the public and the environment should be investigated.
- At the national and international level there are various initiatives in the area of early identification of chemical threats or connected activities. As yet, however, there is no overall approach encompassing the different steps needed in the identification and management of early identification of risks at EU level.

Communication

- One potential gap was identified at the communication stage. Here, the focus is on the identification of new or emerging risks and data gathering, and there is less emphasis on defining suitable risk management measures and communicating this information to the relevant stakeholders.

Costs

- No useful information was found on the costs of establishing and running an EWS.

APPENDIX 6. IDEAS FOR IMPROVEMENT

The ideas for improvements arising from both the 'Strategy for a non-toxic environment' workshop and the literature are presented below.

- Organising the exchange of information within an area of expertise at the international level and establishing cooperation between the different stakeholders in managing the adverse human and environmental health effects of chemicals.
- Establishing a central (EU) system encompassing the different steps in the identification and management of chemical threats (including finding solutions) and supporting the input and output of information relating to NERCs, separated by target group (environment, worker, consumers).
- Selecting suitable approaches to detecting signals and drafting criteria to judge plausibility.
- Improving existing risk assessment by incorporating additional and more specific end-points, e.g. on neurotoxicity, endocrine disruption, etc.
- Exploring existing procedures for the registration of accidents and adverse side effects of chemicals, e.g. poison centres, registration of serious unwanted effects of cosmetics, undertaken at national level.
- Generating an overview of data sources for the selection of signals, and defining future actions to utilise these sources.
- Selecting methodologies for prioritisation.
- Generating environment and health exposure databases that combine all existing exposure and hazard information for a single substance or a category of substances.
- Investigating the feasibility of further interlinking and coordinating all focus areas, i.e. environment, consumers and workers. While each of these areas has its own specific approach, experts, and data sources, some elements of the system could also use the same approaches and tools, or signals picked up via workers could also be relevant for consumers. For practical reasons, however, it might be easier to develop and maintain separate systems and to let them exchange information at a certain level.
- Improving finding the causality between exposure and effect of chemicals in the environment by involving experts from associations and institutes in the field of environmental epidemiology, ecology, and nature conservation.

The strategy for a non-toxic environment of the 7th Environment Action Programme

Sub-study g: Appendix

APPENDIX 1. QUESTIONNAIRES FOR LITERATURE REVIEW

Environment; *Literature source:* https://eurl-ecvam.jrc.ec.europa.eu/databases/eas_database

1. *What is the name of the system /registry/instrument?*
   Endocrine Active Substances Information System (EASIS)
2. *What is the goal of the system/method/instrument/database?*
   EASIS is a database covering 428 substances suspected of having the potential for endocrine disruption. Although it has no normative or pre-normative implications, this database has proven useful in providing stakeholders with a significant amount of information on potential endocrine disrupters.
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?*
   Yes, the database in its current form is static in nature, and does not allow information to be introduced or updated.
   There are plans to build a new database into a Web Portal, so as to provide easy access to additional resources, such as other databases and modelling tools.
4. *Which organization collects the information on possible (new and emerging) risks?*
   Based on the output of four study contracts commissioned over the period 2000-2007, the Directorate-General for the Environment (DG ENV) developed the database.
5. *Which language is used in the system?* English
6. *Is it publicly available or not?* Yes,
7. *What is the scope of the system/method/instrument?*
   European Union; Both human and environment end points are covered
8. *What definition is used for new or emerging risks?*Not relevant
9. *In which way are signals on possible (new and emerging) risks obtained?*
   See information provided with question 3
10. *Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?* Database
11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?*
    ED criteria have been established to evaluate studies and reported data.
12. *Who evaluates a first report of a possible (new and emerging) risks?*
    Study contracts have been commissioned to evaluate ED properties by experts
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?*
    Not relevant
14. *How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?*
    Not relevant
15. *What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?*
    To be checked

Environment; *Literature source:* http://emm.newsbrief.eu/overview.html

1. *What is the name of the system /registry/instrument?* Europe Media Monitor (EMM)
2. *What is the goal of the system/method/instrument/database?*
   The EMM shows and explores current news reported by the world's online media. It monitors thousands of news sources in over 70 languages, the system uses advanced information extraction techniques to automatically determine what is being reported in the news, where things are happening, who is involved and what they said. It provides a unique and independent viewpoint of what is being reported in the world right now. The EMM allows to track what is being said by people and organizations, follow news on a given topic (more than 500 predefined topics) and see what are the biggest stories that are happening right now in the world in a given language.
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?*
   It can be used to follow news on given topics and track signals concerning new and emerging risks of chemicals.The EMM is used for this purpose by the RIVM
4. *Which organization collects the information on possible (new and emerging) risks?*
   The Joint Research Centre produced the EMM
5. *Which language is used in the system?* English
6. *Is it publicly available or not?* Yes
7. *What is the scope of the system/method/instrument?* Worldwide, any topic
8. *What definition is used for new or emerging risks?* Not relevant
9. *In which way are signals on possible (new and emerging) risks obtained?*
   Automated procedure: NewsExplorer produces its results fully automatically every day, by applying a combination of various multilingual Language Technology tools to the news articles gathered automatically by the Europe Media Monitor EMM. NewsExplorer carries out the following tasks:
   - cluster all news articles of the day, separately for each language, into groups of related articles;
   - for each cluster, identify names of people, places, organisations;
   - apply approximate name matching techniques to all names found in the same cluster, in order to identify which name variants may belong to the same person;
   - link the monolingual clusters with the related clusters in the other languages;
   - identify the most typical article of each cluster and use its title for the cluster;
   - store the extracted information in a database, learning more about each person, etc. every day;
   - occasionally, the Wikipedia online encyclopaedia is automatically searched for images and for further multilingual name variants.

   More information can be found at: http://emm.newsexplorer.eu/NewsExplorer/readme.html
10. *Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?*
    NewsExplorer can export data for further computation and analysis. Currently supported formats.
11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?* Not relevant
12. *Who evaluates a first report of a possible (new and emerging) risks?* Not relevant
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?* Not relevant
14. *How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?* Not relevant
15. *What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?* To be checked

Environment; *Literature source: http://www.fao.org/docrep/012/a0822e/a0822e.pdf*

1. *What is the name of the system /registry/instrument?* Generic framework for effective food safety management
2. *What is the goal of the system/method/instrument/database?* The goal is to provide a systematic framework for effective food safety management at the national government level. The framework is based on a food safety risk analysis in order to oversee and manage the risk analysis process.
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?* Focus is on hazards that have long been recognised and addressed by food safety controls as well new and emerging hazards
4. *Which organization collects the information on possible (new and emerging) risks?* Organisations involved in outlining a systematic framework for food safety are:
   WHO: http://www.who.int/foodsafety/risk-analysis/risk-management/en/
   FAO: http://www.fao.org/food/food-safety-quality/empres-food-safety/en/
   Codex (WHO and FAO): http://www.who.int/foodsafety/areas_work/food-standard/Specific work on Public health advice on food safety emergencies and outbreaks of foodborne disease which includes collaboration on international information sharing on foodborne diseases and food contamination via the International Food Safety Authorities Network (INFOSAN) and International Health Regulations (IHR) networks:
   http://www.euro.who.int/en/health-topics/disease-prevention/food-safety/areas-of-work/public-health-advice-on-food-safety-emergencies-and-outbreaks-of-foodborne-disease
   Food safety related to chemical risks:
   http://www.who.int/foodsafety/areas_work/chemical-risks/en/
5. *Which language is used in the system***?** Not relevant at it concerns a presentation of a generic framework
6. *Is it publicly available or not?* Not sure whether there are actually systems running following this concept
7. *What is the scope of the system/method/instrument?* The scope is food safety management at the national level, but food safety risk analysis is carried out by national, regional and international food safety authorities.
8. *What definition is used for new or emerging risks?* A food-borne hazard is defined by Codex as "a biological, chemical or physical agent in, or condition of, food, with the potential to cause an adverse health effect."
9. *In which way are signals on possible (new and emerging) risks obtained?* Automated procedure, expert judgement, expert panels, internet communication platforms
   Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.) The system exists of three basic components of risk analysis, that are risk management, risk assessment and risk communication.
   Risk analysis is used to develop an estimate of the risks to human health and safety, to identify and implement appropriate measures to control the risks, and to communicate with stakeholders about the risks and measures applied.
10. *Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?* Identification is case by case based for instance on epidemiology, food source attribution where information is used from integrated systems in which data from public health surveillance and
    pathogen monitoring of foods of animal origin and animals at primary production and processing are routinely collected, collated and analysed by a single coordinating body are mentioned as examples.
    (At the EU level there is the Rapid Alert System food and feed (RASFF) systemhttp://ec.europa.eu/food/safety/rasff/index_en.htm)

11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?*
    A lot of manual work and expert judgement is needed to collect the information and identify relevant issues (identification and hazard assessment)
12. *Who evaluates a first report of a possible (new and emerging) risks?*
    Risk assessment by national or international coordinating bodies is the first step after identification of a possible food safety issue, see information presented with question 14
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?*
    Risk communication is the final step in the generic framework, see question 14
    Som international or national coordinating bodies for contact are mentioned with question 4.
14. *How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?*
    The three main components of risk analysis have been defined by Codex as follows:
    A) Risk assessment: A scientifically based process consisting of the following steps: i) hazard identification; ii) hazard characterization; iii) exposure assessment; and iv) risk characterization.
    B) Risk management: The process, distinct from risk assessment, of weighing policy alternatives in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.
    C) Risk communication: The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.
15. *What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?*
    A generic concept is presented. There is no information about systems, based on this concept, that are currently running in this information source. Consequently, there is no information on costs.

16. Additional comments

Concluding questions (A and B):

A. Criteria
    a. The system ensures access to latest high quality information;
    b. It provides suitable support for the generation of data;
    c. It takes into account the different routing and triggers for specific targets (health or environment). Such triggers are used to start a follow-up process to further assess:
    d. Whether there is a risk;
    e. If so, which policy framework, regulatory body or actor is most suitable to address the risk?
    f. What kinds of actions are needed to ensure risks are controlled?
    g. It specifies the type of concerns to take into account (effect- or concentration based);
    h. It takes into account the needs to generate further CMR of PBT information;
    i. It fosters streamlining of the flow of information towards the risk managers;
    j. It highlights or provides linkages between the system and chemical policy.
    k. It can be used as a basis for prioritisation.

Environment; *Literature source:*
https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html

1. *What is the name of the system /registry/instrument?*
   IPCheM - the Information Platform for Chemical Monitorin
2. *What is the goal of the system/method/instrument/database?*
   IPChem is a single access point for discovering chemical monitoring data collections managed and available to European Commission bodies, Member States, international and national organisations and researchers. The Platform aims to support a more coordinated approach for collecting, storing, accessing and assessing data related to the occurrence of chemicals and chemical mixtures, in relation to humans and the environment. "This would help identify links between exposure and epidemiological data in order to explore potential biological effects and lead to improved health outcomes
   IPCheM is designed and implemented as de-centralised system, providing remote access to existing information systems and data providers.
   IPCheM primary objective is focused on:
   - assisting policy makers and scientists to discover and access databases of chemical monitoring data covering a range of matrices and media;
   - hosting data currently not readily accessible (e.g. outcomes of research projects, off-line stored monitoring data, etc.) including data on new, emerging and less-investigated chemicals that will be searchable and accessible through the platform;
   - providing chemical monitoring information of defined quality concerning spatial, temporal, methodological and metrological traceability.
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?*
   It is not specifically aimed at identifying or tracing emerging chemicals. As mentioned with question two, one of the goals of IPChem is that it will host data on new, emerging and less-investigated chemical
4. *Which organization collects the information on possible (new and emerging) risks?*
   IPChem is a joint effort initiated by the European Commission. Some of the oganisations joining are JRC, EFSA, EEA and UBA.
   The IPChem platform is managed by the Joint Research Centre of the European Commission.
5. *Which language is used in the system?* English
6. *Is it publicly available or not?* Yes
7. *What is the scope of the system/method/instrument?*
   Scope is international, with focus on EU and its member states.
   Compartments covered are human biomonitoring, Environment (air, water, soil), Food and Feed, Indoor air and Consumer products
8. *What definition is used for new or emerging risks?* Not relevant
9. *In which way are signals on possible (new and emerging) risks obtained?*
   IPChem is an internet communication platform and is open for those who collect and handle chemical monitoring data across Europe and those who would like to share data with, promote activities and make data available for policymaking purposes.
   The type of sources that can be shared are Databases, Digital Media, Scientific papers and reports, watch lists etc.
10. *Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?*
    Not relevant, emerging substances/risk are not specifically addressed.
11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?*
    Not relevant IPChem is an internet data sharing platform, there is not evaluation process involved

12. *Who evaluates a first report of a possible (new and emerging) risks?* Not relevant
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?* Not relevant
14. *How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?* Not relevant
15. *What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?*

    To be done

Environment; *Literature source:* http://www.norman-network.net/

1. *What is the name of the system /registry/instrument?*The NORMAN network
2. *What is the goal of the system/method/instrument/database?*
   The goal of the NORMAN network is to enhance the exchange of information on emerging environmental substances, and encourages the validation and harmonisation of common measurement methods and monitoring tools so that the requirements of risk assessors and risk managers can be better met. It specifically seeks both to promote and to benefit from the synergies between research teams from different countries in the field of emerging substances.
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?*
   One of the primary aims of the NORMAN network is to assign priority action categories to emerging substances. This is done by the NORMAN Prioritisation Working Group.
4. *Which organization collects the information on possible (new and emerging) risks?*
   The NORMAN network became a permanent self-sustaining network of reference laboratories, research centres and related organisations for the monitoring and biomonitoring of emerging environmental substances. It is established as a non-profit association of all interested stakeholders dealing with emerging substances.
5. *Which language is used in the system?*English
6. *Is it publicly available or not?*Yes
   All interested stakeholders dealing with emerging substances could be part of the network
7. *What is the scope of the system/method/instrument?*
   The focus of the network is the European Union and the compartments covered are water (fresh and marine), sediment and suspended matter and biota.
   The NORMAN network is addressed to aquatic ecosystems and human health via the aquatic environment, in line with the objectives of the WFD
   Human health risks associated with drinking water exposure (i.e. via inhalation, skin contact and ingestion) are not considered in the present study
8. *What definition is used for new or emerging risks?*
   "Emerging substances" can be defined as substances that have been detected in the environment, but which are currently not included in routine monitoring programmes at EU level and whose fate, behaviour and (eco)toxicological effects are not well understood.
   "Emerging pollutants" can be defined as pollutants that are currently not included in routine monitoring programmes at the European level and which may be candidates for future regulation, depending on research on their (eco)toxicity, potential health effects and public perception and on monitoring data regarding their occurrence in the various environmental compartments.
9. *In which way are signals on possible (new and emerging) risks obtained?*
   NORMAN has identified a list of the currently most frequently discussed emerging substances and emerging pollutants . These substances are selected by the NORMAN Prioritisation Working Group, based on citations in the scientific literature, and taking into account the definition of "emerging substances" and "emerging pollutants".
   Furthermore within the NORMAN network there are 8 different working groups with the focus on different topics related to emerging substances. Besides the working group on prioritisation of emerging substances there are working groups on:
   - WG2 Bioassays and biomarkers in water quality monitoring
   - WG3 Effect—directed analysis for hazardous pollutants identification
   - WG4 Nanomaterials
   - Cross-Working group on Passive sampling and monitoring of emerging contaminants
   - WG5 Wastewater reus and emerging contaminants
   - Cross-Working Group Activity Non-target Screening (NTS)
   - WG6 Emerging substances in the indoor environment

Information generated within these working groups bringing together existing knowledge on emerging substances and will generate signals on possible new or emerging risks. To facilitate the exchange between the various topics a cross workingroup was establish. One of the goals is to Set-up and maintenance of the Suspect Lists Exchange and the NormaNEWS initiatives to support identification of "unknowns".

10. *Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?*
    NORMAN has identified a list of the currently most frequently discussed emerging substances and emerging pollutants (LIST OF EMERGING SUBSTANCES latest update February 2016): http://www.norman-network.net/sites/default/files/files/Emerging_substances_list_Feb_16/NORMAN%20list_2016_FINAL.XLSX
11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?*
    NORMAN systematically collects in the EMPODAT database monitoring data and information on effects and hazardous properties for these substances. On the basis of this information, the substances are assigned to priority action categories by the NORMAN Prioritisation Working Group.
    A set of criteria is used for the allocation of emerging substances to clearly pre-defined categories (substances for which e.g. there is not yet sufficient information about their toxicity, substances for which there is evidence of hazard but analytical performance is not yet satisfactory, etc.), and their subsequent prioritisation.
    Criteria used are frequency of occurance, exceedance of environmental quality standards and hazard information
    The information needed for the prioritisation is collected in a database (EMPODAT). For the prioritisation process a high degree of manual work and expert judgement is needed.
12. *Who evaluates a first report of a possible (new and emerging) risks?*
    The NORMAN prioritisation Working Group
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?*
    The NORMAN scheme is addressed to all water managers and competent authorities aiming to identify priority substances at national, river basin and European level. It provides decision-makers with a common framework for the creation and updating of the lists of chemical substances for which actions to reduce, monitor or gather scientific or technical data are to be undertaken as a matter of priority.
    There is no clear communication plan to address the chemicals of with high concern. Putting forward the highly prioritised chemicals as candidates for watch list of possible relevant substances in the context of the WFD seems the most straight forward routes. The final goal would be to list of priority substance of the WFD.
14. *How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?*
    NORMAN systematically collects in the EMPODAT database monitoring data and information on effects and hazardous properties for these substances. On the basis of this information, the substances are assigned to priority action categories by the NORMAN Prioritisation Working Group.
    A set of criteria is used for the allocation of emerging substances to clearly pre-defined categories (substances for which e.g. there is not yet sufficient information about their toxicity, substances for which there is evidence of hazard but analytical performance is not yet satisfactory, etc.), and their subsequent prioritisation.

Criteria used are frequency of occurance, exceedance of environmental quality standards and hazard information

The information needed for the prioritisation is collected in a database (EMPODAT). For the prioritisation process a high degree of manual work and expert judgement is needed.

15. *What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?*

Information on costs are included in the yearly program reports:
http://www.norman-network.net/sites/default/files/files_private/JointProgramme2016/NORMAN%20JPA%202016_Final%20to%20GA_29feb2016.pdf

Environment; Literature source: SCENIHR 2009, Emerging Issues and the Role of SCENIHR, Position Paper, 15 pages

1. *What is the name of the system ?* Emerging Issues and the Role of the SCENIHR
2. *What is the goal of the system/method/instrument/database?*
   The early identification of emerging issues that may adversely affect human health and/or the environment in order to help to prevent negative impact by allowing earlier appropriate action
3. *Is it aimed at identifying possible (new and emerging) risks?* Yes.
4. *Which organization collects the information on possible (new and emerging) risks?*
   The members of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)
5. *Which language is used in the system?* English
6. *Is it publicly available or not?* Yes
7. *What is the scope of the system/method/instrument?*
   European scale
   Emerging issues in the non-food area having the potential for a significant impact on human health and/or the environment in the future
8. *What definition is used for new or emerging risks?*
   SCENIHR uses the following definitions:
   - An emerging issue may be defined as one that has very recently been identified and for which the available data base to conduct a risk assessment is very limited.
   - An emerging risk refers to an issue or effect resulting from a newly identified hazard to which an exposure may occur or from new or increased exposure and/or susceptibility to a known hazard.
   - A newly identified health risk is a new issue but one where sufficient data exists to conduct at least a preliminary risk assessment with a reasonable degree of confidence.
   - A stressor is a chemical, biological, or physical agent or process with the potential to cause (an) adverse effect(s)
9. *In which way are signals on possible (new and emerging) risks obtained?*
   Two complementary approaches have been identified to enable the timely identification of emerging issues:
   - A proactive approach based on 'brain storming' sessions by SCENIHR to identify the emerging issues of principal concern, followed by the introduction of procedures to detect and characterise their development.
   - A more reactive approach based on the prior identification of indicators of change and the monitoring of these to detect emerging issues.
10. *Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?*
    The primary sources of SCENIHR information is the active input of all members of SCENIHR in identifying emerging and newly identified health risks. It is expected that members will also utilise their own informal networks and available sources to aid the discussions.
11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?*
    Suggestion (not active yet) of two judgement procedures
    - Decision tree approach using an algorithm for identifying priorities
    - Matrix system approach using a scoring/weighting system for each criterion.

    The used criteria are: (i) Uniqueness, (ii) Soundness, (iii) Scale, (iv) Severity, (v) Urgency,(vi) Severity, (vii) Interactions

12. *Who evaluates a first report of a possible (new and emerging) risks?*
    EC Commission Services
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?*
    SCENIHER and EC Commission Services
14. *How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?* Not clarified
15. *What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?*Not clarified
16. Additional comments

    Position paper suggests a useful and comprehensive approach for identifying NERCs. However, no specific information is available about measures for identified NERCs and the costs of the proposed systems

    The Commission decision 2008/721/EC concerns The setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:241:0021:0030:EN:PDF Annex II informs about rules of organization and indemnities (onkosten)

Environment Literature source: https://www.epa.gov/wqc/contaminants-emerging-concern-including-pharmaceuticals-and-personal-care-products and https://www.epa.gov/sites/production/files/2015-08/documents/white_paper_aquatic_life_criteria_for_contaminants_of_emerging_concern_part_i_general_challenges_and_recommendations_1.pdf

1. *What is the name of the system /registry/instrument?*
   Developing Ambient water quality criteria Under the United States Clean Water Act
2. *What is the goal of the system/method/instrument/database?*
   The purpose of the white paper is to provide general guidance on how criteria development for CECs could be facilitated through a supplemental interpretation of the Guidelines, with
   particular attention to PPCPs with an EDC mode of action (MOA). The white paper describes the Guidelines procedures and identifies several areas in which procedures could be modified to address potential limitations for deriving criteria for CECs.
   The focus of the paper is on the use of non-traditional endpoints in deriving water quality criteria especially related to endocrine disruption.
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?* No
4. *Which organization collects the information on possible (new and emerging) risks?* US EPA
5. *Which language is used in the system?* English
6. *Is it publicly available or not?*Yes
7. *What is the scope of the system/method/instrument?*
   Scope of the paper is water quality criteria in the USA.
8. *What definition is used for new or emerging risks?*
   The term "contaminant of emerging concern" is being used within the Office of Water to identify chemicals and other substances that have no regulatory standard, have been recently "discovered" in natural streams (often because of improved analytical chemistry detection levels), and potentially cause deleterious effects in aquatic life at environmentally relevant concentrations. They are pollutants not currently included in routine monitoring programs and may be candidates for future regulation depending on their (eco)toxicity, potential health effects, public perception, and frequency of occurrence in environmental media. CECs are not necessarily new chemicals. They include pollutants that have often been present in the environment, but whose presence and significance are only now being evaluated.
9. *In which way are signals on possible (new and emerging) risks obtained?* Not relevant
10. *Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?* Not relevant
11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?* Not relevant
12. *Who evaluates a first report of a possible (new and emerging) risks?* Not relevant
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?* Not relevant
14. *How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?*Not relevant
15. *What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?* Not relevant

Environment *Literature source: Hogendoorn et al (2014) Progress report on New or Emerging Risks of Chemicals (NERCs)* http://www.rivm.nl/dsresource?objectid=rivmp:276019&type=org&disposition=inline

1. *What is the name of the system /registry/instrument?* Strategies in finding NERCs
2. *What is the goal of the system/method/instrument/database?*
   To develop a stepwise comprehensive strategy including follow-up measures, where needed, in the identification of NERCS for Workers, Consumers and Environment in order to manage, restrict or reduce the exposure of such compounds.
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?*
   Yes for Workers completed, for environment almost completed and for Consumers under development
4. *Which organization collects the information on possible (new and emerging) risks?* RIVM
5. *Which language is used in the system?* English
6. *Is it publicly available or not?*Yes
7. *What is the scope of the system/method/instrument?*
   To identify and evaluate NERCs for the three compartments Workers, Consumers and Environment
8. *What definition is used for new or emerging risks?*
   The definition of EU-OSHA (EU-OSHA, 2009) is used in this report for New or Emerging Risks of Chemicals (NERCs) involving both new and emerging risks:
   New risks:
   - the issue is new and caused by new types of substances, new processes, new technologies, new types of workplaces, or social or organizational change; or
   - a risk due to a change in social or public perceptions (e.g. stress, bullying); or
   - new scientific knowledge allows a longstanding issue to be identified as a risk (e.g. repetitive strain injury (RSI) where cases have existed for decades without being identified as RSI because of a lack of scientific evidence).

   Emerging risks:
   - number of hazards leading to the risk is growing; or
   - likelihood of exposure to the hazard leading to the risk is increasing, (exposure degree and/or the number of people exposed), or
   - effect of the hazard on the workers' health is getting worse, or
   - More or new information becomes available.
9. *In which way are signals on possible (new and emerging) risks obtained?*
   Various sources, e.g. scientific literature, news sites, websites, electronic databases, stakeholder networks
10. *Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?*
    A Risk Management Options Analysis (RMOa) under REACH will be carried out for identified NERCs .
11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?*
    For both Workers and Environment NERCs are identified by means of prioritization procedure
12. *Who evaluates a first report of a possible (new and emerging) risks?*
    Experts of the RIVM and of international Networks
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?*
    Identified NERCs will be transferred to responsible regulation bodies and/or ministries
14. *How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?* System is under development

15. *What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?*
    The estimated cost for the set-up the system are in the range of 500 kEUR
16. Additional comments
    This still ongoing project has established a useful methodology to identify NERCs for Workers, an almost finished procedure for the Environment, and a strategy under development for Consumers.

Environment *Literature source:*
https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern
https://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf
http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205867%202013%20INIT

1. *What is the name of the system /registry/instrument?* Addressing chemicals of potential concern within the context of the REACH Regulation and Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV) and the SVHC Road map
2. *What is the goal of the system/method/instrument/database?*
   Uses of substances with certain hazardous properties can be of concern for human health and/or the environment. Those substances that potentially have such properties need to be identified and subsequently processed using relevant regulatory steps within the context of the REACH Regulation to make sure that the risks associated with their use are properly addressed. Priority lists of substances that result from the work of the national authorities and ECHA are published by ECHA on its website. There are different activities and regulatory processes such as hazard assessment, compliance check and substance evaluation when there is need for further information. When there is no need for further information is there is a concern a risk management analysis will be done from which the most appropriate option will follow such as harmonised classification, placement on the candidate list of substance of very high concern, inclusion in annex VII (restrictions),annex XIV application for authorisation or other legislation.
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?*
   Yes, the primary goal is to identify, address and regulate substances of very high concern. REACH does not include all uses of chemicals though. Only industrial chemicals (including cosmetics) with a volume of 1 ton or more placed on the market in the EU are covered. Many kinds of chemicals are outside the scope of REACH such as medicines, pesticides, biocides, food and feed additives and others. To some extent, new or emerging risk can be identified and dealt with but the scope is mainly limited to registered substances only. A screening and prioritisation approach is used to select the most relevant substances for amongst others placing on annex XIV, authorisation list.
4. *Which organization collects the information on possible (new and emerging) risks?*
   Primary source of information are the registration dossiers as well as the CLP-inventory and the SVHC in articles notification but also other data sources are used in the screening and prioritisation procedures. Registration dossiers are built by the registrants, industrial companies and submitted to ECHA. Besides the regisation dossier database ECHA also manages the CLP-inventory and the SVHC in articles inventory.
5. *Which language is used in the system?* English
6. *Is it publicly available or not?* Yes, the information and the status of all the processes are publically available to some extent at the ECHA website. Not all of the information in the registration dossiers is publically available though.
7. *What is the scope of the system/method/instrument?*
   The REACH regulation covers the environment as well as consumers and worker health.
8. *What definition is used for new or emerging risks?*
   REACH regulatory processes conducted by ECHA and the EU member states focus on chemcials of concern and safe use of chemicals rather than finding new or emerging risks.
9. *In which way are signals on possible (new and emerging) risks obtained?*
   ECHA and the Member State competent authorities have developed a common screening approach to systematically screen available information for substances in the REACH registration dossiers and other databases to identify substances of concern. Substance of concern are those meeting the criteria for inherent properties as defined in article 57 and information as article 58 (3) of the REACH regulation. Groups of substances included are CMRs, sensitisers, PBTs, vPvBs, endocrine disruptors or substances with equivalent concern. The term "screening" process is used to identify and investigate substance (and dossiers) specific information, to make a

preliminary assessment to support conclusion on how to proceed with the substance. The focus is on the criteria/properties defined in article 57 combined with criteria as defined in article 58 related to the use of a substance such as market volume, wide dispersive, professional and industrial use. Comparing structural similarity to substances on the Candidate List, to other substances is a way to identify new or emerging chemicals substances.

10. *Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?*
    There are several working lists of chemicals of concern depending on the evaluation phase they are in, such as lists of chemicals considered for compliance check, substance evaluation or chemicals going for risk management analysis that might be managed thru authorisation, restriction etc.
11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?*
    Article 57 and 58 (3) criteria and others, see question 9
12. *Who evaluates a first report of a possible (new and emerging) risks?*
    ECHA and EU member state competent authorities
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?*
    There is intensive communication through the ECHA website on the status of all chemicals addressed and the different regulatory processes ongoing.
14. *How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?*
    There are different possibilities such a RMO analysis and follow up actions and regulatory processes such as the authorisation procedure, restriction and harmonised classification and labelling.
15. *What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?*
    Some information on costs might be available in different REACH functioning evaluation reports. REACH REFIT program. Operating Expenditure for REACH by ECHA covering the implementation of the REACH process is about 14 million Euros in 2017. Important to note that the activities included in this number go beyond the activities employed for the identification/screening for substances of concern. The budget for evaluation is 260 000 Euros and for Risk management 900 000 Euros. This excludes the expenditure by the EU member state authorities involved, see
    https://echa.europa.eu/documents/10162/22837330/mb_42_2016_budget_2017_en.pdf

Workers: *Literature source: Expert forecast on emerging chemical risks related to occupational safety and health, EUROPEAN RISK OBSERVATORY REPORT, European Agency for Safety and Health at Work, Luxembourg, 2009.*

1. *What is the name of the system /registry/instrument?*
   Expert forecast on emerging chemical risks related to occupational safety and health
2. *What is the goal of the system/method/instrument/database?*
   An expert forecast on emerging chemical OSH risks
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?* Yes
4. *Which organization collects the information on possible (new and emerging) risks?*
   The European Agency for Safety and Health at work.
5. *Which language is used in the system?* English
6. *Is it publicly available or not?* Yes
7. *What is the scope of the system/method/instrument?* Workers
   Scale (national, EU, Intercontinental) European
   Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.);
   Inhalation and dermal exposure of workers to industrial chemicals.
   Six literature reviews explore in more depth the main emerging risks singled out in the forecast in terms of context, workers at risk, health and safety outcomes and prevention: nanoparticles; epoxy resins; man-made mineral fibers; dermal exposure to dangerous substances; dangerous substances in waste treatment activities; poor control of chemical risks in small and medium enterprises (SMEs).
8. *What definition is used for new or emerging risks?*
   An 'emerging OSH risk' is defined as any occupational risk that is both new and increasing. By 'new' it means that:
   - the risk was previously unknown and is caused by new processes, new technologies, new types of workplace, or social or organizational change; or
   - a longstanding issue is newly considered as a risk due to a change in social or public perceptions; or
   - new scientific knowledge allows a longstanding issue to be identified as a risk.

   The risk is 'increasing' if:
   - the number of hazards leading to the risk is growing; or
   - the likelihood of exposure to the hazard leading to the risk is increasing (exposure level and/ or the number of people exposed); or
   - the effect of the hazard on workers' health is getting worse (seriousness of health effects and/or the number of people affected).
9. *In which way are signals on possible (new and emerging) risks obtained?*
   Automated procedure, expert judgement, expert panels, internet communication platforms
   Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.)
   A survey of European experts was undertaken to identify emerging occupational safety and health chemical risks. The Delphi method was used in order to reach a broad consensus and to avoid non-scientifically founded opinions A first exploratory survey round carried out in 2004 aimed to identify the risks which the experts reckoned to be emerging. A questionnaire with open-ended questions was developed to help the experts formulate their views as to the emerging OSH chemical risks of the next 10 years. The experts were invited to fill in the questionnaire electronically or on paper.
   A second questionnaire-based survey round was carried out in 2005 which aimed to validate and complement the results of the first round. The questionnaire presented a list, drafted from the first round responses and with an indication of the number of times each item was suggested. The

questionnaire invited participants to rate each item, independently from the others, on a five-point Likert scale (non-comparative scaling process). The scale ranged from 'strongly disagree that the issue is an emerging risk', through 'undecided' to 'strongly agree that the issue is an emerging risk'. The experts could add new risks to the list.

The third questionnaire also consisted of a non-comparative scaling process whereby the respondents were asked to rate each issue independently from the others on the same five-point Likert scale used in the second round. The prioritised list of emerging risks established at the end of the third survey round formed the expert forecast on emerging OSH chemical risks

10. *Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?*

    No, the registry is based on expert knowledge. The experts were proposed by members of the Topic Centre Research on Work and Health (TCWH) and the focal points of the Agency to ensure a broad coverage of qualified expertise across the EU. For their answers to be taken into consideration, the respondents had to have at least five years' experience in the field of dangerous substances and related risks.

11. *How is a first report of a possible (new and emerging) risk evaluated and what are the criteria used to evaluate reported signals?*

    Level to which automated procedures, expert judgement, manual work is needed

    Not applicable since the Delphi method was used to identify a NERC. The Delphi method is based on expert judgement.

12. *Who evaluates a first report of a possible (new and emerging) risks?*

    Not applicable since the Delphi method was used to identify a NERC. The Delphi method is based on expert judgement.

13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?*

    Communication between reporter/notifier and the evaluating body is not applicable because of the method chosen (Delphi method). Communicated to the public is done by 'expert forecasts of emerging risks' by the European Agency for Safety and Health at work.

14. *How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?*

    The Delphi method is used to identify and evaluate possible NERCs. The results of this expert survey on emerging chemical risks are based on scientific expertise and should be seen as a basis for discussion among stakeholders to set priorities for further research and actions. Possible follow up actions mentioned are the derivation of occupational exposure limits for CRM.

15. *What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?* No information

16. Additional comments

Concluding questions (A and B):

A. *Does the measure support the development of an early warning system for chemical risks?*

   No, it depends on expert judgement of NERCs that already were identified in the past, and need to be controlled in a better way.

B. *Does the measure improve the knowledge of and access to information on chemical risks?*

   No

Workers *Literature source: Green jobs and occupational safety and health: Foresight on new and emerging risks associated with new technologies by 2020, Report (2013) European Agency for Safety and Health at Work, EU-OSHA, Luxembourg.*

1. *What is the name of the system /registry/instrument?*
   Green jobs and occupational safety and health: Foresight on new and emerging risks associated with new technologies by 2020
2. *What is the goal of the system/method/instrument/database?*
   Develop scenarios of the future in order to *anticipate new and emerging risks* to occupational safety and health associated with a range of new technologies in green jobs. This foresight will be used by EU-OSHA to inform EU policymakers, Member States' governments, trade unions and employers, so that they can make better decisions in order to shape the future of occupational safety and health (OSH) in green jobs leading to safer and healthier workplaces.
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?*
   Yes, it can be used for that goal
4. W*hich organization collects the information on possible (new and emerging) risks?*
   European Agency for Safety and Health at Work
5. *Which language is used in the system?* English
6. *Is it publicly available or not?* Yes
7. *What is the scope of the system/method/instrument?*
   Scale (national, EU, Intercontinental)
   Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)
   The subject of this report, was the identification of the key technological innovations that may be introduced in green jobs over the next ten years that may lead to new and emerging risks in the workplace or have a positive impact on workers' safety and health.
   The decision to use a scenario-building approach project arose out of the workshop 'Shaping the future of OSH — A workshop on foresight methodologies' hosted by EU-OSHA's European Risk Observatory (ERO) in October 2008. The ERO wished to build on earlier forecast exercises, comprising Delphi studies in four different risk areas, which had produced useful summaries and prioritization of key risks as assessed by experts. However, it was felt that in order to consider likely occupational health and safety risks further into the future, an alternative technique should be used. The scenario-building approach was selected as a suitable vehicle to provide a forward look. European scale Compartments: Inhalation and dermal exposure of workers
8. *What definition is used for new or emerging risks?*
   An 'emerging OSH risk' is defined as any occupational risk that is both new and increasing. By 'new' it means that:
   - the risk was previously unknown and is caused by new processes, new technologies, new types of workplace, or social or organizational change; or
   - a longstanding issue is newly considered as a risk due to a change in social or public perceptions; or
   - new scientific knowledge allows a longstanding issue to be identified as a risk.

   The risk is 'increasing' if:
   - the number of hazards leading to the risk is growing; or
   - the likelihood of exposure to the hazard leading to the risk is increasing (exposure level and/ or the number of people exposed); or
   - the effect of the hazard on workers' health is getting worse (seriousness of health effects and/or the number of people affected).
9. *In which way are signals on possible (new and emerging) risks obtained?*
   Automated procedure, expert judgement, expert panels, internet communication platforms

Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.)

This two-year project was conducted between 2010 and 2012 over *three phases* and the methodology for each of these is described in Chapter 2 of the report.

Phase 1 was to *select the key contextual drivers for new and emerging OSH risks associated with new technologies* in green jobs by 2020. These drivers are the major forces or trends that will shape the future environment for workers in green jobs. Those that will have the greatest impact on the range of different future environments were used to define the scenarios. The drivers and the results of the selection process are set out in Chapter 3 of the report.

Phase 2 was to *identify key new technologies* that could contribute to creating new and emerging risks in green jobs by 2020. These were reviewed to select the nine key technologies where there would be the most significant new and emerging OSH risks. The data and results of this are contained in Chapter 4.

Phase 3 saw the development of the base scenarios using the key contextual drivers of change from Phase 1. These base scenarios were then used through a *series of workshops to explore the respective development of the key technologies from Phase 2 and their impact on OSH in each of the scenarios*. The information generated through this process was then integrated into the base scenarios to produce the full scenarios. The descriptions of the base scenarios, the process of their development and the technology developments and their OSH implications are set out in Chapter 5.

The scenarios were tested and consolidated in a consolidation workshop during which it was also demonstrated how the scenarios can be used to support OSH policymaking: the conclusions and the results of the consolidation workshop are in Chapter 6.

The final set of scenarios and guidance on their use are in Chapter 7. The conclusions are in Chapter 8.

10. *Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?*

    Possible NERCs identified by expert judgement are collected and published in a report.

11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?*

    Level to which automated procedures, expert judgement, manual work is needed

    Not applicable; it is scenario buildings by expert judgement

12. *Who evaluates a first report of a possible (new and emerging) risks?* Not applicable; it is expert judgement

13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?*

    Communicated to the public is done by 'European risk observatories' by the European Agency for Safety and Health at work.

14. *How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?*

    Phase I: contextual drivers of change:

    - WP1.1: literature review
    - WP1.2: interviews with experts and internet based exercise to consolidate the list of drivers
    - WP1.3: Voting exercise to prioritise the drivers

    Phase II: key technologies

    - WP2.1: Review of existing material
    - WP2.2: Consultation (interviews and internet based survey) using expertise of key people who may be aware of important technological innovations not yet published
    - Selection of key technologies by invited experts

    Phase III: Scenarios

    - WP3.1: Scenario development. Technology workshops were held to explore the development pathways for each technology across the scenarios and the respective OSH

implications. Invitees included a mixture of technical experts and OSH experts as well as members of EUOSHA's Prevention and Research Advisory Group

- WP3.2: testing and consolidating the scenarios in a workshop

15. *What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?* No information
16. Additional comments

Concluding questions (A and B):

A. *Does the measure support the development of an early warning system for chemical risks?* Yes, could be. Identification of the key technological innovations that may be introduced in green jobs over the next ten years may lead to new and emerging risks in the workplace
B. *Does the measure improve the knowledge of and access to information on chemical risks?* Yes. It may improve knowledge of key technological innovations that may lead to NERCs.

Workers *Literature source: Detecting emerging risks for workers and follow-up actions, N.G.M. Palmen, J.G.W. Salverda, P.C.E. van Kesteren, W. ter Burg, RIVM report 601353004/2013*

1. *What is the name of the system /registry/instrument?*
   Detecting emerging risks for workers and follow-up actions
2. *What is the goal of the system/method/instrument/database?*
   Making an overview of new and emerging risks of chemicals for workers of the last decade.
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?*
   Yes, it makes an overview of new and emerging risks identified by using different methods (clinical watch systems, periodic literature screening, data mining)
4. *Which organization collects the information on possible (new and emerging) risks?*
   National Institute of Public Health and the Environment (RIVM)
5. *Which language is used in the system?* English
6. *Is it publicly available or not*? Yes
7. *What is the scope of the system/method/instrument?*
   Scale (national, EU, Intercontinental)
   Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.); International; Inhalation and dermal exposure of workers
8. *What definition is used for new or emerging risks?*
   An 'emerging OSH risk' is defined as any occupational risk that is both new and increasing.
   By 'new' it means that:
   - the risk was previously unknown and is caused by new processes, new technologies, new types of workplace, or social or organizational change; or
   - a longstanding issue is newly considered as a risk due to a change in social or public perceptions; or
   - new scientific knowledge allows a longstanding issue to be identified as a risk.

   The risk is 'increasing' if:
   - the number of hazards leading to the risk is growing; or
   - the likelihood of exposure to the hazard leading to the risk is increasing (exposure level and/ or the number of people exposed); or
   - the effect of the hazard on workers' health is getting worse (seriousness of health effects and/or the number of people affected).
9. *In which way are signals on possible (new and emerging) risks obtained?*
   Automated procedure, expert judgement, expert panels, internet communication platforms
   Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.). Signals are obtained by expert judgement and expert panels
   Sources: literature search, symposia, notifications in early warning systems
10. *Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?*
    Yes, they are collected in a database by the national institute of public health and environment (RIVM). At this moment RIVM together with National Centre of Occupational Disease (NCOD) are developing a bibliographic reference base for new and emerging occupational health risks. It is a new tool to facilitate the search for similar cases and report evidence from the literature. A reference database is currently built of case descriptions for new and emerging occupational health risks from different sources to be used within the MODERNET[1] network. This online database can both be consulted and complemented by registered users.

[1] MODERNET: Monitoring trends in Occupational Diseases and tracing new and Emerging Risks in a NETwork

11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?*
    Level to which automated procedures, expert judgement, manual work is needed
12. *Who evaluates a first report of a possible (new and emerging) risks?* Not applicable
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?* Not applicable
14. *How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?*
    After prioritising the identified new and emerging risks (see Palmen and Verbist, 2014), a Risk Management Options Analysis identifies the best regulatory option to manage the risk for substances of very high concern, either in REACH (Authorisation, Restriction or Substance Evaluation) or outside of REACH (with another legislation).
15. *What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?* No information
16. Additional comments

Concluding questions (A and B):

A. *Does the measure support the development of an early warning system for chemical risks?*
   No, the measure gives an overview of potential NERCs, which need to be evaluated further.
B. *Does the measure improve the knowledge of and access to information on chemical risks?*
   Yes, RIVM together with NCOD is developing a bibliographic reference base for new and emerging occupational health risks.

Workers *Literature source: Prioritization of new and emerging chemical risks for workers and follow-up actions, N.G.M. Palmen and K.J.M Verbist, RIVM report 2015-009*

1. *What is the name of the system /registry/instrument?*
   Prioritization of new and emerging chemical risks for workers and follow-up actions, N.G.M. Palmen and K.J.M Verbist, RIVM report 2015-0091
2. *What is the goal of the system/method/instrument/database?*
   Prioritization of New and Emerging risks identified in Palmen et.al. (2013) and making an overview of measures already taken (information from EU databases).
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?*
   No. It is aimed to prioritise new and emerging risks and check which measures are already taken to control the health risk.
4. *Which organization collects the information on possible (new and emerging) risks?*
   National Institute of Public Health and the Environment (RIVM)
5. *Which language is used in the system?* English
6. *Is it publicly available or not?* Yes
7. *What is the scope of the system/method/instrument?*
   Scale (national, EU, Intercontinental)
   Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)/ International/ Inhalation and dermal exposure of workers
8. *What definition is used for new or emerging risks?*
   An 'emerging OSH risk' is defined as any occupational risk that is both new and increasing.
   By 'new' it means that:
   - the risk was previously unknown and is caused by new processes, new technologies, new types of workplace, or social or organizational change; or
   - a longstanding issue is newly considered as a risk due to a change in social or public perceptions; or
   - new scientific knowledge allows a longstanding issue to be identified as a risk.

   The risk is 'increasing' if:
   - the number of hazards leading to the risk is growing; or
   - the likelihood of exposure to the hazard leading to the risk is increasing (exposure level and/ or the number of people exposed); or
   - the effect of the hazard on workers' health is getting worse (seriousness of health effects and/or the number of people affected).
9. *In which way are signals on possible (new and emerging) risks obtained?*
   Automated procedure, expert judgement, expert panels, internet communication platforms
   Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.); Not applicable
10. *Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?*
    Yes, by National Institute of Public Health and Environment.
11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?*
    Level to which automated procedures, expert judgement, manual work is needed
12. *Who evaluates a first report of a possible (new and emerging) risks?* Not applicable
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?* Not applicable
14. *How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?*

After prioritization, a Risk Management Options Analysis is made to identify the best regulatory option to manage the risk for substances of very high concern, either in REACH (Authorisation, Restriction or Substance Evaluation) or outside of REACH (with another legislation).

15. *What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?* No information
16. Additional comments

Concluding questions (A and B):

A. *Does the measure support the development of an early warning system for chemical risks?* No, the measure prioritises potential NERCs, which need to be evaluated further
B. *Does the measure improve the knowledge of and access to information on chemical risks?* Yes, RIVM together with NCOD is developing a bibliographic reference base for new and emerging occupational health risks

Workers&Consumers *Literature source: Position Statement on emerging and newly identified health risks to be drawn to the attention of the European Commission, Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR), 2014*

1. *What is the name of the system /registry/instrument?*
   Position Statement on emerging and newly identified health risks to be drawn to the attention of the European Commission, Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR), 2014.
2. *What is the goal of the system/method/instrument/database?*
   Draw the attention of the EU Commission Services to emerging issues in the non-food area that have been identified by the SCENIHR members as having the potential to significantly impact human health and /or on the environment in the future.
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?*
   No, it is aimed to address attention of the EU Cie to issues addressed by the SCENIHR members. SCENIHR members were free to suggest issues to be evaluated.
4. *Which organization collects the information on possible (new and emerging) risks?* Not applicable
5. *Which language is used in the system?* Not applicable
6. *Is it publicly available or not?* Not applicable
7. *What is the scope of the system/method/instrument?*
   Scale (national, EU, Intercontinental)/ Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)/ Not applicable
8. *What definition is used for new or emerging risks?*
   1) Exposure categories: Risks associated with:
   - Agriculture and food, drinking water (chemicals, pesticides, nanomaterials,
   - microorganisms ….)
   - Consumer products (chemicals, pesticides, nanomaterials, microorganisms ….)
   - Energy and energy transmission
   - Environmental changes
   - Evolution of diseases and microbial pathogens
   - Medical technology
   - Pharmaceuticals (excluding drugs: vaccines, DNA & synthetic biology , blood ….)
   - Social and lifestyle activities
   - Urban engineering

   2) Suggested hazard categories:
   A. New origin of risk
   - Development and implementation of new technologies
   - Newly identified pathogens

   B. 'New modifier with pre-existing Origin'
   - Emerging issue related to a change in collective human behaviour
   - Emerging issue related to changing environmental factors

   C. Change in 'scientific knowledge'
   D. Risk perception by the Society
9. *In which way are signals on possible (new and emerging) risks obtained?*
   Automated procedure, expert judgement, expert panels, internet communication platforms/ Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.)/ Not applicable
10. *Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?* Not Applicable
11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?*

Level to which automated procedures, expert judgement, manual work is needed/ Not Applicable

12. *Who evaluates a first report of a possible (new and emerging) risks?* Not Applicable
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?* Not Applicable
14. *How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?* Not Applicable
15. *What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?* No information
16. Additional comments

Concluding questions (A and B):

A. *Does the measure support the development of an early warning system for chemical risks?* No, it is based on expert judgement of NERCs that were identified already and need the attention of the European Commission.
B. *Does the measure improve the knowledge of and access to information on chemical risks?* No

Workers *Literature source: Early warning systems to detect new and emerging risks in Europe, RIVM Letter report 2016-0022*

1. *What is the name of the system /registry/instrument?*
   The publication gives an overview of available early warning systems used in European countries:
   - Clinical watch systems
   - Databases
   - Biomarkers
2. *What is the goal of the system/method/instrument/database?*
   Identification, evaluation and control of potential NERCs
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?*
   Yes, several early warning systems were identified specifically designed for that purpose
4. *Which organization collects the information on possible (new and emerging) risks?*
   It depends on the system; see the report.
5. *Which language is used in the system?*
   It depends on the system. This question is not answered in the report.
6. *Is it publicly available or not?*
   It depends on the system; see the report.
7. *What is the scope of the system/method/instrument?*
   Scale (national, EU, Intercontinental)
   Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)
   Most systems are national systems. One system (OccWatch designed by ANSES, France) is international.
   Compartments: Inhalation and dermal exposure of workers
8. *What definition is used for new or emerging risks?*
   It depends on the system; this question is not answered in the report.
9. *In which way are signals on possible (new and emerging) risks obtained?*
   Automated procedure, expert judgement, expert panels, internet communication platforms
   Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.)
   It depends on the system; this question is answered in the report.
10. *Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?*
    It depends on the system; this question is answered in the report.
11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?*
    Level to which automated procedures, expert judgement, manual work is needed
    It depends on the system; this question is answered in the report.
12. *Who evaluates a first report of a possible (new and emerging) risks?*
    It depends on the system; this question is answered in the report.
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?*
    It depends on the system; this question is answered in the report.
14. *How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?* It depends on the system; this question is not answered in the report.
15. *What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?* No information
16. Additional comments

Concluding questions (A and B):

A. *Does the measure support the development of an early warning system for chemical risks?*
   Yes, this report gives an overview of available early warning systems in Europe.
B. *Does the measure improve the knowledge of and access to information on chemical risks?*
   Yes, it will give information on health effects of chemicals that were not identified already

Consumers *literature source: Martínez V., Carreras J., Popper M., Ferrer J.M. Summary Report of the 2011 ainia-MIOIR Horizon Scanning Events By Emerging Risks & Opportunities in the Food Sector*

1. *What is the name of the system /registry/instrument?*

   Wild cards and weak signals (WI-WE) analyses used in foresight and horizon scanning could be applied to emerging risks identification, so as to support strategic processes aimed to anticipate changes, build resilience and prevent undesirable food safety surprises.Through the application of foresight and horizon scanning, potential emerging risks can be identified systematically by:

   1. Identifying and analysing drivers of change, as underlying causes of emerging risks.
   2. Developing scenarios (including wild cards) associated to the drivers of change.
   3. Identifying, characterising and interpreting weak signals linked to potential scenarios.

2. *What is the goal of the system/method/instrument/ methodology/ database?*

   A number of areas of concern were identified across the agro-food industry and some challenging issues to be addressed by policy-makers were identified. These include: (1) the harmonisation of national agricultural laws and policies which differ between EU members and other countries regarding, for example, the usage, typology and quantity of pesticides; (2) the promotion of more stringent controls for external factors affecting food products such as: export, terrorism, sabotage, hygiene, cross-contamination, etc.; (3) the monitoring and assessment of new technologies and novel foodstuff with uncertain impacts on health, such as Genetically Modified Foods and radiation, among others; (4) the implementation of effective internal risk analysis within businesses using better tools and methods to detect critical control points and other hazards; and (5) the Maintenance of a good communication and dialogue with all stakeholders in the food supply chain.

   The identification of potential emerging risks often involves the combination of creative activities (i.e. brainstorming and scenarios workshops) with other activities interconnecting knowledge based on evidence (e.g. indicators from RASFF5 database), expertise (e.g. interviews) and interaction of key players (e.g. conferences). The identification of emerging risks also requires a structured and forward-looking intelligence approach, whereby networking plays a key role in the analysis and communication of emerging risks and drivers of change. To ensure that not only emerging risks but also potential opportunities in food safety are captured, it is important to promote foresight and horizon scanning processes, as they often involve multidimensional reasoning.

3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?* Yes it can, but the methods are not described in the current summary report.
4. *Which organization collects the information on possible (new and emerging) risks?*

   Information is collected by an interactive community.

5. *Which language is used in the system? English*
6. *Is it publicly available or not?*
   a. Scale (national, EU, Intercontinental)
   b. Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)
   c. The system is available at world scale. Policy/research trends are being collected. Novel ways for risk analyses are used such as wild cards and weak signals (WI-WE) analyses.
7. *What definition is used for new or emerging risks?*

   Foresight is a systematic, participatory, prospective and policy-oriented process which, with the support of environmental and horizon scanning approaches, is aimed to actively engage key stakeholders into a wide range of activities "anticipating, recommending and transforming" (ART) "technological, economic, environmental, political, social and ethical" (TEEPSE) futures. Horizon Scanning (HS) is a structured and continuous activity aimed to "monitor, analyse and position" (MAP) "frontier issues" that are relevant for policy, research and strategic agendas. The types of issues mapped by HS include new/emerging: trends, policies, practices, stakeholders, services, products, technologies, behaviours, attitudes, "surprises" (Wild Cards) and "seeds of change" (Weak Signals).

8. *In which way are signals on possible (new and emerging) risks collected?*
   Automated procedure, expert judgement, expert panels, internet communication platforms
   Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.)/ NA
9. *Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done?*NA
10. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?*
    a. Level to which automated procedures, expert judgement, manual work is needed/ NA
11. *Who evaluates a first report of a possible (new and emerging) risks?* NA
12. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?* NA
13. *How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place?*NA
14. *What has costed the set-up building of the system? What does the Maintenanceof the system cost?* NA

Consumers *literature source: Andrea Altieri (2014), Emerging Risks Identification: an appraisal of the approaches trialled by EFSA. European Food Safety Authority (EFSA);*
EFSA (2006). Forming a Global System for Identifying Food-related Emerging Risks. EMRISK. Final Report Service Contract EFSA/SC/Tender/01/2004 November 2004 - 8 April 2006.

1. *What is the name of the system /registry/instrument?*
   Emerging Risks Identification: an appraisal of the approaches trialled by EFSA/EMRISK
2. *What is the goal of the system/method/instrument/ methodology/ database?*
   EFSA has a legal basis on the identification of emerging risks.
   Article 34 of the food and feed safety directive says the following:
   1. The Authority shall establish monitoring procedures for systematic searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks in the fields within its mission.
   2. Where the Authority has information leading it to suspect an emerging serious risk, it shall request additional information from the Member States, other Community agencies and the Commission. 3. The Authority shall use all the information it receives in the performance of its mission to identify an emerging risk.
   4. The Authority shall forward the evaluation and information collected on emerging risks to the European Parliament, the Commission and the Member States.
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?*
   Yes, this system is built for the identification of new problems (not necessarily incidents or crises), to better anticipate risk assessment needs. It investigates:
   - New and emerging hazard or drivers
   - New research issues
   - New risk assessment methodologies
4. *Which organization collects the information on possible (new and emerging) risks?*
   The key players for data collection are:
   - EU Member States and Norway and observers from the European Commission, EU pre-accession countries, the FDA and FAO.
   - StaCG-ER is composed of EU-wide stakeholder organisations working in areas related to the food chain. The selection of members for StaCG-ER was based on the individual expertise of the nominees, and to ensure a balanced representation of both industry and consumers.
   - The SC's SWG on Emerging Risks was created in 2013 and includes representatives from EFSA Panels.
   - EC.
5. *Which language is used in the system?* English
6. *Is it publicly available or not?*
   a. Scale (national, EU, Intercontinental)
   b. Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)

   It is outcasted by EFSA. The focus is the EU but global signals are being screened.
7. What definition is used for new or emerging risks?
   The definition is a mixture between certain areas of focus being:
   - New hazard
   - New exposure
   - Increased susceptibility
   - Differentiation between
   - Emerging issue = suspicious of a serious risk
   - Emerging risk: "an emerging risk to human, animal and/or plant health is understood as a risk resulting from a newly identified hazard to which a significant exposure may occur or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard" (Statement of the Scientific Committee, 10 July 2007).
8. *In which way are signals on possible (new and emerging) risks collected?*

a. Automated procedure, expert judgement, expert panels, internet communication platforms
b. Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.)

The following steps are part of the system as applied by EFSA:

a. Identification of priority issues: performed by SCER and Scientific Committee WG (Emerging issues are identified though e.g. Consultations with experts, MS Network, Stakeholders), Prioritization based on a set of agreed criteria, including the EFSA definition of ER.

Output 1: first priority list

b. Identification of Data Sources and Data collection. This is performed by the EMRISK Unit of EFSA. The data collection focuses on selected emerging issues identified and takes the available resources into account. It is a prioritization based on a set of agreed criteria, including the EFSA definition of ER.

ii. Output 2: first priority list

c. Final Evaluation: Emerging Risks are Identified. This step is performed by the EMRISK Unit and the Scientific Committee WG.

iii. Output 3: emerging risks and recommendations for possible actions

During the data processing the following items are of importance for EFSA:

i. Medisys customization (search terminology using the European Media Monitor)
ii. Evaluation of a system for the scanning of Eurostat's data to detect trends in trade
iii. Omics technologies in risk assessment
iv. Pilot study for the identification of emerging biological risks
v. A procedure for the identification of chemical risks
vi. Modern methodologies for human chemicals hazard assessment
vii. Chemical mixtures
viii. A framework for the risk assessment of chemical mixtures
ix. Combined toxicity of multiple chemicals: Evidence-based approach for Animal Health and Ecological Risk Assessment using Systematic Review

9. *Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done?*NA
10. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?*
    a. Level to which automated procedures, expert judgement, manual work is needed Emerging Risks Identification (ERI) is done by:
    b. Develop methodology and procedures (e.g. best practices for ERI);
    c. Data collection and tool development (e.g. Sc. Lit,RASFF, Media, Experts);
    d. Evaluation and prioritisation;
    e. Exchange of information (e.g. MS-Network, Stakeholders,Experts);
11. *Who evaluates a first report of a possible (new and emerging) risks?* Experts with various backgrounds.
12. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?* NA
13. *How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place?* NA
14. *What has costed the set-up building of the system? What does the maintenance of the system cost?* As such the cost of this system is not mentioned in the report. Costs have however been predicted on on a project basis and is mentioned below. This could be of support in the estimation of the costs of an EU side Early Warning System.

Consumers *literature source: United States Government Accountability Office (2014). Challenges and Options for Responding to New and Emerging Risks, Report to Congressional Committees, Consumer Product Safety Commission.*

1. *What is the goal of the system/method/instrument/ methodology/ database?*
   In accordance with section 4 of the Consolidated Appropriations Act of 2014, GAO conducted a study of the ability of the Consumer Product Safety Commission (CPSC) to respond quickly to emerging consumer product safety hazards using authorities under the Consumer Product Safety Act (15 U.S.C. §§ 2056-2058), the Federal Hazardous Substances Act (15 U.S.C. § 1262), and the Flammable Fabrics Act (15 U.S.C. § 1193); and report to congressional appropriations committees on an assessment of CPSC's ability to respond quickly to new and emerging risks.1
2. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?*
   This report discusses (1) how CPSC's authorities and other factors may affect the time it takes CPSC to respond to new and emerging risks and (2) proposed options that may be available to improve CPSC's ability to respond to new and emerging risks in a timely manner and trade-offs associated with those options.
3. *Which organization collects the information on possible (new and emerging) risks?*
   US Consumer Product Safety Commission (CPSC)
4. *Which language is used in the system? English*
5. *Is it publicly available or not? NA*
6. *What is the scope ot he system/method/instrument?*
   a. Scale (national, EU, Intercontinental) International literature is investigated but focus is on US
   b. Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)/ Consumers
7. *What definition is used for new or emerging risks?* NA
8. *In which way are signals on possible (new and emerging) risks collected?*
   a. Automated procedure, expert judgement, expert panels, internet communication platforms
   b. Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.)

   To address both objectives, we reviewed our prior work on CPSC's authorities, CPSC standard operating procedures, performance and accountability reports, and agency budget documentation in order to obtain information on the resources currently available to CPSC and how those resources may impact the agency's ability to respond to new and emerging consumer product safety hazards. In addition to our document review, we interviewed cognizant CPSC officials, knowledgeable staff, and three current and three former CPSC commissioners, including CPSC's acting Chairman, regarding CPSC's ability and authority to identify, assess, and address new and emerging risks in a timely manner. 2 To gather perspectives on the sufficiency of CPSC's current statutory authority and specific factors affecting its ability to respond to emerging risks and to seek opinions on potential options that may be available to CPSC to address these risks in a more timely manner, we interviewed representatives from four consumer advocate groups and representatives from seven industry organizations that represented manufacturers for various consumer products, including juvenile products, clothing and home goods, chemical production, and general consumer goods. We also interviewed six consumer safety experts, three of which were legal experts in the consumer product safety field regarding CPSC's existing statutory and regulatory authorities for addressing new and emerging risks and other potential options available to CPSC.
9. *Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done?*NA
10. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?*
    a. Level to which automated procedures, expert judgement, manual work is needed

    To address objective one, we reviewed and analyzed relevant federal laws that authorise CPSC to both promulgate and enforce consumer product safety standards, as well as those that authorise

the agency to take corrective action necessary to remove a potentially hazardous product from the consumer market. We then examined CPSC rulemaking procedures as stipulated in relevant sections of the Consumer Product Safety Act, the Federal Hazardous Substances Act, and the Flammable Fabrics Act. We identified additional administrative and statutory requirements that may impede CPSC's implementation of corrective action, and we reviewed CPSC's ability to issue mandatory standards and enforce voluntary standards designed to address new and emerging consumer product safety hazards.

To address objective two, we conducted a literature review of scholarly articles using Proquest, Nexis.com, and law review databases. Some of the search terms we used to identify articles on options available to respond to new and emerging risks were "consumer safety," "new and emerging risks," "precautionary principle," "premarket model," and the "Consumer Product Safety Commission" either in combination or alone with geographic delimiters such as "European Union," or "United States," and a date boundary of "after 2007". After removing duplicate articles, we selected 96 scholarly articles and legal reviews from the thousands that were identified based on the extent to which they discussed (1) advantages and disadvantages of the precautionary principle approach or premarket approval or (2) the regulation of relevant policy areas such as consumer product safety, public health, or the environment. Two team members independently reviewed these articles for relevance and found that 18 were relevant for our study. We reviewed these articles more closely for background information on CPSC's authorities and factors that affect timeliness of responding to new and emerging risks and also to identify trade-offs for any options the article discussed. Similarly, we also searched for additional material on the Internet using search terms such as "United States," "precautionary principle," and "premarket approval" and identified an additional 4 articles that we used for contextual purposes.

11. *Who evaluates a first report of a possible (new and emerging) risks?* NA
12. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?*

    US Consumer Product Safety Commission (CPSC), , experts, legal experts, consumer advocate groups and representatives from industry organizations.
13. *How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place?* NA
14. *What has costed the set-up building of the system? What does the Maintenance of the system cost?* NA

Consumers *literature source: European Association of Poisons Centres and Clinical Toxicologists (EAPCCT)*

1. *What is the name of the system /registry/instrument?* NA
2. *What is the goal of the system/method/instrument/ methodology/ database?* NA
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?* NA
4. *Which organization collects the information on possible (new and emerging) risks?* NA
5. *Which language is used in the system?* NA
6. *Is it publicly available or not?*
   a. Scale (national, EU, Intercontinental) NA
   b. Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.) NA
7. *What definition is used for new or emerging risks?* NA
8. *In which way are signals on possible (new and emerging) risks collected?*
   a. Automated procedure, expert judgement, expert panels, internet communication platforms
   b. Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.)
   NA
9. *Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done?*
10. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?*
    a. level to which automated procedures, expert judgement, manual work is needed
    NA
11. *Who evaluates a first report of a possible (new and emerging) risks?*
    NA
12. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?*
13. *How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place?* NA
14. *What has costed the set-up building of the system? What does the Maintenanceof the system cost?*
    NA

Consumers *literature source: EFSA (2006). Forming a Global System for Identifying Food-related Emerging Risks, EMRISK*

1. *What is the name of the system /registry/instrument?* EMRISK
2. *What is the goal of the system/method/instrument/ methodology/ database?* Identifying Food-related Emerging Risks
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?*
4. *Which organization collects the information on possible (new and emerging) risks?* EFSA, specific Unit
5. *Which language is used in the system?* English
6. *Is it publicly available or not?* NA
7. *What is the scope of the system?*
   a. Scale (national, EU, Intercontinental); Global, EU
   b. Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)
8. *What definition is used for new or emerging risks?* No clear conclusion was mentioned in this document. In short, the document describes that the emerging character of the hazard that could give rise to a risk may be at different phases of the risk assessment process. It is essential that the system to be developed is adept at identifying and evaluating each step of a trajectory: from the early origins of a new hazard to its final consequences for a given adverse effect in human beings or animals. Therefore, the pre-early warning system should ensure the needed coherence with all steps of the risks assessment process including phase zero, but to different extents.
9. *In which way are signals on possible (new and emerging) risks collected?* In 2006 EFSA was in the process to set up a system. At that time it was thought to collect signals incorporating the following points:
   - Food information sourcesEuropean Union's Rapid Alert System on food and feed (RASFF).
   - Rapid Alert System for Biological and Chemical Attacks and Threats (RAS-BICHAT)
   - USDA-FSIS/HHS-FDA CARVER+Shock method
   - Expert networks
   - Stakeholders
   - Consumer concerns
   - Conferences and symposia
   - Anticipatory systems
   - Several predictive instruments exist in different domains, such as IPCC/CRU, OECD/IEA, CDIAC, FDA/CRED, UNCHS/Habitat, GEMSFOOD, EMPRES (FAO), GRI (UNEP).

   a. Automated procedure, expert judgement, expert panels, internet communication platforms
   b. Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.)
10. *Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done?* In order to be able to identify an emerging hazard as early as possible it is necessary to use indicators that are able to provide signals that indicate (directly or indirectly) the (possibility of) occurrence of this emerging hazard. According to the holistic vision these indicators should be sought in various influential sectors. In order to obtain the necessary information, related to these indicators, from various sources like databases or scientific experts it is important to ask the right questions in order to obtain the (most appropriate) answers, i.e. the predictive signals. Subsequently, evaluation of these signals may lead to a proactive alert that in turn will lead to actions analysing whether an emerging hazard gives rise to a risk. Summarised, the proposed blueprint of the pre-early warning system consists of the following key elements: influential sectors, indicators, questions, information sources and signals.

    Key sources of information: Sources related to the prioritised indicators are: veterinary and wildlife surveillance networks, outbreak management reports, human illness registration systems,

virology experts andApart from recognised sources like databases on morbidity/mortality, scientific publications, regular press and databases on food consumption surveys, it is stressed that no central databases exist on abnormal / atypical clinical findings in farmed and wild animals.

11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?*

    a. Level to which automated procedures, expert judgement, manual work is needed

    The starting point of the EMRISK project was to draw the information necessary for the identification of emerging risks from a combination of knowledge both from inside as well as from outside the food supply chain (i.e. covering the fork to farm continuum and its host environment). This holistic vision was used to identify the various influential sectors (areas of disciplines), which are more or less related to the food production chain.

12. *Who evaluates a first report of a possible (new and emerging) risks?* EFSA Unit
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?* NA
14. *How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place?* NA
15. *What has costed the set-up building of the system? What does the Maintenance of the system cost?* NA

Consumers *literature source: EFSA (2014a). A systematic procedure for the identification of emerging chemical risks in the food and feed chain .Technical Report. European Food Safety Authority (EFSA), Parma, Italy. www.efsa.europa.eu/publications EFSA supporting publication 2014:EN-547*

1. *What is the name of the system /registry/instrument?* NA
2. *What is the goal of the system/method/instrument/ methodology/ database?* Identification of emerging risks and safeguarding food and feed of EU citisens
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?* Yes Identification of emerging risks: an appraisal of the procedure trialled by EFSA and the way forward European Food Safety Authority
4. *Which organization collects the information on possible (new and emerging) risks?* EFSA
5. *Which language is used in the system?* English
6. *Is it publicly available or not?*
   a. Scale (national, EU, Intercontinental)
   b. Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)/ All compartments of food and feed
7. *What definition is used for new or emerging risks?* "An emerging risk to human, animal and/or plant health is understood as a risk resulting from a newly identified hazard to which a significant exposure may occur or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard".
8. *In which way are signals on possible (new and emerging) risks collected?*
   In general, the framework consists of a multi-step selection procedure that starts from a list of chemical substances (referred to as "entry point") to which a sequence of selection (inclusion/exclusion) criteria is applied to identify the chemicals of potential concern in the present context. The selection criteria take into account volumes of production or import, persistence in the environment, bioaccumulation, dispersive uses, toxicity, and any available risk assessment. The procedure is discussed in terms of: (i) main entry points in the selection procedure (e.g. list of chemicals to be screened, such as industrial chemicals registered under the REACH Regulation or chemical contaminants consistently found in the environment) with a subset of more specific entry points depending on particular objectives characterising the application of the procedure and relevant data availability; (ii) several selection (inclusion/exclusion) criteria, including production volume, dispersive use, persistence, bioaccumulation, toxicity, evidence from existing Regulations or previous risk assessments; and (iii) selection process for the chemicals: multi-step procedure with a varying number of steps in which the outcome of each step becomes the entry point for the next step, and the last leads to the identification of emerging risks. The proposed procedure includes two main entry points - industrial chemicals registered under the REACH Regulation, and the non-intentionally produced or natural chemicals detected in different environmental compartments (e.g. water, soil and biota).
9. *Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done?* EFSA uses numerous databases for the screening of signals. It can be assumed that signals are archieved but a specific name of database was not found.
10. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?* The first main entry point is the REACH Registered Substances Information of industrial chemicals produced or imported in the EU. The first two main procedural steps aim at selecting those chemicals which are produced in high volumes (first step) and used with dispersive modalities (second step). The third step of the procedure consists of parallel selection of: (i) high volume industrial chemicals characterised by highly dispersive use modalities, high persistence and tendency to bioaccumulate; and (ii) high volume industrial chemicals characterised by highly dispersive use modalities and high toxicity. The fourth step consists of a probabilistic combination of these two criteria and results in the selection of industrial chemicals characterised by highly dispersive use modalities, high persistence and

tendency to bioaccumulation or high toxicity. The fifth procedural step is intended to exclude from the selected chemicals those that are already regulated as food contaminants, as undesirable substances in feed, or authorised or prohibited for specific uses in the food chain. The sixth procedural step, aiming at the exclusion of chemicals already assessed by EFSA and other scientific bodies, identifies chemicals classified as emerging issues (i.e. unregulated toxic chemicals likely to occur in the food chain). The seventh, and last, procedural step, consists of the selection of chemicals classified as constituting emerging risks according to the EFSA operational definition (i.e. toxic chemicals likely to occur in the food chain that have not been regulated in food/feed and have neither been evaluated by the European Commission or EFSA, nor authorised for use in food/feed).

The second main entry point aims at identifying chemicals, not included in the REACH register, using several different databases, including the Norman Network. This entry point includes, for example, chemicals of natural origin (e.g. mycotoxins, phytotoxins), or substances detected in specific environmental compartments (e.g. water, soil, sediments, biota or wildlife) which may be contaminants of the food/feed chain. After the exclusion of industrial chemicals included in the REACH Registered Substances Information, the previously-described procedure from step three to step seven applies.

The experience gained by EFSA indicates that the evaluation of the seriousness of an emerging risk should be based on expert judgement given the considerable data gaps generally characterising such risks. In fact, reliable data on health effects of and exposure to new agents are not generally available at short times since the inception of exposure. Therefore, establishing a clear threshold for the seriousness of an emerging risk may not always be feasible on pure scientific grounds. An "emerging serious risk" may thus have to be defined in dialogue with risk managers.

11. *Who evaluates a first report of a possible (new and emerging) risks?* EFSA, network and stakeholders EFSA established in 2010 EREN to exchange information with MS on possible emerging risks for food and feed safety. The Network is currently composed of delegates from 21 MS and an EFTA country (Norway) designated through the Advisory Forum of EFSA and observers from the EC, EU pre-accession countries, the Food and Drug Administration of the USA (FDA) and FAO. EREN members are requested to provide information on the issues identified. The first report of EREN was published in 2011 (EFSA, 2011c).
12. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?* NA
13. *How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place?* NA
14. *What has costed the set-up building of the system? What does the Maintenanceof the system cost?* NA

Consumers *literature source: Egeghy P.P., Vallero D.A., Cohen Hubal E.A. (2011). Exposure-based prioritization of chemicals for risk assessment. Environmental Science & Policy Vol. 14, pp. 950 – 964*

1. *What is the name of the system /registry/instrument?* NA
2. *What is the goal of the system/method/instrument/ methodology/ database?* Recognising the critical need for exposure-based prioritization approaches on par with those for toxicity,the U.S. Environmental Protection Agency (EPA) has initiated the ExpoCastTM program to better evaluate and prioritise chemicals based on biologically relevant human exposures.
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?* The research program employs systematic and comprehensive approaches to consolidate existing exposure information and generate new tools to inform chemical design, evaluation, and risk management. Current research seeks robust approaches that use human exposure data, product use information, and modeled human behavior to systematically prioritise potential for exposure, based on chemical properties, product life cycle, and individual and population characteristics (Cohen Hubal et al., 2010). Exposure is influenced not only by the physical and chemical properties of the chemical but also by a multitude of factors, including human activities, acting jointly to produce or control emissions along the entire life cycle. Further, characteristics of the environment and of the individual/organism (e.g., the life stage-related exposure vulnerabilities) influence exposures. This review has identified eleven currently available tools for exposure-based prioritization. Only three (CEPST, ConsExpo, and GExFRAME) rely purely on exposure as the basis of prioritization; the remainder incorporate hazard and employ risk as the basis.
4. *Which organization collects the information on possible (new and emerging) risks?* US EPA
5. *Which language is used in the system?* English
6. *Is it publicly available or not?* NA
7. *What is the scope of the system?* Scale (national, EU, Intercontinental); Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)
8. *What definition is used for new or emerging risks?* NA
9. *In which way are signals on possible (new and emerging) risks collected?* NA
10. *Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done?* NA
11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?* NA
12. *Who evaluates a first report of a possible (new and emerging) risks?* NA
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?* NA
14. *How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place?* NA
15. *What has costed the set-up building of the system? What does the Maintenanceof the system cost?* NA

Consumers *literature source: FAO (2006). Food Safety Risk Analysis, A Guide for national food safety authorities. FAO ISSN 0254- 4725*

1. *What is the name of the system /registry/instrument?* A Guide for national food safety authorities
2. *What is the goal of the system/method/instrument/ methodology/ database?* Ensuring food safety to protect public health and promote economic development. This remains a significant challenge in both developing and developed countries.
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?* Not as such, it is a manual to guide authorities to identify and manage food safety risks by the following risk management activities:
   Step 1: Identify and describe the food safety issue
   Step 2: Develop a risk profile
   Step 3: Establish broad risk management goals
   Step 4: Decide whether a risk assessment is necessary
   Step 5: Establish a risk assessment policy
   Step 6: Commission the risk assessment
   Step 7: Consider the results of the risk assessment
   Step 8: Rank food safety issues and set priorities for risk management
4. *Which organization collects the information on possible (new and emerging) risks?* International (FAO) and national organizations and (competent) authorities dealing with food safety issues.
5. *Which language is used in the system?* English
6. *Is it publicly available or not*? Yes
7. *What is the scope of the system*?
   a. Scale (national, EU, Intercontinental)/Global
   b. Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)/Global
8. *What definition is used for new or emerging risks?* This document described new risks in terms of new hazards: " A new or emerging potential hazard constitutes an unknown level of risk".
9. *In which way are signals on possible (new and emerging) risks collected?* NA
10. *Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done?* NA
11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?* Safety problems may be identified by domestic and international (point of entry)inspection, food monitoring programmes, environmental monitoring, laboratory, epidemiological, clinical and toxicological studies, human disease surveillance, food-borne disease outbreak investigations, technological evaluation of novel foods and difficulties in achieving compliance with regulatory standards, among other ways. Sometimes academic or scientific experts, the food industry, consumers, special interest groups or the media expose food safety problems. At other times, food safety issues that are not necessarily driven by concerns about food-borne risks to consumers become apparent through legal action and disruptions to international trade.
12. *Who evaluates a first report of a possible (new and emerging) risks?* NA
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?* NA
14. *How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place?* NA
15. *What has costed the set-up building of the system? What does the Maintenanceof the system cost?* NA

Consumers *literature source: European Commission, Directorate General Enterprise and Industry (2015). Assessment of responses to the Call for the expression of interest –Selection of six to nine Poison Centres to gather information on incidents and the circumstances of exposure to hazardous mixtures marketed in soluble packaging. Directorate F – Resources Based Manufacturing and Consumer Goods Industries ENTR.F.2 – Chemicals Industry Brussels.*

1. *What is the name of the system /registry/instrument?* NA
2. *What is the goal of the system/method/instrument/ methodology/ database? G*ather information on incidents and the circumstances of exposure to hazardous mixtures marketed in soluble packaging
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?* Goal is not described.
4. *Which organization collects the information on possible (new and emerging) risks?* NA
5. *Which language is used in the system?* English
6. *Is it publicly available or not?* NA
7. *What the scope of the system?* Scale is international, EU; Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)
8. *What definition is used for new or emerging risks?* NA
9. *In which way are signals on possible (new and emerging) risks collected?* NA
10. *Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done?* NA
11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?* NA
12. *Who evaluates a first report of a possible (new and emerging) risks?* NA
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?* NA
14. *How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place?* NA
15. *What has costed the set-up building of the system? What does the Maintenanceof the system cost*? NA

Consumers *literature source: Goldsmith M.R. Grulke C. Brooks R.D. Transue T. Tan Y.M., Frame A. Egeghy P.P. Edwards R. Chang D.T., Tornero-Velez R., Isaacs K.,Wang A., Johnson J., Holm K., Reich M. Mitchell J., Vallero D., Phillips L., Phillips M., Wambaugh J.F., Judson R.S., Buckley T., Dary C.C. (2014) Development of a consumer product ingredient database for chemical exposure screening and prioritization. Food Chem Toxicol. Vol. 65, pp.269-79.*

1. *What is the name of the system /registry/instrument?* NA
2. *What is the goal of the system/method/instrument/ methodology/ database?* To perform exposure prioritization facilitating high-throughput risk assessment.
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?* This article is not presented as a system to identify new and emerging risks. It however, could be used as a tool fopr the identification and strengthening of signals leading to potential risks.
4. *Which organization collects the information on possible (new and emerging) risks?* NA
5. *Which language is used in the system?* NA
6. *Is it publicly available or not?* NA
7. *What is the scope of the system?* Scale (national, EU, Intercontinental). The focus is on consumer products
8. *What definition is used for new or emerging risks?* NA
9. *In which way are signals on possible (new and emerging) risks collected?* The methodology for building the CPCP db can be broken down into three major steps:
   - Building and curating a database for consumer product ingredients and percent compositions using available MSDSs.
   - Identifying and annotating product use categories for all products in the database.
   - Evaluating data quality.
10. *Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done?* MSDS information on the presence of chemicals in consumer products and use categories are stored in a database. Using chemical space analysis exposure based prioritization is being facilitated.
11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?* NA
12. *Who evaluates a first report of a possible (new and emerging) risks?* NA
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?* NA
14. *How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place?* NA
15. *What has costed the set-up building of the system? What does the Maintenanceof the system cost?* NA

Consumers *literature source: Jovanović, A.S., Löscher M. iNTeg-Risk project: How much nearer are we to improved "Early Recognition, Monitoring and Integrated Management of Emerging, New Technology related Risks"? EU-VRi, Willi-Bleicher-Straße 19, 70174 Stuttgart, Germany*

1. *What is the name of the system /registry/instrument?* iNTeg-Risks
2. *What is the goal of the system/method/instrument/ methodology/ database?* Improving management of emerging risks, related to 'new technologies' in European Industries (in the area of "Nano-sciences, Nano-technologies, Materials and new Production Technologies). Improving early recognition and monitoring of emerging risks and decrease reaction times if major accidents involving emerging risks happen.
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?* It can be sued to identify new and emerging risks due to new materials and technologies, within the next 15 years.
4. *Which organization collects the information on possible (new and emerging) risks?* EU Industries and renowed R&D institutions coordinated by the European Virtual Institute for Integrated Risk Management
5. *Which language is used in the system?* English
6. *Is it publicly available or not*?
7. *What is the scope of the system*? Worldwide/New technologies
8. *What definition is used for new or emerging risks?* When iNTeg-Risk project was proposed in 2008, the definition of emerging risks proposed by OSHA in 2005, adapted to major accident risk, was stipulating that a risk was to be considered new and emerging if:
   - the risk was previously not recognised and is caused by new processes, new technologies, new ways of working, or social or organizational change (e.g. risks linked with nanotechnology, biotechnology, ICT technologies, new chemicals, effects of globalization etc.) or
   - a long-standing issue is newly considered as a risk due to a change in social or public perceptions (e.g. stress, bullying) or
   - a new scientific knowledge allows a long-standing issue to be identified as a new risk, e.g. in the situations where cases have existed for many years without being identified as risk because of, e.g., lack of scientific knowledge.

   The risk was considered to be increasing if:
   - the number of hazards leading to the risk is growing, or
   - the likelihood of exposure to the hazard leading to the risk is increasing, (exposure level and/or the number of people exposed), or
   - effect of the hazard is getting worse (e.g. seriousness of health effects and/or the number of people affected).

   Current OSHA definition of emerging risks stipulates that an emerging risk is any risk that is new and/or increasing. In this context (and adapted to major accident and technological risk) "new" means that the risk did not previously exist and is caused by new processes, new technologies, new types of workplace, or social or organizational change; or that a long-standing issue is newly considered as a risk due to a change in social or public perception; or that new scientific knowledge allows a long-standing issue to be identified as a risk. The risk is increasing if the number of hazards leading to the risk is growing, or if the exposure to the hazard leading to the risk is increasing, or that the effects/impacts of the hazards are getting worse (e.g. seriousness of health effects and/or the number of people affected). In iNTeg-Risk project the above definition applies generally, and is taken as a starting reference point.

   On the governance side, the definition of emerging risks provided by IRGC is [21]: "[...] a risk that is new, or a familiar risk that becomes apparent in new or unfamiliar conditions. Of particular interest to IRGC are emerging risks of a systemic nature, which typically span more than one country, more than one economic sector, and may have effects across natural, technological and social systems. These risks may be relatively low in frequency, but they have broad ramifications

for human health, safety and security, the environment, economic well-being and the fabric of societies."

An emerging risk is any risk that is new/and/or increasing (OSHA definition).

9. *In which way are signals on possible (new and emerging) risks collected?* Screening signals, consultation with experts, relevant organizations
10. *Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done?* The signals are stored in the Active Risk Spark in Risk Database The implementation of iNTeg-Risk ERMF relies largely on the iNTeg-Risk 1StopShop and the tools contained in it. The main elements are:

    a. RiskRadar

    b. (1StopShop main) Tools
    - RiskEars
    - RiskAtlas
    - MCDM Tools
    - New Technologies Acceptance Tools
    - Notion clustering (S-RDI) Tools
    - c. Specific Tools (of iNTeg-Risk project)
    - d. Background Tools
    - Safetypedia
    - KPI Library
    - MethodsMart & Glossary
    - iNTeg-Risk Education
    - ENISFER
    - Survey Tool

    The StopShop is organised as a "system of systems", managing
    - Data
    - Information
    - Knowledge
    - Meta-information
    - Analyses/work
    - Communication
11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?*

    The step-wise criteria used are:
    - the systemic nature of emerging risks;
    - link of emerging risks to high-impact-low-probability-events (HILP events, HILPs);
    - multidisciplinary character;
12. *Who evaluates a first report of a possible (new and emerging) risks?* Experts
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?* When a risk is identified it is communicated to experts for consultation . This is considered as important throughout the entire process.
14. *How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place?* NA
15. *What has costed the set-up building of the system? What does the Maintenanceof the system cost?* EU funded project

Consumers *literature source: International Risk Governance Council (2015). Guidance for the Governance of Unfamiliar Risks IRGC Guidelines for Emerging Risk Governance Report.*

1. *What is the name of the system /registry/instrument?* Proactive governance of emerging risks
2. *What is the goal of the system/method/instrument/ methodology/ database?* Proactive governance of emerging risks aims to enhance anticipation and forward-looking capabilities. Projecting managers into their possible future operating context helps highlight decision opportunities and provides them with additional lead time to prevent risks from emerging or to manage their consequences.
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?* This guidance explains how an organization can identify emerging risks that are of stake for the organization. The principles can be used for the identification of an EU wide early warning system.
4. *Which organization collects the information on possible (new and emerging) risks?* The guidance described an approach inspired by existing ER units like within EFSA. A risk conductor is among the advices given.
5. *Which language is used in the system?* English
6. *Is it publicly available or not*? Yes
7. *What is the scope of the system*? NA
8. What definition is used for new or emerging risks? Emerging risks are characterised mainly by uncertainty regarding their potential consequences and/or probabilities of occurrence. This can be due to a lack of knowledge about causal or functional relationships between new risk sources and their environment or to the insufficient application of available knowledge to the case in question.
9. *In which way are signals on possible (new and emerging) risks collected?* NA
10. *Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done?* NA
11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?* NA
12. *Who evaluates a first report of a possible (new and emerging) risks?* A risk conductor
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?* Stakeholders/experts
14. *How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place*? NA
15. *What has costed the set-up building of the system? What does the maintenance of the system cost?* NA

Consumers *literature source: Mitchell J., Pabon N., Collier Z.A., Egeghy P.P., Hubal E.C., Linkov I., Vallero D.A. (2013). A Decision Analytic Approach to Exposure-Based Chemical Prioritization PlusOne. Vol. 8(8), e70911.*

1. *What is the name of the system /registry/instrument?* NA
2. *What is the goal of the system/method/instrument/ methodology/ database?* The goal is prioritise chemicals on the basis of their exposure potential. A model is presented in which chemicals are evaluated based on inherent chemical properties and behaviorally-based usage characteristics over the chemical's life cycle. These criteria are assessed and integrated within a decision analytic framework, facilitating rapid assessment and prioritization for future targeted testing and systems modeling. A case study outlines the prioritization process using 51 chemicals. The results show a preliminary relative ranking of chemicals based on exposure potential. The strength of this approach is the ability to integrate relevant statistical and mechanistic data with expert judgment, allowing for an initial tier assessment that can further inform targeted testing and risk management strategies.
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal*? Yes, it can be used for this goal. It is aimed to prioritise chemicals on the basis of the exposure potential. This paper demonstrates how analytical tools, such as LCA and MCDA, can offer a versatile and transparent approach to exposure-based prioritization utilising results from several approaches evaluated in the EPA ExpoCast model challenge.

   The criterias used are:

- assessment of chemical properties
  - Bioaccumulation
  - Bioconcentration factor (BCF)
  - Log kow
  - Molecular weight
  - Persistence
  - ADME
  - Absorption
  - Metabolism
  - Physical hazard potential

- The potential for human exposure is by assessing three main life cycle phases of manufactured chemicals:
  - Production
  - Projected average annual number of production sites
  - Regional geometric mean production quantity (MQR)

- Consumer use
  - Number of potential exposure sources
  - Projected average annual number of individual consumers
  - Projected average annual number of industrial consumers
  - Projected average annual quantity consumed per individual/industrial consumer.
  - Susceptible populations
  - Disposal: Number of potential exposure sourcesProjected average annual number of disposal events.
  - Projected average annual quantity disposed.

The proposed methodology allows for structured and transparent analysis of chemical exposure potential through integration of heterogeneous metrics used to evaluate exposure risk-related information associated with both chemical properties and life cycle phases.

4. *Which organization collects the information on possible (new and emerging) risks?*
   - Biosystems & Agricultural Engineering, Michigan State University, East Lansing, Michigan, United States of America,
   - Physics Department, Carnegie Mellon University,Pittsburgh, Pennsylvania, United States of America,
   - Environmental Laboratory, Engineer Research and Development Center, United States Army Corps of Engineers, Concord, Massachusetts, United States of America,
   - Office of Research and Development, United States Environmental Protection Agency, Research Triangle Park, North Carolina, United States of America
5. *Which language is used in the system?* English
6. *Is it publicly available or not?* Yes
7. *What is the scope of the system?* USA/Human exposure, not a specific compartment.
8. *What definition is used for new or emerging risks?* NA
9. *In which way are signals on possible (new and emerging) risks collected?* NA
10. *Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done?*NA
11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?* NA
12. *Who evaluates a first report of a possible (new and emerging) risks?* NA
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?* NA
14. *How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place?* NA
15. *What has costed the set-up building of the system? What does the maintenance of the system cost?* NA

Consumers literature source: *Wambaugh J.F., Setzer R.W., Reif D.M., Gangwal S. Mitchell-Blackwood, J., Arnot J.A., Joliet O., Frame A.,, Rabinowitz J., Knudsen T.B., Judson R.S., Egeghy P., Vallero D., Cohen Hubal E.A. High-Throughput Models for Exposure-Based Chemical Prioritization in the ExpoCast Project. Environ. Sci. Technol. (2013), Vol 47, 8479−8488*

1. *What is the name of the system /registry/instrument?* NA
2. *What is the goal of the system/method/instrument/ methodology/ database?* To characterise potential risks to human health and the environment associated with manufacture and use of thousands of chemicals.
3. *Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?* It can be used for this purpose. It is a framework for high-throughput exposure assessment.
4. *Which organization collects the information on possible (new and emerging) risks?* USEPA
5. *Which language is used in the system?* English
6. *Is it publicly available or not?* Yes
7. *What is the scope of the system?*
   It is primarily focused on the US. It consists of:
   - Fate and Transport Models,
   - Chemical Selection
   - Model Parameterization
   - Chemical Use Information
   - Biomonitoring Data
   - Statistical Analysis.
8. *What definition is used for new or emerging risks?* NA
9. *In which way are signals on possible (new and emerging) risks collected?* The ExpoCast exposure prioritization framework here is intended to be sufficiently flexible to incorporate new models as they become available. To rapidly screen a set of chemicals for exposure, we used linear regression to evaluate the predictive power of multiple exposure models.
10. *Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done?* NA
11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?* Intake fractions are predicted (kilograms exposed to the population per kilograms emitted) via exposure factors that translate predicted environmental media concentrations into human exposure metrics.
12. *Who evaluates a first report of a possible (new and emerging) risks?* NA
13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?* NA
14. *How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place?* NA
15. *What has costed the set-up building of the system? What does the maintenance of the system cost?* NA

Consumers Information source: **'Nationaal Vergiftigings Informatie Centrum' (Dutch National Poisons Information Centre, NVIC), University Medical Centre, Utrecht on 14/03/2016**

1. *What is the name of the system /registry/instrument aimed at identifying possible (new and emerging) risks?* All activities of the Dutch National Poisons Information Center (NVIC) are relevant to signaling of emerging risks. Especially the 24/7 information supply to medical healthcare personnel (44000 questions per year) provides us with valuable information on the epidemiology of intoxications and poisoning incidents in the Netherlands.Toxicologische Informatie & Kennisdatabank (Toxicological Information and Knowledge Bank,TIK)
   Note. This system contains only information in Dutch.
2. *Which organization collects the information on possible (new and emerging) risks?* The DPIC uses information received from producers (requirement in CLP, article 45 product notification) on ingredients in products, like household and DIY products, Biocidal and Plant Protection Products, Cosmetic products and industrial chemicals. The NVIC also has broad knowledge on medicines (human/animal), drugs of abuse and plant/animal toxins
   With regard to possible NERCs.
   NVIC (and TIK) is set-up to inform and help professionals. While doing that, requests for information on what to do when for example a kid has swallowed household cleaning agent, is registered. This information on cases comes from physicians/general practitioners. NVIC is only meant for professionals, which can also be the emergency response services as fire brigade, ambulance personal, police
3. *What is the goal of the system/method/instrument?* The goal of the TIK is to support the NVIC professionals in their everyday task to inform physicians how to act upon emergency situation during which contact with potentially toxic substances or mixtures (all chemicals, radiation, biological toxins) took place. The scale of TIK is the Netherlands focusing on the citizen including man indirect, workers and consumers. Only with regard to acute toxicity! All the compartments mentioned are relevant in the questions to the DPIC.
4. *What definition is used for new or emerging risks?* No definition is used. Criteria that trigger closer investigation are: increasing number of intoxications with a certain product or product group, unusual symptoms in relation to the intoxication or poisoning severity that is much worse than expected, based on the exposure.
   Requests and responses are based on acute toxicity. To facilitate signaling of increasing numbers of certain intoxications, TIK is extended with a Business Intelligence tool used for (annual, specific ad hoc) reporting purposes, early warning and trend analysis, potentially leading to the detection new risks (e.g. liquid caps).
5. *In which way are signals on possible (new and emerging) risks collected?* NVIC collects all signals (44000 calls) from the parties specified in the answer of question 2. During the calls information on exposure (quantify, etc.) is collected and inserted into a system. Apart from the telephone service, where it is clear if exposures did actually occur, the DPIC also operates a website for professionals, with 51000 visits in 2015. For the website consultations it is unknown whether exposure actually occurred or the user is just looking for information.
   TIK is updated when necessary, based on continuous literature research and the consultations to the DPIC. Up-to-date dose-response information facilitates dose-response modeling. Using detailed exposure information more precise information can be provided on how to intervene during the emergency situations.
   The information that is screened is scientific literature, Poisindex database, pubmed, and via a world-sharing database on current awareness in toxicology. This database is maintained by the European Association of Poisons Centres and Clinical Toxicologists(society via membership contributions) and provides monthly highlights.

6. *How is a first report of a possible (new and emerging) risk evaluated and what are the criteria used to evaluate reported signals?* With regard to the providing of information, the level of automization is relatively high compared to many other EU poison centres that frequently rely on the expert judgement of the physician of person providing the emergency responds.

   With regard to the registration, NVIC registers all calls (cases) when something deviates from the normal situation (e.g. more emergency situations from a single product in several months) a signal on a potential new of emerging risk could exist. Based on discussion and expert judgment this is followed-up.

7. *Who evaluates a first report of a possible (new and emerging) risks?* Based on three criteria the signal is evaluated by scientific experts (at NVIC/DPIC)
   - Type of signal
   - Causality (where, how, what substance(s) are involved, did exposure occur and to what dose of toxin, can the reported symptoms be attributed to the exposure)
   - External factor influences, like seasonal variations in exposures, like the use of certain products, availability of plants, etc.

   When a new product (for example the liquid washing caps) is introduced the number of intoxications with the product always increases, all signals are new and this is something else than a new signal concerning a new or emerging risk. Only after several months this could lead to some kind of indication. Comparison to intoxications with similar product(groups) are used to evaluate the risk posed by new products.

   With regard to drugs of abuse, TRIMBOS does follow-up which drugs of abuse are causing more visits to hospital emergency rooms .

   VeiligheidNL researches the number of emergency room visits (Letsel Informatie Systeem, LIS) nationwide and evaluates emerging risks (not only chemical, but also accidents, trauma, mechanical safety, etc).

8. *Are possible (new and emerging) risks collected in a someway (national database)?*All calls are stored in the TIK system.

9. *How does the communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place?* This depends on the type of signal. Feedback is given to the experts dealing with the source of the signal. This could be e.g. the advisory body on medicines (college beoordeling geneesmiddelen), the Inspectorate (NVWA or IGZ or CTGB), etc. Sometimes feedback is also given to the DPIC-caller, especially if follow-up of the case is performed.

10. *How does the evaluation and start/set up of follow up of a possible (new and emerging) risk take place?* Within the DPIC the DPIC-experts decide whether to upscale an emerging risk or not. Depending on the product group in which the emerging risk is signaled, the DPIC informs the competent authority and they decide for themselves what actions they find appropriate. The competent authorities contact the producers to find suitable solutions (like smaller packaging, etc.), DPIC can act as expert/advisor.

    Collaboration is also important with laboratory facilities, for analysis of possibly contaminated products (RIVM, hospital pharmacies, NVWA (Dutch Consumer Safety Authority).

    Examples of competent authorities with which DPIC collaborates: IGZ (medication), NVWA (consumer product, food & non-food), CTGB (pesticides).

11. *Could you give an indication of the costs of maintaining your system?* The activities of the DPIC are tightly intertwined: without giving poisons information, to healthcare providers, we wouldn't be able to generate signals about poisoning risks.

    The TIK system is primarily made to facilitate the information supply to healthcare providers. The poisoning information supply helps to lower health care costs by tailored care; no overtreatment of mild or non-poisoning and quick adequate treatment of moderate or severe poisonings in order to reduce health damage. It efficiently supports the

task of the NVIC professional for an adequate response to an intoxication. The Dutch database is more advanced compared to many other EU countries.

Differences exists in both the systems for registering the CLP notification information (because EU member states are free to interpret the Directive according to their own desired, discussion s ongoing in Brussel on an EU system). But they also differ in how they contain the knowledge and expertise at their poison center to be able to provide information and help physicians. The way in which case-information is recorded also differs, but most Poisons Centres (including NVIC) do record information on the following subjects:

- patient characteristics (e.g. age, bodyweight, sex)
- exposure (e.g. substance(s), product(s), dose, route of exposure (ingestion, inhalation, skin, eye, etc.))
- symptoms actually observed in the patient and poisoning severity (e.g. estimated severity, Poisoning Severity Score (PSS), symptoms, measures taken (e.g. therapies, hospitalization yes/no).

Included in the DPIC total budget, the Inspectorate NVWA requests for 70k several trend analyses on the observed new and emerging risks (with regard to consumer products) of their choice. That can be executed because of the existing system.

Cost related information

In general, existing information sources relevant for the three above-mentioned sectors are preferred for the short-term.
a) Technology. Use existing search engines, databases and thesauri already utilised within the sectors agriculture, health & welfare and environment & energy. Technical systems using a worldwide information input are preferred, whether they are used by international (e.g. WHO/FAO) or national (Health Canada) bodies. Although early warning and rapid alert systems are usually responsive systems (see paragraph 4.2.1), available systems in sectors like health & welfare and environment & energy could be used to anticipate a possible transfer of hazards into the feed and food supply chain.
b) Experts. On a European level experts or expert networks operating at the national food authorities/agencies within the EU can be used. Scientific experts or expert networks operating within European research projects (e.g. within FP6 and FP7) are useful. However, these expert networks tend to dry up when the research projects finish and effort is needed to keep them in operation (see also paragraph 6.2.1).
c) Stakeholders. Organised stakeholders like European product boards, commodity organisations, retailer organisations and NGO's can provide valuable input. But also large food producing companies operating in the EU are important suppliers of information. Effort is needed to organise their input to fulfil EFSA's information needs.

Short-term options (2006-2007)
Estimated costs
Much of the initial work is to organise existing information sources in such a way that they meet the specific demands of a system for the identification of ERs. This means: a) using or subscribing to publicly available technical systems supplying information; b) co-operating with organisations that manage existing technical systems; c) organising working groups of experts operating in the sectors agriculture, health & welfare and environment & energy to develop the pre-early warning system.
It is envisaged that a budget of ≈ 200 k€ is necessary for activities b) and c). The costs of subscription per year vary enormously (from free up to 250 k€).
Apart from the pilot studies, the work mentioned under the EFSA management will have to be carried out by EFSA personnel. In the beginning this work could be carried out by at least three full-time employees but heading for the mid-term this could easily increase to a larger number of employees. Especially in the first phase and when no decisions have been made yet on a definite establishment of an ER-unit within EFSA, the introduction and employment of secondments seems to be a flexible possibility.
The estimated costs for one or two pilot studies are ≈100 or 250 k€. Therefore, excluding personnel, overhead costs and subscriptions, the total costs could amount up to 450 k€.

Mid-term options (2007-2008)
Estimated costs
The use of existing information sources (IT, experts and stakeholders) is comparable to that of the short-term period. Organising working groups of issue and sectoral experts operating in the sectors economy & finance, industry & trade and science and technology can probably be carried out at the same costs as calculated for the short-term period (≈ 200 k€). Additional costs for updating the first three primary sectors and/or integrating all primary sectors are foreseeable: ≈ 50 k€.
Apart from contract work, much of the work mentioned under EFSA activities will have to be carried out by EFSA personnel. Independent of scenario A or B the management of the various activities will have to be carried out by a team of full-time employees. The size of the team depends on how much work will or can be subcontracted, a minimum of 4 full-time employees is envisaged, however.
The estimated costs for a cost-benefit analysis are ≈ 50 k€. Therefore, excluding overhead costs and subscriptions, the total costs could amount up to ≈ 400 k€. It must be emphasised that, independent of scenario A or B, the overhead costs increase substantially after the first year.

Long-term options (2008-2010)

Estimated costs

The extension with existing information sources (IT, experts and stakeholders) is comparable to the mid-term period. Organising working groups of experts operating in the sectors government & politics, population & social conditions and information & communication can probably be carried out at the same costs as calculated for the previous periods (≈100 k€). Additional costs for the integration of all sectors are foreseeable: ≈50 k€. Furthermore, the extension of the worldwide activities may involve additional costs: ≈ 200 k€. This adds up to a subtotal of 350 k€.

At the beginning of the long-term period the nature of the chosen scenario will have a distinct impact on the composition and workload of the ER-unit of EFSA employees. Scenario A will not affect the number of the employees involved. The estimated costs for the optimalisation and Maintenance, excluding overhead costs, of the adapted system (scenario A) are estimated to be ≈ 500 k€ per year.

Scenario B will mean that the ER-unit's expertise and skills will have to be enlarged, because the workload and the number of tasks will increase. The costs for the development of a new system are difficult to estimate because it depends very much on the features of a more or less sophisticated system. Moreover, costs for Maintenance usually increase if technical possibilities increase. The project team proposes to implement the required additional expertise including search engine development by means of outsourcing on a three years basis. Thereto following budget estimations can be envisaged in order to build a system fitted to the purpose of EFSA. Within the project to be outsourced a linguist team member (80 k€ per year) is needed for basic multi-lingual ontological research in this area, and needed to adopt contents to mathematical modelling. A mathematician should develop and advance search algorithms in this field (80 k€ per year), whereas two programmes (160 k€ per year) should construct the frame for the search engine technology. A food scientist (100 k€ per year) should be responsible for identifying key sources and is responsible for the judgment of the relevance of the obtained results (project leader). A sociologist (80 k€ per year) should explore the influence of human' behaviours in relation to available information with respect to human health issues and indicators etc. Additionally an amount of ≈ 150 k€ per year will be needed to cover operational expenses.

Therefore, estimated costs for scenario B may easily reach the level of ≈ 1,000 k€ per year (i.e. ≈ 650 k€ for search engine development and of ≈ 350 k€ for integrating sectors and worldwide activities) for the next three years, excluding Maintenance and EFSA staff costs. If firsthand information is essential to EFSA's purposes, it might add substantially to the total costs.

Summarised, the total costs of scenario A, excluding overhead costs and subscriptions, will be approximately 500 k€ per year. The total costs of scenario B, excluding overhead costs and subscriptions, may amount to 1,000 k€ per year. After three years of development the costs of scenario B will be comparable to those of scenario A.

The strategy for a non-toxic environment of the 7th Environment Action Programme

Interim Report

Annex VIII
Workshop report

June 2016 [update: August 2016]

Ökopol Institut für Ökologie und Politik GmbH
National Institute for Public Health and the Environment, Ministry of Health, Welfare and Sport
RPA Risk & Policy Analysts
milieu Law & Policy Consulting

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WORKSHOP REPORT

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INTRODUCTION

This report summarises the Workshop "Strategy for a Non-toxic Environment of the 7th Environment Action Programme (EAP)" held on 8-9 June 2016 in Brussels in the context of the study supporting the development of a strategy for a non-toxic environment.

The workshop was organised with a double objective: (i) informing stakeholders from a wide range of organisations and institutions about the ongoing study and its different sub-studies and (ii) obtaining feedback from these stakeholders about the gaps and barriers identified during the course of the study and preliminary recommendations on how to address them.

This report contains the agenda, list of participants, list of speakers and workshop materials. It also contains a brief summary of inputs provided by stakeholders based on the discussions held during the workshop and the feedback forms submitted by the participants.

The current report is part of Task 4 of the study Strategy for a Non-toxic Environment of the 7th Environment Action Programme (EAP). The inputs received will feed into the Interim Report and the Final Report of the study and each sub-study.

1 AGENDA

WORKSHOP "Strategy for a Non-toxic Environment of the 7th Environment Action Programme (EAP)"

8 and 9 June 2016, 09:00 – 17:30
Committee of the Regions (CoR), Rue Belliard 101 - B-1040 Brussels

Day 1 (8 June 2016)

Time	Plenary, room JDE 52
08:30–9:00	Registration, coffee
	Morning session, chair: Björn Hansen, DG ENV
09:00-09:30	Introduction: *Why a Non-Toxic Environment Strategy?* Speaker: Joanna Drake & Kestutis Sadauskas, DG ENV
09:30-09:45	Presentation of study team and methodology, Julia Lietzmann, Milieu Ltd.
09:45-10:15	*Substitution of hazardous chemicals* Speaker: Professor Joel Tickner, Director of the Chemicals Policy and Science Initiative of the Lowell Centre for Sustainable Production
10:15-10:35	*Grouping of hazardous chemicals to support substitution* Speaker: Anne-Sofie Andersson, ChemSec
10:35-10:50	Coffee break
10:50-11:05	*Weight of evidence – a catch phrase or a discipline?* Speaker: Professor James Bridges, University of Surrey, UK
11:05-11:35	*Protecting vulnerable populations (The health perspective)* Speaker: Professor Philippe Grandjean, Harvard University
11:35-12:05	*The importance of sustainable chemistry for a non-toxic environment* Speaker: Professor Klaus Kümmerer, Leuphana University, Lüneburg
12:05-12:50	Q&A Plenary discussion
12:50-14:00	Lunch break

14:00-16:00 **Break-out sessions:**

***Vulnerable groups*, room JDE 2253** Presentation of the related sub-study, including initial findings, Yoline Kuipers Cavaco, Milieu Ltd. **Feedback from participants** Facilitators: Philippe Grandjean, Yoline Kuipers Cavaco	***Substitution and grouping*, room JDE 52** Presentation of the related sub-study, including initial findings, Marco Camboni, RPA **Feedback from participants** Facilitators: Group 1: Joel Tickner, Marco Camboni Group 2: Anne-Sofie Andersson, Linda-Jean Cockcroft	***Non-toxic substance development* room JDE 3253** Presentation of the related sub-study, including initial findings, Antonia Reihlen, Ökopol **Feedback from participants** Facilitator: Klaus Kümmerer, Antonia Reihlen

16:00-16:30 Coffee break

Afternoon session, chair: Cristina de Avila, DG ENV

16:30-16:50 Summary of break-out sessions by rapporteurs,

16:50-17:30 Plenary discussion
Closing by EC

17:30-19:00 Cocktail reception

Day 2 (9 June 2016)

Time	Plenary, room JDE 52

08:30–9:00 Registration, coffee

Morning session Part I, chair: Cristina de Avila, DG ENV

09:00-09:30 Recap of Day 1

Speaker: Cristina de Avila, DG ENV

09:30-10:00 *The problem of persistent chemicals in the environment*

Speaker: Professor Ian Cousins, Stockholm University

10:00-10:30 *Chemicals in products and non-toxic material cycle*

Speakers: Erwin Annys, CEFIC and Alain Heidelberger, HAZARDOUS WASTE

EUROPE (HWE)

10:30-10:45 Coffee break

Morning session Part II, chair: Björn Hansen, DG ENV

10:45-11:15 *Promoting innovation to safer chemicals*

Speaker: Michael Warhurst, ChemTrust

11:15-11:45 *Getting on top of early warnings*

Speaker: Jukka Malm, ECHA

11:45-12:45 Q&A

Plenary discussion

12:45-14:00 Lunch break

14:00-16:00 **Break-out sessions:**

<table>
<tr>
<td rowspan="2">Persistent chemicals,

room JDE 3253
Presentation of the sub-study, including initial findings, Gretta Goldenman/Robert Pederson, Milieu Ltd.

Feedback from participants

Facilitators: Ian Cousins, Gretta Goldenman</td>
<td colspan="2">Chemicals in products and non-toxic material cycle, room JDE 52

Presentation of the sub-study, including initial findings, Antonia Reihlen, Ökopol</td>
<td rowspan="2">Innovation, room JDE 2253

Presentation of the sub-study, including initial findings, Marco Camboni, RPA

Feedback from participants

Facilitators: Michael Warhurst, Marco Camboni</td>
</tr>
<tr>
<td>Feedback from participants

Group 1: Chemicals in articles legislation

Facilitators: Erwin Annys, Antonia Reihlen</td>
<td>Feedback from participants

Group 2: Circular Economy

Facilitator:

Knut Sander</td>
</tr>
<tr>
<td colspan="4">Early Warnings, room tbd

Presentation of sub-study by sub-study leader, including initial findings

Speaker: Joost Bakker or Yuri Bruinen de Bruin, RIVM</td>
</tr>
</table>

Feedback from participants

Facilitators: Jukka Malm, Joost Bakker and Yuri Bruinen de Bruin

16:00-16:30 Coffee break

Afternoon session, chair: Björn Hansen, DG ENV

16:30-16:50 Summary of break-out sessions by rapporteurs

16:50-17:30 Plenary discussion

Closing by Björn Hansen, DG ENV

2 PARTICIPANTS

In total 118 participants (excluding speakers and study team) registered and were confirmed as participants to the workshop. The registration process was carried out through an online Google form that allowed the study team to continuously track the number of registrations. On this basis, a selection was made to avoid the over-representation of one sector (e.g., NGO, industry) or a particular institution. The registration process also allowed to track the number of participants interested in each of the break-out sessions.

The share of registered participants was as illustrated in the table below.

Type of participants	Nb
Public authorities (including agencies and European Commission)	56
Industry and industry representatives	30
NGOs	19
Research	5
Consultancy	5
Trade unions	3

The complete list of participants is included in Annex I to this report.

3 SPEAKERS

Ten speakers were selected for their expertise in the fields of the different sub-studies taking into account the need to balance the perspectives of speakers with different backgrounds (i.e. academia, industry, NGO). The speakers were selected upon discussion between the study team and the European Commission. The following table outlines the presentations made by the different speakers, and to which sub-study they related.

Sub-study	Title of the presentation	Title	First name	Name	Organisation
a	*Grouping of hazardous chemicals to support substitution*	Ms	Anne-Sofie	Andersson	ChemSec
a	*Substitution of hazardous chemicals*	Dr	Joel	Tickner	University of Massachusetts Lowell
b	*Chemicals in products and non-toxic material cycles*	Mr	Alain	Heidelberger	Hazardous Waste Europe
b	*Chemicals in products and non-toxic material cycles*	Mr	Erwin	Annys	Cefic
c	*Protecting vulnerable populations - the health perspective*	Dr	Philippe	Grandjean	University of Southern Denmark
d	*The problem of persistent chemicals in the environment*	Dr	Ian	Cousins	Stockholm University
e	*Promoting innovation to safer chemicals*	Dr	Michael	Warhurst	CHEM Trust
f	*The importance of sustainable chemistry for a non-toxic environment*	Dr	Klaus	Kümmerer	Leuphana Universität Lüneburg
g	*Getting on top of early warnings*	Mr	Jukka	Malm	European Chemicals Agency ECHA
-	*Weight of evidence – a catch phrase or a discipline?*	Dr	James	Bridges	University of Surrey

Each presentation was based on a set of PowerPoint slides which were circulated to the participants after workshop, upon agreement of the speakers.

4 WORKSHOP MATERIALS

In order to induce fruitful discussions, the participants received ahead of the workshop summaries ('workshop materials') of the different sub-studies including identified gaps/deficits and related improvement opportunities. This material was kept short and synthetic with a view to allow participants to read the materials provided under all of the sub-studies.

Tailored feedback forms were included in the workshop materials to facilitate feedback from participants beyond the discussions held at the workshop.

The seven sets of workshop material are included in Annex II - Workshop materialsto this report.

5 SUMMARY OF DISCUSSIONS

5.1 SUMMARY OF PLENARY WORKSHOP

The workshop started with opening speeches by Joanna Drake and Kestukis Sadauskas from DG Environment, as well as from Julia Lietzmann (Milieu Ltd) on the study team and the methodology.

The plenary sessions of the workshop were structured around the seven sub-studies that form the overall study. The topics covered under each sub-study were approached by the speakers through separate presentations (see point 3). During the afternoons of June 8 and 9, the participants chose among several break-out sessions that correspond to each of the sub-studies in order to continue discussions in a more detailed and dynamic manner. Rapporteurs from the different break-out sessions provided their feedback in plenary sessions. The detailed discussions and outcomes from the break-out sessions are described in the following sections.

The workshop was closed by Björn Hansen (DG Environment) highlighting, among others, the following needs:

- The question of the extent of **information** needed in order to make suitable decisions is debatable and remains open. Two different approaches are often conflicting. The first one requires perfect data to be available before moving forward. The second reflects the precautionary principle and implies that approximate data can be sufficient to ensure that appropriate measures are taken. Greater availability of information was generally seen as a positive and needed step, but should not be considered as a prerequisite for action.
- Stronger and more consistent **enforcement** of the applicable legislations (e.g. REACH, CLP) are of the utmost importance. In many instances the participants highlighted that the regulatory framework in place can satisfy the regulatory needs, if enforcement is ensured.
- **Incentives** from European or national policies are needed (push);
- Ensuring a **demand** for sustainable substitutes/innovations is crucial (pull) ("If there is a demand, there will be supply"). The demand could be stimulated through legal, economic incentives, e.g. public procurement;
- **Substitution** should be facilitated at both EU and MS levels;
- Increased use of **grouping** approaches is seen as generally important in order to achieve a non-toxic environment;
- **Education**, **training** and interdisciplinary **cooperation** are crucial in the mid- and long term;
- It is important to improve the **communication tools** in order to present data and to provide tools in a way that makes it available to people working on the practical level, e.g. in SMEs.
- Greater freedom for creativity including in research & development should be created .

5.2 SUB-STUDY A - SUBSTITUTION OF HAZARDOUS CHEMICALS AND GROUPING OF CHEMICALS

5.2.1 Introduction

The session opened with a presentation by Marco Camboni on the objectives of the sub-study, the methodology followed and the preliminary findings in terms of gaps and deficits, ideas for improvement and available tools (economic instruments, co-regulation, information based instruments, civic and self-regulation, support and capacity building).

Given the high number of workshop participants interested in contributing to the break-out session on substitution and grouping of chemicals, the attendants were split into two groups, one facilitated by Joel Tickner and Marco Camboni, one by Anne-Sofie Andersson and Linda-Jean Cockcroft. The ses-

sion followed the so-called "world café" formula:

- Participants were first invited to propose topics related to substitution and grouping that they would have liked to discuss more in-depth;
- The topics that received more support were selected for further discussion;
- Participants were asked to discuss each topic for around 15 minutes, to record the key points and messages on a flip-chart to then switch to the following topic.

The topics mentioned by the attendants are listed below (the topics that were selected for further discussion are in bold and are presented in the following sub-sections):

- Stakeholders' engagement;
- How to reward innovators;
- What instruments to use to incentivize substitution;
- Criteria for defining sustainable substitution;
- Imported articles and mixed signals;
- Focus on functions rather than chemicals;
- How do we keep manufacturing in the EU and do not export unsustainable solutions outside the EU;
- How we define and operationalize "non-toxic environment";
- Quality and availability of data;
- Alternatives assessment, hazard/risk assessment methodologies and life cycle assessment;
- Networking and collaboration;
- Development of more specific (sectorial) guidelines for substitution / highlight best practices;
- Whether competition law is an obstacle to collaborate on substitution;
- Market vs regulation: what do we leave to the market / what we regulate;
- Grouping strategies;
- How to achieve a non-toxic environment;
- How to change the mindset of the leadership.

It must be noted that, although only some of the topics have been used as headlines for the discussion, all the topics have been discussed horizontally by the groups during the session.

5.2.2 Criteria for defining sustainable substitution

The workshop participants felt that the definition of "sustainable substitution" and "safer substitutes" is mainly a political decision on how to weigh hazard, risk and socioeconomic arguments. The definition of what is meant with "non-toxic" environment would be already a big step towards the development of its strategy. The different perspectives of businesses and society as a whole may lead to different criteria. The question is therefore: how to reconcile these different perspectives in order to ensure the protection of the human health and the environment without hindering innovation and competitiveness of the EU industry. In the weighing process, groups vulnerable to chemicals' exposure should be carefully taken into account. It was deemed that the clear definition of the function of the chemicals used in the processes/products would be a good starting point of a step by step process. Indeed, a recurrent theme in the discussion across the different topics has been that the first important question to be asked is whether the chemical substance is needed to achieve the desired functionality. Once this has been established, the assessment should take into account not only hazards and risks during the production of the chemicals and their use in the processes/products but also life cycle impacts and other aspects, such as impact on energy consumption. These types of assessments, however, are resource and time intensive and require good quality data that, despite the implementation of the REACH Regulation, are not available for most of the chemicals of concern yet. Transparency in the assumptions used to overcome these information gaps but also in the weighing process is of vital importance while we put more efforts on the development of the assessment methodologies and in filling the data gaps.

5.2.3 Alternatives assessment, hazard/risk assessment methodologies, life cycle assessment and Quality and availability of data

Workshop participants agreed that there is a trade-off between the quality and the quantity of data needed for the assessment of chemicals and their potential substitutes. While some participants were of the opinion that life cycle impacts should be considered not only in the assessment but also in the designing of the chemicals, others considered that methodologies should be kept as simple as possible, possibly trying to enhance the available tools and not to develop new ones. In this regard, participants agreed that co-ordination at EU level would be beneficial in order to avoid the multiplication of efforts and initiatives at national and local level, often sharing the same objectives but not the resources to achieve them. Harmonisation of the guidance documents referring to different pieces of legislation may also help in identify remaining gaps and increase awareness.

Participants also agreed that the development of databases searchable by the functionalities delivered by different chemicals would be beneficial for the assessment of safer alternatives. Some participants were of the opinion that a better and more inclusive stakeholders' consultation in the gathering of data and in the decision making process of the Scientific Committees would be beneficial too, but other pointed out that in the formation of scientific evidence, stakeholders' consultation should be avoided.

All data gaps should be made transparent and highlighted so that downstream users can avoid untested materials and put pressure on suppliers to fill in data gaps.

Furthermore, a lot can be learnt from successful stories: the development of best practices is an important tool.

5.2.4 Networking and collaboration

There was a wide consensus that enhancing the co-ordination of the different initiatives on substitution and the sharing of information among scientists, industry and regulators would be very beneficial for the promotion of the substitution of hazardous chemicals and the development of safer alternatives. The creation of a platform at European level may be an option to achieve this enhancement, possibly in combination with databases searchable for functionalities, hazardous properties and upcoming/current regulations of the substances. The databases maintained by ECHA are a good starting point but are still not sufficient for substitution purposes.

Collaboration across the supply chain was also seen as very important, in terms of traceability of hazardous substances along the supply chain (and in imported articles) but also for the development of safer alternatives targeted to the needs of the articles manufacturers and users. Examples of successful collaborations across the supply chain should be used to identify best practices (e.g. Italian glass sector, IKEA).

5.2.5 What instruments to use to incentivize substitution

As highlighted in the discussion on networking and collaboration, information support instruments play a vital role to promote substitution. Moreover, a "shared knowledge" between chemists and toxicologists should be facilitated through the formation of university courses on green chemistry and sustainable substitution. Factual information on the hazardousness and impacts of the chemicals contained in articles should be provided to the public, avoiding the "greenwashing" phenomena and the multiplication of ecolabels.

Green public procurement, but also green private procurement by large corporations with sustainability strategies, has an important role to play in rewarding innovators and thus incentivise the development of safer chemicals, shaping market demand and raising public awareness. Engaging the direc-

tors' boards of large enterprises, to change their mind sets and to commit them on green chemistry may be an important part of the strategy.

Technological support should be offered to SMEs, but also incubators (see DexLeChem's experience in Berlin[1]) and easier entry to markets to innovative start-ups dedicated to green chemistry.

Taxation on the production or use of hazardous chemicals gives also a clear signal to stakeholders and incentivises substitution (see Scandinavian experiences on taxation of pesticides and solvents).

5.2.6 Grouping strategies

Workshop participants recognised the importance that grouping strategies may play in avoiding regrettable substitution. However, the definition of the groups is challenging and enough flexibility should be left for dealing with different situations as, in some cases, it may be not possible to obtain the same functionality from a substance not pertaining to the same structural group of the substance to be substituted.

Different strategies have been proposed by the participants, e.g. grouping of substances of concern for certain vulnerable groups (pregnant women, children), by intrinsic properties (persistence), by effect type or mode of action (also referring to combined exposure) or by functionality/application. Some participants suggested following a tiered approach, others suggested leaving the possibility to prove that a substance from the same group is safer or requiring more information on toxicity and exposure if the substitute is from the same problematic group as the substance to be substituted. An example of a different approach is the German evaluation procedure for volatile organic compounds (VOC) from building products. All emissions have to be identified and assessed according to a list of 180 chemicals with threshold values. Sometimes the industry substitutes chemicals on the list with other compounds for which no threshold values are derived. To avoid surprises (not knowing the toxicological potential of these new compounds) the authorities set a criterion to limit the emissions of unknown chemicals or chemicals without threshold values. However, industry can apply for the derivation of a threshold values for this new compound. They have then to provide the German authorities with the toxicological data.

In any case, the transparency of the criteria used to define the groups as well as the objectives of the grouping strategy was deemed very important. The promotion of a public debate on which groups of chemicals should be considered for regulatory purposes may ensure more transparency in the decision making process. At the same time, some participants suggested that downstream leading companies are already applying grouping strategies to avoid classes of hazardous substances, hinting that legislative measures are not the only way to proceed but that information based instruments and raising public awareness may play a role as important.

Some participants suggested that a question should be asked and answered even before considering grouping strategies, i.e. whether the functionality delivered by the substance in a certain application can be achieved by non-chemical means or, in other words, whether the use of a chemical product is necessary.

5.2.7 Conclusions

Thanks to the participation of different stakeholders to the breakout session on substitution and grouping of chemicals, the project team has gathered a range of ideas that should be further explored:

- Clear signals should be provided to the market. These can be in the form of economic instruments such as taxation on the use of hazardous chemicals or through the creation of a market demand

[1] http://www.dexlechem.com/home_en.html

for safer alternatives, using green public procurement and raising awareness along the supply chain of chemical products, starting with the directors' boards of large companies;
- While more research is required on the assessment methodologies and on the chemicals life cycles impacts, transparency should be ensured in the decision making process, from the assumptions used to overcome information gaps to the criteria used in grouping strategies;
- A flexible approach should be followed in developing grouping strategies for regulatory purposes;
- More and better co-ordination is needed at European level to increase the efficiency and effectiveness of the multiple initiatives on substitution currently ongoing at international, national and local level, across different sectors and under different legislative frameworks;
- The networking of SMEs should be promoted and market access of innovative SMEs in green chemistry should be facilitated through the provision of funds and administrative burden ease;
- Most of the workshop participants felt that the current legislative framework provides sufficient incentives to substitute hazardous substances and argued that there is no need for new legislation but there is a strong need for a better enforcement, in particular on imported articles. Some suggested that lessons can be learned from the enforcement of legislation regulating the electronics sector.

5.3 SUB-STUDY B – CHEMICALS IN PRODUCTS AND NON-TOXIC MATERIAL CYCLES

5.3.1 Plenary

The topic "toxic substances in articles and material cycles" was highlighted in the introductory presentations as very important for achieving a non-toxic environment.

Erwin Annys introduced the move from the linear to a circular economy via a significant increase in (qualitative and quantitative recycling targets). While he suggested the ultimate goal of phasing out SVHC from the material cycles, he saw a need for an interim solution until respective alternatives are available and sufficiently well introduced, including a risk assessment based decision making on recycling. He pointed out that communication on substances in articles (until the waste sector) is challenging and not yet functioning well. He suggested extending communication on the absence of SVHC in articles and on the maximum content of SVHC and restricted substances and pointed out that industry would not support disclosure of the full composition. He pointed out a need for support in identifying which restrictions exist for which substances, materials and articles in the EU and worldwide. Erwin Annys closed his presentation with pointing out the need to approach the issue at global level.

In his complementing presentation, Alain Heidelberger highlighted challenges to the management and the treatment of hazardous wastes due to its highly variable compositions, phases and hazardous properties as well as the low volumes. He indicated that in some cases decontamination technologies are available but not yet in use because the market conditions would not allow profitable operation. He pointed out, that among others the following aspects are necessary to achieve non-toxic material cycles:

- Coupling of quantitative and qualitative recycling and/or recovery targets;
- Availability of information on hazardous properties (HP1 - HP14) and substances;
- Increasing the demand for decontaminated recycling materials and prohibition of backfilling of hazardous waste
- All actors of the waste management chains must comply with depollution and recycling requirements including producer responsibility organisations (PRO) in areas of extended producer responsibility (EPR).
- Monitoring and compliance shall be ensured for all actors in the waste management area in the same way.

In the plenary session, it was also stressed that the waste / chemicals interface should be clarified. This would regard for example: the relation between CLP and the list of waste, the implementation of "end-of-waste" decisions and the beginning of a "new product life" in the Member States, as well as harmonizing definitions under REACH and waste legislation (e.g. placing on the market).

5.3.2 Break-out groups

The group of participants was divided into two sub-groups. One discussing chemicals and articles policy and the other focusing on waste – related aspects of non-toxic products and material cycles.

5.3.2.1 Chemicals and articles policy

Legal aspects
Several participants criticised the current legal framework as insufficient in preventing the use and emissions of toxic substances from articles, in particular from the perspective of consumers.

REACH
Several stakeholders confirmed the REACH legislation as insufficiently preventing exposure to hazardous substances. The current provisions of REACH Article 33 would lead to relevant communication on (and avoidance of) toxic substances in articles, among others due to a lack of awareness, understanding and enforcement. However, improvement possibilities should be envisaged, e.g. in the scope of the review / ongoing REFIT process.

The import of (toxic substances in) articles was consensually seen as the most important gap in REACH. Some stakeholders supported the proposal to extend the authorisation scheme to (imported) articles. ECHA mentioned the possibility to develop restrictions complementing authorisation, if relevant. However, if no authorisation applications are received indicating that a particular application is not relevant, ECHA would not initiate restrictions for these uses to fully ensure that imported articles do not contain the substances.

In addition, NGO stakeholders noted that authorisation would be weakened as substitution trigger, if the Commission would continue granting authorisations to "critical" uses.

The current situation was characterized as dead-lock by some participants, where companies tended to defend (the use of) toxic substances and the Commission continues assessing and not regulating them (yet). Therefore, market demand was seen as important (complementary) driver to enhance phase-out and/or communication on toxic substances in articles.

Articles legislation
"Product" legislation was criticised as inconsistent and not strict enough to ensure a non-toxic environment. Stakeholders recommended the sub-study team to use publications on legal gaps and improvement proposals as starting point.

A consistent approach for regulating chemicals in articles was supported by the majority of participants of the break out group. It should systematically consider product types, exposed groups, the expected exposure levels and substance hazards. An example of a current legal inconsistency is that CMRs are restricted in toys but not in children clothing. The lack of legal provisions for specific food contact materials (apart from plastics) was mentioned as another inconsistency. Another suggestion related to lowering requirements to justify a restriction based on the precautionary principle.

In developing new legislation threshold limits in articles should be carefully derived and measures foreseen that their circumvention, e.g. by using several similar and critical substances is prevented. As a minimum, CMR in articles/article parts accessible to consumers (in particular children) should be restricted. Guidance would be essential to implement respective restrictions.

The RoHS Directive was mentioned as an example of legislation, which works well.

All stakeholders admitted that compliance with chemical requirements on articles is challenging for companies due to the diversity of regulations. Industry representatives therefore welcomed a central repository of legal requirements.

Another proposal mentioned was to implement a database or register with information on the use of toxic substances in articles.

Enforcement
NGOs and authorities emphasized the importance of adequate enforcement. They pointed out that current inspections are insufficient (quality and quantity), particularly with view to the import of articles. Here, Member States should step up efforts, provide more resources and implement strategic enforcement actions. New and better analytical standards to detect SVHC in different article matrices would support both market actors and inspectors. The US approach was presented, which requires third party analytical measurements of substances in toys to ensure compliance.

Although they do not have a "formal role", NGOs were mentioned as opportunity to strengthen the implementation of legal requirements. In the US, models to support civil society groups to e.g. screen products on the shelves for SVHC or conduct consumer campaigns were very effective.

Communication and phase-out beyond legal requirements
In order to support phase-out and/or communication on toxic substances in articles, market pressure needs to be built up and capacity and competences be increased, including by providing training and tools to market actors, NGOs and consumers, according to a large number of stakeholders in the break-out group. Functioning supply chain communication is necessary to obtain information that could be forwarded to consumers.

Supply chain communication / phase-out
The UNEP programme on chemicals in products (CiP) is an important global approach to increasing awareness and activities in companies to consider phase-out and communicate the content of toxic substances in articles. Companies joining the programme are to accept its principles and commit to regular progress reporting. The project highlights good examples, strengthens knowledge of companies on their products and creates new marketing opportunities for brands. Several stakeholders supported the idea of a globally harmonized format to communicate on substances in articles. There are considerations to develop such format(s) in the context of CiP.

The automotive industry runs an information system to avoid the use of toxic (restricted) substances, which works well and includes the entire supply chain. However, the IMDS is not complete and it should be borne in mind, which information consumers and therefore customers would need. Industries would need sufficient time to implement changes in legislation, i.e. to find substitutes for restricted substances; therefore early warning systems would be of high importance.

Company incentives for phase-out/communication would be, among others:

- Ensuring legal compliance;
- Protecting the brand image;
- Competitiveness and marketing opportunities;
- Investor requirements on „low business risks";
- Awards for front-runners
- Naming and shaming of laggards.

Tools that could support phase-out/communication include education of non-EU actors in the supply chains, awareness raising and IT-instruments for information provision. New tools should take note of existing, successful communication models.

Communication with/to consumers
Most participants were in favour of significantly strengthening consumer market power and informed decision making by providing more/better information on toxic substances in articles. There were differences in opinion on the means to achieve this. Some stakeholders suggested providing as much relevant information to consumers as possible and at a high level of detail, whereas others believed consumers should not be overloaded but receive aggregated information, e.g. in the form of (eco-)labels and focussing on safe use. This was supported by the view that consumers have difficulties in understanding chemical pictograms.

Some stakeholders were in favour of full declarations and labelling of (all) articles, whereas others strongly opposed a universal labelling system.

The project "chemical footprint[2]" of the US NGO clean production action guides companies in improving their chemicals management and respective communication. The system would increase communication and improve the currently insufficient knowledge of downstream users, on the chemical composition of their products (awareness raising). It could be considered good practice and the concept is well received, among others due to high interest of investors.

Another input from experience in the US are NGOs using XRF-detectors to identify products in the shops that contain toxic substances.

Another proposal to increase the knowledge of consumer demands was to establish a panel of around 12-16 year old persons with regard to their needs and preferences on the content of and information on toxic substances in articles.

5.3.2.2 Waste policy

At the beginning of the sub-group focussing on waste policy, some stakeholders stressed that there are cases where producers take a life cycle perspective to optimize their product. In doing so, they would take into account several diverging targets and requirements in the different life cycle phases and within each life cycle phase (examples: furniture, construction products).

Balancing quantitative and qualitative targets
Recycling of furniture and construction products is hampered for some components by their content of flame retardants. Mere quantitative recycling targets were not seen as appropriate for such cases. Participants stated that a consistent and systematic approach to decide about depollution activities is missing. Further, it was mentioned the standards or requirements in legislation sometimes created problems in making products/materials fit for a circular economy/easy recyclable as they occasionally require the use of a certain problematic substance, such as e.g. a brominated flame retardant. Such provisions might also hamper substitution, which otherwise would make it possible to achieve the desired functionality by means of an alternative solution.

Two important problems were highlighted: the import of articles contaminated with toxic substances (which are not known) and recycling of contaminated material, for which information on the contamination is not conveyed / lost during article service life. An example given for the latter was PVC recycling: PVC with DEHP is recycled in beacon bases; when the beacon bases reach the end of service life it is usually not known whether they contain toxic substances from recycling or not.

[2] https://www.chemicalfootprint.org/

Information availability and communication
Information about toxic substances were seen as crucial for appropriate waste management. The way how the information is made available to the waste collectors and the waste treatment sites has been stressed as crucial for a proper application. According to some participants, electronic data bases (where available) are partly not used by waste management companies because the identification of the respective end of life product in the bulky waste and construction and demolition waste is too costly (if possible at all).

It has been stressed that only that information should be collected in data bases or labels, which are actually applied by waste management companies. In order to identify, which information should be provided by the producers it will be necessary to consider the daily practice in the respective waste processes and to communicate the needs into the product development and/or the production phase. Considering dynamic aspects (product composition and design, waste management operations) will be important.

Better alignment of CLP and characterisation / determination of hazardous waste in the European List of Waste has been seen desirable.

Economic aspects
Separation of end of life products with toxic substances from other products and depollution activities have been described as technically possible in many cases. Anyhow, those activities are often costly and respective financing may be problematic, especially when the revenues from secondary raw materials are low.

It was mentioned that usually extended producers responsibility (EPR) concepts are related to end user products. It was discussed if a material oriented approach would be more sensible in case of e.g. plastics with flame retardants. This connects to a remark made in the plenary session where a producer of end products called the producer of hazardous chemicals to take responsibility for non-toxic material cycles.

A stakeholder asked for a more differentiated picture of who is the "producer". If, from a legal perspective, a retailer is the actor who places the product on the European market, an approach is needed to implement EPR with regard to communication flows.

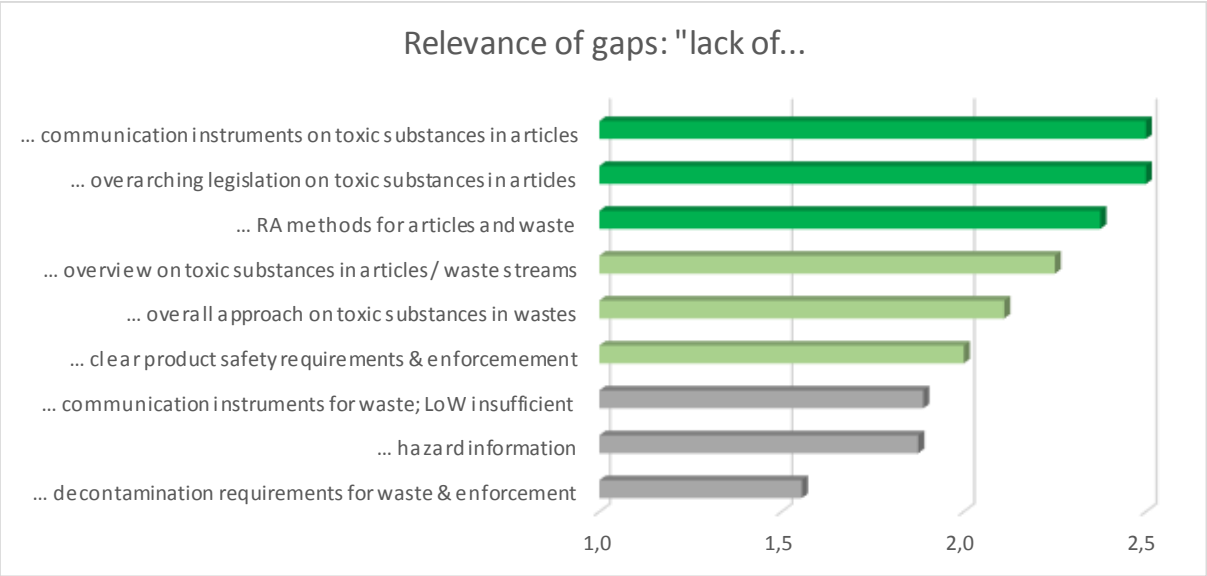
Harmonisation
Harmonisation of approaches to determine end of waste status in the Member States and different limit values for toxic content in different areas (example POP regulation vs. CENELEC standards) was stressed as necessary, because different approaches are an obstacle for non-toxic material cycles.

Overall approaches
Priority material flows for improvements regarding non-toxic material cycles should be identified by considering overall mass and concentration of toxic substances and toxicity.

The development of political strategies for non-toxic material cycles should not only take restricted substances or substances of very high concern into consideration but all hazardous substances.

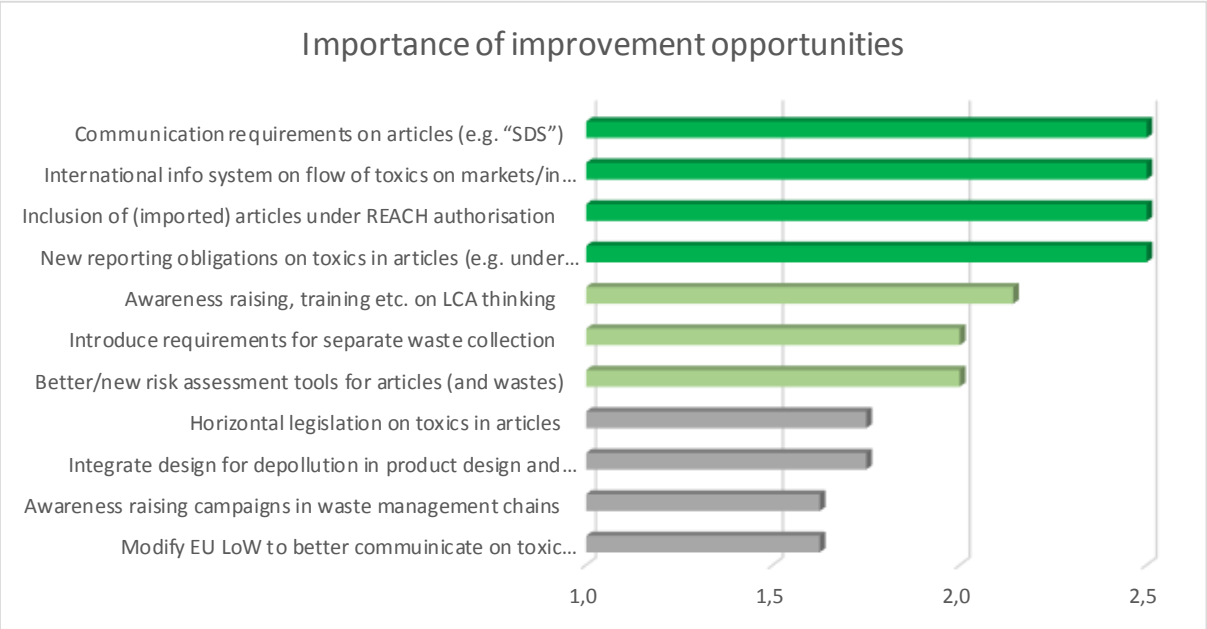
5.3.3 Written feedback received after the workshop

In total 8 feedback forms were received and 1 statement on toxic substances in articles and material cycles. 4 feedback forms were from public bodies and 4 from industry. The statement was also submitted by industry. The ranking of relevance of gaps is shown in the following figure.



Accordingly, lack of decontamination requirements, hazard information and the LoW are regarded as least important gaps, whereas the lack of communication instruments and overarching legislation / approaches on substances in articles, overview on toxic substances in articles and wastes, as well as of risk assessment methods are evaluated as relevant deficits. This may reflect the fact that no waste management companies replied to the questionnaire. Furthermore, it mirrors the workshop discussion on the need for more consistency and information on substances in articles, which would also effect work in the waste sector. In the explanation, authorities tended to emphasise that regulation is needed if risks are known and support instruments useful but insufficient, while the industry represented pointed out that consistency should be ensured. All actors agree on the necessity to have (good quality) information on substances in articles and wastes in order to adequately manage them.

The assessment of improvement opportunities corresponds to the identification of gaps: improved legal obligations to communicate on substances in articles, as well as implementing restrictions complementing the authorisation scheme rank highest. However, new legislation on articles is not identified as high priority. Improvement opportunities related to the waste sector are ranked lowest.



In the comments, several stakeholder stress that all actors in the supply chain need to be involved in communication and awareness raising, in order to ensure common understanding and use of tools. The implementation of respective information systems is viewed as a long-term goal rather than a "quick measure".

5.3.4 Annex: summary of detailed answers

Evaluation of gaps

Gap/deficit	Ave-rage	SE	Du-Pont	Euro-met	BASF	TIE	FI	CT	DK	BE	Main (negative) consequences of the gap/deficit regarding a non-toxic environment
Lack of hazard information on substances	1,9	3	1	1	1		1	3	3	2	No safe handling and use in the entire lifecycle, if there is no information (2) Hazard information is available from different sources (OECD HPV, REACH, CLI, SDS) (3) Focus should not only be on hazards, but also on releases Unkown hazards are not controlled
Lack of risk assessment methods for articles (service life) and waste stage	2,4	3	2	2	2		2	2	3	3	LCAs insufficiently address chemicals; other impacts which are easier to measure (but not necessarily more relevant) prevail Lack of information on environmental exposures due to complex supply chains (2) Existing guidance and approaches in different policies / legislation should be integrated, also to allow identification of gaps Development of leakage tests for articles in contact with the environment might be useful; development in cooperation with industry and criteria, when they are applicable
Lack of communication instruments on toxic substances in articles	2,8	3	3	2	3		3	3	3	2	No safe handling and use in the entire lifecycle, if there is no information (5) Measures needed for imported articles; Art. 33 too weak (3) Communication between all actors needed to identify risk management and decide on recycling of hazardous materials More recycling, less disposal of articles, also if they do include SVHC Tools should particularly target information flow from article producers to waste management operators No communication on all classified substances, but only SVHC
No comprehensive and overarching legislation on toxic substances in articles	2,6	3	3	2	3		3	3	2	2	Many articles are not controlled; general public partly believes all products are safety assessed Certification of some articles requires use of certain substances and create conflicts with circular economy goals (2) Legislation (too) complex; overall approach would increase consistency and coherence but should ensure a level playing field, too (2)

Gap/deficit	Ave-rage	SE	Du-Pont	Euro-met	BASF	TIE	FI	CT	DK	BE	Main (negative) consequences of the gap/deficit regarding a non-toxic environment
											If product legislation includes risk assessment procedures, they should regulate substance content, otherwise REACH should do Particularly needed to protect vulnerable groups
Lack of overview information on toxic substance content in articles / waste streams	2,3	2	2	2	2		3	3	2	2	Lack of possibility to segregate materials and efficiently treat waste streams (3) Hazard-based sorting prior to recycling not useful, as hazardous substances could be destroyed, transformed and/or recovered during recycling (metals) Information on imported articles is missing No information on usability of material for new products
Chemical product safety requirements are "vague" and not sufficiently implemented and controlled	2,0	2	1	2	1	3	2	3	1	3	Implementation is insufficient (3) Product safety is more sector specific; unclear if cross-sector approach could work RMMs are communicated with exposure scenarios under REACH; these are not vague and need to be implemented For toys, the legal requirements are very clear
Lack of an overall approach, including on information management, towards toxic substances in waste streams	2,1	3	2	2	2		3	3	2	2	If the design of article does not include respective requirements, sorting and recycling efficiently is hardly possible (3) As substances could be "destroyed" during recycling, no sorting prior to recycling should take place (metals)
Lack of decontamination requirements for end-of-life articles / waste streams, as well as related monitoring and enforcement practices	1,6	2	1	1	1		2	2	2	3	May become more important even, with new (extended) recycling targets Alignment of rules on preventing contamination comes first (3) Decontamination purposes should be linked to assessment of risks (3) Balance needed between value of resources and toxic substances, some waste should not be recycled
Lack of communication instruments on toxic substances in wastes / insufficient suitability of LoW for communication and related permitting	1,9	2		2	2		3	3	2	3	The concept of hazardous and non-hazardous waste seems not do give the right incentives for" proper waste management of the "non-hazardous. Lack of possibilities to segregate wastes (2)

Additional comments on gaps (including statement)

- Overall lack of awareness of threats posed to society by chemicals, resulting in a lack of driving forces for better product design a legislation
- Hazard-based approach for SVHC to be maintained, in particular as non-hazardous waste may contain them
- Unclear situation for "end-of-waste"; need to establish criteria to determine, when chemicals legislation (re)-applies
- Information is lost also between chemicals (industry) and articles production
- Enhance concepts like polluter pays and extended producer responsibility to increase recycling and information flow to waste sector
- Quantitative AND qualitative goals for environmental protection are needed.
- Imported articles not covered by the authorisation scheme

Evaluation of improvement opportunities

Idea for improvement	Average	SE	DuPont	Euromet	BASF	TIE	FI	CT	DK	BE	What is the strength, what is the weakness of the idea for improvement?
Awareness raising, training and practical implementation of life-cycle thinking with regard to (the prevention) of toxic substances in articles and waste streams	2,1	3	2	2	2		2		2	2	Need for better understanding confirmed Ensure all understand the same with regard to circular economy, enforce and specifically propose to all SC actors (3) Increases coherence and harmonised lifecycle thinking May change behaviour but not of everybody and as strongly as if there was regulation
Creation of an (international) information system on toxic substance uses and flows on the markets, including amounts, and entering the waste stage	2,9	3	3	2	3		3	3	3	3	CIP is important reference point No "one" system possible Responsibility to be placed on the producer, regardless of type of solution Good to have a central resource with specific information (3) Long term approach and requiring lots of resources from all actors (3) Good to have common approach Difficult to get international system up and running, but EU could lead together with OECD (2)
Introduction of more detailed reporting/notification obligations on toxic substance uses in articles, e.g. under REACH	2,5	3	2	2	2		2	3	3	3	Would create a good basis for risk management (if not only on SVHC) To be practical and understandable and putting low extra burden on industry (3) Answers acc. to Art. 33 might be of better quality, creation of a good database from that Strength: obligation; weakness: additional burden
Development of improved and more specific risk assessment tools for articles (and wastes)	2,0	2	2	2			2	2	3	1	Align with REACH, waste legislation and CLP (3) Build-up need much expertise across legislation as well as time and resources Develop tools jointly with industry Common approach
Development of	1,8	2	1	1	1		1	3	3	2	No need for new legislation,

Idea for improvement	Average	SE	DuPont	Eurometet	BASF	TIE	FI	CT	DK	BE	What is the strength, what is the weakness of the idea for improvement?
horizontal legislation addressing toxic substances in articles, generically complemented by product specific restrictions, for particular aspects (e.g. children articles)											adapt existing ones (3) Sector specific issues need to be addressed, this might need time If product legislation includes risk assessment procedures, they should regulate substance content, otherwise REACH should do Allows specific regulation (consumer groups, products) Furniture, furnishings, textiles and construction products are gaps
Inclusion of (imported) articles under the authorisation procedure of REACH	2,5	3	2	3	2		1	3	3	3	Treat imported articles same as EU produced; same protection goal (2) Might stimulate substitution, integrate efficiently and avoid regrettable substitution (2) Restores level playing field Alternatively, restriction process
Development of communication requirements and tools on toxic substances in articles (e.g. extension of Art. 33 of REACH or "SDS" for articles)	3,0	3	3	3	3		3	3	3	3	Information on SVHC on the candidate list is not sufficient Avoid doubling with overarching approach (2) Need to involve all actors including awareness raising, guidance development, training etc. (2) Would create a good starting point for data on substances in articles (2)
Integration of design for depollution in product design requirements or respective product standards or ecolabel requirements	1,8	3	1	1	1		2	3	1	2	This is beneficial and would imply that responsibility is put where the life cycle properties could be managed Also consider recyclability not only decontamination
Introduction of legal requirements for separate collection of specific waste streams	2,0	2	2	2	2		1	2		3	Integrate with waste framework directive in national approaches (2) All supply chain actors should pay for system, including consumers (2) Certification systems might be in conflict (2) Unclear if there will be benefits (2) Could increase efficiency of waste management, if all actors are involved Need for impact assessment and spread of costs Could be useful but costly
Development of the EU LoW to (also) be an appropriate tool for communication on toxic	1,6	2	1	1	1		2	2	2	2	Modifications should target improving waste management practices Classification of wastes as hazardous should be risk based, not hazard based

Idea for improvement	Average	SE	DuPont	Eurometet	BASF	TIE	FI	CT	DK	BE	What is the strength, what is the weakness of the idea for improvement?
substances in wastes											(only) weak indication of substance content
Awareness raising campaigns in waste management chains	1,6	3	1	1	1		2	2	1	2	There is a very high need Helps but is not sufficient

Additional comments on improvement opportunities (including statement)

- Identification and prioritisation of substances in materials for risk management (restrictions)
- Management of waste streams should be started from the need for secondary raw materials; this needs an assessment of market demands and an assessment of which virgin materials can be substituted at all
- Value of materials depend on their nature a prior use / handling in waste phase
- Product design measures and waste sorting / recovery measures need to go hand-in-hand
- Encourage efforts to use existing tools to manage and communicate on toxic substances in articles and waste
- Harmonisation of approaches: Terms (placing on the market), waste management and end of waste (member states), limit values (different legislation)
- Mandatory minimum quality requirements for secondary raw materials should be introduced
- There should be a common substance evaluation for REACH and RoHS
- Quality of secondary raw materials must fulfil requirements of products produced from them
- No risk should occur for consumers during the article service life
- Good market surveillance of imported articles is needed
- Do not double work, e.g. with the strategy on plastics and the REACH review
- Toy safety directive is a good example of hazard based legislation that works well

5.4 SUB-STUDY C – PROTECTION OF VULNERABLE GROUPS

5.4.1 Plenary session: Philippe Grandjean – Protecting vulnerable populations

Prof Grandjean started his presentation by outlining some of the wrong assumptions that were made by scientific researchers in the past in relation to vulnerable groups and chemical exposure (e.g. protection granted by the placenta, children considered as "little adults", reversibility of adverse effects). He emphasized how sensitive the brain development process is for children given the critical development periods of the process in question, notably the early prenatal (week 1-16), mid-late prenatal (week 17-40) and postnatal (birth-25 years) stages. Prof Grandjean explained how toxic effects of chemicals are characterized by the so called 3T(s): toxicant dose, target organ and timing with regard to windows of vulnerability.

Prof Grandjean noted that industrial chemicals can be considered a silent pandemic disrupting brain development. Particularly, he illustrated that there are currently 213 industrial chemicals (including pesticides, solvents and metals) that are known to be capable of cause brain toxicity to humans, and that there are 12 chemicals, which he called "brain drainers", that are known to have neurotoxic effects on humans during development. Examples include arsenic, lead, methylmercury, toluene, polychlorinated biphenyls (PCBs), fluoride manganese, tetrachloroethylene, chlorpyrifos DDT/DDE, and brominated diphenyl ethers.

In addition, Prof Grandjean pointed out that endocrine-disrupting chemicals (EDCs) can also be qualified as neurotoxicants. He referred to studies that demonstrate how bisphenol A (BPA) can produce estrogenic effects in the neonatal rat brain (Rebuli et al., 2014). Further, he elaborated on the benefits

that will accrue from protecting brain development against EDCs. Prof. Grandjean also showed how, during the past ten years, the scientific community has had the tendency to consistently focus on the same substances (e.g. copper, lead, zinc, cadmium, iron, nickel, chromium, etc.) when studying the harmful effects of chemicals. This further adds to the current context, in which full extent of the chemicals world and their potentially harmful impacts on human health are not fully understood, particularly of vulnerable groups such as the foetus and children.

Finally, he outlined that:

- Brain development involves multiple stages that need to be completed sequentially and these processes are uniquely vulnerable;
- Brain damages stemming from chemicals exposure can lead to permanent effects;
- Optimal brain function depends on the integrity of the complete organ;
- The absence of disease/diagnosis does not mean absence of adverse effects;
- IQ deficits are very costly to society;
- Untested chemicals may not be innocuous.

5.4.2 Break-out group

After an introductory presentation held by the chair, Ms Yoline Kuipers Cavaco, the following direct comments were made by co-chair Prof. Grandjean and participants of the break-out session:

- More research concerning the protection of vulnerable groups from the exposure to harmful chemicals is certainly needed; however, it would be wise to:
  - Streamline the future research agenda and identify key areas of concern, as the topic is of a significant size and it will be complicated to analyse it in an all-encompassing manner; and
  - Carefully consider and make use of the wealth of scientific data collected so far, instead of using precious economic and temporal resources for future research.
- Efforts have to be made to address new challenges and to focus on those gaps in research that still need to be (further) explored. Rather than channeling all resources on one substance or disease, a multidisciplinary approach should be considered and researchers should be given the opportunity and resources to investigate new areas of interest.

After this, participants were split up in three smaller groups to discuss different elements related to the gaps and improvement opportunities relevant to the scope of the sub-study and that were identified by the project team: legislation, policy programmes, awareness raising, risk assessment and research. The following lists the key conclusions per element.

Risk assessment & testing methods

- There was a discussion among participants on whether we need to harmonise risk assessment methods and overall risk management across legislation and areas, or that we need to create new risk assessment methodologies that specifically assess the risks for vulnerable groups. A consensus could not be reached, but overall people agreed that we need to refine current approaches.
- Moreover, an integrated approach for screening and testing chemicals, which pays attention to vulnerability (low cost, high volume), was discussed.
- Participants also underlined that there is a need to translate the scientific evidence into effective tools in order to improve the risk assessment system. For instance, by conceiving a new hazard classification.

Research

- There is a need to employ (more) biomonitoring studies as they are useful tool for understanding

the chemical exposure levels, particularly for the foetus and breastfed child. However, it was stressed that such studies do not explain routes of exposure and sources;
- There was consensus among participants that more research is not always the solution. While scientific gaps most certainly still exist, a wealth of information has already brought together. The scientific agenda needs to be rationalised and scientific efforts need to be channeled towards i) the available evidence, ii) specific vulnerable groups.
- There is a need to strengthen communication between scientists, regulators and the wider public (see further points on awareness raising).
- One of the speakers also pointed out that, while animal studies are important, increased efforts are required to develop and implement epidemiological studies, and to obtain data and evidence on the adverse health effects of chemicals on humans (in addition to animals). Too little data is currently available from these types of studies and it would be a real benefit to have access to this evidence.

Legal framework

- There was consensus among the discussants about the fact that the provisions of the EU legislation addressing the issue of vulnerable groups are often vague and/or not binding. The issue is addressed horizontally, leaving a lot of room for maneuver and failing to provide solid protection of vulnerable groups, particularly children.
- However, participants agreed that it is not feasible nor desirable to change *all* relevant EU legislation in order to ensure that vulnerable groups are specifically addressed – such a process would be too time consuming and too politically sensitive. Nevertheless, a couple of specific pieces of EU legislation were highlighted that do need to be amended (e.g. the food contact materials and the drinking water legislations). It was also suggested to adopt a specific legislation on water contact materials.
- Participants stressed that for most products, a proper legal framework protecting certain vulnerable consumer groups does not exist (e.g. products for children, textile, furniture, etc.);
- Others outlined how the precautionary principle should be the principle that must underpin all the legislation in this matter.
- The majority agreed on the need to ensure more coherence between the legislation.

Policies & awareness raising

- There was general consensus about the necessity of having better information about the routes of exposure, and in particular the need to raise awareness among the general public. However, it was stressed that raising awareness among people should not result in a shift of responsibilities from politicians and consumers.
- In addition to generic information for the overall public, specific, targeted information (campaigns) should be developed for the vulnerable groups, as they are at increased risk. This information should be presented in an integrated and comprehensive manner, which makes it clear that the responsibility is not only theirs but that others have a role to play as well. Moreover, the information should be presented in a neutral way that will not scare them.
- It is key to involve politicians in awareness raising and prevention initiatives; they will facilitate a better targeting of certain vulnerable groups (e.g. better able to reach schools, asylums, etc.) and you need them to put the necessary legislation in place to make restrictions.

5.4.3 Feedback forms

In total, eleven feedback forms were submitted with comments about the workshop document on substudy c and the proposed gaps and improvement opportunities. The following presents an overview of the feedback received.

Answers received from:

Public body	Academia	Industry/Commerce	NGO	Other (pls specify)
5	2	3	1	

Feedback on gaps and deficits:

Gap/deficit	Relevance (from 1 to 3) *		Main (negative) consequences of the gap/deficit
No risk assessment methods that are able to capture/address sensitive life stages available	1 2 3	1x 4x 3x	▪ Not sufficient protection ▪ Early life exposures are unable to be quantified ▪ None in pre-mkt RA anyway! ▪ The IPCS EHC 237 reports methods but not yet validated. ▪ http://www.inchem.org/documents/ehc/ehc/ehc237.pdf
Not enough knowledge on the extent to which vulnerable groups in society are exposed to potentially harmful chemicals (sources and exposure routes)	1 2 3	1x 2x 5x	▪ Not enough knowledge on the risk ▪ A lack of knowledge in this area may mean that prioritization of chemicals for restriction or control will be impaired ▪ Worst case scenarios, which might not be representative of the reality, are taken when none or low information on exposure is available. ▪ If exposure is not known, a worst case based on hazard is chosen
No approaches are available to examine the effects of mixtures of chemicals and compounds on disease susceptibility and etiology	1 2 3	1x 4x 3x	▪ The risk is underestimated when effect of mixtures is not taken into account ▪ Not possible to identify that there are in fact negative consequences. ▪ This statement is also valid for non-vulnerable groups.
Insufficient research on the latency period (period between exposure and onset of symptoms) after chemical exposure	1 2 3	1x 6x 1x	▪ Latency is less important than understanding the pathways to toxicity and when considered in isolation may not take into the account the natural aging process that results in cell deregulation and may therefore lead to inaccurate assumptions with regard to the adverse effects potentially caused by exposure to a chemical. ▪ This statement highly depends on the endpoint considered. The insufficient research on the latency period is particularly true in the case of cancer disease. ▪ Regulatory approach should only follow relevant information showing a concern and be focused
Lack of a comprehensive EU regulatory approach to protect vulnerable groups from harmful exposure to chemicals	1 2 3	2x 3x 4x	▪ Not sufficient protection ▪ Significant exposures from unregulated product groups may occur. ▪ The regulatory approach should focus on concrete concerns justified by relevant information.

* Number of people who rated the relevance of each gap as: 1 = 'no or little relevance', 2 = 'medium relevance', 3 = 'important relevance'.

Other gaps/deficits identified:

- Risk Assessment in silos is typically not considering exposure from the whole life-cycle of products, or 'non-intentional' uses (mis-uses, spillages etc) into account => underestimate total exposures from products.
- Policy instruments / RA procedures are needed which can deal with mixtures of chemicals and which can protect for 'acute' (peak) exposures to groups of chemicals during pregnancy
- Other regulations not considering vulnerable groups: FCM (EC 10/2011, 1935/2004), cosmetics/personal care products, medical devices – e.g. allowing for a certain proportion of exposure limit to be used for single substances, or from single sources.
- Risk governance methods are needed to deal with emerging risks, for which there is not yet a lot of particular exposure data to perform traditional scientific RA.
- Not enough knowledge on exposure sources
- A global strategy on how to protect vulnerable groups is missing.
- A clear definition of who are considered as vulnerable group is missing:
  - "normal" workers exposed to high level of chemicals should not be considered as vulner-

able group if the risk assessment (RA) takes into account the most sensitive endpoint (hazard).
    - vulnerable groups are the ones that are not covered by current RA approaches: because they are more sensitive (e.g. different metabolism), more susceptible to have irreversible effects (e.g. during development phases)
- Scientific data is available, but are not always understandable to regulators (e.g. neutoroxicity, immunotoxicity,…)
- First check results of the E&H Action Plan of M. Walström; then add some more scientific facts. For combination effects, a tiered approach is suggested by Cefic: http://www.cefic.org/Policy-Centre/Environment--health/Combination-effects-of-chemicals/
- Please do not forget prenatal exposure. Please do not forget epigenetic changes.

Feedback on improvement opportunities:

Idea for improvement	Relevance (1 to 3) *		What is the strength, what is the weakness of the idea for improvement?
Development of new risk assessment methods, addressing sensitive life phases as well as exposure to chemical mixtures	1 2 3	1x 3x 6x	■ Essential to have criteria and to address the mixtures. ■ Better protection ■ Strength: Enables chemical restrictions to be prioritized based on risk. Weakness: Approach may be overly complex and will introduce multiple uncertainties ■ Also crucial. Why use industry's 120 y.o. methods when academics have more realistic methods? Pre mkt RA chronic tests do not even test the doses we experience! ■ We need models and tools ■ The IPCS EHC 237 guidance can serve as a basis for improvement of current risk assessment procedures. ■ Improve RA guidance, Use IPCS EHC 237 as reference
Further research to identify unknown properties and new chemicals	1 2 3	0x 3x 7x	■ gap in cooperation between public health and industry. ■ A combination of two questions. Important to address new/emerging chemicals (3) – but this topic might better fit in under the first category. Also good to keep an eye open for unknown properties (2), but these two goals might be achieved by different means. ■ Strength: Will improve knowledge for decision making. Weakness: Not feasible unless funding priorities for academia are re-aligned ■ Need for screening tests to identify emerging concerns: e.g. neurotoxicity, immunotoxicity… ■ Further knowledge on chemical exposure routes are always welcome. ■ Always good to know more but resources should be focused where the need is bigger
Development of an evidence-based, targeted and interdisciplinary EU strategy	1 2 3	0x 5x 5x	■ This question is somewhat broad and vague – not sure what is meant by targeted? It is however most important to address chemicals from all sources, ie across silos (ie interdisciplinary?) ■ Strength: Gives critical mass to support innovation. Weakness: Time for implementation ■ We need a global strategy at EU level, to protect the vulnerable groups. ■ The current regulatory framework is effective to protect normal population. As a first step, the possibilities for improvement of the current system should be evaluated. For this, further knowledge on the criteria that define a vulnerable population and on the differences in exposure compared to normal population are required. ■ First there is a need to know more; this topic was already discussed in the early 2000 under E and H action plan looking at children health
Awareness raising campaign on the health impacts of hazardous chemicals on vulnerable populations	1 2 3	3x 4x 3x	■ In order to get political goodwill to prioritise these topics, awareness is needed in society – not sure if a campaign is the only way, but disseminating the scientific knowledge via social and other media, to MEPs, to business organisations etc. is important to gain support for new criteria

Idea for improvement	Relevance (1 to 3) *		What is the strength, what is the weakness of the idea for improvement?
			▪ Awareness raising is good but hazardous chemicals posing a risk should be regulated. It is not a choice the consumer should make. ▪ Strength: Better informed consumers can drive market change. Weakness: Consumers may not fully appreciate the risk/benefit equation regarding the use of certain chemicals. ▪ Better information about vulnerable groups ▪ Only if the campaign is focused on a specific chemical product or family of products for which there are robust evidences on the mode of action in the vulnerable populations. ▪ Only if focused on real effects otherwise it increases fears for nothing (which is damageable per se)

* Number of people who rated the relevance of each gap as: 1 = 'no or little relevance', 2 = 'medium relevance', 3 = 'important relevance'.

Other improvement opportunities identified:

- A definition of what non-toxic means is essential, otherwise it is too easy to say, that everything is toxic, if you get too much, and hence all chemicals are OK, if you just control the exposure.
- Focus on in-equalities, that chemicals causing harm hit vulnerable groups such as children, socio-economic poor ones, workers, geographic regions etc.
- Ethical/legal instruments: Could human rights be of use?
- Calculate the economic burden of hazardous chemicals.
- More focus on effects on sensitive ecosystems.
- We need new insights, including consideration of how new technologies might help to identify vulnerable groups, indications of where the arbitrary use of safety factors in many risk assessments is failing to protect, an improved understanding of all the work that was done during a previous DG Environment initiative of child health.
- Take into account the problematics of vulnerable groups in all sectors.
- Clear definition of the vulnerable groups.
- More communication: e.g. exchange platform with scientists on the regulatory needs.
- Improvement of current safety assessment procedure to cover vulnerable populations (e.g. via the refinement of the safety assessment factors or the weight of evidence approach).
- Improvement of current guidance at ECHA, EFSA levels can be made.
- One important factor regarding the exposure of children and other vulnerable groups to harmful chemicals is the indoor air quality. Due to the energy efficiency directive the shell of the buildings becomes often so air-tight that the air change necessary for reasons of hygiene is not achieved. The result is humidity and indoor air pollution by volatile organic compounds. Unless sufficient airing takes place, room users (and especially vulnerable groups) face avoida-

Examples of well-functioning legislation, non-legal measures and actions

Which existing legal or non-legal practices do you regard as a good measure / activity / starting point for achieving a non-toxic environment in the area of the sub-study, which have not been mentioned yet?

- The precautionary principle, using a hazard approach, and grouping substances which have the same toxicological properties. Grouping exist under EC 10/2011 for e.g. primary aromatic amines (restriction) and isocyanates (limit value), and organotin compounds evaluated by EFSA Contam panel.
  If a risk based approach is used, then
  - allow room for unknown chemicals also contributing to exposure, e.g. by assigning a fraction (e.g. 10-20%) of the safe exposure to a single chemical. As done for BPA in food contact materials.
  - do not use a tiered approach but, multiply hazard with expected exposure of chemicals with the same toxicological endpoints – done under REACH (cf Elina Karhu)
  - When establishing 'safe' practices and uses, use acute toxicity, and peak exposures, rather than average exposures, to account for exposures during pregnancy, and exposures causing sensitisations/allergies/asthmatic attacks. For effects being caused by chemicals that bioaccumulate in biota and humans, internal exposures should be calculated taking minimal excretion into account.

  To discover changes in health, possibly caused by unknown effects/chemicals, combine RA with systemic/epidemiological studies of both humans AND the environment, as done for ecosystems assessments.
- The Danish EPA has made investigations on 2-year olds and pregnant women combined exposure to endocrine disrupters. These give an indication of the exposure. Reports are available in English on website: www.eng.mst.dk.

5.5 SUB-STUDY D – VERY PERSISTENT CHEMICALS

5.5.1 Introduction

Gretta Goldenman presented the main topics, priorities and focus of Sub-study d on very persistent chemicals, and the preliminary findings on gaps in knowledge/policy and ideas for improvement. In addition, it was explained that the main purpose of the breakout session was to collect stakeholder input for the sub-study from a broad range of stakeholders to further develop the sub-study report on very persistent chemicals.

The breakout session used a "world café" approach to facilitate discussion:

- Participants were invited to propose the topics relating to very persistent chemicals that would like to discuss in more detail or felt were the most important topics to discuss
- These topics were then discussed, collated and grouped in plenum.
- Participants discussed these priority topics approximately 15 minutes, then rotated to the next topic. Key points were recorded on flip charts for each topic and presented in plenary.

The topics identified by participants are listed below:

- The need for P criteria in products;
- How much evidence and burden of evidence;
- Downstream user education;
- Criteria for P and grouping;
- Benefit of PBT regulation:
- Why just Persistence? Should new criteria be Persistent and Mobile? What about Bioavailability?
- Next steps after identification;
- Practical, pragmatic steps - REACH and CLP regulation;
- How to avoid release of vP chemicals;
- Translating success into regulation;

- Stakeholder responsibility;
- Transformation products;
- Development and assessment of alternatives;
- Global emissions e.g. production moving to China; and
- Imported articles

Through the process of collating, grouping, and prioritising, three priority areas for more detailed discussion were identified:

- Criteria and evidence;
- Next Steps – regulation and management; and
- Global perspectives

Approx. 25 people representing a broad range of stakeholders from research, regulators, industry and civil society organizations attended the session. The breakout session was facilitated by Gretta Goldenman (Milieu) and Ian Cousins (Stockholm University).

5.5.2 Criteria and evidence

The evidence needed to identify very persistent (vP) chemicals is particularly difficult. Established degradation tests e.g. "ready test" and "inherent test" can show which chemicals are not vP. Estimation methods like the USA BIOWIN tool can be useful as training and test sets to predict persistence or screen chemicals. More realistic half-life tests, such as simulation tests of environmental compartments, are time and labour intensive, and costly. Participants highlighted the challenge of testing for persistence in very or extremely persistent chemicals i.e. using a 90-day test of biodegradability and extrapolating test data to determine how long these substances will remain in the environment, because extrapolation is associated with a degree of uncertainty.

There were two main views on this challenge, on one hand participants indicated there is enough information available and the pursuit of better information or evidence should not impair our ability to take action or regulate. On the other hand, participants noted that we do not have enough information to assess how persistent chemicals actually are, and that in the case of extremely persistent substances there is a need to develop new screening procedures and test protocols, this was highlighted as homework for the scientific/academic community. Participants agreed that as a first step, it would be useful to take a very pragmatic approach, and suggested that one possible first step would be to develop a list of very persistent chemicals or candidates for this list within the remit of the European Chemicals Agency (ECHA).

5.5.3 Next Steps – regulation and management

There is currently no regulatory paradigm to prevent poorly reversible chemical exposures and regulation is often retrospective i.e. regulation is first put in place after enough evidence is gathered on the environment and health impacts. In addition, the current criteria for persistent, bioaccumulative and toxic (PBT) and very persistent, very bioaccumulative (vPvB) are not particularly useful in predicting planetary boundary threats. For this reason, reliable methods for predicting hazards and risk management are needed. There was general consensus amongst the participants that the current regulatory framework is not adequate for regulating and managing vP substances. Participants suggested that a number of improvements could be made within the current regulatory framework, such as:

- Including criteria for P and vP under the Classification, Labelling and Packaging (CLP) legislation;

- Consideration of vP under Art. 57 (f)3 as having level of equivalent concern

Workshop participants also pointed out that there is always some leakage during the manufacturing of vPs or manufacturing processes using vPs and suggested that creating a system for environmental permits for releases of vP substances could be one way to effectively reduce releases of vP substances into the environment. At the same time, participants suggested that providing incentives for downstream users to avoid vP substances would be effective in reducing release of vP chemicals in combination with environmental permits.

5.5.4 Global perspectives

Persistent chemicals are a global problem because of their long-range transport potential. In practice this means that persistent chemicals have the ability to be transported and in some cases accumulate in areas far from their point of release into the environment. Participants stressed the importance of maintaining a global perspective, when discussing regulation and management of vP substances. Restricting vP substances in Europe alone, would likely lead to production being moved to other parts of the world i.e. production of PFOS to China. Because of vPs long-range transport potential (LRTP), restricting vPs in Europe alone will not necessarily reduce exposure.

The majority of the participants agreed, that the starting point should be the Stockholm Convention, but that currently it is narrow in its coverage of chemicals i.e. only 23 substances are regulated. Participants also discussed what the chain of responsibility should be, and in this respect highlighted several ideas for improvement in global management and governance. There was general agreement that identification of vP substances in imported products was an important first step. Currently it is virtually impossible to know what substances or chemicals are in or used in manufacturing imported products. Along the same line, participants suggested that certification schemes could be used to promote higher product standards in articles and promote transparency in supply chains. Naming and shaming was mentioned, but there was broader acceptance for developing a global hub to communicate success stories, including voluntary efforts by industry. The OECDs current work in this area was highlighted as a positive model for communicating success stories and that a logical first step would be to expand upon this model. Finally, participants stressed that it was important to find solutions that benefit multiple targets i.e. providing information and incentives that facilitate downstream users to move away from "high performance" chemicals.

5.5.5 Conclusions

The workshop provided valuable stakeholder input for identifying gaps and opportunities for improvement relating very persistent chemicals within the context of a strategy for a non-toxic environment:

- Very persistent and extremely persistent chemicals pose a number of challenges in relation to testing, their possible poorly reversible effects and planetary boundaries.
- There are several indications that the current regulatory regime, including PBT and vPvB classification is not adequate for regulation and management of chemicals that are extremely persistent. The German environment agency are working on a new classification system using the parameters persistence and mobility.
- However, there was not consensus among workshop participants on when is persistence alone enough to act and participants didn't not see the added value of developing additional criteria for extremely persistent and category for (vvP) chemicals.
- Improvements can be made within current European legislation i.e. REACH and CLP to better

[3] This article under reach specifies that substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points under article 58 in REAC for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an *equivalent level of concern*.

regulate and manage very persistent chemicals and improve enforcement
- Maintaining a global perspective both in terms of improving regulation and management, and increasing transparency in supply chains.

Workshop participants represented a broad range of interests, and showed that although different stakeholder have different positions on the concept of persistence and chemical regulation, stakeholders worked to identify a number of gaps and ideas for improvement to develop a strategy for very persistent chemicals.

5.6 SUB-STUDY E - POLICY MEANS, INNOVATION AND COMPETITIVENESS

The session opened with a presentation by Marco Camboni on the objectives of the sub-study, the methodology followed and the preliminary findings in terms of gaps and deficits, ideas for improvement and available tools (economic instruments, co-regulation, information based instruments, civic and self-regulation, support and capacity building).

The break-out session on innovation was facilitated by Michael Warhurst and Marco Camboni.

The participants agreed that well-designed regulation can promote innovation (Porter and Van der Linde paradigm) but held diverging views on whether the current legislative framework is posing a high administrative burden on SMEs and therefore diverting resources from research and development, ultimately hindering innovation. Moreover, chemical legislation on downstream sectors such as too narrow restrictions on specific applications may stifle innovation, as downstream users (in particular SMEs) do not have the chemical expertise to research safer alternatives or enough market power to push chemical manufacturers to provide safer alternatives.

Another important point is that well-designed regulation needs to be properly enforced: poor enforcement is an issue, in particular on imported articles. The work of the Enforcement Forum is a good starting point, but more resources should be dedicated to the co-ordination of enforcement across member states.

The availability of information on the availability of safer alternatives is an issue: actors along the supply chain willing to engage on the substitution of hazardous chemicals need to be aware of the availability of possible solutions. In this regard, distributors have a potential role in bringing together demand and offer of safer alternatives. Another measure that could foster innovation is the creation of a marketplace for safer alternatives (currently being developed by Chemsec).

The participants agreed that there are plenty of initiatives trying to promote innovation at European, national and local level, providing funds, knowledge sharing, incubators for start-ups or other networking platforms. However, it would be good to have a better co-ordination of these initiatives, may be under the OECD umbrella. Moreover, some participants questioned whether is the responsibility of the public authorities to provide funding to scale up production of innovative solutions, arguing that their role should be limited to facilitate innovation.

In this regard, economic instruments such as taxation, public procurement and fee waivers can definitely play a role in providing the market with clear signals towards the changes that are needed to achieve a non-toxic environment. Moreover, innovation should not be seen as the substitution of hazardous chemicals with chemical alternatives only, but product design should start from the question on whether chemicals are necessary to achieve the functionalities required.

Industry stakeholders were of the opinion that free and open markets boost the development of the global economy for industrial and developing countries alike and ensure worldwide availability of products based on the most efficient processes and therefore strongly encourage governments to en-

gage in free trade negotiations with all major trading partners. Importantly, Free Trade Agreements or other (international) agreements must include provisions on intellectual property rights (IPR) protection. Industry needs transparency and predictability with regard to IPR protection because of the duration and complexity of innovation processes. A stable regulatory environment allows the long-term planning that is needed to innovate. Furthermore, international agreements should define adequate IPR enforcement rules, as the value of IPRs is strongly linked to their effective enforcement.

5.7 SUB-STUDY F - RESEARCH AND DEVELOPMENT OF NEW SUBSTANCES

5.7.1 Presentation

Prof. Klaus Kümmerer opened his speech, outlining core challenges related to chemicals management, in particular the high number and increasingly complex substances and materials on the EU market. Against this background, the chemical industry should innovate towards non-toxic, sustainable solutions. Targeted substance design, as implemented in the pharmaceutical industry (rational drug design), and using in silico tools could be one option to meet this challenge.

Substance design needs guidance on the term "toxic" according to Prof. Kümmerer. Explanation is needed on what are relevant properties (e.g. biochemical or behavioural endpoints, shape of substances and materials) and what should be the protection goal (cells, organisms, ecosystems etc.). From the business perspective, stability / persistence is often assumed as an essential property, as complete mineralization of a compound in the environment would signify a lack of exposure; i.e. a certain toxicity could be acceptable for fully degradable substances. Considering the "end of life" of a molecule at the very beginning, i.e. already in the phase of its conceptualisation, is an essential element of the concept "benign by design". In silico assessment tools could be used to screen substances at the design stage but predictions should be tested after the synthesis of new substances and before further product development takes place. In any case such an approach is a more targeted one and can significantly reduce time to market, maybe also time and money for testing and authorization. That could be also an incentive for chemical industries to develop new compounds with the above mentioned properties.

Prof. Kümmerer reminded that lack of toxicity is only one of the 12 principles of "Green Chemistry" and that the chemical industry should provide "sustainable contributions in a sustainable manner". Only then one could speak of sustainable chemistry. This includes a reduction of the dynamics, volume and heterogeneity of substance and material flows. Consequently, he recommended including additional considerations on environmental impacts from chemicals production and use as well as ethical and economic aspects.

One business model to reduce overall exposures to toxic substances is the concept of chemical leasing, which is promoted, among others, by UNIDO. Chemical leasing would make best use of the chemical industry's competences and create synergies in converging the suppliers' and buyers' interests: the function should be achieved rather than a substance be sold.

5.7.2 Break out group

The participants in the break out group stressed that the term "non-toxic" needs to be defined in order to guide the development of new substances. However, stakeholders agreed that this is (also) a political decision and the issue was therefore not further discussed.

A stakeholder envisaged three overarching goals for 2050. Substances on the market are:

- able to satisfy societal needs;
- safe in their uses;
- "gone" after their use.

According to the group's feedback, innovation drivers for substitution largely overlap with drivers for the development of new substances. Stakeholders could not specify outstanding criteria or situations for taking the decision to rather develop a new substance than researching if existing substances could be used[4]. One (obvious) reason described by the participants was a lack of suitable alternatives.

The group discussed the model of the substance development process introduced from the sub-study and recommended amending it in several aspects. The main comments were:

- Focus on the first three steps, because only these relate to unique aspects of substance development, whereas the other steps are "regular business";
- Whereas the steps may be similar now and in the future (2050), the focus of what would be considered and guiding decision making would / should shift within each step.
  - The needed function should be the focus when considering phase-out / replacement of substances. This may also lead to non-chemical innovations / substitution.
  - Currently, the prevention of hazardous properties follows the technical feasibility assessment in many companies. In the future, these steps should be carried out at least in parallel, also to avoid costs.
  - (Future) legal requirements and certification needs should be considered early in the substance design stage as they also guide the assessment of needed properties.
  - Recyclability and/or (lack of need for) disposal of substances should be integrated early in the design phase.

Error! Reference source not found. presents the revised model process.

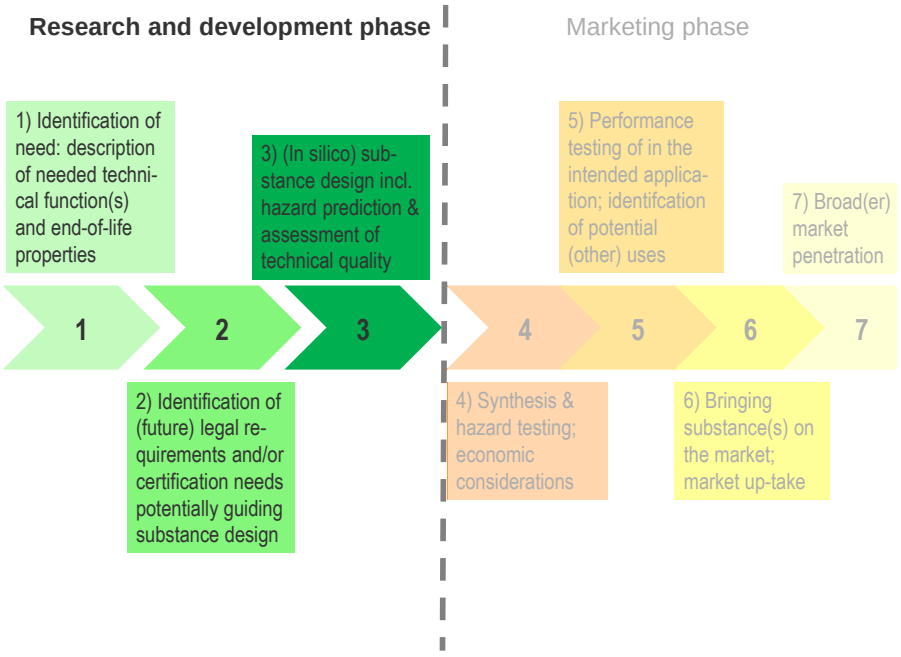


Figure 1: Revised figure illustrating the stage model for the development of new, non-toxic substances

Main barriers for companies to invest in the development of new, non-toxic substances mentioned during the break out session are:

- Existing facilities and equipment largely determine the processes and products; the production of new/different chemicals would require large investments from companies; there is a high degree of (understandable) resistance to take this risk.

[4] However, it was reported that, in order to contain risks, innovation is often incremental and that bigger innovations depend on basic new ideas and inventions, which are more difficult to achieve.

- Downstream users have difficulties in identifying companies that could supply new, non-toxic substances if these companies / actors are not already part of their supply chains[5]
- Change-over costs might be particularly high for new, non-toxic substances that replace existing (commodity) substances; the lack of internalization of environmental and health costs from production and use of toxic substances lead to unrealistically low costs for the toxic substances.
- Lack of education:
  - chemists are not sufficiently trained on how to use the available tools for in silico substance development; tools are comparatively new, available in differing quality (including some that are not recommended for use); some of them are expensive, whereas others are not;
  - substance development requires transdisciplinary cooperation; each profession should know enough of the other, to facilitate understanding each other and organise an efficient, common work process;
  - deciders in all types of enterprises should be educated in the opportunities and benefits of new, non-toxic (or sustainable) chemistry to promote initiatives in this direction from all supply chain stages. This might also pose new business opportunities, such as patents or products with improved functionalities
- Lack of cooperation between universities and companies[6];
- The issue of non-toxic substances is perceived as of low profile and priority, other topics are more important and therefore became focal aspects in R&D.
- It is unclear, what would be a substance „safe enough to use".

The participants in the break out group were unsure, if there is actually a lack of research funding. Horizon 2020 makes 75 billion Euros available for R&D, including on the development of new substances and materials. As current research is organised in consortia, also SMEs are involved and could obtain their share. Individualised SME funding was not seen as necessary by a number of participants in the break out group. However, the existing opportunities might be used more, if more information and practical support (for grand applications) were provided, in particular to SMEs. Furthermore, encouraging (research) success stories could be published.

Proposals to foster R&D on new, non-toxic substances included:

- Increase legal pressure for substitution (of substance groups), e.g. via the authorisation scheme.
- Link the topic of non-toxic substances to other research issues; make it an integral part of all funded research, if possible.
- Promote considering the use of non-toxic substances if companies „anyway change" their production or products.
- Create a space for innovation and development of new ideas, which is not immediately under pressure to „produce for the market"; i.e. also allow basic research and give freedom / take the risk of not knowing the desired outcome of R&D projects, including by the funding agencies. Create trust in „new thinking" to allow for major innovation.

The stakeholders discussed that new substance development could be initiated anywhere in the supply chain.

There was agreement that toxicologists and chemists should cooperate (very) early in the design process and that more interdisciplinary cooperation would create new ideas and opportunities.

None of the participants stressed a lack of tools for substance design and/or hazard prediction; howev-

[5] It should be noted that in most cases the development of substances is conducted with all supply chain actors participating, in particular where the final use of a substance is in an article, because all processes need to be able to work with the new substance and hence all actors must be involved. This step follows the identification of a potential supplier.

[6] This was not supported by all participants; one university actor pointed out that also basic research (without industry participation and clear development goals for substances) would be necessary. Otherwise, i.e. if there was no freedom for research, universities could not create really new ideas and related innovations.

er, better data to improve these tools were mentioned as important deficit, in particular with regard to the predictability of persistence. In addition, the accessibility of design tools, in particular for SME (costs!) could be increased.

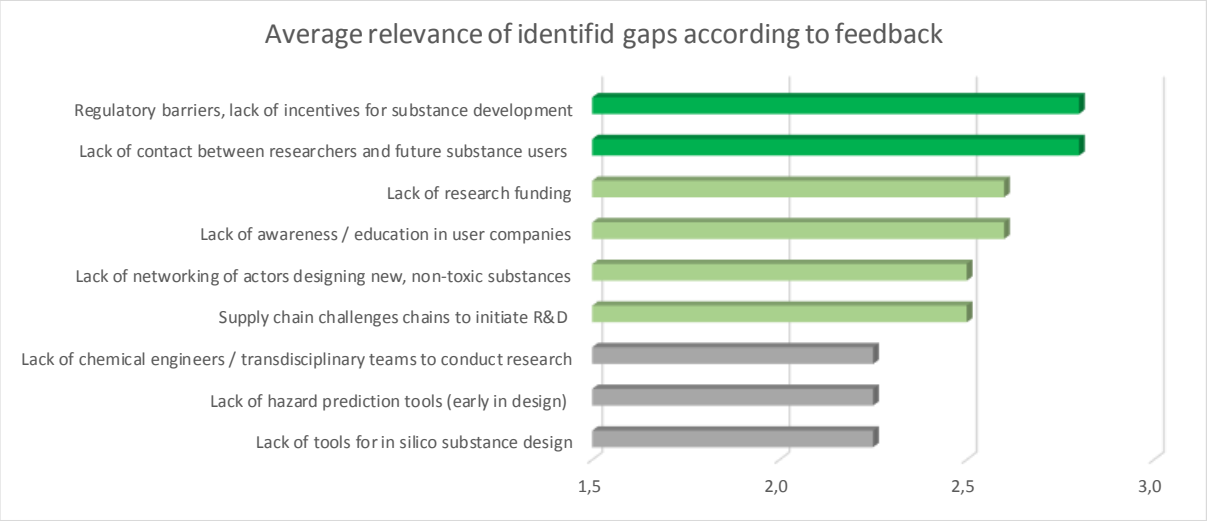
The break out group concluded that the design of new, non-toxic substances is a moving target, implying the need to define and review potential progress indicators flexibly. Furthermore, it was emphasized that the chemical industry's activities should be measured in the context of sustainability, including aspects of environmental soundness, social and ethical aspects as well as (macro)economic considerations; hence highlighting the need for integrating additional aspects into the design process.

5.7.3 Written feedback provided after the workshop

Five feedback forms were received:

- Ministry of the Environment and Ministry of Social Affairs and Health (FI)
- FPS Health, Food chain safety and Environment (BE)
- DuPont
- EEB
- Chemtrust

The following Figure shows the average relevance assigned to the identified gaps

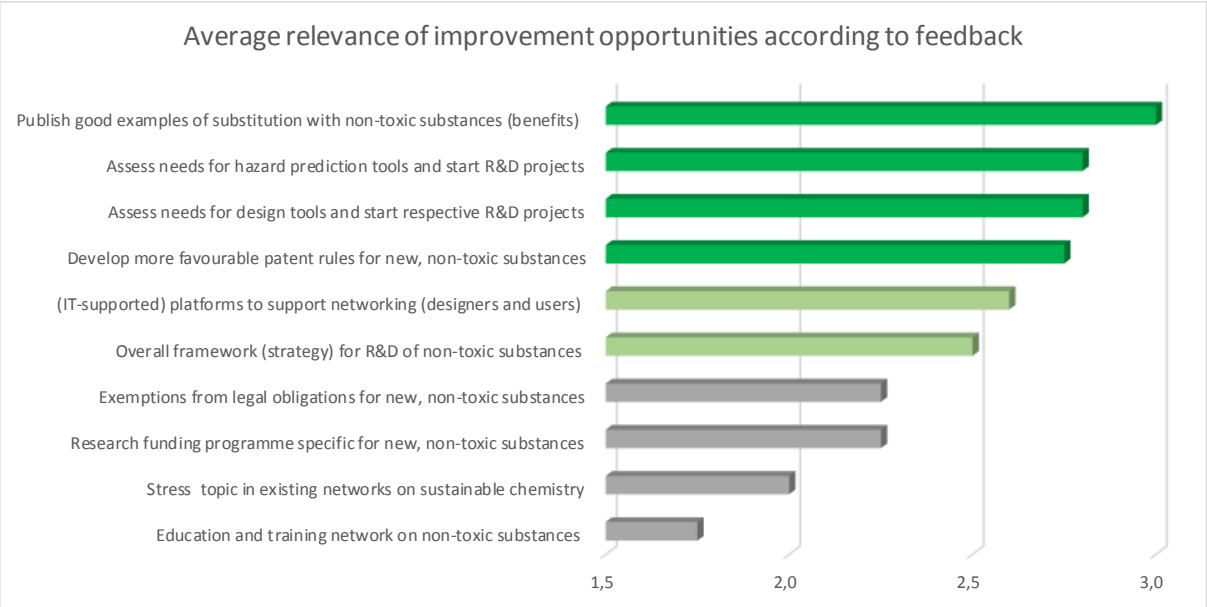


More regulatory incentives and opportunities of suppliers and users of new, non-toxic substances are evaluated as most important gaps, closely followed by lack of research funding and lack of awareness. Also lack of networking and supply chain coordination / communication were identified as important gaps.

Comments on tools pointed out that these are available and should be improved but the consequences of them "not being perfect" are so low, that these aspects did not get a high priority[7].

The improvement opportunities were evaluated as illustrated in the following figure.

[7] Only two stakeholders evaluated the relevance of these tools, however.



In contrast to the evaluation of gaps and deficits, the work on hazard prediction and in silico substance design tools is evaluated as important. Furthermore, the low relevance assigned to awareness raising and education/training does not reflect the discussions at the workshop or the information identified in literature.

Supportive measures, such as an overall framework, patent rules and IT-supported networking are ranked as of medium importance.

In viewing this feedback, one should keep in mind that it is not representative, as very few stakeholders commented. However, overall, the feedback matches the discussion in the break-out group.

Annex: Detailed tables with comments received

Gap/deficit		FI	CT	EEB	BE	Du-Pont	Main (negative) consequences of the gap/deficit regarding a non-toxic environment
Lack of tools for in silico substance design	2,3	2	3	2		2	Negative: testing needed; Tools exist but need improvement (2)
Lack of tools to predict / exclude substance hazards early in the design phase	2,3	2	3	2		2	Negative: testing needed for each endpoint; attention to modifying existing tools according to needs, grouping not too rough Tools should also consider recyclability
Lack of contact between researchers and future users of new, non-toxic chemicals	2,6	3	3	3	3	1	The development of new substances is always demand driven Research should focus on substances not (yet) meeting technical demands
Lack of research funding	2,5	3	3	3		1	Total amount of funding is high; rather a question of which projects should receive the funding
Lack of networking of actors designing new, non-toxic substances	2,8	3	3	3	3	2	Dialogue and discussion opportunities are important to efficiently develop alternatives Information on alternatives is not shared
Lack of awareness / education in user companies	2,6	3	3	3	3	1	Low awareness of SMEs and converters; education to be improved in universities and high-school (2)
Lack of chemical engineers / transdisciplinary teams to conduct research	2,3	2	3	1		3	Education of chemists / toxicologists important
Challenges in supply chains to initiate research for new, non-toxic substances	2,5	2	3	3		2	SMEs lack resources to conduct long-during research Market demand is not a strong enough driver due to the high costs and risks
Regulatory barriers, lack of incentives to develop new, non-toxic substances	2,8	3	3	3	3	2	Freedom of creativity and thinking to be supported by regulation; no "fostering of blockbusters" necessary; mainly lack of incentives and lack of enforcement (REACH) Insufficient actin on toxic chemicals Implementation of legislation necessary, in particular authorisation, to create a predictable business environment

Idea for improvement		FI	CT	EEB	BE	Du Pont	What is the strength, what is the weakness of the idea for improvement?
Overall framework (strategy) for R&D of non-toxic substances	2,8	3	3	3		2	Might help, but should be flexible Should promote development of new, non-toxic substances & availability of information to select alternatives.
Assess needs for design tools and start respective R&D projects	2,3	2	3	1		3	Several tools are necessary, to be used in parallel with other (hazard prediction) methods, such as grouping A lot of tools are already available and experience in the pharmaceutical industry
Assess needs for hazard prediction tools and start R&D projects	2,3	2	3	1		3	Several tools are necessary, to be used in parallel with other hazard prediction methods, such as grouping Hazard prediction tools are widely available, for example compiled in the OECD QSAR Toolbox. New tools may be needed to address the recyclability of the substance to promote non-toxic material cycles.
(IT-supported) platforms to support networking (designers and users)	2,6	2	3	3	3	2	Helps information sharing, consult stakeholders during development phase A web based platform to identify required technical functions to substitute SVHC and provide information on alternatives
Research funding programme specific for new, non-toxic substances	2,5	3	3	3		1	Stimulate investment in alternatives
Stress the topic in existing networks on sustainable chemistry	2,8	3	3	3	3	2	May help integrating idea into circular economy Provide information on substitution
Education and training network on non-toxic substances	2,8	3	3	2	3	3	Important, start now and continue for a long time
Exemptions from legal obligations for new, non-toxic substances	2,0	2	1	3		2	Supports innovation and flexibility (has to be clear, simple and practical) Registrants considered DecaBDE as non-hazardous, hence take care Rather work with market instruments, such as taxes and fees
Develop more favourable patent rules for new, non-toxic substances	1,8	1	1	3		2	Supports innovation and flexibility (has to be clear, simple and practical) (2)
Publish good examples of substitution with non-toxic substances (benefits)	3,0	3	3	3	3	3	Crucial to help stakeholders, also show what should NOT happen (regrettable substitution) Influence market demand in a positive way. Increase awareness of SME and public.

Additional comments

The sub-study should relate to non-toxic solutions, hence including non-chemical alternatives.

Better enforcement of REACH and other chemicals legislation is needed.

5.8 SUB-STUDY G – CREATION OF A JOINT EARLY WARNING SYSTEM

5.8.1 Introduction

During the workshop a presentation about ECHA's view on early warning system (EWS) and how the work done by ECHA could contribute was given by Jukka Malm (Deputy Executive Director at the European Chemicals Agency). During the break-out session the RIVM gave a presentation (Yuri Bruinen de Bruin, Joost Bakker) about the findings of the review of existing EWS. Also, during the discussions and the break-out sessions an inventory was made of the expectations of what an EWS should contain and facilitate.

5.8.2 Inventory of EWS expectations

During the breakout session on the creation of an EWS the expectations of the functioning and ability of an EWS was discussed. The outcome was that an EWS should be able to:

- Forecast;
- Prevent;
- Facilitate safe products (use/design);
- Connect data;
- Identify new end-points;
- Be flexible;
- Include vulnerable groups (children, workers);
- Have a multiple compartment (air, water and soil) focus;
- Include post-marketing surveillance;
- Function on proper methods and procedures for signal identification;
- Include measuring strategies such as analytical chemistry;
- Connect to circular economy;
- Facilitate follow-up choosing the best risk management measure or policy options;
- Involve industry and public;
- Include ranking/scoring systems based on for instance (Q)SARs;
- Able to identify substances with PBT-properties;
- Facilitate informed-decision making;
- Use input from enforcement authorities/inspectors;
- Create for instance a high score for situations with signals but with little information, think about ways on how to deal with it;
- Include alternative or new end-points such as neurotoxicity, immunotoxicity, biodiversity loss or ecosystem risk for prioritisation.

Other issues that were discussed during the presentation were:

-
- It should be clear what the aim is of the system, what to protect;
- The focus is traditionally on target groups such as authorities and policy makers, what about others?
- Consider different ways to prioritise. This also relates to how different pieces of legislation function for instance REACH and Water Framework Directive look at environmental risk defined as the exceedance of no-effect-levels or quality standards;
- Look at systems that are not 'working' or useful in the identification of emerging risks for instance RAPEX and targeted analysis where to focus is on the knowns;
- Different methodologies should be identified for each building block of the system;
- Going through the whole procedure might take too long, essential to find the right balance between timely action and gathering data for building a case;
- Information needs should be defined.

5.8.3 Basic building components of an EU EWS

In general, the review found that the basic components of an EWS are similar for all existing ESWs and it was agreed that an EWS should also entail similar building components as presented in the figure presented below.

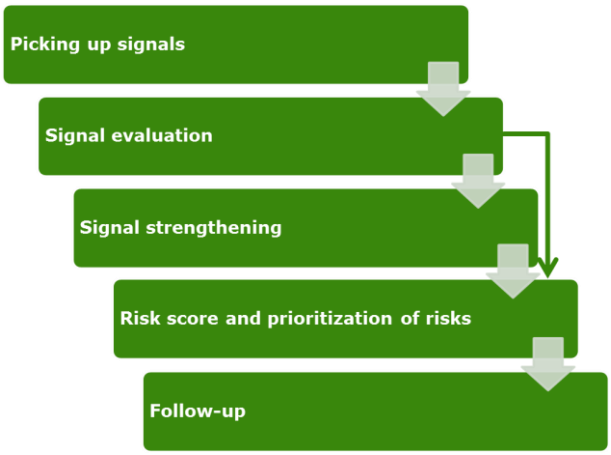


Figure 2: Basic building components of an EWS.

The group was divided into three smaller groups during which the contents of the building components was discussed. In the following paragraph, the outcomes of those break-out sessions are presented.

5.8.4 Contents of the building components

5.8.4.1 Picking up signals

Key to an EWS is flexibility and (self-learning/learn from failures) building on existing experiences (e.g. drug side effects, data collection from citizens) to deal with background noise.

Involvement stakeholders:
The picking up of signals should involve proper stakeholders, like physicians, trade unions, companies, physicians ((suspected-)disease reporting), inspectors, ECHA and other EU Agency. In addition, EU databases should be data-mined.

European central focal point/depository
There should be a central point and platform for all countries including a service to translate the language to English. A harmonized template should facilitate the reporter to describe the signal identification the main parameters being input for the scientific community.

Focus
The focus should be on both human and environment health-incorporating citizens (workers, consumers, and environmental media).

5.8.4.2 Signal Evaluation and Strengthening

Evaluation: Filtering out noise
The focus of these components should be on how to filter out signal noise:

- Filter-out negative irrelevant ones, minimise false negatives

- How to filter out?
  - There should be a link between the observed exposure and effect or the other way around
  - Expert consultation need for signals that are related to either only effects or exposure in order to link exposure and effect.
  - Plausibility check (define criteria)
  - Causality criteria (simplified Bradfort Hill criteria)

Strengthening: The strengthening should include criteria such as:

- Scale/number of affected people
- Severity of effects
- Different signals (from various entries/sources)

Inclusion novel end-points/criteria
New ways of toxicity assessment and new end-points should be incorporated, like inclusion of neurotoxicity criteria
New ways of risk assessment should also be considered, like inclusion of ecosystem risks, planetary boundaries, loss of biodiversity, appreciation of nature linking to ecosystem services.

5.8.4.3 Risk Score and prioritization of risks (human and environment)

Designed for the scope
Support decisions on which actions to take

Scoring mechanism
The risk is a function of (probability, hazard)*factors in which:

- Probability is a combination between use, exposure and practices
- Hazard entails chronic vs. acute toxicity
- Factors applied if there are triggers
  - Relevance of data? (how old is it)
  - Quality of the data
  - Irreversibility (vP, vB)
  - Fast increase/change in use pattern
  - Critical types of exposures (food, water, more time indoor, dust)
  - Vulnerable groups, timing of exposure, SVHCs/restricted substances
  - Inclusion novel end-points/criteria (see Signal Evaluation and Strengthening)

Testing of functioning
These components should be tested using a test dataset with 'knowns and comparing that to the outcomes of 'unknowns' (known risks vs. unknown risks)

Threshold criteria
An EWS should entail threshold criteria to guide users when to act.

5.8.5 Evaluation of feedback forms

Four forms were send as feedback by (1) Veronique Garny from Cefic (Industry), (2) Violaine Verougstraete form Eurometaux (Industry) (3) Prikklo Kivela and Hanna Korhonen from the Finish Ministry of the Environment and Ministry of Social Affairs and Health (Public body) and (4) Belgian REACH CA from FPS Health, Food chain safety and Environment – BE (Public body). The input of the four forms on Gaps/deficits are given in the table below. This table also includes our own (summa-

rized) input obtained at the Workshop. The second table provides an overview of the input of the four feedback forms on Improvement and Opportunities, including the RIVM input obtained at the Workshop.

Feedback on Gaps/deficit

Gap no	Gap/deficit	Relevance (from 1 to 3); Main (negative) consequences of the gap/deficit regarding a non-toxic environment				
		Cefic	**Eurometaux**	**Belgian REACH**	**VM/STM (Finland)**	**RIVM**
1	Problem in funding of expertise centres, where professionals can go to study a possible work-related health effect.	(1); The second option seems more adequate	(1); Duplication with function occupational medicine /hygiene. Can we not make better use of that network?	No info	(1);	(2); Until at a funding level the need for good early warning systems is not yet understood the need for a good plan is of upmost important. Without funding nothing can be done and diseases with high costs cannot be prevented (incl. claims).
2	Lack of an international platform working on work related health effects and occupational diseases.	(3); This would be a first thing to settle based on national expertise	(1);	No info	(1);	(3); Stakeholders who are active do double work and cannot share and connect experiences. The burden of disease might get higher and additional costs will be made.
3	No information on costs of early warning systems was found.	(3); The cost could be tremendous if the system is not focussed; biomonitoring costs can help as surrogate	(2);	No info	(1);	(2); In order to increase the likelihood of getting funding the EWS developers should try to make an estimation of the costs.
4	No system has been identified that interlinks all areas of focus.	(1); Too complex	(2);	(3); Lack of efficiency and effectiveness	(1);	(3); At least a system that understands and is aware of what plays a role or what is going on in the various focus areas is desirable.
5	Early indications of a systematic review of exposure and risk assessment procedures in current early warning systems raise questions about its effectiveness.	(2); Need to focus on most (potentially) dangerous chemicals	(1); Need for a good filtering system to avoid both false negatives and false positives	No info	(2);	(3) Frequently the substances and situations with the highest score are also the substances and situation with most information (norms, classification, exposure data (monitoring, measurements, etc.). Maybe substance and situation without lots of information should get the highest score, however, based on some sort of pre filter/assessment.
6	Lack of information frequently jeopardizes the attribution of an appropriate ranking during the prioritization phase.	(2); QSAR can be used for ranking	(2);	(3); If lack of info, often no action	(3);	(3); See above
7	An identified gap is the communication stage. The focus is on the identification of new or emerging risks and proposing suitable risk management measures.	(2); This comes next after identification of harm or potential harm	(2);	(3); Communication is key. Info are already available, but not always communicated between authorities DGs inside of the Commission	(3);	(3); Also decision makers want to based decisions on as much as possible information and facts. Proper communication with decision makers and the public from scientists should be developed. Think of the early warnings of climate change (60s/70s) and the process to internationally develop policy/public opinion. More closely related to substances and health is the process to develop policy on asbestos (120 years).

Improvement opportunities

Idea for improvement	Relevance (1 to 3); Gap no. it would address [see above]; What is the strength, what is the weakness of the idea for improvement?				
	Cefic	**Eurometaux**	**Belgian REACH**	**VM/STM (Finland)**	**RIVM**
More cooperation/adjustment (exchange of information) at international level	(2); This could speed the process	(2); [2]; Strength: improving consistency and plausibility (and thereby could decrease time lag)	(1); communication is key, but first start at EU level	(3);	(3); Individual, cultural, stakeholder differences and interests could block progress.
The set-up of a central (European) system serving in the in- and output information of NERCs	(2) Issue of cost to clarify	(1); [2, 7]	(1); More communication between existing systems (Cosmetic, water framework, REACH….) is needed	(1);	(3); Better and quicker information on the diversity and severity on a geographical basis. Suitable location best fitting solutions can be developed
Decision to take measures at a European level	(1); Only after priorities are determined	(1); [4, 7]	(3);	(2);	(3); Inactive but willing stakeholders get support. Active stakeholders do not get the pollution and health problems due to unwilling stakeholder into their territories.
Improvement of existing Risk Assessment by incorporating additional and more specific end points, e.g. on neurotoxicity, endocrine disruption	(2);	.	(3);	(1);	(3); Potential enormous improvement in terms of source mitigation instead of end of pipe thinking (which could be the current RA process not taking on board early life stages after and even pre conception.
- Define purpose and scope of the early warning system	(2);	(2); [5]		(3);	(3); See contents of building components
- Select suitable approaches for detecting signals	(2);	(1); [5]		(3);	(3); See contents of building components
- Generate overview of data sources for selection and prioritisation	(2); Should be transparent	(2); [6]; Should be transparent	(3); More transparency	(3);	(3); See contents of building components
- Develop blue print for method of prioritisation	(2);Should be transparent and communicated	(2); [6]; Should be transparent and communicated		(3);	(3); See contents of building components
- Exploring possibilities on how to organise and operationalise an early warning system	(2);	(1);		(3);	(3); See contents of building components
- Define future actions to utilize data sources	(2);		(3); Better use and follow-up of the available information	(2);	(3); See contents of building components
Investigate the feasibility interlinking all areas of focus, environment, consumers	(1); too complex	(2); [2, 4]	(3); Communication between authorities is	(2);	(3); Many times an identified problem in one focus area sooner or later becomes a problem for another

Idea for improvement	Relevance (1 to 3); Gap no. it would address [see above]; What is the strength, what is the weakness of the idea for improvement?				
and worker.			key		focus area (e.g. first workers, later the environment). Interlinking all areas means to make better use of prevention (and thus cost saving).

5.8.6 Examples of well-functioning legislation, non-legal measures and actions

Cefic: Take account of the drug reporting side effects systems in place and ensure filtering of the information to make it relevant.

5.8.7 Additional considerations (RIVM)

General aims of an EWS:

- Policy means, innovation and competitiveness: reviewing product, process, organisational and marketing innovations and looking at possible incentives for promoting these that contribute to a non-toxic environment, and the impacts that environmental policies have;
- R&D of new, non-toxic substances: increasing supply of new, non-toxic substances, or substances of lower toxicity as alternatives to toxic substances and supporting development of improved materials; and
- early warning systems for emerging chemical risks: exploring whether it is possible to establish an EU-wide "early warning system" for newly emerging chemical risks, which could be risk to environment, workplace health or consumers.

Instruments identified to be part of an EWS:

Guidance

- Provision of guidance for authorities and industry for best-fit exposure science use for regulatory risk assessment
- Provision of guidance how to best use exposure science to protect vulnerable groups
- Provision of guidance how to substitute chemicals within the frame of a -on toxic environment
- Provision of overview of information resources on tools, methods and databases
- Provision on exposure grouping of use, situations, chemicals applicable for substitution or during the design phase of new green chemicals
- Provision of guidance on the identification of product ingredients and exposure likelihood
- Provision of guidance for European and global SME's to choose for sustainable chemicals

Tools

- Provision of accessible tools for better prioritization and selection of chemicals in need for more detailed information and data (an early warning system)
- Provision of regulatory tools to support green choices
- Provision of indicators for non-toxic substances.

Education and communication tools

- Provision of education to integrate toxicity (exposure and risk) thinking within designing molecules and products
- Sector tools to overcome barriers for collaboration and competition tools.

An EWS possibly also needs to look at the connection of the four sub study themes being substitution and grouping of chemicals (avoiding "regrettable substitutions"), designing non-toxic products and material cycles, focus on exposure-prevention of children and other vulnerable groups, stopping the use and production of very persistent chemicals.

Make sure the goal is a population-driven and an accepted way forward to a healthy environment by sharing wealth and prosperity. Make sure this initiative is coordinated by stakeholders from all disciplines and levels of society. Stimulate new comers in the field who share similar goals and create opportunities that they can survive and grow in a market with existing and traditional huge corporations who did fail to prove to share similar goals.

6 ANNEX I – LIST OF REGISTERED AND CONFIRMED PARTICIPANTS

	Title	First Name	Name	Company	Attendance
1	Mr	Jesus	Alquézar	European Commission- DG Research and Innovation	Days 1 and 2
2	Dr	Tho-mas	Backhaus	University of Gothenburg	Days 1 and 2
3	Dr	Tobias	Bahr	ACEA	Days 1 and 2
4	Ms	Jelena	Bakusic	KU Leuven	Days 1 and 2
5	Ms	Els	Bedert	EuroCommerce	Days 1 and 2
6	Mr	Sami	Belkhiria	Dow Corning Europe SA	Days 1 and 2
7	Mr	Domi-nique	BILLERET	Toy Industries of Europe	Days 1 and 2
8	Dr	Ana maria	Blass Rico	European Commission	Days 1 and 2
9	Ms	Jonath	Blokker-Rowe	European Commission, DG ENV	
10	Dr	Chris-topher	Blum	German Environment Agency	Days 1 and 2
11	Mr	Kevin	Buckley	Health and Safety Authority	Days 1 and 2
12	Mr	Vito	Buonsante	ClientEarth	Days 1 and 2
13	Mr	Luke	Buxton	Chemical Watch	Days 1 and 2
14	Mr	Darren	Byrne	Ministry of Environment (Ireland)	Days 1 and 2
15	Mr	Peter	Cech	European Recycling Industries' Confederation (EuRIC)	Days 1 and 2
16	Ms	Helen	Clayton	European Commission	Days 1 and 2
17	Mr	Kevin	Cockshott	AGC Chemicals Europe	Days 1 and 2
18	Ms	Mara	Curaba	federal Public Service of health, food chain safety and environment	Days 1 and 2
19	Ms	Cathe-line	Dantinne	FPS Health...& Environment -Belgium	Days 1 and 2
20	Ms	Cristina	de Avila	European Commission, DG ENV	
21	Mr	Jack	de Bruijn	ECHA	Days 1 and 2
22	Ms	Timo-teo	de la Fuente	European Commission	Days 1 and 2
23	Ms	Anne-lies	den Boer	Wemos Foundation	Days 1 and 2
24	Ms	Maria Chiara	Detragiache	Orgalime	Days 1 and 2
25	Ms	Marie-Chris-tine	Dewolf	Thamagoria	Days 1 and 2
26	Ms	Shima	Dobel	Danish Environmental Protection Agency	Days 1 and 2
27	Ms	Joan-na	Drake	European Commission, DG ENV	
28	Ms	Shiraz	DROMI ZERNITSKY	Israeli Mission to the EU	Days 1 and 2
29	Mr	Timo-thy	Eden	PAN - Europe	Days 1 and 2
30	Mr	Eric	Edmonds	Toy Industries of Europe	Days 1 and 2
31	Dr	Peter	Fantke	Technical University of Denmark (DTU)	Days 1 and 2
32	Dr	Franz	Fiala	ANEC/Consumer Council ASI	Days 1 and 2
33	Mr	Kevin	Flowers	European Commission, DG ENV	
34	Mr	Silvia	Freni Sterrantino	Plastics Recyclers Europe	Day 2
35	Mr	Mateo	Gallego	European Commission	Days 1 and 2
36	Ms	Véro-nique	GARNY	Cefic	Days 1 and 2
37	Dr	Cecile	Gonzalez	International Fragrance Association	Days 1 and 2
38	Ms	teresa	goulao	Portuguese Permanent Representation to the	Days 1 and 2

	Title	First Name	Name	Company	Attendance
				EU	
39	Mr	Chris-tian	Heidorn	European Commission, DG ENV	
40	Mr	Mehdi	Hocine	European Commission	Days 1 and 2
41	Ms	Rikke	Holmberg	Danish EPA	Days 1 and 2
42	Ms	Daph-né	Hoyaux	Federal Public Service Economy	Days 1 and 2
43	Dr	Mary	Iakovidou	Swedish Chemicals Agency	Days 1 and 2
44	Ms	Marija	Jevtic	University of Novi Sad	Days 1 and 2
45	Ms	Anne-Marie	Johansson	The Swedish Chemicals Agency	Days 1 and 2
46	Ms	Anna Maria	Kaczmarek	Kreab	Days 1 and 2
47	Ms	Elina	KARHU	ECHA	Days 1 and 2
48	Mr	Emma-ma-nuel	Katrakis	EuRIC	Days 1 and 2
49	Ms	Karin	Kilian	European Commission, DG ENV	
50	Ms	Pirkko	Kivelä	MInistry of the Environment	Days 1 and 2
51	Ms	Hanna	Korhonen	Finnish Ministry of Social Affairs and Health	Days 1 and 2
52	Dr	Peter	Korytar	Permanent Representation of the Slovak Re-public	Days 1 and 2
53	Mr	Charle s	Laroche	IFRA	Days 1 and 2
54	Mr	Otto	Linher	European Commission, DG GROW	
55	Dr	Hélène	Loonen	EEB	Days 1 and 2
56	Ms	Angeli-ki	Lysimachou	Pesticide Action Network Europe (PAN Europe)	Days 1 and 2
57	Ms	Adela	Maghear	HCWH Europe	Days 1 and 2
58	Dr	Giu-seppe	Malinverno	Solvay	Days 1 and 2
59	Mr	Wesley	Martin	Foreign Commercial Service, United States Mission to the European Union	Days 1 and 2
60	Dr	Ol-wenn	Martin	Brunel University London	Days 1 and 2
61	Mr	Bengt	Mattson	EFPIA	Days 1 and 2
62	Ms	Sylvia	Maurer	BEUC, The European Consumer Organisation	Days 1 and 2
63	Mr	Helmut	Maurer	EU COM	Days 1 and 2
64	Ms	Alicia	McCarthy	ETUI	Days 1 and 2
65	Mr	Hans	Meijer	Ministry of Infrastructure and the Environment	Days 1 and 2
66	Mr	Grego-ry	Moore	Swedish Chemicals Agency	Days 1 and 2
67	Mr	Pelle	Moos	BEUC, The European Consumer Organisation	Day 1
68	Mr	Denis	Mottet	European Chemicals Agency (ECHA)	Days 1 and 2
69	Mr	Tony	Musu	European Trade Union Institute	Days 1 and 2
70	Mr	Takahi-ro	Oki	Daikin Europe	Days 1 and 2
71	Ms	Maria Anto-nietta	Orrù	Italian National Institute for Health	Days 1 and 2
72	Dr	An-drea	Paetz	Bayer AG	Days 1 and 2
73	Ms	Nishma	Patel	Chemical Industry Association	Days 1 and 2
74	Dr	Marie-Amelie	Paul	DuPont	Days 1 and 2
75	Mr	Je-rome	Pero	FESI	Days 1 and 2
76	Ms	Carla	Pinto	DG ENV	Days 1 and 2

	Title	First Name	Name	Company	Attendance
77	Mr	Mau-rits-Jan	Prinz	European Commission	Days 1 and 2
78	Dr	Jacqu es	Ragot	Covestro AG	Days 1 and 2
79	Mr	Ge-raint	Roberts	Chemical Watch	Days 1 and 2
80	Ms	Mar-tine	RÖHL	SPF santé publique	Days 1 and 2
81	Ms	Dolores	Romano	European Environmental Bureau	Days 1 and 2
82	Mr	Robert	Ruzicka	Permanent Representation of the Slovak Re-public to the European Union	Days 1 and 2
83	Mr	Kestutis	Sadauskas	European Commission, DG ENV	
84	Dr	Serena	Santoro	Italian Ministry for the Environment, Land and Sea	Days 1 and 2
85	Mr	Mauro	Scalia	Euratex	Day 1
86	Mr	Stefan	Scheuer	Stefan Scheuer SPRL	Day 2
87	Mr	Tho-mas	Schram	Counsellor	Days 1 and 2
88	Dr	Agnes	Schulte	Federal Institute for risk assessment (BfR)	Days 1 and 2
89	Mr	Mark	Schwägler	Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB)	Day 2
90	Ms	Elisa	Setién	European Federation for Construction Chemi-cals (EFCC)	Day 2
91	Dr	Soballa	Volker	EVONIK Industries AG	Days 1 and 2
92	Dr	Hans-Chris-tian	Stolzenberg	German Environment Agency (UBA), Interna-tional Chemicals Management	Days 1 and 2
93	Dr	Marko	Susnik	UEAPME/WKÖ	Days 1 and 2
94	Ms	Alek-sandra	Terzieva	CIEL	Days 1 and 2
95	Ms	Bever-ley	Thorpe	Clean Production Action	Days 1 and 2
96	Ms	Moni-ca	Törnlund	Ministry of the Environment and Energy	Days 1 and 2
97	Mr	Valters	Toropovs	Baltic Environmental Forum Latvia	Days 1 and 2
98	Ms	Xenia	Trier	EEA	Days 1 and 2
99	Mr	Antho-ny	Tweedale	R.I.S.K. Consultancy	Day 2
100	Dr	Kerstin	Ulrich	BASF SE	Days 1 and 2
101	Mr	Albert	Vallejo	Mattel	Days 1 and 2
102	Mr	Jurgen	van Belle	Ministry of Health, Welfare and Sport	Days 1 and 2
103	Ms	Lisette	van Vliet	Health & Environment Alliance (HEAL) NGO	Day 2
104	Mr	Phi-lippe	Vandendaele	HCWH Europe	Days 1 and 2
105	Ms	Silvia	Vecchione	ACEA	Days 1 and 2
106	Ms	Vio-laine	Verougstraete	Eurometaux	Days 1 and 2
107	Mr	Stefa-no	Vettorazzi	European Commission	Days 1 and 2
108	Ms	Lena	Vierke	German Environment Agency	Days 1 and 2
109	Dr	Zha-nyun	Wang	ETH Zurich	Days 1 and 2

	Title	First Name	Name	Company	Attendance
110	Dr	Meng-jiao	Wang	Greenpeace	Days 1 and 2
111	Dr	Wolf-gang	Weber	BASF	Days 1 and 2
112	Dr	Roland	Weber	POPs Environmental Consulting	Days 1 and 2
113	Mr	Hans	Wendschlag	Hewlett-Packard	Days 1 and 2
114	Dr	Mau-rice	Whelan	European Commission Joint Research Centre	Days 1 and 2
115	Dr	An-drew	Worth	European Commission - Joint Research Centre	Days 1 and 2
116	Ms	Jo-hanna	Wurbs	Umweltbundesamt Germany	Days 1 and 2
117	Ms	Valérie	Xhonneux	Inter-Environnement Wallonie	Days 1 and 2
118	Ms	Marta	Yuste Prieto	CECED	Day 2

7 ANNEX II - WORKSHOP MATERIALS

7.1 WORKSHOP MATERIAL FOR SUB-STUDY A ON SUBSTITUTION OF HAZARDOUS CHEMICALS AND GROUPING OF CHEMICALS

7.1.1 Aim

The sub-study on substitution and grouping of chemicals aims to provide information on:

- The status quo of the application/implementation of the substitution principle as well as substitution in general in the field of chemicals, on the basis of legislation and other policy measures as well as voluntary work of business and industry. Identify the incentives, driving forces and obstacles;
- The pros and cons of regulatory requirements for the substitution of chemicals, including the effects on overall research and development activities in companies;
- The problems related to the large amount of structurally related chemicals, the management of these in chemicals legislation as well problems related to the users of chemicals and their substitution work;
- The main gaps regarding policy measures, knowledge and access to information.

The description of the current initiatives for the promotion of the substitution of hazardous substances will inform the provision of:

- Ideas for improvement in the short, medium and long term, including possible grouping approaches for chemical policy and substitution, which could contribute to streamlining and improve the level of protection of health and the environment;
- Possible supportive and enabling measures for substitution, in particular, by SMEs.

7.1.2 Scope

Important aspects of a future EU strategy for a non-toxic environment would be to enhance the application of the substitution principle in the policy context, by creating further incentives for substitution of hazardous chemicals at different levels of the value chain.

The substitution principle is already a fundamental aspect of the EU chemicals acquis, having been enshrined in chemical policy, occupational health and safety regulation, product safety and environmental legislation. Different measures are also found at national level, with mandatory reporting schemes, databases to share information on alternatives, guidelines to implement substitution of hazardous chemicals and support for substitution initiatives.

The project team is looking at a wide range of activities and initiatives in order to identify such that might be considered to effectively promote substitution. For the purpose of this study, we are considering three types of substitution:

- By replacing hazardous substances with less hazardous substances;
- By other technological measures; or
- By organisational measures.

While intended to promote sustainability and reduce negative impacts on human health and the

environment, the application of the substitution principle in policy-making may lead to unintended consequences, for example the substitution of one chemical with another which proves to have similar or other negative human health or environmental effects and that, in due course, may be expected to come under regulatory pressure itself, requiring further substitution.

The project team is looking at grouping of chemicals as a possible means to contribute to the avoidance of such "regrettable substitutions".

7.1.3 Gaps and deficits (interim results)

Up to now, the following gaps and deficits have been identified through the review of the relevant literature (it should be noted that different stakeholder groups have diverging opinions; what is regarded as a deficit by one stakeholder group, may be considered an incentive by another stakeholder group):

- Gaps in (eco)toxicological information. Despite the entry into force of the REACH Regulation, there are still gaps in (eco)toxicological information, in particular for low production volume substances. These substances may prove to be a good pool of potential alternatives;
- Information gaps on chemicals in articles. Information on the uses and presence of hazardous substances in articles is missing, making risk assessment challenging for all actors and preventing informed choices and focused substitution initiatives by downstream users and consumers;
- Scarce availability of information on alternatives;
- Insufficient risk assessment methodologies. Risk assessment methodologies for the article service life and waste stage are not sufficiently developed to assist all actors;
- REACH authorisation does not cover imported articles: although ECHA must consider if the use of the substance in articles is adequately controlled and if it isn't, prepare a dossier which conforms to the requirement of an Annex XV dossier for restriction (Article 69(2)), some stakeholders suggest that the lack of an automatic restriction on imported articles containing Annex XIV substances may result in a potential competitive disadvantage for the companies opting for substitution. Moreover, if a substance is used only as a process chemical or otherwise is not present in the end product, there will be no impact for imported articles but EU manufacturers have to substitute where non-EU manufacturers don't, possibly leading to competitive disadvantage;
- Insufficient time to identify and develop suitable alternatives. Once a substance comes under regulatory scrutiny, the time to move to suitable alternatives may not be adequate, resulting in regrettable substitutions or in second best solutions (such as minimizing occupational exposure but neglecting environmental fate at the end of life stage);
- Excessive lengthening of the time to market for products containing alternatives. Once an alternative is developed, where product approval by authorities is necessary (e.g. in aerospace or medical devices), this process can prolong excessively the product time to market;
- Administrative burden. The relatively high administrative burden of the legislation (in particular for SMEs) may result in the diversion of resources from R&D to comply with the legislation;
- Limited internalization of human health and environmental costs by the chemical or product manufacturers. For example, chemicals regulated by the Water Framework Directive may leak from products during their life cycle or during the waste stage. However, the costs to clean up such pollution is borne by the wastewater treatment companies and drinking water suppliers and, ultimately, by the citizens;
- Overwhelming and sometimes inconsistent regulatory framework (at EU and national levels).
- Regulatory signals to innovation. The granting of authorisation for the use of substances in

applications for which safer alternatives are available, may stifle, rather than reward, innovation;
- Regulatory uncertainty as regard available alternatives;
- Poor enforcement of the legislation;
- Functionality constraints. A significant proportion of alternatives can be part of the same functional group or a structurally similar group as the original substance, as it is difficult to find the required functionality, properties and qualities when deviating from a certain chemical families or groups. In practice, companies find that product and application innovations come from working closely with customers in understanding their needs and applications, and by making small changes in the composition and purity (e.g. reduced aromatics) of substances and products, which lead to enhanced performance, and/or enhanced health and environmental properties, including the facilitation of compliance, or opening up new applications;
- Access to affordable raw materials. Access to raw materials in the relevant quantities and at the right cost may be an issue. For instance, a major commodity chemical can require as many as six raw materials or feed-stocks, each with its own complex supply chain, which has been developed over many years with huge investment.

7.1.4 Improvement Opportunities

Up to now, the following ideas for improvement have been identified through the literature review:

- Development of an EU-level substance-regulation navigator. This database should include implemented and upcoming international and national legislation by substance/application;
- Increase information requirements for low production volume substances;
- Develop tools to track hazardous chemicals in articles;
- Automatic restriction on imported articles containing authorised substances;
- Make importers pay for imports that are not compliant;
- Enhance the available databases with information on alternatives;
- Extend the available time to identify and move to sustainable alternatives;
- Shorten product safety assessment by public authorities (e.g. product approval for aviation or medical devices);
- Refuse authorisations to substances of very high concern for which alternatives are available on the market;
- Dedicate more resources to enforcement of every aspect of the chemical legislation;
- Start a public debate, involving all relevant stakeholders, on the identification of applications for which the use of certain chemical groups raise concerns that are higher than the benefits delivered;
- Reduction of the administrative burden for SMEs (e.g. more time to comply with the legislation, lower fees, promotion of co-operation networks on substitution initiatives, more funding on R&D);
- Reward/incentivise sustainable substitution;
- Tax the use of hazardous substances;
- Fund further research into chemical product life cycle risk assessment;
- Raising awareness on the benefits of – and stimulate market demand for - safer alternatives;
- Enhance stakeholders' collaboration on substitution initiatives;
- Promote circular economy business models (e.g. chemical leasing);
- Increase transparency and stakeholders' participation in the decision-making process of the Scientific Committees.

7.1.5 Annex - Feedback form

Filled in by

Name:

E-Mail address:

Name of organisation:

Please indicate (X) the type of your organisation				
Public body	**Academia**	**Industry/Commerce**	**NGO**	**Other (pls specify)**

Please send the feedback form back <u>by 16 June</u> to: nontoxicenvironment@milieu.be

7.1.5.1 Gaps/deficits

The main gaps/deficits identified in the sub-study are listed in the table below. How would you rank their relevance? Please rate 1 for 'no or little relevance', 2 for 'medium relevance', 3 for 'high relevance'. Please also add your opinion on what are the main negative consequences of the gap/deficit with regard to the goal of a non-toxic environment.

Gap no	Gap/deficit	Relevance (from 1 to 3)	Main (negative) consequences of the gap/deficit
1	Limited internalisation of the human health and environmental costs of the production, consumption and disposal of chemicals by chemical manufacturers		
2	Lack of (eco)toxicological information, in particular for low volume production substances		
3	Lack of information on chemicals in articles		
4	Risk assessment methodologies for the article service life and waste stage are not sufficiently developed to assist all actors		
5	The REACH authorisation does not cover imported articles, resulting in a potential competitive disadvantage for the companies opting for substitution		
6	Scarce availability of information on alternatives		
7	Once a substance comes under regulatory scrutiny, the time to move to suitable alternatives may not be adequate		
8	Once an alternative is developed, product approval by authorities can prolong excessively the product time		

Gap no	Gap/deficit	Relevance (from 1 to 3)	Main (negative) consequences of the gap/deficit
	to market		
9	High number of EU and national acts regulating chemicals, with sometimes overlapping and inconsistent requirements		
10	Relatively high burden of EU legislation (especially on SMEs), causing the diversion of resources from innovation		
11	The granting of authorisation to substances in applications for which alternatives are available, that may stifle, rather than reward, innovation		
12	Regulatory uncertainty over the developed alternatives		
13	Poor enforcement of legislation		
14	A significant proportion of alternatives are part of the same functional group or structurally similar group as the original substance		
15	Access to raw materials in the relevant quantities and at the right cost may be an issue		

Which other important gaps/deficits exist in the focus area of sub-study a (substitution), if any?

7.1.5.2 Improvement opportunities

The ideas for improvement identified up to now are listed in the table below. Please rank their relevance, identify which gaps / deficits they would address (use numbers of the respective table) and identify strengths and weaknesses of the improvement ideas with regard to achieving a non-toxic environment

Idea for improvement	Relevance (1 to 3)	Gap no. it would address (see above)	What is the strength, what is the weakness of the idea for improvement?
EU-level substance-regulation navigator			
Increase information requirements for low production volume substances			
Develop tools to track hazardous chemicals in articles			
Fund further research into chemical product life cycle risk assessment			
Automatic restriction on imported articles containing authorised substances			

Idea for improvement	Relevance (1 to 3)	Gap no. it would address (see above)	What is the strength, what is the weakness of the idea for improvement?
Enhance available databases with information on alternatives			
Extend the available time to develop alternatives			
Shorten product safety assessment by public authorities			
Reduction of the administrative burden for SMEs (e.g. more time to comply with legislation, lower fees, promotion of co-operation network on substitution initiatives, more funding on R&D)			
Refuse authorisations to substances of very high concern for which alternatives are available on the market			
Dedicate more resources to enforcement of every aspect of the chemical legislation			
Start a public debate, involving all relevant stakeholders, on the identification of applications for which the use of certain chemical groups raise concerns that are higher than the benefits delivered;			
Make importers pay for imports that are not compliant			
Raising awareness on the benefits of – and stimulate market demand for - safer alternatives			
Enhance stakeholders' collaboration on substitution initiatives			
Promote circular economy business models (e.g. chemical leasing)			
Reward/incentivise sustainable substitution			
Tax the use of hazardous substances			
Increase transparency and stakeholders' participation in the decision-making process of the Scientific Committees			

Which (other) responses/instruments could help addressing the gaps/deficits (the ones identified by the study team, and the ones added by you, where applicable?

7.1.5.3 Examples of well-functioning legislation, non-legal measures and actions

Which existing legal or non-legal practices do you regard as a good measure / activity / starting point for achieving a non-toxic environment in the area of the sub-study, which have not been mentioned yet?

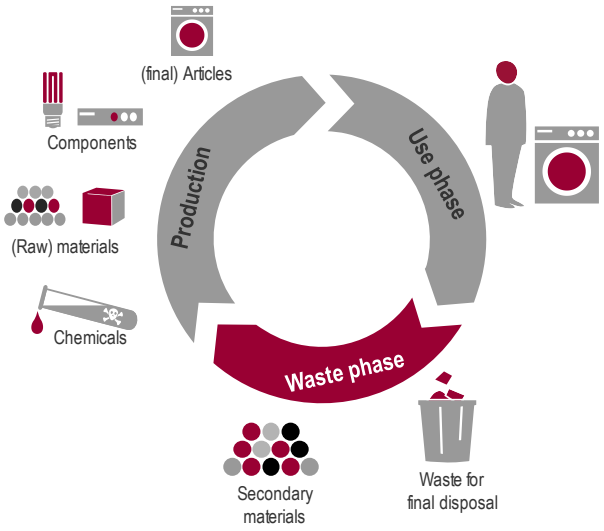
7.2 WORKSHOP MATERIAL FOR SUB-STUDY B ON NON-TOXIC PRODUCTS AND MATERIAL CYCLES

7.2.1 Aim

The aim of the sub-study on non-toxic products and material cycles is to identify gaps, deficits and related improvement opportunities in the management of chemicals in material cycles in order to decrease unwanted effects from chemicals, such as toxic emissions or material stream contaminations. It comprises, inter alia, preventative aspects such as the management of chemicals in article supply chains, so as to decrease the use and emissions of toxic substances from all related life cycle stages, and remedial activities to manage "contaminated" material streams.

7.2.2 Scope

The sub-study mainly addresses articles as defined under REACH Article 3(3). Mixtures are considered if they are used in the production of articles but not if they are consumed during use (e.g. solvents, cosmetics).



Considerations of non-toxic material cycles focus on article wastes. Wastewaters or issues related to sewage sludge are not regarded as a main study topic.

The range of substances that could be relevant to the sub-study is not limited to a specific group, such as SVHC on the candidate list, but an open approach is adopted. However, priorities may be identified for substances with specific properties (such as SVHC).

Figure 3: Flow of (toxic) chemicals in articles and material streams

The analysis of the status quo and improvement opportunities includes measures in international conventions, EU legislation and national legislation (some selected examples) as well as any non-legal programme or activity conducted by governments, industry, academia, NGOs or other actors in the field.

A core challenge of this sub-study is to structure the three legal areas covering chemicals' management, production and placing on the market of articles and waste management and to identify the relevance of identified gaps and deficits (within legislation and at their interfaces) for achieving a non-toxic environment.

7.2.3 Relevance of the topic for Health, environment and resources

The core concerns related to toxic substances in articles and material cycles are their potential emissions, exposures and resulting risks for human health and the environment.

It is challenging to identify priority articles and waste streams, due to, among other things, the high number of possible combinations of articles and substances (including how they are integrated into matrices) and a lack of knowledge of substance uses. In the case study, the aim will be to identify conditions and combinations of substance properties, article types and material cycles that suggest high exposure potentials (and hence could be a priority for action).

Risks from toxic substances during article service lives is another aspect where gaps and deficits may exist in current policy/legislation. This may include issues of consumer and environmental exposure to a variety of substances from multiple sources.

Finally, the case study will analyse what aspects and potential decision criteria could be used to identify the "best" waste management option. On the on hand, resources should be used efficiently and the hierarchy of waste management starts with the reuse and recycling of wastes. On the other hand, the aim of detoxifying material cycles could suggest refraining from material reuse or recycling in order to prevent toxic substances being re-introduced. This conflict of interest will be most

pinpointed in those cases where separation of toxic substances from the materials/wastes they are contained in is either technically not feasible or not economic.

7.2.4 Gaps and deficits (interim results)

In the following sub-chapters, the gaps and deficits identified up to now in EU legislation with relevance for the sub-study are listed. Gaps and deficits are listed in the three blocks "chemicals' management", "toxic substances in articles" and "waste management". It is not always possible to allocate a legislation to only one area, e.g. REACH covers all three and some product-related legislation concerns articles but was initiated based on waste management considerations (e.g. RoHS and ELV). In addition, the gaps and deficits arising from a lack of functioning interfaces between the three areas, in particular regarding communication on hazardous substances, are addressed.

7.2.5 Chemicals' management

The following legislation is considered as part of the chemicals' regime and relevant for this sub-study: REACH; the CLP Regulation; the Regulation on Persistent Organic Pollutants, and the Biocidal Products Regulation[8].

The main gaps and deficits identified in the legislation that prevent a higher level of achievement of a non-toxic environment are:

- There is a lack of information on health and environment properties, in particular for substances registered in low amounts under REACH (e.g. to identify SVHC);
- Information on the uses of (toxic) substances in articles is generally missing, making risk assessment challenging for all actors and preventing informed choices;
- Risk assessment methodologies for the article service life and waste stage are not sufficiently developed to meet the needs of the different actors (e.g. producers, retailers, waste managers, recyclers and authorities);
- Only a few communication instruments on toxic substances in articles exist; the information chain almost completely breaks between articles and the waste sector;
- Authorisation under REACH does not cover imported articles.

7.2.6 Toxic substances in articles

The following main legal acts are considered relevant for the sub-study: General Product Safety Directive, Construction Products Regulation, Eco-design Directive, Toys Directive, Directive on Medical Devices, Regulation on Food Contact Materials, Ecolabel Regulation, Biocidal Products Regulation, and REACH. The following main gaps and deficits in EU articles legislation were identified up to now:

- A systematic approach regulating the content of toxic substances in articles is missing; existing restrictions neither cover all relevant substances nor all article types;
- Requirements on chemical product safety are general and vaguely phrased, which is difficult to implement for market actors and authorities;
- Established methods, procedures and tools for chemical safety assessment of articles are missing;

[8] The Cosmetics Regulation, the Plant Protection Products Regulation and other legislation on specific mixtures are not included here, because the related products are chemical mixtures which are not used to produce articles.

- Current risk management fails to systematically consider exposure to one substance from several sources as well as combined exposure to different substances from one or several sources;
- No communication requirements exist on (toxic) substances in articles (except REACH Art. 33);
- Little information on candidate list substances becomes available through REACH notifications.

In addition to the legal gaps and deficits, there appear to be challenges with regard to the (perceived) business risk of losing confidential information on substances in articles and a disproportionate relation between efforts for communication on toxic substances in articles and related benefits. Both aspects appear to be hindering relevant progress in supply chains which are not dominated by a few large economic actors (such as the automotive or electronics' industry).

7.2.7 Waste management

Core legislation within our analysis of the waste stage has been the framework legislation (Waste Framework Directive), EoL-product related legislation (such as Waste Electric and Electronic Equipment, End of Life Vehicles, Batteries) and substance related legislation (e.g. the RoHS Directive) as well as communication instruments such as the European List of Waste. The main gaps and deficits, which are regarded relevant for this sub-study are:

- There is no overall approach from a life cycle perspective regarding the decontamination of waste streams. Resource efficiency by recycling is promoted by increasing quantitative recycling targets but no qualitative approaches and respective quality targets are systematically applied, including on the content of toxic chemicals.
- Monitoring of decontamination or separation activities is related to high efforts; separation requirements on an operational level are fixed for few waste streams. Effective control and monitoring of decontamination and separation activities is rarely implemented as a self-steering process.
- A comprehensive and systematic information management on toxic chemicals in materials, which would inform decision making on how a particular waste (consisting of particular objects or not) should be treated regarding decontamination or discharge, is missing to a large extent.
- The European List of Waste (LoW) shows limited suitability as a comprehensive tool to communicate the content of hazardous substances in wastes or hazardous properties of wastes; hence only limited information on the content of toxic substances is communicated along the waste chain based on existing legal requirements.
- The system to characterise wastes as hazardous differs from the classification of chemicals, e.g. regarding limit values and calculation methods (e.g. the consideration of M-factors) or for hazardous substances (e.g. the categories of substances highly hazardous to the environment identified under REACH and included in the concept of SVHC is missing).
- Waste codes are parts of installation permits that recycle/use wastes. In many cases such waste input permits are combined with limit values regarding the content of hazardous substances. Due to the fact that the LoW codes are often not combined with limit values, waste codes are not a sufficient communication tool for that interface between waste management and installations.
- Financing of additional efforts for decontamination or separation activities are often not related to the "polluter pays principle" but are sometimes covered by general waste fees.

7.2.8 Improvement Opportunities

7.2.8.1 Overarching opportunities

Several options exist to implement policies and practices that could lead to less usage and emissions of toxic substances in/from articles and waste material streams.

First and foremost a strengthening and further integration of lifecycle thinking and general awareness of aspects related to toxic substances by all actors, in particular those handling articles and wastes, would be an essential step in identifying and implementing solutions to current problems. This regards specifically any potential solutions to bridge the currently existing discontinuities in the information chain[9], as neither the need, nor the opportunities and duties for information provision are entirely clear and implemented. This affects the ability of the market actors (and consumers) to make informed decisions on their product use, the design of articles and the selection of waste treatment options.
In addition, an information system monitoring the flow of (specific, toxic) substances on the market, including in waste streams, would improve the possibilities of risk assessments, priority setting and risk management by policy makers.

The following sections indicate exemplary improvement opportunities that could be implemented in the context of the three policy areas chemicals, articles and wastes.

7.2.8.2 Opportunities in chemicals' management

- Implementation of methods to collect more specific information on the use of (toxic) substances in articles under REACH, e.g. by providing more specific (article-related) use descriptors to improve the information basis on substance uses;
- Introduction of an unspecific safety factor in article risk assessments to account for combination effects or multiple exposures and/or develop better emission and exposure assessment tools for substances in articles;
- Extension of the concept of product stewardship of the chemicals' industry to explicitly include the service life of articles (where relevant) and related considerations of waste disposal;
- Enhancement of the use of restrictions under REACH to address the use of toxic substances in articles, while also creating incentives for voluntary/proactive substitution and phase-out of such substances.

7.2.8.3 Opportunities in the area of articles

Very effective potential improvement opportunities have been identified in the area of articles' policy as these can be targeted and also reach up and down the supply chains, i.e. affect chemicals' supply and waste management. Core improvement opportunities[10] could be:

- Development of a consistent, horizontal regulatory approach to toxic substances in articles, including generic and specific chemical restrictions for all product types;
- Inclusion of (toxic substances in) imported articles in the REACH authorisation procedure;

[9] Loss of information upon transfer from the chemicals to the articles' regime and almost complete stop of information flow from articles to the waste management area.
[10] Please note that the list includes options that address the same issue in alternative ways. Therefore, some opportunities overlap or target the same effect (e.g. chemicals' restrictions in articles and including (imported) articles under REACH authorisation.

- Installation of (internationally) standardised communication format(s) for toxic substances in articles and respective obligations along the supply chains; complementing of the communication format with labelling of articles containing (specific) toxic substances;
- Establishment of a register of toxic substances in articles;
- Implementation of systems defining roles and responsibilities for chemical product safety along the supply chains in accordance with the abilities and capacities of actors;
- Establishment of an obligatory product declaration scheme for all consumer products indicating the content (in concentration ranges/intervals) of all classified substances that exceed specific concentrations;
- Making the market surveillance system more efficient, including random tests and control measures; allocation of adequate funding for inspections;
- Initiation of dialogues with sectors on substitution goals/non-toxic articles, support to respective stakeholder dialogues and (consumer) campaigns;
- Development of a "good manufacturing practice" for articles (potentially with sector focus), to limit toxic substances in articles as contaminations, e.g. carry over from machinery.

7.2.8.4 Opportunities in the area of waste management

In the area of waste management, improvement opportunities relate to the content of toxic substances in articles and their separability as well as the organisation and decision making on waste treatment in the sector. Some core opportunities are the following:

- Increase the availability of information on the presence of toxic substances in waste streams (availability as such and adaptation to the needs of daily practice in waste management);
- Creation of a systematic basis for deciding about depollution activities for waste streams, which includes a balancing of resource and toxicity aspects; this would include clearer policy objectives when materials containing toxic substances should not be recycled but rather taken out of the circle for energy recovery or other safe disposal;
- Improved control and enforcement of closed loops for hazardous materials and communicated use areas of waste streams; this includes market surveillance e.g. with regard to the use of contaminated plastics in products;
- Integrating of a "design for depollution" (DfD) in product developments (dismantle ability), which considers depollution and separation approaches and techniques in waste management; development and application of recycling techniques that eliminate toxic substances from recycled material for cases where depollution is not sufficient;
- Inclusion of (more specific) design requirements regarding chemical recyclability of articles into eco-labels;
- Enacting depollution requirements on a legal basis for additional waste streams as "guard railing" for waste management companies;
- Legal requirements on separate collection of specific wastes;
- Recycling fees for products requiring specific end-of-life treatment;
- Extended Producer Responsibility;
- Further development of the European List of Waste towards a communication instrument on waste characteristics (covering resource and toxicity aspects);
- Awareness raising campaign in waste management chains.

7.2.9 Annex - Feedback form

Filled in by

Name:

E-Mail address:

Name of organisation:

Please indicate (X) the type of your organisation				
Public body	**Academia**	**Industry/Commerce**	**NGO**	**Other (pls specify)**

Please send the feedback form back by 16 June to: nontoxicenvironment@milieu.be

7.2.9.1 Gaps/deficits

The main gaps/deficits identified in the sub-study are listed in the table below. How would you rank their relevance? Please rate 1 for 'no or little relevance', 2 for 'medium relevance', 3 for 'important relevance'. Please also add your opinion on what are the main negative consequences of the gap/deficit with regard to the goal of a non-toxic environment.

Gap no	Gap/deficit	Relevance (from 1 to 3)	Main (negative) consequences of the gap/deficit regarding a non-toxic environment
1	Lack of hazard information on substances		
2	Lack of risk assessment methods for articles (service life) and waste stage		
3	Lack of communication instruments on toxic substances in articles		
4	No comprehensive and overarching legislation on toxic substances in articles		
5	Lack of overview information on toxic substance content in articles / waste streams		
6	Chemical product safety requirements are "vague" and not sufficiently implemented and controlled		
7	Lack of an overall approach, including on information management, towards toxic substances in waste streams		
8	Lack of decontamination requirements for end-of-life articles / waste streams, as well as related monitoring and enforcement practices		
9	Lack of communication instruments on toxic substances in wastes/insufficient suitability of LoW for communication and related permitting		

Which other important gaps/deficits exist in the focus area of sub-study b (non-toxic articles and waste streams), if any?

7.2.9.2 Improvement opportunities

The ideas for improvement identified up to now are listed in the table below. Please rank their relevance, identify which gaps / deficits they would address (use numbers of the respective tables) and identify strengths and weaknesses of the improvement ideas with regard to achieving a non-toxic environment.

Idea for improvement	Relevance (1 to 3)	Gap no. it would address (see above)	What is the strength, what is the weakness of the idea for improvement?
Awareness raising, training and practical implementation of life-cycle thinking with regard to (the prevention) of toxic substances in articles and waste streams			
Creation of an (international) information system on toxic substance uses and flows on the markets, including amounts, and entering the waste stage			
Introduction of more detailed reporting/notification obligations on toxic substance uses in articles, e.g. under REACH			
Development of improved and more specific risk assessment tools for articles (and wastes)			
Development of horizontal legislation addressing toxic substances in articles, generically complemented by product specific restrictions, for particular aspects (e.g. children articles)			
Inclusion of (imported) articles under the authorisation procedure of REACH			
Development of communication requirements and tools on toxic substances in articles (e.g. extension of Art. 33 of REACH or "SDS" for articles)			

Idea for improvement	Relevance (1 to 3)	Gap no. it would address (see above)	What is the strength, what is the weakness of the idea for improvement?
Integration of design for depollution in product design requirements or respective product standards or eco-label requirements			
Introduction of legal requirements for separate collection of specific waste streams			
Development of the EU LoW to (also) be an appropriate tool for communication on toxic substances in wastes			
Awareness raising campaigns in waste management chains			

Which (other) responses/instruments could help to address the gaps/deficits (the ones identified by the study team, and the ones added by you) where applicable?

7.2.9.3 Examples of well functioning legislation, non-legal measures and actions

Which existing legal or non-legal practices do you regard as a good measure / activity / starting point for achieving a non-toxic environment in the area of the sub-study, which have not yet been mentioned?

7.3 WORKSHOP MATERIAL FOR SUB-STUDY C ON THE PROTECTION OF VULNERABLE GROUPS

Sub-study c focuses on those groups in the population that are particularly vulnerable to the negative effects arising from exposure to chemicals. More specifically, the sub-study aims to:

- Provide an overview of the status quo regarding the issues of protection of children and vulnerable groups from harmful exposure to chemicals;
- Identify and describe the most important health issues relating to children and vulnerable groups and the main causes of these (e.g. source of and/or route of chemical exposure);
- Provide a general analysis of current policy measures and other activities with regard to their impact on and effectiveness in improving the protection of children and vulnerable groups; and
- Identify and describe the most important knowledge gaps relating to the protection of children and vulnerable groups, as well as the main gaps in relevant policy areas; and

- Identify and describe improvement opportunities to the gaps identified in short, medium and long term perspective, including legislative and other policy measures.

7.3.1 Who are the vulnerable groups in society?

Vulnerable groups are populations groups who are at greater risk of suffering adverse health effects from harmful exposure to chemicals compared to the general population, due to lower exposure thresholds for health effects or a reduced ability to protect themselves from exposure. Vulnerable groups include early life stages, such as **pre-conception germ cells** and developing **foetuses**. Exposure to chemicals during the embryonic stage can be particularly harmful, and might result in a range of long-term or chronic developmental effects.

Chemicals can also have particularly damaging health effects on **pregnant women**, including changes to the functioning of the thyroid as well as increased risks of miscarriage, maternal anaemia, pre-eclampsia, placental abruption and postpartum haemorrhage.

Children – from birth to the final stages of adolescence - possess some distinct characteristics that contribute to differences in susceptibility to chemical exposures. For example, they are more likely to be in contact with potential hazardous chemicals as they tend to put objects in their mouths, move closer to the ground where chemicals accumulate in dust and soil and because they are less aware of the potential danger of substances, therefore showing less precautionary behaviour.

As people age, their metabolism slows down, the functioning of their excretion system reduces, and they must deal with levels of chemicals in their body that have been accumulating during their lifetimes. This, together with the generally weakened ability of the **elderly** to respond to physiological challenges such as chemical exposure, makes them a vulnerable group.

Certain **occupational groups** are more vulnerable due to more frequent or higher levels of chemical exposure compared to the general population. For example, toxic chemicals in beauty salon products can result in respiratory and skin related health problems and adverse human health effects from agricultural pesticides have been frequently reported as well.

Finally, **lower socio-economic groups** are more vulnerable as chemical exposure varies with social disparities. For example, certain housing factors, such as poor indoor air or drinking water quality or use of biocides to control pests, which can significantly impact children's health, are more common among lower socioeconomic households. Lower socio-economic groups are also more likely to work in an environment where they are more frequently exposed to (higher levels of) damaging chemicals.

7.3.2 How are vulnerable groups exposed to harmful chemicals?

7.3.2.1 Main routes of exposure

Chemicals can enter the human body through **ingestion**, e.g., by swallowing contaminated mucus which has been expelled from the lungs, or by eating and drinking contaminated food. Children are particularly exposed to ingested chemicals because they eat more food and drink more water per kilogram of body weight than adults. Moreover, their diets consist of food that is more likely to be contaminated by harmful chemicals such as pesticides. Also, the younger they are, the more limited their ability to metabolise and eliminate residual toxic substances.

Inhalation of contaminated air is one of the most common ways that chemicals can enter the body. Certain groups such as asthmatics and elderly people with chronic respiratory diseases are particularly susceptible to air pollutants. Indoor air pollution can be a significant source for people breathing in harmful chemicals such as formaldehyde, benzene, naphthalene, radon and organophosphate pesticides. Air pollutants may disrupt the proper development of the lungs in foetuses and young children, may cause cough, bronchitis and other respiratory diseases, or worsen asthmatic symptoms.

Chemicals can also enter the body through **skin contact**. Of particular concern are chemicals used in cosmetics and personal-care products, some of which have shown to have endocrine-disrupting properties. Ethanolamine compounds, commonly found in shampoos, soaps and facial cleaners, have been demonstrated to be carcinogenic and exposure to synthetic "fragrances" can affect the central nervous system. Chemicals that are used to treat textiles such as clothing and furniture, as well as in toys and childcare articles, are another important source of exposure to chemicals through the skin.

7.3.2.2 Exposure through the placenta and breast milk

Studies have shown that the majority of toxins that the mother is exposed to are transported to the foetus through the placenta. A study in 2011 found that 99-100% of pregnant women included in the study had detectable levels of polychlorinated biphenyls, organochlorine pesticides such as DDT, perfluorinated compounds, phenols, polybrominated diphenyl ethers, phthalates, polycyclic aromatic hydrocarbons, perchlorate PBDEs and compounds used as flame retardants.

Also after birth, the mother remains an important route of exposure to potentially harmful chemicals to the child, through the provision of breastmilk. Research shows that while levels of the organochlorine pesticides, PCBs, and dioxins have declined in breast milk in countries where these chemicals have been banned or otherwise regulated, the levels of PBDEs are rising.

7.3.2.3 Occupational exposure

Many occupations involve the use, or generation, of substances that can be harmful to humans. Adverse health effects can occur as a result of a single episode of high exposure or from sustained, lower level, long term exposure. Types of occupation that carry a higher risk include agriculture, construction and painting, cleaning services, hairdressers and beauty salons. For example, a growing number of studies focusing on the exposure of cleaners to chemicals have found adverse health effects of the skin and the respiratory tract. Hair sprays, permanent waves, acrylic nail application and numerous other salon products have been linked to higher incidences of cancers, neurological diseases such as dementia and depression, immune diseases, birth defects, reproductive disorders including a high rate of miscarriages, skin diseases, asthma and other breathing problems.

7.3.3 Which chemicals can cause adverse health effects in vulnerable populations?

A significant body of research has identified harmful effects of **reproductive toxins**, such as endocrine disrupting chemicals (EDCs). Examples of chemicals that can impact reproductive health include diethylstilbestrol (DES), phthalate esters, flame retardants, phytoestrogens, dioxins and polychlorinated biphenyls (PCBs). For male reproductive health, exposure to EDCs during early life can result in hypospadias, poor semen quality, testicular dysgenesis syndrome and testicular germ cell cancer. Females may develop reproductive disorders such as polycystic ovary syndrome (PCOS),

uterine fibroids and endometriosis, all causing infertility and subfertility. Exposure to EDCs during pregnancy can lead to a number of adverse pregnancy outcomes, including miscarriage, preeclampsia, intrauterine growth restriction, poor weight gain during fetal development and preterm delivery. Prenatal exposure to lead and glycol ethers has been linked to an increased risk of miscarriage.

A large variety of ubiquitous chemicals, such as dioxin-like compounds, certain flame retardants, PCBs, bisphenol A (BPA), perchlorate, pentachlorophenol and several other common contaminants have shown to have **thyroid-disrupting properties**. Small modifications in thyroid serum levels during pregnancy have been associated with cognitive deficits and other deleterious effects on neurological outcome. Moreover, hypothyroidism in the mother can result in impaired intellectual development in her children as well as hearing loss. Perinatal exposure to thyroid-disrupting chemicals such as PCBs has been associated with poorer neurodevelopment in neonates, toddlers and school-age children. Thyroid disruptors can also impact the health of adults: a study has shown the excess risk of thyroid cancer among pesticide applicators and their wives.

Strong evidence exists that a number of chemicals that are widely disseminated in the environment are important contributors to **neurodevelopmental toxicity**. For example, ADHD is over-represented in populations with elevated exposure to organophosphate pesticides. Five industrial chemicals have been identified as developmental neurotoxicants: lead, methylmercury, arsenic, polychlorinated biphenyls (PCBs), and toluene. Moreover, 201 chemicals have been reported to cause injury to the nervous system in adults, mostly in connection with occupational exposures, poisoning incidents, or suicide attempts. Moreover, during sensitive life stages, these chemicals can cause permanent brain injury at low levels of exposure that would have little or no adverse effect in an adult. Children – especially during foetal development – are particularly sensitive to the neurotoxic effects of lead and mercury, even at low levels. Exposure to mercury during foetal life has been associated with mental retardation, loss of vision and hearing, language disorders and developmental delays.

Various chemicals are considered **carcinogenic**; the most dangerous of these are bioaccumulative and persistent (e.g., dioxins, furans, PCBs, chlorinated pesticides). An elevated risk of prostate cancer has been linked to unspecified agricultural pesticides, PCBs, cadmium and arsenic, while dioxins, PCBs and solvents have been associated with breast cancer. The involvement of in-utero exposure to DES in vaginal cancers and breast cancer has increased the concern that a variety of other hormonally active chemicals in everyday use are causing these diseases. Moreover, children are at increased risk as they are at the early stages of their lives, which allows for greater acquisition and bioaccumulation of environmental chemicals. Concentrations of persistent organic pollutants (POPs), such as dioxins, PCBs, chlorinated pesticides, and brominated flame retardants can accumulate in the adipose tissue. These additional toxins can potentiate the effect of earlier exposures, contributing to the onset of malignant disease many years, or even decades, after the initial exposure.

Chemicals can also **disrupt the metabolic system** and play a role in the onset of conditions such as diabetes and obesity, as well as cardiovascular disease and hypertension. Certain EDCs have been described as affecting the function of beta cells in the pancreas, which are responsible for insulin production and, therefore, crucial for glucose homeostasis. Moreover, there is growing epidemiological evidence that exposure to EDCs in adulthood may contribute to the development of type-2 diabetes.

In recent years, the impact of exposure to chemicals and their **immunological effects**, including the development of **allergy**, has been a topic of great interest. Early-life exposure to chemicals com-

monly found in households has been associated with the occurrence of allergic airway diseases, asthma and rhinitis (hay fever). Positive relations have been found between phthalates in dust or phthalate-related products, such as PVC flooring, and asthma or allergic symptoms. Also of concern is the finding that exposure to perfluorinated compounds can suppress antibody response to routine childhood immunisations.

7.3.4 The EU legal framework for chemicals and for vulnerable groups

There is no single comprehensive EU framework aimed at protecting vulnerable groups from the risks stemming from chemical exposure. Instead, vulnerable groups are protected through various provisions spread out in different pieces of EU legislation. Baseline protection for human health and the environment is provided through the horizontal chemical legislation, as per the table below:

EU Act	Specific provisions for vulnerable group
■ Regulation (EC) 1907/2006 (REACH)	DNELs may be needed for certain vulnerable groups; Annex XVII restrictions of reproductive toxicants
■ Regulation (EC) 1272/2008 (CLP)	Child-resistant packaging; labelling for reproductive toxicity, lead & other chemicals.
■ Regulation (EC) 1107/2009 on plant protection products	Definition of vulnerable groups; PPP residues shall not have harmful effects on i.e. vulnerable groups; risk assessment shall take into account possibility of exposure of different population groups
■ Regulation (EU) 528/2012 on biocides	No active substances classified as R1A or 1B; no unacceptable effects including on vulnerable groups; evaluation of dossiers and exposure assessments to pay attention to protection of vulnerable groups

Pieces of legislation that focus specifically on certain categories of vulnerable populations include:

- Directive 2009/48/EC on safety of toys
- Regulation No 609/2013 on food intended for infants and young children
- Directive 92/85/EEC on pregnant workers
- Directive 94/33/EC on young people at work

Examples of other references to and/or provisions protecting vulnerable groups can be found in Regulation (EC) 1223/2009 on cosmetic products, Directive 2001/83/EC on medicinal products for human use, Regulation (EC) 1881/2006 setting maximum levels for certain contaminants in foodstuffs, Regulation (EC) 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin, Directive 2001/95/EC on general product safety, Directive 93/42/EEC on medical devices, Regulation (EC) No 850/2004 on persistent organic pollutants, and Directive 2008/50/EC on ambient air quality and cleaner air for Europe.

An example of an EU act aimed at protection of human health which does not mention vulnerable groups is Directive 98/83/EC on the quality of water intended for human consumption. However, the limited number of chemicals (25) covered in the parameters set forth in Annex I, Part B includes some neurotoxicants, such as lead, mercury and chromium, which are important for protection of children.

7.3.5 Gaps and deficits (interim results)

- **Pinpointing critical life stages to refine risk assessment**

Comprehensive, longitudinal measurements (instead of biomonitoring at specific time points) are needed to study the susceptibility of an individual during a lifetime. This will significantly contribute to obtaining a clearer picture of the impacts of chemicals during specific sensitive windows of development. This information could greatly contribute to refining risk assessment procedures, as current, internationally agreed and validated test methods only capture a limited range of the known spectrum. Being able to better define the critical life stages and the risks associated with these will increase the likelihood that harmful effects in humans, particularly in vulnerable groups, will be captured fully.

- **Sources and their routes of exposure**
  The extent to which vulnerable groups in society are exposed to potentially harmful chemicals is not yet fully understood. While a wealth of information and evidence exists, the sources of exposure, particularly at home and through daily-use products, are not yet fully known. A host of parameters can influence the impact of contaminants, which adds further to the complexity of demonstrating a cause-and-effect-relationship. Mapping of the full picture of exposure, as well as clear criteria for chemicals with potential hazardous impacts on human health, such as endocrine-disrupting properties, is needed.
- **Mixtures of chemicals and effects**
  So far the majority of research has focused on studying the impacts of one specific chemical or property or has tried to link a chemical or property to one specific disease or symptom. This significantly underestimates the disease risk from mixtures of chemicals as well as the total impact that a chemical can have on different systems within the human body. Approaches to examine the effects of mixtures of chemicals and compounds on disease susceptibility and etiology are currently lacking. Although the number of possible chemical combinations is potentially unlimited, making it neither realistic nor useful to test every possible combination, there is a strong need for new methodologies that can assess the combination effects of chemicals.
- **Latency period in the context of an ageing Europe**
  While the effects of exposure to chemicals (particularly those with endocrine-disrupting properties) may begin early and can be persistent, diseases may only be manifested later in life. This shows the great importance of fully understanding the impacts of hazardous chemicals on the different health systems of the foetus as well as children. Addressing the latency period is particularly relevant in light of the ageing of the population in Europe. The share of older people will continue to rise significantly during the upcoming decades, which makes a solid understanding of the health implications later in life due to early exposure even more relevant.
- **EU regulatory framework**
  A more comprehensive and targeted approach is required to protect vulnerable groups from harmful exposure of chemicals, one that addresses a wider range of sources of possible contamination. For example, only the Toys Directive deals directly with possible exposure of children to hazardous chemicals from consumer products, while in real life, children are exposed to a wide range of chemicals from all different types of everyday products. While the Regulation on food intended for infants and young children provides this vulnerable group with protection against the possibility of exposure to harmful chemicals through ingestion, the protection provided by the Drinking Water Directive is limited and does not cover many of the contaminants now found in groundwater and other sources of water for human consumption.

7.3.6 Opportunities for improvement

- **The development of new risk assessment methods**
  New analytical techniques and approaches to risk assessment are greatly needed to address the critical life periods and their associated risks as well as the specific susceptibilities of vulnerable groups. Moreover, risk assessments of human health effects also need to address the effects

of exposure to chemical mixtures on a single disease, and the effects of exposure to a single chemical on multiple diseases. Interdisciplinary efforts that combine knowledge from wildlife, experimental animal and human studies could provide a more holistic approach for capturing the whole spectrum of diseases and dysfunctions caused by hazardous chemicals among vulnerable groups.

- **Addressing unknown properties and new chemicals**
  Researchers are still trying to understand the full extent to which chemicals have hazardous impacts on human health, and in particular on vulnerable population groups. While a wealth of evidence and data has been gathered through the past decades, significant opportunities for improving the knowledge base still remain. Moreover, new research areas such as nanomaterials are evolving, making it key to understand their chemical characteristics in relation to their size, composition and morphology, as it will allow us to understand what health and safety measures needs to be put in place.
- **Translating the existing evidence into a targeted and interdisciplinary EU strategy**
  Although much is still unknown, more than enough scientific evidence is now in place concerning the need to act to protect vulnerable groups, particularly children. This science needs to be synthesised into solid, evidence-based legislative and policy decisions and actions. More specifically, there is a need for an EU level, interdisciplinary strategy, which would foster collaboration and data sharing among scientists and between governmental agencies and countries - particularly those that stimulate new, adaptive approaches that break down institutional silos and traditional scientific barriers.
- **Awareness raising**
  Increasing efforts to raise awareness on the health impacts of hazardous chemicals on vulnerable populations will greatly contribute to ensuring that available evidence will be translated into targeted action to protect susceptible groups. Information campaigns are needed to build momentum for political action, as well as to alert the general public and specific vulnerable groups concerning measures they can take to protect themselves from potentially harmful exposures. Target groups could include those vulnerable to occupational exposure, e.g. workers from specific sectors such as beauty salons and hairdressers, as well as farmers. Information on steps to take to avoid exposure during pregnancy and early life phases is of particular importance.

7.3.7 Annex - Feedback form

Filled in by

Name:

E-Mail address:

Name of organisation:

Please indicate (X) the type of your organisation				
Public body	**Academia**	**Industry/Commerce**	**NGO**	**Other (pls specify)**

Please send the feedback form back by 16 June to: nontoxicenvironment@milieu.be

7.3.7.1 Gaps/deficits

The main gaps/deficits identified in the sub-study are listed in the table below. How would you rank their relevance? Please rate 1 for 'no or little relevance', 2 for 'medium relevance', 3 for 'important relevance'. Please also add your opinion on what are the main negative consequences of the gap/deficit with regard to the goal of a non-toxic environment.

Gap no	Gap/deficit	Relevance (from 1 to 3)	Main (negative) consequences of the gap/deficit
1	No risk assessment methods that are able to capture/address sensitive life stages		
2	Not enough knowledge on the extent to which vulnerable groups in society are exposed to potentially harmful chemicals (sources and exposure routes)		
3	No approaches are available to examine the effects of mixtures of chemicals and compounds on disease susceptibility and etiology		
4	Insufficient research on the latency period (period between exposure and onset of symptoms) after chemical exposure		
5	Lack of a comprehensive EU regulatory approach to protect vulnerable groups from harmful exposure to chemicals		

Which other important gaps/deficits exist in the focus area of sub-study c (vulnerable groups), if any?

7.3.7.2 Improvement opportunities

The ideas for improvement identified up to now are listed in the table below. Please rank their relevance, identify which gaps / deficits they would address (use numbers of the respective tables) and identify strengths and weaknesses of the improvement ideas with regard to achieving a non-toxic environment

Idea for improvement	Relevance (1 to 3)	Gap no. addressed (see 1.1 above)	What is the strength, what is the weakness of the idea for improvement?
Development of new risk assessment methods, addressing sensitive life phases as well as exposure to chemical mixtures		1 + 2 + 3	
Further research to identify unknown properties and new chemicals		2 + 3 + 4	
Development of an evidence-		5	

Idea for improvement	Relevance (1 to 3)	Gap no. addressed (see 1.1 above)	What is the strength, what is the weakness of the idea for improvement?
based, targeted and interdisciplinary EU strategy			
Awareness raising campaign on the health impacts of hazardous chemicals on vulnerable populations		1-5	

Which (other) responses/instruments could help addressing the gaps/deficits (the ones identified by the study team, and the ones added by you, where applicable?

7.3.7.3 Examples of well functioning legislation, non-legal measures and actions

Which existing legal or non-legal practices do you regard as a good measure / activity / starting point for achieving a non-toxic environment in the area of the sub-study, which have not been mentioned yet?

7.4 WORKSHOP MATERIAL FOR SUB-STUDY D ON VERY PERSISTENT CHEMICALS

This sub-study focuses on "very persistent" chemical substances, i.e., those substances that resist degradation and therefore will remain in the environment for a long time. It aims to provide:

- An overview of the status quo regarding very persistent chemicals, including a description of the most important health and environmental issues relating to very persistent chemicals;
- A review of current EU-level legislation and policy measures, activities in international organisations as well as at national level, and activities of industry and civil society organisations;
- An analysis of the main gaps in relevant legislation and policies;
- A review of activities aimed at developing alternatives, including non-chemical solutions.

The sub-study also aims to put forward a number of ideas for improvement in the short, medium and long term, which could contribute to the protection of health and the environment.

7.4.1 Relevance of the topic for health, environment and resources

Persistence in chemicals can be a desirable quality. Chemicals that are not readily biodegradable last longer, which can be important for particular applications where durability is a requirement. At the same time this persistency can be a cause for concern because this property means that they will

accumulate in the environment. Because the environment cannot readily get rid of these materials, they will remain for an indefinite time. They may also, depending on the degree of persistence and other properties, have time to be transported over long distances and reach remote regions in all parts of the world. These very persistent chemicals might accumulate to high levels in the environment and become sources of exposure. If these substances turn out to be toxic at a later point and if exposure levels have become sufficient to cause adverse effects in humans, domestic animals, or wildlife, it may not be possible to reverse their impacts.

Unease about the global spread of some types of chemicals, e.g., the persistent organic pollutants (POPs) covered by the Stockholm Convention, has led some scientists to identify chemical pollution as one of nine so-called 'planetary boundaries' – thresholds beyond which non-linear, abrupt environmental change might occur on a global scale and which would be difficult to reverse.

Persistence is normally defined in terms of a substance's biodegradability in different environmental media (soil, water and air), e.g., by sunlight, through reactions with other substances, or metabolized by naturally occurring micro-organisms. The structural characteristics that enable a chemical to persist in the environment can also help it to resist metabolic breakdown in people and animals. Humans, domestic animals, and wildlife are more likely to be exposed if a chemical does not easily degrade.

The problems related to very persistent chemicals are particularly challenging in view of the goal of a circular economy that strives to close the loops by e.g. increasing reuse and recycling of material. Exposure might occur throughout the material circle, from manufacturing of the chemicals to manufacturing and use of products, during waste management and recycling as well as in connection to use of recycled materials. If this problem is not properly managed, it might lead to increasing dispersal and presence of very persistent chemicals in the technosphere, with associated exposure as well as releases to the natural environment.

7.4.2 Which chemicals are persistent and very persistent?

In the regulatory context, persistence is defined by single-media half-life criteria. Microbial transformation ("biodegradation") depends on factors such as type of micro-organisms, composition of soil, temperature, humidity, etc., and results can be highly variable even for the same chemical. Moreover, assessment of persistence has to take into account the persistence of breakdown products and whether any transformation products after release into the environment are also of concern.

The time, cost and many uncertainties involved in testing for multimedia half-lives is one of the major challenges relating to very persistent chemicals. Established degradation tests include: (i) the test for ready biodegradation ("ready test"), described by OECD guidelines 301; (ii) the test for inherent biodegradability, described by OECD guidelines 302; and so-called simulation tests, e.g., as described by OECD guidelines 303.

If a chemical does not pass the ready test, its half-life might be anything between 20–30 days and many years or even decades. The next test (inherent biodegradability) applies conditions to support the biodegradation process (such as a co-substrate for the bacteria to metabolize). If a chemical passes this test, the chemical has at least a potential for biodegradation and may or may not be P.

The most informative results in terms of biodegradation half-lives are provided by simulation tests (where the conditions in a sewage treatment plant or soil are simulated), but the procedure is time- and labor-intensive and expensive. Simulation tests are required under REACH only for chemicals

above 100 t/yr. According to UNEP, only some 220 chemicals out of a set of 95,000 industrial chemicals have been evaluated in relation to their biodegradation half-lives.

Criteria for persistence (degradation half-life) used in identification of PBT/vPvB/POP substances

Criteria	PBT (REACH)	vPvB (REACH)	POP (Stockholm Convention)	PBT (OSPAR)
- in marine water	>60 days	>60 days	>60 days	>50 days
- in fresh/estuarine water	>40 days	>60 days	>60 days	>50 days
- in marine sediment	>180 days	>180 days	>180 days	>50 days
- in fresh/estuarine sediment	>120 days	>180 days	>180 days	>50 days
- in soil	>120 days	>180 days	>180 days	

Long or very long half-lives are particularly difficult to measure in simulation tests because tests must be run for many weeks or months. This increases the costs substantially. For (very) persistent chemicals, degradation half-lives have to be extrapolated from results of a few percent degradation during the time the test was run (e.g., 6% degradation in 3 months used to estimate the point in time when 50% degradation would be reached).

Estimation methods that calculate a degradation half-life on the basis of the structure of the test chemical could provide a way forward, in particular for (very) long half-lives. A tool available from the US EPA website free of charge is BIOWIN, a model used by one study to estimate persistence for a set of 93,144 organic chemicals. In addition to the 26 chemicals already acknowledged as POPs under the Stockholm Convention, the study identified another 510 chemicals as additional POPs. Such a method might be useful for screening of new chemicals before they enter the market or reach high production volumes. However, no common framework for carrying out such screenings has been adopted or accepted. Meanwhile, it might be argued that given the potentially serious health and environmental problems associated with highly persistent chemicals, testing and screening for such chemicals should be decreed/imposed regardless what test methods are currently available.

7.4.3 highly fluorinated chemicals

Highly fluorinated chemicals have been widely produced and marketed for use since the 1950s. The persistence of the fluorine-carbon bond means that these chemical compounds are also very stable and durable, which makes them useful for a broad range of applications, including fluorocarbons and hydrofluorocarbons as well as the per- and polyfluorinated alkyl substances (PFAS).

In the 1980s and 1990s, evidence emerged of the toxicity and bioaccumulability of the long-chain PFAS, which include the so-called C-8 substances used in the manufacture of Teflon-coated cookware, water- and stain-resistant textiles, food contact materials and fire-fighting foams. In Europe and the USA the long-chained PFAS are being replaced by short-chain homologues -- the C-6s and C-4s. Hundreds of these chemicals are now on the global market.

The short-chained alternatives and/or their breakdown products are equally persistent. Moreover, they are reportedly less efficient from a technical point of view. There is concern that larger quantities may be needed to achieve the same performance as the longer chained PFAS, with the potential of significantly increasing the overall load of highly fluorinated chemicals in the environment.

Risk to human health once these substances are in the environment is a growing concern, particularly the number of different PFAS now frequently found in drinking water due to releases from manufacturing sites, industrial sites, fire/crash training areas, and industrial or municipal waste sites.

The strongest evidence of human health risk comes from the C8 Health Project which is monitoring 70,000 people exposed via drinking water contaminated by discharges from a West Virginia manufacturing facility. It has gathered epidemiological evidence of associations between PFOA exposures and later age of sexual maturation, alterations of thyroid hormone levels among children, ulcerative colitis and kidney and testicular cancer.
While a few of the long-chain PFASs – notably PFOS and PFOA -- are partially regulated under the EU legal framework, most PFASs remain unregulated. The European Chemicals Agency (ECHA) is currently coordinating a network of Member State representatives which is jointly developing a work plan to restrict the use of PFAS in the EU through classification, SVHC/authorisation and restrictions. The network foresees regulating PFAS by utilising methods of grouping (such as PFO-restrictions), and is overseeing several substance evaluations which are under way. National level efforts to regulate PFAS are also under way in Sweden, Germany, Denmark, Norway, Canada, and the USA.

Voluntary initiatives to date include the Greenpeace DE-TOX campaign, an effort which has succeeded in getting 66 brand name manufacturers and retailers of apparel, such as Puma, H&M, and Levis, to commit to phasing out the use of all PFAS by certain dates. They have now joined together to establish the cooperation entitled Zero Discharge of Hazardous Chemicals (ZDHC), and have published a "joint roadmap" for the elimination of products associated with PFOA and PFOS by the end of 2012, initially with short-chain alternatives; efforts to find non-fluorinated water- and stain-repellent alternatives are still having only limited success.

The FluoroCouncil, representing the major producers of PFAS has stated that the short-chain alternatives do not pose the same risks to human health and the environment as the C-8s, and that '[d]ecisions on the societal acceptability of strategic materials such as PFASs cannot be wisely made on a single attribute such as persistence'. However, information needed to confirm this reduction in risk, e.g., on the structures, properties and toxicological profiles of the short-chain fluorinated alternatives, is not publicly available. Moreover, the persistence of the highly fluorinated chemicals is extreme. Scientists who study these chemicals have not been able to estimate how long it will take for them to disappear -- probably hundreds of years or even longer.

7.4.4 Other possible groupings of very persistent substances

The research carried out to date has also identified some other possible groupings of very persistent substances. For example, **chlorinated organic substances** tend to be highly hydrophobic, to accumulate in biological systems, and degrade slowly in the environment, particularly those having a carbon ring structure and multiple chlorine substitution. The negative health and environmental effects of the well-studied highly chlorinated organic substances are well documented, including certain cancers, birth defects, dysfunctional immune and reproductive systems, greater susceptibility to disease and damages to the central and peripheral nervous system. More recently, evidence has emerged of endocrine disrupting properties as well as possible increased risk for Type 2 Diabetes (T2D) and obesity. **Chlorinated paraffins** (CPs) are a sub-group of highly chlorinated organic substances. The WHO human milk study found global CP contamination to be comparable to levels of PCBs. Short chain CPs (SCCPs, C10–13) are listed as substances of very high concern (SVHC) under REACH as well as under the EU POPs-Regulation. Their degree of chlorination determines their persistence; the higher chlorinated SCCPs meet the criteria for PBT and vPvB under REACH.

Seventeen (17) of the 21 chemicals listed for elimination in the Stockholm Convention are highly chlorinated substances.

Also of concern are the highly persistent **polychlorinated and polybrominated dioxins and furans** often found in other chemicals as contaminants. These substances can be unintentionally formed during the production of chlorinated or brominated organics as well as when halogenated chemicals such as flame retardants are burned, intentionally or unintentionally. Unintentional dioxins and furans have been detected in pigments used in consumer products such as paints, plastics, print/magazines or packaging (including food packaging). Research on house dust in Japan and the US has found levels of dioxin-like toxicity comparable to fly ash from waste incinerators.

Siloxanes are silicone-based compounds used in a variety of products ranging from personal care items to water repellants, sealants and lubricants. They are resistant to chemical reactions such as oxidation, reduction and photodegradation, and have the potential for long-range transport. However, because they are superhydrophobic, they behave differently compared to other persistent organic pollutants. Both D4 and D5 meet the REACH criteria for vPvB; D4 is also classified as an endocrine disruptor. The UK has proposed restricting D4 and D5 in personal care products because of potential harm to the environment.

Organometallics are metal or metalloid ions combined with organic components. Their inorganic components are basic elements and cannot be further broken down and destroyed in the environment. Metals known to result in adverse human and environmental impacts include lead, mercury, chromium, cadmium, arsenic and antimony. Metals and organometallics may undergo transformation in the environment resulting in potentially more toxic compounds, e.g., inorganic mercury can be transformed into methylmercury, a neurotoxin which can enter food chains. There is a pressing need to monitor these substances as well as their transformation products.

The term *'pseudo-persistence'* is sometimes used to refer to certain substances not considered persistent because of their relatively short half-lives but that, because of their continuous release, result in the type of continuous exposure associated with persistent chemicals. Bisphenol A (BPA) – a known endocrine disruptor -- is considered 'pseudo-persistent', because of its widespread use in consumer products. Because '*pseudo-persistence'* is not an intrinsic property of a substance, it is not relevant to this study.

7.4.5 Regulatory framework relevant for very persistent chemicals

Persistent chemicals are increasingly a global problem requiring international action, because of the potential for long-range transport as well as the worldwide production, use and the global trade with a wide range of products containing these chemicals. International efforts to control persistent substances include the 2001 Stockholm Convention on Persistent Organic Pollutants (POPs Convention) and the 1998 Aarhus Protocol on Persistent Organic Pollutants (POPs Protocol). The Stockholm Convention covers 26 substances and groups of substances which are acknowledged to meet the screening criteria for POPs within the meaning of the Convention. Four other substances are under consideration -- only a fraction of the hundreds of substances that meet the criteria for POPs identified to date.

At EU level, several acts consider persistence as a property of concern. The overarching framework is REACH, which provides for the possibility of authorisation only if a persistent substance is also shown to be bio-accumulative and toxic (PBT), or very bioaccumulative (vPvB), or to show an equivalent level of concern. However, it takes years under the REACH system to identify a com-

pound as a Substance of Very High Concern (SVHC) and to carry out the analyses and consultations required to reach agreement to whether to restrict it under Annex XVII or include it in Annex XIV as subject to authorisation. In addition, the 2009 Plant Protection Products Regulation and the 2012 Biocidal Products Regulation, which regulate substances that may be released directly into the environment, provide that active substances cannot be approved for use in such products if they are found to be PBT or vPvB.

The 1996 PCBs Directive and the 2004 POPs Regulation implementing the Stockholm Convention regulate and restrict a few specific chemicals because of their persistence as well as their toxicity and potential for bioaccumulation. Also important to mention are those acts aimed at preventing polluting emissions, including of certain persistent substances, during manufacturing or product use, such as the 2010 Directive on industrial emissions and the 2000 Water Framework Directive, together with the 2008 Directive on environmental quality standards in the field of water policy.

In the EU, polychlorinated dioxins/furans are regulated in food and feed, through legislation establishing residue limits, and for air emissions of industrial sources. However, polybrominated dioxins/furans are not regulated at all. The EU REACH framework does not regulate unintentional POPs that may be present in chemical formulations or in consumer products, or as a result of cross-contamination (e.g. from using recycled materials in the production of products).

7.4.6 Gaps and deficits (interim results)

- At this point REACH and other EU legal acts regulate persistent chemicals only if other hazardous properties are also present. Except for the 2004 Detergents Regulation, which sets requirements for the biodegradability of surfactants, regulation solely on the basis of a substance being 'persistent' or 'very persistent' is not yet part of the EU legal framework. Moreover, REACH does not require information on PBT properties (including persistence) for low volume substances (less than 10 tonnes a year).
- No criteria have been developed to define when a substance might be considered extremely persistent, i.e., when no evidence of degradation potential has yet been identified, when the degradation half-life could be on the order of decades to centuries, and when contamination would be poorly reversible. For adequate management of such pollutants, other persistence criteria are likely to be needed.
- The traditional approach in chemicals legislation has been substance by substance, which has not been adequate to handle the range of chemicals known to be very persistent.
- There is a lack of publicly available information on the health and environmental impacts of many persistent chemicals, as well as on damages caused to natural resources such as water and soil. This is a particular problem for the more recently commercialized 'very persistent' substances, such as the short-chain PFASs.
- Safe/less problematic alternatives to very persistent chemicals are occasionally lacking, insufficient, or need support to penetrate the market. For example, for many uses of PFASs, non-fluorinated alternatives are not yet available.
- The EU legal framework does not provide a way to regulate unintentionally formed very persistent substances that may be present in chemical formulations or in consumer products or in products as a result of cross-contamination (e.g. from using recycled materials).
- One of the major challenges relating to persistent and very persistent chemicals is that testing environmental half-lives is time consuming and costly. A number of studies have suggested ways in which chemicals can be screened based on chemical structures and characteristics to estimate their persistence, however no common framework for doing this has been adopted or accepted.

- Transformation products are not sufficiently taken into account when considering the health and environmental impacts of a very persistent chemical.
- There is a lack of systematic monitoring for the presence and/or build-up of very persistent chemicals in the environment, including in specific environmental media and biota. The lack of monitoring also relates to the technosphere, e.g. products, waste and recycled materials (which could form reservoirs for future exposure).

7.4.7 Improvement opportunities

- Developing a harmonized approach to screening for persistence could help close the gap in identifying priority chemicals for more rigorous testing of actual multimedia half-lives.
- An automatic obligation to industry to perform simulation tests for substances identified as potentially very persistent could be a way forward. Possibilities/options for obtaining information on the persistence of low volume substances (<10 tonnes) could also be considered.
- The grouping approaches increasingly applied under REACH could make it possible to bring very persistent substances with similar chemical structures under the same umbrella of controls before concentration levels in the environment reach levels where health or environmental impacts occur, and reversing of contamination is no longer possible.
- For very persistent substances, particular attention may be required to keep any releases to the environment at a minimum, e.g., by restricting very persistent chemicals only to those uses considered 'essential' and only when the substances are manufactured or used in closed systems. Another option could be to limit the use of persistent substances to certain essential uses which due to technical reasons/functionality absolutely require such persistence.
- The possibility of an additional classification for extreme persistence could also be considered for those chemicals that may not degrade for decades or longer.
- Systematic environmental monitoring and surveillance of substances known to be very persistent could be considered, included human bio-monitoring and monitoring in e.g. waste streams and products, in order to track their presence and to be aware of any build-up in the environment, e.g., as part of any early warning system.
- Environmental monitoring of very persistent chemicals could be facilitated if producers would be required to provide scientists with standard samples, including of all transformation products formed upon release into the environment.
- Central registries of products containing very persistent chemicals, along with annual statistical data of the volumes of very persistent chemicals produced, used and emitted could be an essential element of monitoring systems for persistent chemicals.
- Infrastructure is needed for the safe transport, disposal of and destruction of very persistent chemicals and vP-containing products, at end of their useful product life.
- Research to enable the development of alternatives to highly persistent substances could be supported.

7.4.8 Annex - Feedback form

Name:

E-Mail address:

Name of organisation:

Please indicate (X) the type of your organisation				
Public body	**Academia**	**Industry/Commerce**	**NGO**	**Other (pls spec-**

				ify)

Please send the feedback form back by 16 June to: nontoxicenvironment@milieu.be

7.4.8.1 Gaps/deficits

The main gaps/deficits identified in the sub-study are listed in the table below. How would you rank their relevance? Please rate 1 for 'no or little relevance', 2 for 'medium relevance', 3 for 'high relevance'. Please also add your opinion on what are the main negative consequences of the gap/deficit with regard to the goal of a non-toxic environment.

Gap no	Gap/deficit	Relevance (from 1 to 3)	Main (negative) consequences of the gap/deficit
1	No regulation solely on basis of a chemical's persistence		
2	No criteria for defining when a substance is extremely persistent		
3	REACH's substance-by-substance approach is not adequate for groupings of chemicals known to be extremely persistent		
4	Lack of publicly available information on health/ environmental impact of many persistent chemicals		
5	Lack of non-fluorinated alternatives for e.g. stain and water repellency		
6	EU regulatory framework does not explicitly cover polybrominated or brominated/chlorinated dioxins/furans		
7	EU regulatory framework does not cover contaminants in products such as unintentional POPs		
8	Testing of persistence in chemicals is prohibitively costly		
9	No common framework in place for screening chemicals for persistence		
10	Insufficient consideration of the impacts of a chemical's breakdown products or formation products		
11	Insufficient monitoring of persistent chemicals in various environmental media, e.g., possibility of reservoirs developing		

Which other important gaps/deficits exist in the focus area of sub-study d (very persistent chemicals), if any?

7.4.8.2 Improvement opportunities

The ideas for improvement identified up to now are listed in the table below. Please rank their relevance, identify which gaps / deficits they would address (use numbers of the respective tables) and identify strengths and weaknesses of the improvement ideas with regard to achieving a non-toxic environment

Idea for improvement	Relevance (1 to 3)	Gap no. addressed (Section 1.1 above)	What is the strength, what is the weakness of the idea for improvement?
New classification for extremely persistent chemicals			
More extensive toxicological testing for vP chemicals			
Develop harmonised approach for screening for persistence			
Use grouping approach for control of very or extremely persistent chemicals			
Put in place restrictions to keep any environmental releases of very persistent chemicals to a minimum			
Require producers to make information on chemical structures, properties & toxicology of vP chemicals publicly available			
Systematic environmental monitoring & surveillance of all known vP substances, as an early warning system			
Facilitate environmental monitoring by requiring producers to provide samples of all vPs they produce			
Establish central registries of products containing vPs			
Develop global inventories of vP substances, including annual statistical data of all vP chemicals produced, used and emitted			
Develop infrastructure and require the safe transport, disposal of and destruction of all vvP chemicals			
Support research as needed to develop safer alternatives to vvP chemicals			

Which (other) responses/instruments could help addressing the gaps/deficits (the ones identified by the study team, and the ones added by you, where applicable?

7.4.8.3 Examples of well functioning legislation, non-legal measures and actions

Which existing legal or non-legal practices do you regard as a good measure / activity / starting point for achieving a non-toxic environment in the area of the sub-study, which have not been mentioned yet?

7.5 WORKSHOP MATERIAL FOR SUB-STUDY E ON POLICY MEANS, INNOVATION AND COMPETITIVENESS

7.5.1 Aim

The aim of the sub-study on policy means, innovation and competitiveness is to provide information on the large and complex set of key factors and driving forces influencing the development of the chemical industry, and how chemicals policy can contribute to strengthening the competitiveness of the industry and fostering innovation.

7.5.2 Scope

For the purpose of this sub-study, we consider innovation as defined by the OECD guidelines for collecting and interpreting innovation data (the so-called "Oslo Manual"). It encompasses a wide range of changes in firms' activities broadly classifiable as:

- Product innovations: involve significant changes in the capabilities of goods or services. Both entirely new goods and services and significant improvements to existing products are included.
- Process innovations: represent significant changes in production and/or delivery methods.
- Organisational innovations: refer to the implementation of new organisational methods. These can be changes in business practices, in workplace organisation or in the firm's external relations.
- Marketing innovations: involve the implementation of new marketing methods. These can include changes in product design and packaging, in product promotion and placement, and in methods for pricing goods and services.

The sub-study looks into the possible incentives for the promotion of innovation aiming or contrib-

uting to a non-toxic environment but also into the impacts of environmental policies on the wider innovation context.

7.5.3 Factors affecting innovation and competitiveness of the chemicals industry

The following factors have been identified as key determinants of the competitiveness of the chemical industry:

- **Energy and oil prices:** Energy products, such as oil and gas, are important to the chemicals industry as a source of energy and as a principle raw material. The impact of an oil-price change is differentiated along the chemicals value chain and also varies depending on the strength and elasticity of the links between products costs and prices. Europe suffers a competitive disadvantage against the USA and Middle East in terms of raw material and energy costs.
- **GDP growth and chemical demand:** The development of the chemicals industry is closely linked to economic growth due to its strong linkages with different sectors of the economy. Global chemical sales and consumption were hit by the 2008 economic crisis leading to a contraction in EU sales, driven significantly by reductions in economic activity in key EU market segments such as construction and automotive, on which chemical demand is highly dependent.
- **Currency appreciation/ exchange rate:** A weaker currency can be expected to be followed by an increase in chemical exports, although higher import prices could have an offsetting impact in some sub-sectors. Exchange rates were favourable for Europe during much of the 2000s, but during the post-crisis period, the Euro has strengthened while the currencies of Japan and China have depreciated.
- **Access to raw materials and new markets/ trade agreements:** In some chemical segments (e.g. petrochemicals), the proximity to raw materials has a significant impact on the costs of production which has resulted in the emergence of the Middle East as a key producer of petrochemicals. In contrast, the EU market is mature with high levels of saturation, an ageing population, low levels of population growth and a shrinking working class; growth in internal demand is therefore expected to be relatively slow in the future. For the EU chemical industry, it will be crucial to secure extra-EU markets, where more than 90% of the global GDP growth will occur, and EU chemical companies are strong advocates of new trade agreements (in particular with key partners such as the US and Japan).
- **R&D intensity, innovation rates, investment in primary production and technological capability:** Unlike other regions, the EU chemicals industry is unable to base its growth on inexpensive resources and labour. With a high level of technological development, skilled workforce and strong research base, innovation is one area where the EU chemicals industry has some competitive advantage. Capital investment in existing infrastructure and production facilities, as well as research and development, is considered a driver of future competitiveness and growth in the EU chemicals industry. However, internationally, evidence suggests that the EU is falling behind globally in terms of capital investment. While many countries are expanding and creating new production facilities, the EU is consolidating.
- **Labour costs:** While Europe suffers a competitive disadvantage against the USA and Middle East in terms of raw material and energy costs, high labour costs, capital costs and other fixed costs are the main weaknesses versus China. Nevertheless, an econometric assessment by Oxford Economics finds that while higher labour costs have a negative impact on competitiveness of the EU chemical industry, the quantitative effect is not significant.
- **Efficiency within the industry:** The rise in oil prices in the 1990s and the first part of the new millennium has driven the increase in fuel and power-consumption efficiency in the EU chemical industry. The global challenge of climate change has strengthened the call from civil socie-

ty and the commitment of industry to ever increasing efficiency. Moreover, given the limited availability of domestic sources, efficiency in the consumption of energy and raw materials is a key factor for the competitiveness of the industry.

- **Regulation:** Regulation has the potential for both negative and positive impacts on the competitiveness and innovation of the EU chemical industry: negative impacts can occur when the cumulative costs of the environmental legislation on the industry add to other adverse global trends; positive impacts can be achieved by regulation through the promotion of green innovation and by ensuring a level playing field for all the actors.

7.5.4 Types of policy means

A wide range of policy means are available to policy makers to influence the economic, social and environmental performance of the chemicals industry.

The paradigm explored in the paper by Porter and van der Linde[11] is that international competitiveness is dynamic and based on innovation, which is a natural and ongoing process in all companies that wish to remain competitive and/or leaders in their field. Previous studies of hundreds of industries worldwide show that those which are the most internationally competitive are those with the capacity to improve and innovate continually. The main argument of the authors is that "*properly designed environmental standards can trigger innovation that may partially or more than fully offset the costs of complying with them*".

An important aspect of environmental legislation is that it can expose resource inefficiencies and potential technological improvements. Regulations that collect and disseminate information on resource inefficiencies and potential technological improvements can raise corporate awareness and lead to increased efficiency in industry, boosting competitiveness. Regulation can put direct and indirect pressure on companies to change, motivating innovation and progress, whilst aiming to level the playing field so that one company cannot opportunistically gain position by avoiding investments in the environment (though the success of this approach ultimately depends on enforcement).

Concepts put forward by Porter and van der Linde that could be considered in the design of environmental regulation intended to stimulate innovation and competitiveness include:

1. Maximum opportunity for innovation should be created, leaving the approach to industry rather than to standard-setting authorities.
2. Regulations should foster continuous improvement, not favouring one form.
3. Regulations should leave as little room for uncertainty as possible. Making information available to all is a start.
4. Market incentives should be included, e.g. pollution taxes, tradeable permits.

The findings of the 2014 paper by the OECD on environmental policies and productivity[12] reinforce the conclusions of Porter and van der Linde. The authors suggest that the introduction of more stringent environmental policies have had no negative effect on overall productivity growth. Before the introduction of such policies, a country's overall production growth slowed, perhaps due to the anticipation of change and the preparation of new operating conditions. This was followed by a

[11] Porter M E & van der Linde C (1995): Towards a new conception of the environmental-competitiveness relationship
[12] OECD (2014): Policy Brief. Green growth: environmental policies and productivity can work together.

rebound, resulting in no cumulative loss. Those firms that are most productive and technologically advanced saw a temporary boost in production due to their early moves to take advantage of new, more environmentally friendly opportunities, resulting in them reaping the rewards of early innovation and creating a favourable market position.

The key policy message in this OECD paper is that "*more stringent environmental policies, when properly designed, can be introduced to benefit the environment without any loss in productivity*". Policies should be encouraging cleaner technologies and new business models that benefit the economy and the environment. Authorities should continue to design environmental policies with streamlined administrative procedures so as not to create barriers to business. The emphasis should be on flexible, market-based instruments such as taxes.

In order to classify the policy means that may be of use in the context of the 7th EAP, the categorisation set out in the table below is presented as a basis for further development. Categories and sub-categories can be added as examples are identified that do not fit the proposed categorisation. The purpose is to maintain consistent definitions and stimulate ideas.

Type	Sub-type	Examples of current use
Economic instruments	Taxes and subsidies	Fertilizer taxation e.g. .Denmark, Finland, Norway, Netherlands, Sweden Pesticide taxation e.g. Denmark, Finland, Norway, Sweden Chlorinated solvent taxation e.g. Denmark, Norway
	Payments	Payments for ecosystem services for water quality, UK Deposit refund schemes for lead acid batteries, USA
	Tradable rights	CO2 emissions trading scheme, EU SO2 allowance trading scheme, USA
	Public procurement	Municipal procurement of cleaning products, France Chemicals Action Plans of the cities of Gothenburg and Stockholm Central government sustainable procurement rules, UK
	Liability/insurance	EU Environmental Liability Directive Comprehensive Environmental Response Compensation Act, USA
Co-regulation	Covenants and negotiated agreements	Environmental Covenants, Netherlands Nanomaterials voluntary reporting, UK
Information based instruments	Targeted information provision	Children's health public campaign, Denmark REACHReady, UK
	Registration, labelling and certification	EU Ecolabel The Green Dot, EU Ecocert, global
	Naming and faming/ shaming	Bathing water interactive map, EU E-PRTR interactive map, EU Local Air Quality Network, UK
Civic and self-regulation	Voluntary regulation	Responsible Care, global VinylPlus, EU
	Civic regulation	Eagle Nickel Mine Community Environmental Monitoring Programme, USA Bucket Brigades, Global Community Monitor, USA
	Regulation by professions	Chartered membership of IChemE, global Chartered Environmentalist, UK/global
	Private corporate regulation	Boots Code of Conduct for Ethical Trading, global BASF Supplier Code of Conduct, global
	Self-regulation	ISO14001, global ISO 45001, global
Support and capacity building	Research and knowledge generation	EPA Green Chemistry funding, USA
	Demonstration projects/ knowledge diffusion	Eco-Innovation Program Lighthouse Projects, Denmark National Demonstration Test Catchments Network, UK Small Business Technology Transfer (STTR) Program, USA
	Network building and joint problem solving	European Technology Platform for Sustainable Chemistry (SusChem), EU ResearchGate, global

Type	Sub-type	Examples of current use
	Crowd-funded research	Crowdcube, UK Experiment.com, USA

7.5.5 Gaps and deficits (interim results)

Up to now, the following gaps and deficits have been identified through the review of the relevant literature:

- Limited internalization of the human health and environmental costs of the production, consumption and disposal of chemicals by chemical manufacturers;
- Lack of (eco)toxicological information for low volume production substances;
- Lack of information on chemicals in articles;
- High number of EU and national acts regulating chemicals, with sometimes overlapping and inconsistent requirements;
- Relatively high administrative burden of EU legislation (especially on SMEs), causing the diversion of resources from innovation;
- Lack of legal certainty undermining confidence to invest in innovation;
- Lack of appropriate and strategic use of EU funding in supporting transformative technologies with strong innovative potential and added value for manufactured products and services;
- Funding available for innovation projects does not meet the ambition of industrial scale projects, mainly due to scattering of support over calls and topics across a large range;
- Lack of support or encouragement for co-operation between geographical areas;
- Lack of support or encouragement for co-operation within and/or between sectors (e.g. between large businesses and SMEs; between industry and academia);
- Insufficiently effective international trade policy/agreements to attract foreign investment to enable innovation;
- Insufficiently effective policy to develop an appropriately skilled European workforce.

7.5.6 Improvement Opportunities

Up to now, the following ideas for improvement have been identified through the literature review:

- Development of a EU-level substance-regulation navigator. This database should include implemented and upcoming international and national legislation by substance/application;
- Greater use of policy means that communicate environmental performance to customers/ consumers;
- Undertaking ex-ante and ex-post assessments of impact on innovation of policy options, legislative proposals and implementing decisions;
- Develop technology infrastructure networks to support industry and share knowledge;
- Direct more funding to pilot lines and demonstration activities;
- In partnership with industry, direct more EU investment (e.g. through European Investment Bank) to innovative manufacturing;
- Escalate regional Smart Specialisation Strategies to a European level;
- Develop a European strategy to link EU policies on all societal challenges to Key Enabling Technology (KET) policy;
- Improve access to markets through trade agreements to facilitate investment opportunities;
- Improve intellectual property rights protection;
- Improve procurement reciprocity in access to public procurement through trade agreements;
- Establish an expert group and direct funding to enhance the dual-use of new technologies;

- Invest in KETs-related skills in Europe e.g. through partnerships between industry and education providers.

7.5.7 Annex - Feedback form

Filled in by

Name:

E-Mail address:

Name of organisation:

Please indicate (X) the type of your organisation				
Public body	**Academia**	**Industry/Commerce**	**NGO**	**Other (pls specify)**

Please send the feedback form back <u>by 16 June</u> to: nontoxicenvironment@milieu.be

7.5.7.1 Gaps/deficits

The main gaps/deficits identified so far in the sub-study are listed in the table below. How would you rank their relevance? Please rate 1 for 'no or little relevance', 2 for 'medium relevance', 3 for 'high relevance '. Please also add your opinion on what are the main negative consequences of the gap/deficit with regard to the goal of a non-toxic environment.

Gap no	Gap/deficit	Relevance (from 1 to 3)	Main (negative) consequences of the gap/deficit
1	Limited internalisation of the human health and environmental costs of the production, consumption and disposal of chemicals by chemical manufacturers		
2	Lack of (eco)toxicological information for low volume production substances		
3	Lack of information on chemicals in articles		
4	High number of EU and national acts regulating chemicals, with sometimes overlapping and inconsistent requirements		
5	Relatively high burden of EU legislation (especially on SMEs), causing the diversion of resources from innovation		
6	Lack of legal certainty undermining confidence to invest in innovation		
7	Lack of appropriate and strategic use of EU funding in supporting transformative technologies with strong innovative potential and added value for manufactured products and services		
8	Funding available for innovation		

Gap no	Gap/deficit	Relevance (from 1 to 3)	Main (negative) consequences of the gap/deficit
	projects does not meet the ambition of industrial scale projects, mainly due to scattering of support over calls and topics across a large range of scientific fields and technologies		
9	Lack of support or encouragement for cooperation between geographical areas		
10	Lack of support or encouragement for cooperation within and/or between sectors (e.g. between large businesses and SMEs; between industry and academia)		
11	Insufficiently effective international trade policy/agreements to attract foreign investment to enable innovation		
12	Insufficiently effective policy to develop an appropriately skilled European workforce		

Which other important gaps/deficits exist in the focus area of sub-study e (policy means, innovation and competitiveness), if any?

7.5.7.2 Improvement opportunities

The ideas for improvement identified up to now are listed in the table below. Please rank their relevance, identify which gaps / deficits they would address (use numbers of the previous table) and identify strengths and weaknesses of the improvement ideas with regard to achieving a non-toxic environment

Idea for improvement	Relevance (1 to 3)	Gap no. it would address (see above)	What is the strength, what is the weakness of the idea for improvement?
EU-level substance-regulation navigator			
Greater use of policy means that communicate environmental performance to customers/ consumers			
Undertaking ex-ante and ex-post assessments of impact on innovation of policy options, legislative proposals and implementing decisions			
Develop technology infrastructure networks to support industry and share knowledge			
Direct more funding to pilot			

Idea for improvement	Relevance (1 to 3)	Gap no. it would address (see above)	What is the strength, what is the weakness of the idea for improvement?
lines and demonstration activities			
In partnership with industry, direct more EU investment (e.g. through European Investment Bank) to innovative manufacturing			
Escalate regional Smart Specialisation Strategies to a European level			
Develop a European strategy to link EU policies on all societal challenges to Key Enabling Technology (KET) policy			
Improve access to markets through trade agreements to facilitate investment opportunities			
Improve intellectual property rights protection			
Improve procurement reciprocity in access to public procurement through trade agreements			
Establish an expert group and direct funding to enhance the dual-use of new technologies			
Invest in KETs-related skills in Europe e.g. through partnerships between industry and education providers			

Which (other) responses/instruments could help addressing the gaps/deficits (the ones identified by the study team, and the ones added by you, where applicable?

7.5.7.3 Best practice examples of legislation, non-legal measures and actions

Which existing legal or non-legal practices do you regard as a good measure / activity / starting point for achieving a non-toxic environment in the area of the sub-study, which have not been mentioned yet?

7.6 WORKSHOP MATERIAL FOR SUB-STUDY F ON RESEARCH AND DEVELOPMENT OF NEW SUBSTANCES

The aim of sub-study f is to identify the needs for and consider useful contents of a possible "Programme to Support Research and Development for New, Non-Toxic Substances" (in the following "R&D Programme"). The R&D Programme should enhance achieving the goals of a non-toxic environment by increasing the (targeted) supply of new, non-toxic substances or substances of lower toxicity as alternatives to toxic substances (substitution) and/or by supporting the development of improved materials including new, non-toxic substances.

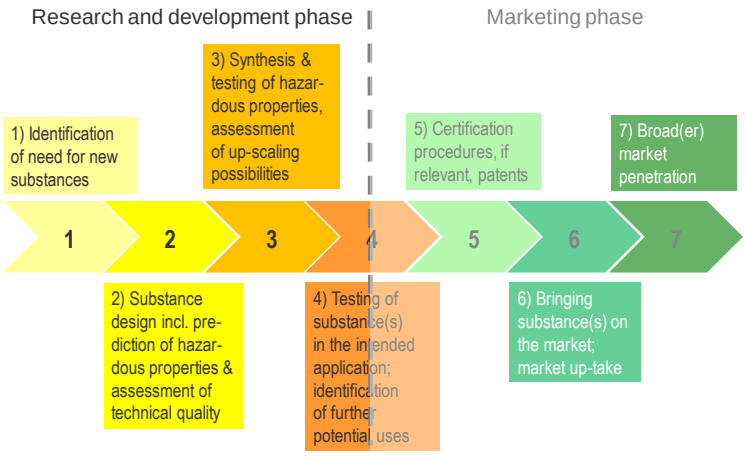
The term "non-toxic substance" is used in the context of this sub-study as either a "substance lacking hazardous properties" as defined in chemicals' legislation or as "substance which is less hazardous than the substance(s) it should replace in a particular application".

In sub-study f, general challenges of substitution are only addressed if they directly relate to the R&D of new substances (e.g. how do the actors demanding a new, non-toxic substance to replace a toxic substance identify the actors who can supply them and/or commonly work on the identification and design of a respective substance?) [13].

The focus of the R&D Programme does not relate to the concept of "Green Chemistry" or "Sustainable Chemistry" but only to substances that are not toxic. Aspects of "Green" or "Sustainable Chemistry", such as resource efficiency or installation safety, may be side effects of production and use of a new, non-toxic substance, but are not primary objectives of the R&D Programme.

7.6.1 Relevance of the topic for Health, environment and resources

The R&D Programme should strengthen the supply of non-toxic substances with favourable properties for human health and the environment, and with regard to closing material cycles (recyclability of substances). These could replace hazardous substances in existing uses or be applied in novel applications, materials or products. The R&D Programme should help to overcome the main obstacles in the design of new, non-toxic substances.



The identification of needs and opportunities to foster the R&D of new, non-toxic substances is structured according to the main steps of the process.
Figure 1 illustrates the model of new, non-toxic substance development. The R&D Programme could target the first four steps, whereas steps 5-7 are related to fostering substitution and supply chain cooperation in general. However, they may also be important incentives for R&D and may therefore also be addressed

[13] For more details on substitution, c.f. sub-study a.

Figure 1:Steps in the development of chemicals

in the R&D Programme.

7.6.2 Existing Green chemistry programmes

International
There are no specific programmes to support the R&D of new, non-toxic substances at international level. The United Nations Environment Programme and the Strategic Approach on International Chemicals Management focus on chemicals' management and communication. Also the OECD does not run respective R&D Programmes.

United States
Although no documented framework outlining a respective policy exists, the US EPA's activities could be regarded as a programme. They support/fund R&D, conduct (national) research, organise education and training, provide tools and methods for green chemistry actions, organise conferences, fund the "Green chemistry presidential award" and support networking of actors.

The bill to establish a sustainable chemistry framework, introduced to the US Congress in 2014, could initiate the development of a formal, national sustainability programme, including R&D actions.

Several of the US Federal States also have "Green Chemistry Programmes", most of which, however, focus on legal restrictions and substitution support.

The Green Chemistry and Commerce Council (GC3) is an example of a corporate network that aims at promoting the use of green chemistry. Among others, it published an "Agenda to Mainstream Green Chemistry"[14] outlining strategies and specific actions in this regard.

EU Member States
No dedicated Green or Sustainable Chemistry Programmes could be identified in the EU Member States, which may be due to an actual lack of respective programmes, or the fact that related actions are integrated in other work areas, such as innovation research or sector specific support. The only area where new (non-toxic) substances development is explicitly addressed is research on nanomaterials.

Conclusions on R&D programmes on new, non-toxic substances
No consistent, strategic framework to promote R&D on new, non-toxic substances could be identified. However, several activities are ongoing in relation to the wider concepts of Green or Sustainable Chemistry, in particular in the United States. Viewing the individual research activities and support measures in the overall field of "sustainable chemistry", which includes elimination or at least reduction of toxicity, the following elements are identified as potentially relevant for an EU R&D Programme:

- programme organisation responsible institution(s), timelines, metrics to measure progress etc.
- developing tools and/or making them accessible
- education and training of all stakeholders
- research and development funding
- networking instruments and opportunities

[14] Green Chemistry and Commerce Council, 2015.

- (regulatory) market incentives

7.6.3 Barriers to and drivers of Green Chemicals development

Available literature mostly relates to barriers and drivers of "green" or "sustainable" chemistry, whereas little information is available on the challenges of the organisation of actual R&D processes. The items on the following lists, which are compiled from this literature, therefore relate to green/sustainable chemistry and may only indirectly target R&D activities.

It is common understanding that barriers to substitution and/or the use of less or non-toxic substances largely originate from challenges in supply chain interaction. Some of these are closely related to the R&D of new, non-toxic or less toxic substances such as:

- conflicts of interest between increased transparency needs of users and protection of confidential business information of suppliers;
- suppliers and potential users of non-toxic or less toxic substances do not know each other/lack opportunities to meet;
- fear of hidden costs and resource needs for change to new products, change-over cost;
- fragmented demand due to complexities of the supply chains (one manufacturer - many clients, one retailer - many products);
- challenges in the evaluation solutions involving the use of new, non-toxic or less toxic substances (financial implications, market uptake, hazard and risk assessment (in particular for nanomaterials));
- lack of research funding;
- regulatory uncertainty, registration/notification/approval procedures.

Among the core drivers for the use of less toxic substances/substitution are legal requirements, consumer demand, increased level of protection for workers and the environment, cost savings, and competitive advantages. These drivers incentivise the process of substitution and thereby indirectly stimulate demand for new, non-toxic substances. However, this may firstly be satisfied with the use of existing, less hazardous substances. The only core driver that may specifically incentivise R&D for new, non-toxic substances is a demand for improved materials, which would trigger larger research processes (e.g. new composite materials).

Further needs in support of the R&D of new, non-toxic or less toxic substances identified from literature and stakeholder interviews are:

- opportunities to bring actors in demand of non-toxic substances together with actors developing them;
- promotion of partnerships between academia and companies for developing new, non-toxic substances;
- improvement of opinions on the performance and costs of new substances, e.g. by publishing best practice examples of related substitutions;
- creation of incentives to develop new, non-toxic substances, e.g. through awards, tax reductions, patent rules favourable to new, non-toxic substances, facilitated market access, "labels" to enhance promotion.

The process of substance design using computer tools and models ("in silico design") is comparatively new and requires a high level of expertise. Furthermore, the prediction of hazardous proper-

ties and linking the substance design to avoiding (eco-)toxicologically hazardous properties are partly new scientific disciplines. Models for hazard prediction are only partly available.

In relation to hazard prediction of new substances, the following appears to be needed:

- review of availability of hazard prediction models, identification of gaps and related research needs;
- education and training on the substance design;
- R&D on the "designing out" of toxic properties;
- networks to combine expertise of different actors.

7.6.4 Ideas for improvement

Based on the analysis of deficits and potential needs of the actors involved in the development of new, non-toxic substances, the following elements could be considered as components of a possible EU Programme to support the R&D on new, non-toxic substances.

Programme Framework
An overall documented programme framework would be a guideline for all actors. It should include a description of overarching goals and roles and responsibilities of the actors that should contribute to achieving them. Activities in the following areas could be outlined as part of the programme, including individual targets, specific actions and indicators to measure the success. The programme might define an institution that should oversee the programme implementation.

R&D on tools
The programme could support the R&D regarding the tools needed to design new, non-toxic substances. This action area should start with an in-depth assessment of needs for tools as well as of the related ongoing activities, such as under Horizon 2020 or by the US Tox21 programme. It is expected that tools for substance design "in silico" including hazard prediction models constitute the most relevant needs. After the needs are identified, projects should be awarded to support respective development activities.

Education and training
Education and training of the relevant actors on the design and use, as well as overall benefits of non-toxic substances, could be an important element of the future programme. It could aim at increasing competences of chemical engineers in substance design as well as their awareness of the regulatory, as well as health and environmental, context. Education and training of non-chemistry actors could support transdisciplinary work, general understanding of chemical risks and benefits of reducing toxicity, or creating a more positive research environment in general.

Funding of pilot projects
Funding of projects could be another element of the R&D Programme that would foster the development of new, non-toxic substances, including by communicating best practice examples. Research funding could support activities, which have a pilot character and/or a wide ranging improvement effect on health and the environment or on an important innovation area. Furthermore, research awards could be established to incentivise R&D in general. Respective actions should build upon existing programmes and research contexts, e.g. Horizon 2020.

Networking of actors
Some networks already exist at EU and national level in relation to "Sustainable Chemistry" (e.g.

SusChem). These networks could be supported and the focus on new, non-toxic substances be more emphasised than is currently the case. Another aspect could be the creation of new networks and platforms, e.g. in the context of education and training or to support the establishing and maintaining of contacts between the users and suppliers of new, non-toxic substances.

Policy and market actions
Legal and economic instruments could be applied to increase R&D on new, non-toxic substances, including for example an extension of existing or introduction of new exemptions for new, non-toxic substances' development (PPORD[15]), and/or developing advantages for substances with low toxicity in patent rules.

7.6.5 Annex - Feedback form

Filled in by

Name:

E-Mail address:

Name of organisation:

Please indicate (X) the type of your organisation				
Public body	**Academia**	**Industry/Commerce**	**NGO**	**Other (pls specify)**

Please send the feedback form back by 16 June to: nontoxicenvironment@milieu.be

7.6.5.1 Gaps/deficits

The main gaps/deficits identified in the sub-study are listed in the table below. How would you rank their relevance? Please rate 1 for 'no or little relevance', 2 for 'medium relevance', 3 for 'important relevance'. Please also add your opinion on what are the main negative consequences of the gap/deficit with regard to the goal of a non-toxic environment.

Gap no	Gap/deficit	Relevance (from 1 to 3)	Main (negative) consequences of the gap/deficit regarding a non-toxic environment
1	Lack of tools for in silico substance design		
2	Lack of tools to predict / exclude substance hazards early in the design phase		
3	Lack of contact between researchers and future users of new, non-toxic chemicals		

[15] Product and Process Oriented Research and Development according to Article 9 in the REACH regulation.

Gap no	Gap/deficit	Relevance (from 1 to 3)	Main (negative) consequences of the gap/deficit regarding a non-toxic environment
4	Lack of research funding		
5	Lack of networking of actors designing new, non-toxic substances		
6	Lack of awareness / education in user companies		
7	Lack of chemical engineers / transdisciplinary teams to conduct research		
8	Challenges in supply chains to initiate research for new, non-toxic substances		
9	Regulatory barriers, lack of incentives to develop new, non-toxic substances		

Which other important gaps/deficits exist in the focus area of sub-study f, if any?

7.6.5.2 Improvement opportunities

The ideas for improvement identified up to now are listed in the table below. Please rank their relevance, identify which gaps / deficits they would address (use numbers of the respective tables) and identify strengths and weaknesses of the improvement ideas with regard to achieving a non-toxic environment

Idea for improvement	Relevance (1 to 3)	Gap no. it would address (see above)	What is the strength, what is the weakness of the idea for improvement?
Develop an overall programmatic framework to coordinate and strengthen work to promote the development of new, non-toxic substances			
Assessment of needs for substance design tools and initiating respective R&D projects			
Assessment of needs for hazard prediction tools and initiating respective R&D projects			
Development of (IT-supported) platforms to sup-			

Idea for improvement	Relevance (1 to 3)	Gap no. it would address (see above)	What is the strength, what is the weakness of the idea for improvement?
port networking of substance designers with users of substances			
Establish research funding programme specific for new, non-toxic substances			
Stress the topic of new, non-toxic substance design in existing networks on sustainable chemistry, such as SusChem			
Initiate education and training network to integrate aspects of non-toxic substances in higher and general education			
Create exemptions from legal obligations for new, non-toxic substances (e.g. PPORD exemptions)			
Develop more favourable patent rules for new, non-toxic substances			
Publish good examples of substitution, where new, non-toxic substances bring benefits to all parties to increase interest and awareness			

Which (other) responses/instruments could help addressing the gaps/deficits (the ones identified by the study team, and the ones added by you, where applicable?

Which existing legal or non-legal practices do you regard as a good measure / activity / starting point for achieving a non-toxic environment in the area of the sub-study, which have not yet been mentioned?

7.7 WORKSHOP MATERIAL FOR SUB-STUDY G ON THE CREATION OF JOINT EARLY WARNING SYSTEM

This sub-study considers the possibilities of establishing a joint early warning system for newly

emerging chemical risks. Such risks could arise due to a new substance or application, new technological developments or process innovations. Alternatively, a long-term use of a substance could lead to adverse effects on health and the environment not previously recognised. Further, new scientific knowledge could change the interpretation of health and environment threats involved. This sub-study aims to provide:

- An overview of existing projects and studies in the area of early warning systems that could be of inspiration for the development of an early warning system for chemical risks;
- An assessment of existing mechanisms that can trigger risk management actions when chemical risks are identified;
- Aspects of a possible EU-wide early warning system for chemical risks, including potential components that already exist or would need to be developed;
- An initial view of the potential benefits as well as costs if such a system would be developed.

The work carried out to date has focused on the first aim – to gather an overview of existing projects and studies in this area. The research has identified three policy areas where early warnings of chemical risks are considered particularly important: (i) environmental protection, (ii) occupational health and safety, and (iii) consumer protection, including food safety.

7.7.1 Early warning systems for environmental protection

Two systems that aim at the identification and management of new or emerging risks of chemicals (NERCS) for the environment are currently operational in the EU – the NORMAN network[16] and the system operated by the RIVM (Hogendoorn et al, 2014).

The activities of the NORMAN network are up to now mainly aimed at the Water Framework Directive. Identified and prioritized chemicals are proposed as candidate substances for the EU Watch List of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council (Art 8 ter of Directive 2013/39/EU)

The NERC system operated by the RIVM is not aimed at any specific piece of legislation in the field of chemicals. The focus until now has been on the aquatic environment. Identified new or emerging chemicals have been put forward in the different REACH processes.

7.7.2 Definition and scope of an early warning system

Important aspects of the organision and operation of an early warning system are the definition of new or emerging risks and the specific aim of the system. The kind of information that is generated within a certain system pre-defines what the system will be able to do.

At the moment the main actors involved in early warning systems (US-EPA, NORMAN Network, SCENHIR) use a variety of terms and definitions such as new risk, emerging risk, emerging issue, emerging pollutant, emerging substance, and contaminant of emerging concern. These can be grouped into three main categories:

- newly created risk;
- newly identified risk,
- increasing risk or risks becoming widely known or established.

[16] http://www.norman-network.net/

The scope of the early warning system for emerging threats is set on the hazards posed by chemicals to human health and the environment. The kind of chemicals covered are industrial chemicals, biocides, pesticides, food and feed additives, cosmetics, medicines, combustion by-products. The different media to be considered are air, water, soil and human exposure via the environment, consumer products, food and at the workplace.

Some steps for setting up an Early Warning System

- Define purpose and scope of the early warning system
- Select suitable approaches for detecting signals
- Generate overview of data sources for selection and prioritisation
- Develop a blue print for a method of prioritisation
- Define future actions to utilize data sources

Based on the work carried out by FAO (2006), Dulio and von der Ohe (2013), the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR, 2009) and RIVM (Hogendoorn et al, 2014 and Palmen, 2016), the main components of an early warning system are:

1. Detecting signals
2. Prioritisation, risk characterisation
3. Follow-up actions, risk management measures
4. Communication

7.7.3 Detecting signals, setting priorities and characterising risks

Several ways or tools exist to pick up signals. The main ones are foresight approaches (including expert consultation), monitoring and sampling, citizen science and media monitoring.

Many different approaches are available for ranking the relevance of a potential chemical of concern. In general a risk based approach is applied using information on the exposure and hazards of the chemicals of concern. The kind of information used as proxies for exposure and hazard varies significantly. The information used depends on the availability and accessibility of the data and the amount of effort needed to generate specific data, such as modeled exposure concentrations or QSAR estimates.

An inventory of potential available data that can be used for prioritization purposes is particularly needed. For each data source, the availability should be indicated and the actions and amount of effort needed to gather or generate specific type of information should beassessed.

Several potential data sources and platforms have been reviewed, such as IPChem (2016), NORMAN network databases and EASIS (2016). These are data sources rather than a system or concept for the early identification of new and emerging chemical risks. Table 1 provides a short overview of the data that potentially can be used in the prioritization of new of emerging chemicals in the system.

Table 1: Overview of potential data source that can be applied in prioritisation.

Description	Source	Degree of uncertainty

Description	Source	Degree of uncertainty
Hazard		
Environmental quality standards, limit values etc.	Legislation (WFD, Air Quality Directive etc.)	Low
Predicted no effect concentration, no observed effect levels etc.	REACH registration data	Medium
Hazardous properties	C&L notification database ECHA, EASIS database. PBT assessments	Low
QSAR based assessment hazardous properties	OSAR models/software	High
Hazard scores and prediction of potentials or mode of action based on QSARS and models	QSAR models/software	High/Indicative
Exposure		
Measured concentration	NORMAN databases, IPChem, National databases	Low/Medium
Production volumes	ECHA registration database	Low/Medium[1]
Modelled concentrations based on emissions and used volumes	SOLUTIONS project	Medium/High
Exposure categories	ECHA registration database	Indicative[2]
Risk		
Measured data case by case, accidents		Low
Epidemiology		Low-High
Modeled results from risk assessments	Risk assessment reports, CSA REACH registrations	Medium

[1)] The exact production volumes is not public available but is usually provided in ranges, class widths generally covers a factor of 10: 1-10; 10- 100; 100-1 000 etc.
[2)] The exact share of the different uses in the total (production) volume is unknown, main use should be identified using broad exposure categories

7.7.4 Risk management and risk communication

Before identifying suitable risk management measures, current or upcoming measures and legislation need to be assessed to see whether the identified risk is already addressed and if that is the case, weather the measures imposed are appropriate and sufficient. If not, possible risk management measures have to be worked out. Follow-up actions also need to be defined for the most important measures. As an example, the REACH regulation includes some alternative risk management measures which could be used to address an identified risk.

The aim of developing and operationalizing an early warning system strongly relates to the risk management stage. It would hence be desirable for an early warning system to pre-define the risk management measures to be triggered, e.g. by identifying types of chemicals, related risks and the pieces of legislation that addresses these risks.

The systems reviewed so far focus mainly on the identification of new or emerging risks related the chemicals in the aquatic environment. In these cases, when the aim and the risk management measures are pre-defined, the risk communication might be less relevant. Nevertheless, in a system with a more open scope, there are more different ways to address an identified risk. Hence, this will increases the need for exploring options for risk communication as well as alternative risk management measures.

7.7.5 Early Warning systems for worker health and safety

An early warning system for worker health and safety could take two different approaches. The first approach would be proactive, i.e., "exposure first". This method would aim to identify possible new and emerging chemical risks (NERCs) based on the physical/chemical properties of a substance or the (altered) use of a substance, taking into account technological and societal developments. No typical system using the "exposure first" method was identified for workers.

The second approach would be reactive, i.e., "disease first". This method would try to identify health effects of NERCs as soon as possible by identifying cases using clinical watch systems and performing research on databases containing information on job/exposure and health effect. This inductive way of reasoning works from observations toward generalizations and theories. It is necessary since there is lack of toxicological knowledge, especially after inhalation and dermal exposure, for many substances on the market. The "disease first" method is also used in pharmacovigilance. Drugs are tested thoroughly before introduction on the market but negative side effects are often found after introduction on the marked.

A recent study found that in the occupational safety and health context European countries typically use the reactive, "disease first" method to identify NERCs. A questionnaire was sent to representatives of all European countries with questions on the presence of a clinical watch system, i.e., a sentinel surveillance system to enable the ongoing and rapid identification of sentinel health events in occupational health (cases and their corresponding occupational risks) for the purposes of follow-up and for developing statistical trends (Samant et al, 2015). The survey also sought information on the availability of databases for epidemiological research to study a causal relationship between exposure and health effects (e.g. cancer).

Of the 23 (out of 51) European countries that responded, seven countries reported having clinical watch systems that were specifically designed to detect NERCs and another 10 countries had systems that can be used for that purpose. The main institutions collecting information aimed at detecting NERCs were occupational health and safety authorities, research organizations and insurance funds. Medical doctors can report NERCs in all systems. Under several systems, industrial hygienists, occupational nurses, employers, trade unions and workers could also report. Literature search and discussions in an expert group also played a key role in the evaluation of a possible causal relationship between the exposure and the reported health effect.

Another way of detecting NERCs is by using databases containing information on 1. exposure to hazardous substances and/or occupational activities which might involve exposure and 2. observed health effects. Several databases were identified that could be used to study work related health effects. Some of them are directly connected to the clinical watch systems, but there are also other databases that can be used for the same purpose. Most of these databases are associated with research on occupational health and connected to expert groups dedicated to their operation and maintenance.

Identification of new and emerging risks requires several complementary methods. Besides clinical watch systems and databases with information on exposure and health effect, active detection via health surveillance, active literature search using text mining, and secondary analysis of other sources can be used to identify new and emerging risks (Palmen et al., 2013).

7.7.6 Early warning systems for consumer protection and food safety

Less information was found on possible layout of early warning systems for consumer protection. Those in place were highly dependent on observations and on documented signals related to observed effects. So far, the EFSA system for consumer protection related to food seems to be the most advanced early warning system in this field.

Other systems, not necessarily made for the identification of new and or emerging risks, have developed mechanisms for prioritization based on the possibility of exposure to chemicals.

A general observation is that an early warning system is data hungry and requires sophisticated search and filtering strategies. In this respect, an exposure-based prioritization model presented by Mitchell et al. (2011) and Wambaugh et al. (2013) is the most advanced and directly related to exposure prevention.

7.7.7 Gaps and deficits identified (interim results)

- The identification of possible NERCs in the field of occupational safety and health is difficult in several countries, as it is challenging to achieve funding of expert centres focused on the study of occupational health effect.
- Several early warning systems for workers are available in Europe but an international platform dealing with work-related health effects and occupational diseases is lacking.
- No information on costs of early warning systems was found.
- A general question relating to health as well as environment is how to cope with the time lag between exposure and adverse effects. It will always be hard to establish a causal link between exposure to chemicals and e.g. diseases. Another issue is the limitations of epidemiology, which means that a harmful effect often must be rather drastic and widespread to be detectable.
- No system that interlinks all focus areas has been identified. The continuous screening and filtering of signals is a process that is labor intensive and highly dependent on the focus areas chosen. These could be e.g. food, consumer products, acute poisoning incidences, ecosystems, etc. For instance, if the purpose of an early warning system is to quickly pick-up signals of effects, e.g. on consumers, workers or the environment, and to contribute to the prevention of further damages, there is a need to establish a centralized signal processing function (e.g. at EU level).
- Early indications derived from a systematic review of exposure and risk assessment procedures in current early warning systems raise questions about their effectiveness. This is particularly the case in view of indications which remains indicative, after undergoing amplification and prioritization procedures.
- Lack of information frequently jeopardizes the attribution of an appropriate ranking of possible risks/damages during the prioritization phase. This lack of information might be due to the absence of a human or environmental health based quality standards, the absence of exposure and use information or other types of information related to the identification of NERCs. Therefore, it is important to identify all available useful sources of information and databases.
- An identified gap is the knowledge on communications methods. The current focus is rather on the identification of new or emerging risks and proposing suitable risk management measures.

7.7.8 Improvement opportunities

- More cooperation and exchange of information at the EU or international level is needed to achieve development and constant improvement

- The set-up of a central (EU) system supporting the input and output of information relating to NERCs
- A principal decision at the EU level to clarify intention or taking action to support the development of an early warning system.
- Improvement of existing risk assessment methodology/schemes by incorporating additional and more specific endpoints, e.g. on endocrine disruption.
- Some decisions which needs to be taken in the process of setting up a possible future joint early warning system include:
  - Defining purpose and scope of the early warning system
  - Selecting suitable approaches for detecting signals
  - Generating an overview of data sources for selection and prioritisation
  - Develop a blue print for method of prioritisation
  - Exploring possibilities for organising and operationalising an early warning system
  - Define future actions to utilize data sources
- There is a need to further investigate the feasibility of interlinking and coordinating all focus areas such as environment, consumers and worker. Each of these areas has its specific approach, experts and data sources. Nevertheless, some parts of the system could well use the same approaches and tools. However, for practical reasons it might be easier to develop and maintain separate systems and to let them exchange information at a certain level.

7.7.9 Annex - Feedback form

Filled in by

Name:

E-Mail address:

Name of organisation:

Please indicate (X) the type of your organisation				
Public body	**Academia**	**Industry/Commerce**	**NGO**	**Other (pls specify)**

Please send the feedback form back by 16 June to: nontoxicenvironment@milieu.be

7.7.9.1 Gaps/deficits

The main gaps/deficits identified in the sub-study are listed in the table below. How would you rank their relevance? Please rate 1 for 'no or little relevance', 2 for 'medium relevance', 3 for 'important relevance'. Please also add your opinion on what are the main negative consequences of the gap/deficit with regard to the goal of a non-toxic environment.

Gap no	Gap/deficit	Relevance (from 1 to 3)	Main (negative) consequences of the gap/deficit regarding a non-toxic environment
1	Problem in funding of expertise centres, where workers can go to study a possible work-related health effect.		
2	Lack of an international platform working on work related health effects and occupational		

Gap no	Gap/deficit	Relevance (from 1 to 3)	Main (negative) consequences of the gap/deficit regarding a non-toxic environment
	diseases.		
3	No information on costs of early warning systems was found.		
4	No system has been identified that interlinks all areas of focus.		
5	Early indications of a systematic review of exposure and risk assessment procedures in current early warning systems raise questions about its effectiveness.		
6	Lack of information frequently jeopardizes the attribution of an appropriate ranking during the prioritization phase.		
7	An identified gap is the communication stage. The focus is on the identification of new or emerging risks and proposing suitable risk management measures.		

Which other important gaps/deficits exist in the focus area of sub-study g (Early Warning Systems for Chemical Threats), if any?

7.7.9.2 Improvement opportunities

The ideas for improvement identified up to now are listed in the table below. Please rank their relevance, identify which gaps / deficits they would address (use numbers of the respective tables) and identify strengths and weaknesses of the improvement ideas with regard to achieving a non-toxic environment

Idea for improvement	Relevance (1 to 3)	Gap no. it would address (see above)	What is the strength, what is the weakness of the idea for improvement?
More cooperation/adjustment (exchange of information) at international level			
The set-up of a central (European) system serving in the in- and output information of NERCs			
Decision to take measures at a European level			
Improvement of existing Risk Assessment by incorporating additional and more specific end points, e.g. on endocrine disruption. Steps needed in setting up an early warning system :			
■ Define purpose and scope of the early warning system			
■ Select suitable approaches for detecting signals			
■ Generate overview of data sources for			

Idea for improvement	Relevance (1 to 3)	Gap no. it would address (see above)	What is the strength, what is the weakness of the idea for improvement?
selection and prioritisation			
■ Develop blue print for method of prioritisation			
■ Exploring possibilities on how to organise and operationalise an early warning system			
■ Define future actions to utilize data sources			
Investigate the feasibility interlinking all areas of focus, environment, consumers and worker.			

Which (other) responses/instruments could help addressing the gaps/deficits (the ones identified by the study team, and the ones added by you, where applicable?

7.7.9.3 Examples of well functioning legislation, non-legal measures and actions

Which existing legal or non-legal practices do you regard as a good measure / activity / starting point for achieving a non-toxic environment in the area of the sub-study, which have not been mentioned yet?

The strategy for a non-toxic environment of the 7th Environment Action Programme

Appendix to: Sub-study c

Literature write-up

Written by Milieu Ltd.
August – *2017*

The strategy for a non-toxic environment of the 7th Environent Action Programme

Appendix to: Sub-study c

Literature write-up

Directorate-General for Environment
Sustainable Chemicals

2017

Appendix to sub-study c: literature write-up

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1 WHO ARE THE VULNERABLE GROUPS IN SOCIETY?

As indicated by the World Health Organisation (WHO, 2009), susceptible subpopulations exist in all groups of individuals. Such susceptible subpopulations may have a greater inherent risk of suffering adverse health effects from a chemical incident, for example, because:

- their exposure thresholds for health effects are lower;
- they receive a relatively high exposure;
- their mobility is reduced or their ability to protect themselves from exposure is reduced
- they have an increased sensitivity to chemicals.

Their common denominator is that vulnerable people are at an increased risk to their health, should exposure to a certain chemical arise.

Risk is the likelihood that a harmful health event will occur in a given population during a specific time period (ANHE, webpage). Environmental hazards can increase human risk of illness, disability and premature death. The Environmental Protection Agency (EPA) defines risk as the "*chance of harmful effects to human health or to ecological systems*" that results from exposure to an environmental hazard (EPA, 2010). An environmental hazard is "*any physical, chemical, or biological entity*" that causes harm. Some common factors that affect the risk of harmful health events cannot be changed. Such factors include age, gender, race or ethnicity. Other factor that affect the risk of harmful health events and which result from biophysical, environmental, psychosocial and socio-political circumstances, can be changed. When environmental threats to health are examined, all humans are at risk in relation to global climate change and the increasing use of untested and toxic chemicals.

Vulnerability can be defined as "*a varying state of weakness or strength that can be mobilized when one encounters a threatening event*" (Leffers et al, 2004). This definition includes individual and experiential factors that result in variability of outcomes across populations. Risk and vulnerability are related to each other. Some describe vulnerability as a series of threshold factors that increase or amplify risk and lead to poorer health outcomes. Others argue that vulnerability can vary according to the capacity of the individual and many not lead to poorer health outcomes (Clark and Driever, 1983; Speirs, 2000). This view says that positive attributes of those identified as vulnerable can enable them to overcome risk and vulnerability leading to better outcomes (Leffers et al, 2004).

The notion of 'windows of vulnerability' refers to specific times during human development that have been identified for higher risks to health. For example, at times a child can have better recuperative capacity than adults. In other situations, children are at far greater risk (Brent, Tanski, & Weitzman, 2004).

Various populations have been identified as more vulnerable to environmental hazards. As stated earlier, individual and experiential factors can lead to different vulnerability across populations. These factors include those whose biophysical characteristics make them more vulnerable such as the developing foetus, infants, children and older adults. People with acquired biophysical factors such as chronic illness, those with differences in functioning due to trauma, and altered immunity also become more vulnerable to poor health outcomes. Additionally, those born with congenital anomalies and with variations in cognitive and physical abilities may be at more risk from specific toxic exposures.

Behavioural factors such as developmental age appropriate behaviour, activities, hobbies and occupational exposures all raise vulnerability. Social factors such as where a person lives, works or spends a great deal of time can also make him or her more vulnerable.

1.1 CHILDREN

1.1.1 Introduction

According to the World Health Organisation (WHO, 2006), children, who comprise over one third of the world's population, are one of the most vulnerable categories of the population. Children in fact are not simply little adults; they possess distinct characteristics across life stages that contribute to their different susceptibility to chemical exposures. For example, infants gain more weight during the first four to six months than during the rest of their lives and organ systems grow at different rates at any time from infancy to early childhood. With respect to anatomical and functional characteristics, most organ systems lack structural or functional maturity. The developing organs are particularly susceptible to toxic insult, given the increased rate of cell division and immaturity of some functional excretion systems. Uptake of chemicals is also likely to vary between children and adults. For example, the respiratory ventilation rate in infants is significantly larger relative to lung surface compared with adults. Therefore, infants potentially have greater uptake of airborne compounds on a body weight basis.

The physiological distribution volume for chemicals may vary between children and adults because of differences in water and lipid content as a function of age. For example, the relatively larger extracellular fluid volume of the infant means somewhat greater dilution of water-soluble chemicals. However, the lipid-soluble substances would be distributed in a smaller volume of fat in infants relative to adults (WHO, 2006). Because of differences in physiology, behaviours, body weight, and body surface area, the exposure levels in children may be different from and often higher than exposures in adults. Furthermore, in terms of risk, children may also be more susceptible to environmental pollutants because of differences in absorption, metabolism, and excretion. Moreover, children's exposure will differ according to geographic area, activities undertaken, settings they live in, and the social realities they experience.

As explained by Landrigan and Goldman (2011), the realisation that children are uniquely sensitive to toxic chemicals was catalysed by the publication in 1993 of a National Academies report, *Pesticides in the Diets of Infants and Children* (US National Research Council, 1993). Studies cited in the report found that children are quantitatively and qualitatively different from adults in their sensitivity to pesticides and other chemicals. Prior to the report's publication, little attention was paid to the unique risks of infants, children, or other vulnerable groups within the population. The report produced a paradigm shift in that approach to health and environmental policy.

The report identified four differences between children and adults that contribute to children's heightened susceptibility to chemicals in the environment.

- First, children have greater exposures to toxic chemicals for their body weight than adults. A six-month-old infant drinks seven times more water per pound than an adult. Children take in three to four times more calories per pound than adults. The air intake per pound of an infant is twice that of an adult. These differences result in children being disproportionately exposed to toxic chemicals in air, food, and water. Children's hand-to-mouth behaviour and play on the ground further magnify their exposures.
- Second, children's metabolic pathways are immature, and a child's ability to metabolize toxic chemicals is different from an adult's. In some instances, infants are at lower risk than adults because they cannot convert chemicals to their toxic forms. More commonly, however, children are more vulnerable because they lack the enzymes needed to break down and remove toxic chemicals from the body.
- Third, children's early developmental processes are easily disrupted. Rapid, complex, and highly choreographed development takes place in prenatal life and in the first years after birth, continuing more slowly throughout childhood into puberty. In the brain, for example, billions of cells must form, move to their assigned positions, and establish trillions of precise

interconnections. Likewise, development of the reproductive organs is guided by a complex and precisely timed sequence of chemical messages and is shaped by maternal and foetal hormones. Recent research in paediatrics and developmental toxicology has elaborated the concept of "windows of vulnerability." These are critical periods in early development when exposures to even minute doses of toxic chemicals - levels that would have no adverse effect on an adult - can disrupt organ formation and cause lifelong functional impairments. If, for example, cells in an infant's brain are injured by lead or a pesticide, the consequences can include developmental disabilities in childhood and possibly increased risk of neurological degeneration, such as Parkinson's disease, in adult life. If inappropriate hormonal signals are sent to the developing reproductive organs by a synthetic chemical endocrine disruptor - such as certain chemicals commonly found in household products, plastics, and cosmetics (phthalates), and on clothing (flame retardants) - lifelong reproductive impairment may ensue. These windows of vulnerability have no equivalent in adult life.

- Fourth, children have more time than adults to develop chronic diseases. Many diseases triggered by toxic chemicals, such as cancer and neurodegenerative diseases, are now understood to evolve through multistage, multiyear processes that may be initiated by exposures in infancy. This insight has catalysed new research to identify how early environmental influences may affect health in childhood and across the human lifespan. Notable research includes the US National Children's Study, the Japan Environment and Children's Study, and the International Childhood Cancer Cohort Consortium.

Cohen Hubal et al (2014) studied exposure-related issues to consider in determining the most appropriate age ranges and life stages for risk assessment. Children's physiology changes over time in ways that can impact both their exposures to environmental contaminants and their susceptibility to certain health effects. Children's behaviour also changes over time in ways that can have an important impact on exposure to environmental contaminants. These developmental changes occur as a continuum that contributes to an exposure function over all ages. However, typically existing information is not adequate to construct an exposure function that reflects continuous behavioural and anatomical development. In these cases, a consistent, default approach using age group "bins" is required to provide a reasonable surrogate for the continuous function.

Two aspects of physiological changes are relevant for risk assessment. The first is anatomical changes resulting from physical growth. The second is changes in toxicokinetics and toxicodynamics that affect the absorption, distribution, excretion and effects of environmental contaminants. Although the issues are organized in two categories – issues associated with behavioural changes in children and those associated with anatomical changes and physical growth – to facilitate the development of harmonized age bins, it is understood that these two categories are considerably intertwined.

Changes in childhood behaviour over time are linked to physical and mental growth and can influence where children spend their time, what physical activities they engage in and what foods they eat. To define standard age bins, aspects of behaviour most important for characterizing exposure and risk must be identified, as well as critical changes in these behaviours over the course of development. In developing the proposed age bins for harmonized risk assessment, the following behaviour-specific issues were considered by Cohen Hubal et al:

- Important developmental milestones in children's behaviour;
- For each milestone, the range of ages during which the behaviours are typically observed;
- Variability among children with respect to the age of onset and the age of abandonment (if applicable) for these behaviours;
- Observed changes in behaviour associated with these milestones that are likely to affect children's exposure to environmental contaminants, such as mouthing hands and objects and crawling;
- For those behaviours that are likely to have an important impact on exposure, existing information that is representative of the impact of this behaviour on exposure;

- How these behaviours and milestones impact exposure by different routes (e.g. dermal, inhalation and ingestion).

A review by Choi et al (2015) further emphasised that children should be regarded as a population of high risk for health impairment due to behavioural tendencies (e.g. hand-to-mouth contact, crawling, chewing toys), making them more susceptible to chemical exposure. Moreover, interest in children's environmental health is increased by rapidly rising rates of chronic disease in children of asthma, cancer, autism, attention-deficit/hyperactivity disorder, birth defects, obesity, and diabetes (Landrigan & Etzel, 2014).

Choi et al (2015) have summarised known and studied observations in relation to children's vulnerability to environmental health hazards as follows:

Table 1: Summary of children's vulnerability to environmental health hazards

Developmental stage	Developmental characteristics	Exposure	Vulnerability
Preconception	Lack of awareness of gonadal exposure	All environmental exposures	Potential for genotoxicity
Pregnancy	High calorie intake Permeable placenta	All environmental exposures Ad-hoc diagnostic investigations	Potential for teratogenicity due to embryonic development of various organs and apparatuses
First three years	Oral exploration Beginning to walk Stereotyped diet	Food (milk and baby foods) Air (indoor) Water Mattress/carpets/floor	Potential for damage to brain (synapses) and lungs (developing alveoli) Allergic sensitization Injuries
Preschool and school-age child	Growing independence Playground activities	Food (milk, fruit, vegetables) Air (indoor and outdoor)	Potential for damage to brain (specific synapse formation, dendritic trimming) and lungs (volume expansion) Injuries
Adolescence	Puberty Growth spurt Risk-taking behaviour Youth employment	Food (any) Air (indoor and outdoor) Water Occupational exposure	Potential for damage to brain (continued synapse formation), lungs (volume expansion) and pubertal development Injuries

The following sections set out in further detail the result of the literature review of children's vulnerability to environmental health hazards, according to their specific developmental stage.

1.1.2 Foetus

As explained on the website of ANHE (Alliance for Nurses for Healthy Environments), healthy foetal development requires precise timing and feedback for cells to divide and mature properly for necessary cell replication and differentiation. For this to occur there is an interaction between genetic and environmental factors. For the developing foetus, any exposure to the foetus from the mother is considered environmental. While the only exposure pathway for foetal toxic exposures is placental, the foetus is particularly sensitive to the broad range of all environmental toxins that the mother is exposed to before and during her pregnancy. Toxins may affect both the structural development and biochemical function of cells in foetal organ systems. Foetal sensitivity to toxins occurs as a result of the flexibility of the cell and the capacity for changes during embryonic development.

For each specific exposure, many things interact to create the risk and health outcomes. The magnitude of the exposure, the dose of the toxin, the embryonic stage, and metabolism of the mother

and embryo all interact to vary the risk and the outcomes. The embryo is particularly sensitive to structural damage due to these mechanisms. Additionally, the blood brain barrier is not fully developed in the embryo allowing neurotoxins greater access to the foetus (ANHE, webpage). Often, the woman is unaware that she is pregnant during this critical period when she may be exposed to toxins. Additionally, many chemicals have not been tested for toxicity to human development. Due to the stage of foetal development the impact of these risks can be very serious and harmful, resulting in life long impairments.

Many adverse health outcomes for the developing foetus are referred to as birth defects. Genetic factors as well as environmental exposures interact in ways to create problems with organ structure or function. While scientists agree that environmental exposures are not well understood, those exposures that are known require more action and those that are not known require more research. Reported adverse health outcomes from environmental health threats such as toxic chemicals include low birth weight infants, congenital anomalies, pregnancy loss from miscarriage, and neurodevelopmental problems. The following table was put together by ANHE (ANHE, webpage) and is based on research by Swanson et al (2009):

Table 2: Commonly identified chemical exposures and birth defects

Exposure	Birth defect or low birth weight
Arsenic	Cardiac defects
Bisphenol A	Reproductive system anomalies
Dioxin	Neural tube defects; Neurobehavioural problems; Hypospadias; Oral clefts
Lead	Cardiac defects; Neural tube defects; Neurobehavioural problems; Hypospadias; Oral clefts
Methyl mercury	Neural tube defects; Neurobehavioural problems
Particulate Matter in Air	Vascular defects
PCBs	Impaired hearing
Sulphur Dioxide	Musculoskeletal defects; Cardiac defects
Environmental Tobacco Smoke	Low birth weight; Attention deficit hyperactivity disorder
Air pollution	Low birth weight
Pesticides	Low birth weight; Congenital anomalies

Endocrine disrupting chemicals (EDCs) have been linked to altered gender development and sexual organ malformations. Common environmental oestrogens that mimic oestradiol and attach to oestrogen receptors, are certain PCBs, Bisphenol A (BPA), phthalates, and pharmaceutical oestrogens. High level exposures have been confirmed for their role in gender related effects and scientists fear that even low level exposure can also result in these birth defects. Additionally, lead accumulates in children's bones and can be released to continue exposing the child to lead poisoning and serious neurological outcomes.

As explained by the World Health Origination (WHO, 2014), exposure to EDCs during the early, vulnerable periods of human and wildlife development – from fertilisation through foetal development and the nursing of offspring − gives particular rise for concern. When chemicals with endocrine-disrupting activity are present during development, they will affect the programming of cell and tissue development and, thus, their effects are expected to be permanent. When the same endocrine disruptor is present later – in childhood or adulthood – the effects will be different and could be transient.

Exposure to harmful substances may affect the development of functional body systems and, as a result, have a lifetime effect on an individual's health. Periods of increased vulnerability range from

preconception to the final stages of adolescence (WHO, 2006). Exposure during foetal development can cause changes that, while not evident as birth defects (the new-born may look healthy), can induce permanent changes that lead to an increased risk for disease incidence throughout life.
The Generation R Study, as described by Snijder et al (Snijder 2012), is a population-based prospective cohort study on growth, development and health from early foetal life until young adulthood in Rotterdam, the Netherlands. The study showed that maternal occupational exposure to several chemicals, such as PAHs, phthalates, alkylphenolic compounds and pesticides during pregnancy, adversely influenced their foetal growth rates of weight, foetal head circumference (HC) and length. These differences in foetal growth rates could already be demonstrated during pregnancy, and were partly reflected in a decreased placental weight. These findings suggest that early exposure during the critical window of foetal development is crucial.

The strength of this study was the population-based approach with recruitment during the prenatal period and the availability of a large number of potential confounders. A limitation of this study was the selective participation with mothers from ethnic minorities and with lower socioeconomic status less represented in the study population, which may have influenced the prevalence of exposure to chemicals at the workplace, but bias is unlikely since exposure status was assessed independently from and prior to the foetal growth characteristics by a recently updated job exposure matrix (JEM).

Furthermore, the JEM does not contain specific chemicals, but only contains broad groups of chemicals, and the mechanisms of action can vary between specific chemicals in a group. A major drawback of JEMs is that they do not account for variability in tasks and working environments within job titles. However, from the task description, it may become clear that some subjects within a specific job title, for example, subjects who have odd jobs around a farm (feeding animals) are less likely to be exposed to pesticides. The overlap between the categories phthalates, organic solvents and alkylphenolic compounds was considerable for mothers (κ values of 0.47–0.77), indicating that women exposed to one of these substances were likely to be exposed to other substances as well. We must conclude that due to this interrelationship among exposure groups, it was not possible to disentangle the specific role of phthalates and alkylphenolic compounds in the observed lower fetal growth rates.

In the study of Snijder et al. (2012), three characteristics of foetal growth were measures, namely weight, HC and length. Several chemicals were associated with impaired foetal weight, resulting in a decrease in SD at birth varying between 0.2 and 0.7. This corresponds to ~100–400g difference in birthweight. The effect of occupational exposure to chemicals seems of similar magnitude than other well-known lifestyle factors, such as smoking, alcohol use and caffeine intake. However, the population-attributable fraction is low, due to the low prevalence of exposure to these chemicals compared with other well-known lifestyle factors.

Workplace health is an important topic since women who intend to become pregnant, and pregnant women are at risk for adverse pregnancy outcomes, thus, it is important to identify occupational-related risk factors for prevention. Occupations in which women have a high exposure probability are agricultural and horticultural workers (pesticide exposure), hairdressers, beauticians, furniture makers (phthalate exposure) and cleaners (alkylphenolic compounds). Since the effects of occupational exposures on foetal growth are considerable, one could argue that pregnant women working in agriculture or horticultural trades must be informed about the risks of pesticide exposure in the workplace. However, the underlying mechanism is largely unclear, and results from earlier studies are conflicting, warranting further research into this important topic.

The study by Snijder et al. supports existing evidence from human studies regarding occupational exposures and adverse pregnancy outcomes. Although the chemicals in the study were considered to be potential endocrine disrupters, it remains to be established whether the mode of action is through endocrine disruption. A recent review by Caserta et al. (2011) summarizes the literature regarding exposure to endocrine-disrupting chemicals on the pregnancy outcome. They conclude that

epidemiological studies on endocrine disruptors are not always consistent. This is further illustrated by occupational studies, for example, in hairdressers, that show conflicting. Further studies are urgently needed to identify the molecular basis of the effects, to study the epigenetic effects of these exposures and to develop strategies to prevent exposure to these agents to improve birth outcomes.
In the US, the Environmental Working Group (EWG) recently conducted a review of scientific literature and publicly available human biomarker datasets, and used this data to compile an inventory of known or likely carcinogens that have been measured in people. EWG found more than 400 known or likely carcinogens, measured in a diverse array of populations. Moreover, exposure could not solely be linked to on-the-job contact, meaning that exposure took place in different environments too.

Wootruff et al. (2011) showed that exposure to chemicals during foetal development can increase the risk of adverse health consequences, including adverse birth outcomes (e.g., preterm birth and birth defects), childhood morbidity (e.g., neurodevelopmental effects and childhood cancer), and adult disease and mortality (e.g., cancer and cardiovascular effects). Biomonitoring studies report nearly ubiquitous exposure to many chemicals in the U.S. population -- for example, bisphenol A (BPA), perchlorate, and certain phthalates and polybrominated diphenyl ethers (PBDEs). These studies, along with more geographically targeted studies of pregnant women, show that pregnant women are also exposed to many chemicals (Bradman et al. 2006; Swan et al. 2005). Chemicals can cross the placenta and enter the foetus, and a number of chemicals measured in maternal urine and serum have also been found in amniotic fluid, cord blood, and meconium. In some cases, such as for mercury, foetal exposures may be higher than maternal exposure.

Chemicals may also concentrate in the foetus, which could influence maternal concentrations (Takahashi and Oishi 2000). Further, behavioural changes occurring during pregnancy, such as diet modification (e.g., quantity and food type), may also influence chemical body burdens in pregnant women (Mirel et al. 2009). Understanding whether some of these factors can influence maternal concentrations of chemicals helps inform our ability to use measurements of chemicals in non-pregnant women as a surrogate for pregnant women

In addition, recent publications in the scientific literature have highlighted the increasing evidence of adverse pregnancy outcomes due to environmental chemical exposures during pregnancy and the preconception period. Evidence suggest that lead, some types of pesticides, mercury, and endocrine disrupting chemicals (EDCs) can adversely affect birth outcomes (Buchanan 2012).

1.1.3 Neonates

As explained on the website of ANHE (Alliance for Nurses for Healthy Environments) infants are a particularly vulnerable to the exposure stemming from toxic chemicals due to both biophysical and social factors. With regard to the biophysical factors, it is explained that resting respiratory rate in infants is twice that of adults which means that infants are exposed to 2 times more toxins per body weight than are adults. Moreover, infants take in 2 ½ times more water and 3 to 4 times more food per body weight than adults. This increases their exposures to pesticides and other toxins in food and water much greater than exposures in adults. In addition, infants have less developed brain, respiratory, gastrointestinal, immune, reproductive and metabolic systems than older children and adults (Bearer 1995).

With regard to the social factors, ANHE's website explains that infants are delivered in hospitals where they are exposed to chemicals used the nursery and hospital settings, particularly polyvinyl chloride (PVC), di 2-ethylhexyl phthalate (DEHP) and Bisphenol A (BPA). As reproductive and developmental toxins these chemicals can expose infants at the time when they are adjusting to extrauterine life and have immature organ systems. Additionally, the webpage pointed out that infants spend most of their time in a single environment for prolonged periods such as a crib where the exposures do not vary and they may be susceptible to indoor air contaminants. While breastfeeding is still recommended as the best nutrition for infants, chemicals such as polybrominated diphenyl ethers

(PBDEs), PCBs, organochloride pesticides and dioxins that accumulate in human fat tissue in the breast have been shown to be transmitted to the infant during breastfeeding. These chemicals can also be found in formulas made from cow's milk. Further, the skin of a newborn is a highly absorptive surface and infants are exposed to a number of toxic chemicals in the personal care products that are applied to their skin (Bearer, 1995).
Other scientific papers have also showed that a wide range of toxic chemicals are found in the umbilical cord blood of newborns, indicating the potential for health risks from exposure that begin in utero (EWG, 2005). Furthermore, it has been stressed that in the neonatal intensive care unit (NICU) setting, neonates are especially vulnerable to toxic chemical exposures because of the extreme immaturity of their anatomy and physiology (Sattler et al., 2012). It has been also emphasised that chemical exposures are often silent, accumulate over time, and result in illness or disease that may not be evident for years to come. In umbilical cord blood analyzed for the presence of toxic chemicals that should never be in the human body, a total of 287 chemicals were detected. The report noted that 180 of the 287 chemicals are known or suspected carcinogens in humans or animals, 217 are toxic to the brain and nervous system, and 208 create risks for birth defects or abnormal development in animal tests (EWG, 2005).

A growing body of scientific evidence has shown that the developing fetus and neonate exhibit different sensitivities and responses to environmental chemicals than do adult organisms, and that exposure of parents even before conception can alter the risk of cancer and other diseases in the offspring. Because neonates and infants are still in active development, it is critical that toxic exposures be eliminated as much as possible. In particular, Sattler et al. (2012) argues that it is paramount to find safer alternatives to DEHP, BPA, certain skin care products, cleaning products and disinfectants, as well as mercury used in NICU settings.

1.1.4 Toddlers and school-aged children

The term "toddler" refers to children who are learning to walk, so it is typically used for children aged 1 to 2 years, but sometimes also up to 3 years (Berk 2009).

According to the WHO toddlers are particularly vulnerable to chemicals exposure. In fact, as they start moving around, exploring, touching and testing, toddlers may come into contact with or ingest cleaners, pesticides and other products unsafely stored in the home and these may be toxic or caustic. One of the main dangers to toddlers is the ingestion of caustic products that may cause permanent damage to the mouth and oesophagus (WHO, 2005). In this regard a study pointed out that the majority of cases of accidental caustic ingestion happen in the toddler age group between the ages of 12 months and 2 years (SCCS, 2011).

Another study reported that toddlers, on average, carried more than three times the amount of flame retardants in their blood than their mothers. In particular, the study found that in 19 of the 20 families, concentrations of flame retardants were significantly higher in children than in their mothers (EPA, 2008). Moreover, studies shown that preschool children have greater exposures than older children or adults to pesticides and semivolatile organic pollutants, including some compounds that may have endocrine-disrupting effects or developmental toxicity. These greater exposures may result from what children eat and drink, where they spend their time, and what they do there. The impact of the exposures may be greater on young children because of their smaller body masses, immature body systems, and rapid physical development (EPA, 2004).

The scientific literature also reports different cases of ingestion of toxic substances. For instance, it has been reported a case of a two-year-old girl who ingested endosulfan: a polychlorinated hydrocarbon pesticide used in agriculture. Characteristic clinical signs of exposure to this compound included: seizures, nausea, vomiting, abdominal discomfort, hyperaesthesia, headaches, agitation, hyperactivity, incoordination, confusion, dizziness, and myoclonus. While endosulfan episodes of poisoning are rare, its occurrence in the toddler age-group who live in rural areas remain above average and raised the

question of the link between chemical exposures and socioeconomic status (Kamate & Jain 2011).

The scientific literature also reported that accidental ingestion of foreign bodies like coins, fish bones, plastic toy parts, batteries and needles are common in toddlers and pre-school children. In particular, battery cells are potentially hazardous as they cause chemical mucositis and because of their capability to generate electric current. In this regard, a study reported the case of a male child aged 1 year and 9 months who was brought to the hospital after having accidentally swallowed a computer battery cell, a circumstance who lead the toddler experiencing dysphagia and respiratory obstruction. This study also showed that reduced observation and supervision of children may increase the risk of exposure and subsequent accidental poisoning, e.g. during holiday periods, festivals and other events (Majumdar et al., 2011)

When children start moving around, they become more likely to go outside and to be exposed to outdoor air. Children's exposure to air pollution is a special concern because they breathe higher volumes of air relative to their body weight and their tissue and organs are growing (Canha, 2011). In addition, their immune system and lungs are not fully developed when exposure begins, raising the possibility of different responses than seen in adults. Moreover, children spend more time outside, where the concentrations of pollution from traffic, powerplants, and other combustion sources are generally higher. Although air pollution has long been thought to exacerbate minor acute illnesses, recent studies have suggested that air pollution, particularly traffic-related pollution, is associated with infant mortality and the development of asthma and atopy. Other studies have associated particulate air pollution with acute bronchitis in children and demonstrated that rates of bronchitis and chronic cough declined in areas where particle concentrations have fallen (Schwartz, 2004).

1.1.5 Adolescence

According to the ANHE website, during puberty the adolescent experiences changes in hormones and the metabolic interactions of neurochemicals for development. This poses a "window of vulnerability" for the adolescent whose endocrine, immune, musculoskeletal and reproductive systems are undergoing maturation and can be heavily exposed to chemicals known to affect many systems.

According to Carpenter & Bushkin-Bedient (2013) puberty and adolescence are periods of increased risk from exposure to chemicals. They explain that, although adolescents have greater independence than children regarding choice of activities, foods, and beverages, they still lack full neurological maturity that limits their capacity for good judgment and may actually increase exposure to toxic substances such as tobacco, substances of abuse, and chemicals in some personal care products. This may ultimately expose them to greater risks. Moreover, during adolescence, the endocrine, reproductive, neurological, and other systems undergo remarkable development and growth. The developing tissues and functions of these organ systems are particularly sensitive to the effects of carcinogenic and endocrine-disrupting chemicals.

Carpenter & Bushkin-Bedient (2013) also explain that life expectancy is another factor that increases the risk of teenagers. In fact, more years allows for greater acquisition and bioaccumulation of environmental chemicals, including persistent organic pollutants (POPs). An example is dioxin, a known human carcinogen, which has a half-life of about 7 years. Because humans are unable to detoxify and excrete dioxin-like chemicals efficiently, the daily intake exceeds elimination under most circumstances. Therefore, levels in humans at background exposures increase with age. In addition, concentrations of other persistent organic pollutants (POPs), including polychlorinated biphenyls (PCBs), chlorinated pesticides, and brominated flame retardants also accumulate in the adipose tissue. These additional toxins can potentiate the effect of earlier exposures, contributing to the onset of malignant disease many years, even decades, after the initial exposure. Therefore, exposures that occur during any or all of the developmental phases of early life through adolescence may contribute to an elevated risk for cancer in later life (Carpenter & Bushkin-Bedient 2013).

With regard to adolescent girls, a study from Harley et al (2016) described that cosmetics, fragrances, and other personal care products are a possible source of human exposure to potentially endocrine disrupting chemicals, such as phthalates, parabens, and phenols (Braun et al. 2014; Meeker et al. 2013). Harley et al (2016) also explains that because women are the primary consumers of many personal care products, they are disproportionately exposed to these chemicals. In particular, adolescent girls are at risk of exposure through this route. For example, a study published by the EWG (2008) found that the average adult woman uses approximately 12 individual personal care products each day, while the average teenage girl uses 17. The Harley's study also demonstrated that techniques available to consumers, such as choosing personal care products that are labelled to be free of phthalates, parabens, triclosan, and BP-3, can reduce personal exposure to possible endocrine disrupting chemicals (Harley et al 2016).

Previous studies also confirmed that adolescent girls are likely to increase their use of personal care products and cosmetics increasing their exposure to toxic chemicals in such products. Studies indicate that, on average, girls have up to 13 hormone altering chemicals from 4 chemical families - phthalates, triclosan, parabens, and musks in their bodies. In addition to posing serious health effects as hormone disruptors, these chemicals also have the potential to cause cancer as well. Results suggest that young women are being exposed to a wide variety of cosmetic preservatives that puts them at serious risk during this important period of development (Sutton, 2010).

According to the ANHE website adolescent boys are also at risk due to their occupational exposures. During this phase of life, they are most likely to begin employment in a variety of settings and more than 80% do work during some part of the year. Frequently, adolescent boys go to work in the summer in lawn care services, painting and sealing driveways. At times they begin to work as entrepreneurs creating their own summer employment in such positions which are not monitored by Occupational Safety and Health Administration (OSHA). They may be unaware of the hazardous materials to which they are exposed. Adolescents employed in a variety of settings can be exposed to environmental tobacco smoke, solvents, and other cleaning agents. Beyond the dangers of heavy equipment injuries are adolescents' exposures to the fertilizers and pesticides used in agricultural settings. These include chemicals known to be carcinogenic, neurotoxicants and hormone disruptors.

The significance of chemical exposure before or during puberty was also demonstrated in the results of a study on the possible association between breast cancer and exposure to DDT at a young age. It was found that, in women born after 1931, high levels of p,p'−DDT were associated with a five-fold increase in the risk for breast cancer (Cohn et al. 2007).

Moreover, the chemicals bisphenol A and phthalates are linked to obesity and insulin resistance in adolescents in two new studies. In one study, the researchers measured the levels of DEHP, a phthalate found in processed foods, in the urine of 766 adolescents ages 12 to 19. They found that teens with higher amounts of DEHP in their urine had increased rates of insulin resistance, a condition that can lead to Type 2 diabetes (Trasande 2013). Another study published in the same journal examined the relationship between bisphenol A (BPA) and obesity in more than 10,000 children ages 6 to18. Children with the highest amounts of BPA in their urine had double the risk of being obese, compared with children with the lowest urinary BPA levels (Braun 2014).

Table 3: Examples of adverse effects of developmental stage-specific exposures on various organ systems

Period of susceptibility for exposure	Neurological	Reproductive	Renal	Endocrine	Cardiac	Respiratory	Cancer
Embryonic age	Neural tube defects from retinoic						

Period of susceptibility for exposure	Neurological	Reproductive	Renal	Endocrine	Cardiac	Respiratory	Cancer
	acid, arsenic and valproic acid						
Foetus	Decreased intelligence, increased behavioural problems with lead	Delay in pubertal development from exposure to PBBs (polybrominated biphenyl)	Neonatal renal failure due to maternal exposure to angiotensin inhibitors	Maternal smoking causes decreased birth weight and increased risk for diabetes and osteoporosis later in life	Decreased heart rate variability in children exposed prenatally to methylmercury	Altered airway growth with increased collagen deposition in airway walls with exposure to maternal smoking	Inorganic arsenic in drinking-water causes adrenal, ovarian or lunch tumours later in life
Neonate						Increased incidence of respiratory mortality following exposure to particulates in the air	
Child				Lead poisoning causes abnormal bone structure and poor growth		Exacerbation of pre-existing asthma from exposure to particulates in the air	
Adolescent		Delayed puberty with ethanol consumption					

Source: WHO, 2011a.

1.2 PREGNANT WOMEN

According to WHO (2011a) the physiological changes during pregnancy influence the toxicokinetics *of* the mother and the growing foetus. For instance, the renal blood flow and glomerular filtration rate are increased during pregnancy, which may enhance renal clearance of certain xenobiotics, thus protecting the foetus from exposure to chemicals in the systemic circulation. The complex interplay of molecular and physiological factors in the functional and structural development of various organ systems ultimately influences the toxicokinetics and toxicodynamics of chemicals.

The Alliance of Nurses for Healthy Environments (ANHE) remarks that during pregnancy, women experience decreased motility of the gastro intestinal tract increases intestinal transit with delayed absorption. This delay can lead to greater absorption of toxins. Moreover, due to decreased plasma albumin concentration during pregnancy, compounds that are normally bound to albumin are altered kinetically (Balk et al 2004). Increased plasma and extracellular fluid volumes affect the transfer of compounds dependent upon fluid concentration. Therefore, many toxins can actually move more

readily into the pregnant mother. In addition, there are changes in renal elimination, changes in maternal liver metabolism, and variations in uterine blood flow that affect her ability to detoxify and clear toxins from her body. Elevated blood lead levels in the pregnant mother may lead to pregnancy induced hypertension, a most serious and potentially life threatening complication of pregnancy.

According to Woodruff et al (2011), exposure to chemicals during fetal development can increase the risk of adverse health consequences, including adverse birth outcomes (e.g., preterm birth and birth defects), childhood morbidity (e.g., neurodevelopmental effects and childhood cancer), and adult disease and mortality (e.g., cancer and cardiovascular effects) (Gluckman and Hanson 2004; Stillerman et al. 2008). Biomonitoring studies report nearly ubiquitous exposure to many chemicals in the U.S. population—for example, bisphenol A (BPA), perchlorate, and certain phthalates and polybrominated diphenyl ethers (PBDEs) [Centers for Disease Control and Prevention (CDC) 2009a]. These studies, along with more geographically targeted studies of pregnant women, show that pregnant women are also exposed to many chemicals (Bradman et al. 2003; Swan et al. 2005). Chemicals can cross the placenta and enter the fetus, and a number of chemicals measured in maternal urine and serum have also been found in amniotic fluid, cord blood, and meconium (Barr et al. 2007). In some cases, such as for mercury, fetal exposures may be higher than maternal exposure (Barr et al. 2007).

Because few data are available on levels of individual or multiple chemicals in pregnant women, levels in reproductive-age women have often been used as an indicator of chemical levels in pregnant women (Blount et al. 2000). Some studies have directly compared pregnant women in their cohort and reproductive-age women from the National Health and Nutritional Examination Survey (NHANES), a nationally representative sample of the U.S. population. For example, phthalates measured in pregnant women from three U.S. locations were lower than those measured in reproductive-age women from NHANES (Swan et al. 2005). Numerous physiological changes occur during pregnancy, including weight gain and increases in blood and plasma volume, which can affect concentrations of chemicals (Chesley 1972; Pirani and Campbell 1973). Chemicals may also concentrate in the fetus, which could influence maternal concentrations (Takahashi and Oishi 2000). Further, behavioral changes occurring during pregnancy, such as diet modification (e.g., quantity and food type), may also influence chemical body burdens in pregnant women (Mirel et al. 2009).

In their study of 2011, Woodruff et al (2011) found widespread exposure to pregnant women in the United States to multiple chemical analytes, including both banned and contemporary contaminants. These include phthalates and increased risk of adverse male reproductive outcomes (Swan et al. 2005), mercury and developmental neurological outcomes (Lederman et al. 2008), PBDEs and neurodevelopmental outcomes (Herbstman et al. 2010), and PCBs and maternal thyroid hormone disruption during pregnancy (Chevrier et al. 2008). Additionally, pregnant women were exposed to multiple chemical analytes at one time, many of which can affect the same adverse outcomes. Examples include maternal thyroid hormone disruption [e.g., perchlorate, PCBs, PBDEs, and triclosan (Crofton 2008)], male reproductive development (multiple phthalates), and the developing brain (mercury, lead, PCBs) (National Research Council 2008a).

According to Caserta (2011) there is significant evidence that continuous and prolonged exposure to several endocrine disrupting chemicals (EDC) is a risk factor for reduced fertility and fecundity in women. EDCs in particular appear to affect reproductive success and outcomes by disturbing hormone regulation and/or placental function

A recent Spanish cohort study issued in 2016 shown a link between prenatal acetaminophen exposure – an over-the-counter medication that is widely used by pregnant women as an antipyretic and analgesic – and a greater number of autism spectrum symptoms in male children. The study included 2644 mother-child pairs recruited during pregnancy. Over 40% of mothers reported using acetaminophen. Maternal use of acetaminophen during pregnancy may be also harmful to attention function and may be associated with a higher risk of hyperactivity/impulsivity symptoms in the

offspring (Avella-Garcia, et al 2016).

Finally, Choj et al (2016), in their article, summarised all the relevant studies showing the vulnerability of pregnant women and their newborns to chemical exposure. In particular, according to the French ELFE study that pregnant women have a significant exposure to phthalates, reflecting a potential high exposure in the hospitals (Zeman et al., 2013), and findings from the South Korean MOCEH study suggested that prenatal exposure to phthalates may be inversely associated with the neurodevelopment of infants (Kim et al., 2011b). Moreover, in the Flanders' FLEHS study, a strong correlation for Pb, As, and Tl was found between levels in cord blood and maternal blood, suggesting that these metals are transported to the fetus from the mother (Baeyens et al., 2014), and it appears that prenatal exposure to metals have adverse effects on newborns. The MOCEH study indicated a negative relationship between maternal Pd and Cd levels during late pregnancy period and neurodevelopment (Kim et al., 2013b). The EU-wide DEMOCOPHES project showed elevated levels of methyl mercury in fish eating subgroups of the investigated populations (i.e. mothers), and the Norwegian MoBa cohort study reported negative association between maternal exposure to mercury (via reported dietary intake during pregnancy) and birth weight (Vejrup et al., 2014). The Japanese Tohoku HBM study also reported a negative relationship between maternal hair mercury level and motor abilities of infants (Suzuki et al., 2010).

In addition, Aside from phthalates and metals, the MoBa study also showed that maternal exposure to dioxins, PCBs, or benzo(a)pyrene resulted in decreased birth weight (Duarte-Salles et al., 2013a; Papadopoulou et al., 2013), and the Japanese Hokkaido HBM study observed lower birth weight, higher risk of infections in infants, and reduced motor development due to maternal exposure to PFOS, 2,3,4,7,8-PeCDF, and PCDDs, respectively (Konishi et al., 2009; Miyashita et al., 2011; Nakajima et al., 2006; Washino et al., 2009). Collectively, these studies emphasised the importance to monitor the chemical levels in pregnant women in order to reduce chemical exposure and health risks in newborns.

1.3 ELDERLY

As described by Choi J et al (2016) the elderly are not just older adults, but rather are individuals with unique challenges and different medical needs than younger adults. The ability of the body to respond to physiological challenge presented by environmental chemicals is dependent upon the health of the organ systems that eliminate those substances from the body. Any compromise in the function of those organ systems may result in a decrease in the body's ability to protect itself from the adverse effects of xenobiotics. With increasing life expectancy, more and more people will confront the problems associated with advancing years. Moreover, although proper diet and exercise may lessen the immediate severity of some aspects of aging, the process will continue to gradually degrade the ability to cope with a variety of injuries and diseases. Thus, the adverse effects of long-term, low-level exposure to environmental substances will have a longer time to be manifested in a physiologically weakened elderly population.

When such exposures are coupled with concurrent exposure to prescription medications, the effects could be devastating (Risher et al., 2010). Among the HBM programmes, it has been observed that several metals appear to accumulate in the elderly population. FLEHS findings showed that the highest levels of total Hg in blood were found in the elderly (aged 50-65) (Croes et al., 2014), and the PROBE study also showed that both blood lead and palladium concentrations increased with age (Alimonti et al., 2011). The Slovenian HBM study found that the blood cadmium, blood lead, and hair mercury levels were the highest among the older women (aged 50-60) compared to children or adults (Tratnik et al., 2013). Aside from metals, urinary levels of phthalates also appeared to be higher among subjects with older age in the South Korean KorSEP study (Lee et al., 2011), and a scientific HBM study from Australia observed the highest level of PFOS in the serum of subjects aged 60 or older (Toms et al., 2009). These findings suggest slower clearance of these chemicals out of the body.

Therefore, it is likely that the elderly is at a higher risk of developing adverse effects from exposure to chemicals, making it important to monitor the chemical levels in the elderly within a HBM programme.

Risher et al (2010) remarked what makes elderly particularly vulnerable to environmental chemicals. They noted that among the elderly, functional disability occurs faster and takes longer to remediate. In fact, the ability of the body to respond to physiologic challenge imposed by potentially toxic substances in the environment is dependent upon the health of the organ systems that eliminate those substances from the body. Age-related changes in sensitivity to environmental chemicals can result from alterations in either toxicokinetic or toxicodynamic processes. Pathologic states that compromise the function of any of the organ systems cause a decrease in the body's ability to protect itself from the adverse effects of exposure to those contaminants.

Furthermore, according to report issued by the SCCS in 2011 at ages of 75 and above, a proportion of the population may show signs of aging, such as physical and mental deterioration. This is due to a combination of factors including physical and mental disease, under-/malnutrition and relative deprivation superimposed on the various physiological changes that occur with age alone. This latter group is at special risk of adverse effects of drugs, chemicals and the environment. The elderly are exposed and respond to xenobiotic chemicals differently than younger people in a number of important aspects.

The report pointed out that Poisoning is a significant problem in the elderly. However, most of the research on poisonings in elderly people is focused on the accidental intake of medication (Hahn et al. 2006, Klein-Schwartz and Oderda 1991). Research on the possible causes for accidental ingestions and poisonings in the elderly is scarce, but the following factors are likely to play a role:

- Frequently, the olfactory and gustatory perception is reduced. More than half ofpeople between 65 and 80 years of age show major olfactory impairment. Thisincreases to more than three-quarters in those over 80 years old (Doty et al.1984)
- Impaired vision is also likely to decrease the ability of distinguishing betweenacceptable (edible, drinkable) and unacceptable products. The legibility of printed warnings therefore becomes especially important for older adults with impaired vision (Parsons et al. 1999).
- Older people are aware of hazards in the home and of safety information on products. However, they often report usability problems when using household products. In a focus group study with 45 older adults between 61 and 84 years of age, 55% of respondents reported motor difficulties in handling products, 42% reported memory difficulties, 40% perceptual difficulties, and 29% difficulties with symbol comprehension and text comprehension (Mayhorn et al. 2004).
- Older adults often have problems understanding product warning information, especially when product-specific knowledge cannot be used and memory demands are high (Hancock et al. 2005). In general, short-term memory capacity decreases as age increases, so warnings should be kept as brief and direct as possible (Parsons et al. 1999).
- Unlike young children, elderly people are often left by themselves for extended periods and they are not under constant observation, as a rule.
- Elderly people may not call for help immediately, or they may keep silent about what has happened, for reasons of shame or uncertainty.
- If elderly people are disoriented (e.g. due to illnesses or medications), they often lack the ability of distinguishing between acceptable and unacceptable products, even if their senses have been preserved (Klein-Schwartz and Oderda 1991).

1.4 OCCUPATIONAL GROUPS

Many substances used in the workplace have the potential to cause harm to workers, and to other individuals who may be inadvertently exposed to such substances. In order to tackle this issue, the

European legislation sets out the basic requirements to achieve adequate exposure control (Council Directive 98/24/EC).

In some instances, special conditions must be applied to protect vulnerable individuals or groups. These include workers who are intrinsically vulnerable, such as migrant workers, young workers and those with certain medical conditions. Other workers may also be vulnerable at certain times for different reasons, for example when conducting high risk, non-routine work activity, such as maintenance work (EU-OSHA, oshwiki).
Dangerous substances can be found in many different contexts, and may not be easy to identify. Toxic compounds can be found in paints and glues, cleaning fluids, and even foodstuffs. For instance, according to recent scientific evidence, exposure to flour dust may cause adverse health outcomes ranging from conjunctivitis to baker's asthma (Stobnicka A & Górny RL, 2015).

In the EU, supplied chemicals must have accompanying safety data sheets, which include information about the properties of the substance, its hazards, instructions for handling, as well as exposure control measures (Regulation (EC) No 1907/2006). However, many harmful substances are process-generated materials, and as such can't require safety data sheets. For example, stone dust contains respirable crystalline silica, which can cause irreversible effects on workers' lungs, while wood dust can cause asthma. Both of these types of dust can also cause cancer (IARC, 1995).

Controlling exposure to dangerous substances often needs skills that many businesses, especially small and medium-sized enterprises (SMEs) do not have in-house. For these reasons, certain groups of workers may be at increased risk when working with dangerous substances, due to (EU-OSHA, oshwiki):

- Increased susceptibility to the effects of chemicals;
- Communication difficulties;
- Poor working conditions;
- Inexperience (coupled with inadequate supervision);
- Workers conducting high-risk, non-routine activities;
- Service workers exposed to multiple lower level exposures;
- Lack of training or experience;
- Lack of access to preventative services;
- Working at client premises with changing or unregulated conditions.

1.4.1 Migrant workers

According to the International Labour Organisation (ILO) migrant workers are particularly vulnerable to chemicals for a variety of reasons (ILO, 2004):

- Higher risks: migrant workers usually work in poorer conditions than local workers. For instance, migrant workers are often employed in higher risk sectors, such as farming and construction. These jobs involve working with dangerous substances, such as pesticides or silica dust, that further increase the risk of toxic exposure (Eurofund, 2007).
- Language barriers: these barriers can significantly hamper communication of written and verbal occupational safety and health (OSH) information. Migrant workers in countries where the language is not their mother tongue may fail to understand safety regulations and thus are likely to receive higher exposure to dangerous substances (Guldenmund FW et al., 2010).
- Cultural issues: workers moving to more developed countries may be accustomed to different and/or less structured safety and health standards to those applied in the country to which they have migrated. This may result in a different culturally based risk perception which may ultimately increase the exposure to dangerous substances (Renn O & Rohrmann B, 2000).
- Longer working hours and a tendency to regularly work overtime: the longer the time workers spend with dangerous substances, the higher their chances of being exposed to toxic substances

(ILO, 2004).

1.4.2 Young workers

According to the ILO, young workers are those within the age group of 15 to 24 years (ILO, 2012). This subgroup thus includes adolescents. All of the categories included in this subgroup have one thing in common: all are relatively immature and lack experience in the workplace, which means they may not always be fully aware of OSH regulations and the risks around them. Young workers may also be unsure, or afraid to ask for help or information because they are not used to questioning an adult. As a result, compared with the rest of the workforce, young workers are 50% more likely to be involved in an accident at work (EU-OSHA, webpage 'young workers). In order to protect this category, which is uniquely vulnerable to chemical exposure, specific EU legislation was adopted (Council Directive 94/33/EC).

The reasons for the increased risk among young people when working with dangerous substances are given below:

- Unique vulnerability: during this particular stage young people are still developing their mental and physical conditions.
- Increased susceptibility: data indicate that the prevalence of allergic reactions (such as asthma) and work-related skin disorders are higher among young workers. For instance, it is acknowledged that lead exposure may be especially harmful to young people, given its effects on the development of the nervous system (EU-OSHA, 2016).
- Employment in high-risk sectors: young workers are often employed in temporary or precarious jobs and in industries that are acknowledged to be more hazardous than others, such as agriculture, construction, transport, and hairdressing. For instance, young workers tend to be employed on farms, where they could be exposed to toxic substances such as pesticides. Young workers are also employed in low-skilled manufacturing jobs or the construction sector, with the potential for exposure to a range of dangerous substances (EU-OSHA, 2007).
- Lack of awareness of health and safety issues: young people lack experience in the workplace and are often unfamiliar with safety standards. This leads them to take greater risks than older people, magnifying their exposure to chemical substances. The risks stemming from toxic exposure are also exacerbated in situations where young workers receive little or no appropriate supervision or training (EU-OSHA, 2016).

1.4.3 Maintenance workers

Maintenance is defined as a 'combination of all technical, administrative and managerial actions during the life cycle of an item intended to retain it in, or restore it to, a state in which it can perform the required function' (EU-OSHA, 'young workers'). Since maintenance operations take place in very different sectors, from the chemical industry to manufacturing and agriculture, maintenance workers may come into contact with a huge variety of dangerous substances. Generally, the following three major sources of exposure can be identified:

- Exposure through products that need to be used in certain operations (e.g. detergents, solvents, acids, etc.) (EU-OSHA, 2012);
- Exposure via contact with substances that are generated by the products during the maintenance operations, such as welding fumes, diesel exhaust, and dust (EU-OSHA, 2009);
- Exposure through compounds that may be encountered during the maintenance process, such as lubricants and hydraulic fluids, dusts, ammonia, poisonous gases, etc. (EU-OSHA, 2012).

As a consequence, maintenance workers may be exposed to all of the substances that have been identified as 'emerging chemical risks' by EU-OSHA: ultrafine particles, diesel exhaust, nanoparticles, man-made mineral fibers, isocyanates, epoxy resins silica and wood dust (EU-OSHA,

2009). Among the maintenance activities which involve exposure to hazardous substances are (EU-OSHA 2012):

- Cleaning activities (exposure to detergents and acids);
- Metal degreasing (exposure to solvents);
- Painting (exposure to dust, ammonia, solvents and detergents);
- Welding (exposure to gases);
- Vehicle repair activities (exposure to solvents, isocyanates, and polyester resin);
- Maintenance of façades of buildings (exposure to acids, solvents, lyes);
- Maintenance of refrigeration and cooling systems (exposure to ammonia, propane/butane);
- Maintenance of swimming pools (exposure to toxic chlorine gas);
- Road maintenance (exposure to asphalt fumes, and traffic exhaust);
- Maintenance of diesel motor exhaust (exposure of gases and particles).

As the toxic substances to which a maintenance worker may be exposed are various, so too are the health effects associated with such exposures. For instance, skin contact with acids or dyes may lead to acute irritation or burns; detergents, epoxy resins, isocyanates, cement, oils and greases may cause irritant contact dermatitis (eczema).

Inhalation of chlorine or ammonia may result in acute irritation of the airways. Irritants may also exacerbate existing airway complaints (e.g. asthma, COPD). Wood dust causes airway and eye irritation, and may lead to airway disease, such as bronchitis (EU-OSHA, 2009); exposure to isocyanates (e.g. in car refinishing), may result in allergic rhinitis or asthma, which has been demonstrated in spray painters (Pronk A, 2007). Exposure to silica and diesel motor exhaust may contribute to the development of lung cancer (Tjoe Nij E, 2003). Additionally, the inhalation of hazardous substances in maintenance activities might lead to a range of additional health effects. High exposure to solvents – e.g. in spray painting and degreasing activities – may lead to neurological diseases, such as chronic toxic encephalopathy (Meyer-Baron M, 2008).

Given the several routes of exposure, as well as the multiple substances that they may encounter, maintenance workers are a subcategory of the population which is particularly vulnerable to chemicals.

1.4.4 New workers

There are various issues that make new workers especially susceptible to the risks associated with exposure to dangerous substances. These include:

- Lack of training: new workers should be equipped with all of the necessary information about the routes of exposure for the substances with which they work, as well as the associated risks. New workers should also be subject to a high level of supervision until it is clear that they understand the requirements of the job, including the need to protect themselves from exposure to dangerous substances (EU-OSHA, oshwiki).
- Increased susceptibility: there is a great deal of variation in individual responses to exposure to dangerous substances. It is possible that new workers may experience symptoms at levels of exposure which do not cause any difficulties for more established workers (EU-OSHA, oshwiki).

1.5 LOWER SOCIO-ECONOMIC GROUPS

According to US EPA, 2013) some communities (e.g., low income, minority, indigenous groups) bear greater exposure and disease burdens associated with where they live, work, or play that can increase their risk of adverse health effects from environmental hazards. Some studies have found that location of pollution sources (e.g., high-traffic roadways, industrial site, hazardous waste site) correlates positively with a location's composition of minority, low-income, or indigenous populations. Factors

such as socioeconomic status (income, level of education, occupation) or lifestyle may have indirect effects on environmental exposures and health outcomes. For example, people with low incomes may not have the same access to health care as those in higher socioeconomic groups (U.S. EPA, 2000).

In addition, the Environment Justice Hypothesis, which is part of the Environmental Justice Movement, states that hazards in the physical and chemical environment disproportionately affect those individuals and households that also face hazards in their social environment (Brown, 1995). The Environmental Justice Movement emerged in the 1980s and strives for fair treatment and meaningful involvement of all people regardless of race, colour, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies (Environmental Protection Agency, 2012).

The major focus of the Environmental Justice Movement remains on individuals in lower socioeconomic groups, as there is a significant evidence base that these individuals have greater burdens of environmental toxicants. Health outcomes and disease burdens (e.g. asthma, cancer and diabetes) are known to associate with low socioeconomic status (SES) (Jemal et al., 2008 and Zheng and Land, 2012), and this is hypothesised to relate to increased exposure to environmental contaminants. Evidence suggests that there is social and racial disparity in toxicant burden with higher exposure to lead (Iqbal et al., 2008), pesticides (Cox et al., 2007) and polychlorinated biphenyls (PCBs) (Borrell et al., 2004 and Vrijheid et al., 2012) noted.

Furthermore, the study published by Tyrell et al (2013) gave a comprehensive overview of the extent to which overall burden of toxicant exposure in the US general population is determined by socioeconomic status. They demonstrated that higher SES groups are not always protected from increased levels of environmental toxicants. In fact over a third of the associations observed involved increased risk of toxicant burdens for higher socioeconomic status individuals. This suggests that efforts to reduce exposure inequalities need to be group specific, and that public health messages may be targeted more effectively. Tyrell et al (2013) concluded that a better understanding of environmental inequalities and their determinants are essential in order to address them.

A recent study has further investigated the relationships between socioeconomic status and chemical concentrations in the body, finding that chemical body burdens affect people across the poverty spectrum, not just those from economically deprived backgrounds as previously thought (Tyrrell J *al*., 2013). These findings contradict the standard environmental justice hypothesis, which states that lower socioeconomic status will lead to a greater prevalence of harmful elements in the body. Instead, this study shows that lifestyle and diet are the factors with the greatest influence on the accumulation of chemicals in the body (Tyrrell, 2013).

While this study should be taken into account, recent research also shows associations between the chemical body burdens of two different types of chemicals and socioeconomic status. Poor people – especially young children dependent upon food assistance – are more likely to have higher levels of BPA, while wealthier people are more likely to have higher levels of perfluorinated compounds (PFCs). BPA exposure is particularly harmful for the human body, as it may lead to behavioural impacts, developmental changes that increase the risk of mammary and prostate tumours, decreased sperm count and increased risk of Type 2 diabetes and obesity (Nelson, 2012). These results are also consistent with a smaller, earlier study published in 2007 (Calafat, 2008).

2 HOW ARE VULNERABLE GROUPS EXPOSED TO HARMFUL CHEMICALS?

A chemical can make contact with or enter the body and become hazardous to a person's health through four major routes: ingestion, inhalation (breathing), skin contact and injection. As the first three routes of exposure are most relevant to the scope of the study, these are further discussed below. Exposures through the placenta and breastfeeding as well as at the workplace are discussed separately, as foetuses, children, and workers involved in certain occupations represent specific vulnerable groups in society. The route of exposure is important to consider as it often predicts which organ system or part of the body will be affected directly or in later years.

2.1 INGESTION

Chemicals can enter the human body through ingestion, e.g., by swallowing contaminated mucus which has been expelled from the lungs, or by eating and drinking contaminated food. Food and drink are frequently contaminated by contact with unwashed hands, gloves or clothing, or by being left exposed in the workplace. Nail-biting, smoking, and applying cosmetic products or medicines are also routes through which chemicals may be ingested (Canadian OSH website, 2016).

Once inside the mouth, chemicals travel down the oesophagus and into the stomach. Certain chemicals, such as alcohol, may pass through the stomach wall and enter the veins and the blood stream here, but most chemicals move from the stomach into the small intestine, where they then pass through the walls of the villi and into the blood stream. Some chemicals which contaminate food or drink can also pass across the thin walls of the villi and into the blood stream in this manner. Insoluble chemicals, or those whose basic units (molecules) are too big to pass through the villi walls, will stay in the gut and pass out through the faeces without being absorbed into the blood stream to any significant extent. Some acids, caustics and organics may cause severe 'burn' damage to the digestive system if ingested in high concentrations (Canadian OSH website, 2016).

Children are particularly exposed to ingested chemicals because they eat more food and drink more water per kilogram of body weight than adults, their diets consist of food that is more likely to be contaminated by harmful chemicals such as pesticides (e.g. fruits and vegetables), and the younger they are, the more limited their ability to metabolise and eliminate residual toxic substances. Moreover, children have hand-to-mouth behaviour, which means they are more likely to ingest chemicals that should not be ingested. Such chemicals can include the non-volatile and semi-volatile chemicals used to treat home furnishings such as carpets, curtains, wall decorations and some furniture, which then partition into the indoor environment and accumulate in house dust (Section 1.1.).

2.2 ININHALATION

Inhalation of contaminated air is one of the most common means of chemicals entering the body. Chemical vapours, gases and mists which reach the alveoli in the lungs, pass into the blood stream and are distributed around the body. Sometimes, the concentration of chemicals reaching the alveolar air sacs is lower than in workplace air, as a portion of the gases, vapours and mists may be dissolved in the mucus of the airways before they reach the alveolar sacs. Solid, visible particles found in dusts, fumes and smoke that have escaped the filtering mechanisms of the nose may also be trapped by the mucus. The mucus is wafted by the tiny cilia hairs until it reaches the back of the throat where it is either expelled through the mouth or swallowed and passed to the stomach. In this latter case, the contaminating chemicals will enter the body in the same way as contaminated food or drinks (Canadian OSH website, 2016).

Solid particles which cannot pass through the thin walls of the air sacs may lodge and remain where they are. Some may dissolve, some may be removed by the body's immune system, and others may prove too big or too insoluble to be disposed of in this way and simply stay in the air sacs. Some of these particles may damage the surrounding alveolar walls, which can result in permanent damage or cause scars to form, which eventually interfere with the lung's ability to pass oxygen into the blood stream. Some acids, caustics or organic chemicals, when inhaled in sizable amounts, can cause serious and irreparable 'burn' damage to the mouth, nose, trachea, bronchi and lungs (Canadian OSH website, 2016.). With inhalation exposure, it is important to differentiate between indoor and outdoor pollutants.

With regard to indoor air pollution, vulnerable groups are represented by children, pregnant women, elderly persons over 65 years of age, and persons suffering from asthma or other respiratory diseases, and cardiovascular diseases. For some pollutants (e.g. microbes) other health compromises (immunodeficiency) may render people more vulnerable. Genetic traits, nutritional status and life-style factors may also contribute (TNO and RIVM, 2006). The assumption of different susceptibility of vulnerable groups (children, pregnant, elderly) to pollutants is based on age-dependent differences in physiology and toxicokinetics and varying responses due to existing diseases and genetic factors (IPCS 1993).

Air pollutants may affect adversely foetal and infant lung development, cause post-neonatal infant mortality due to respiratory diseases, cause cough and bronchitis and aggravate asthma (WHO 2005b). The effect on lung function during development has been observed below the NOEL of effects of single air pollutants in adults, suggesting a higher susceptibility of children. The causative pollutants have not been identified but the association to adverse effects has been detected most consistently with outdoor particulate matter (PM), nitrogen dioxide and ozone (WHO 2005b). Children's higher susceptibility is known for lead and environmental tobacco smoke (Tamburlini et al., 2002, DiFranza et al., 2004); some concern has been expressed also for organophosphate pesticides (Grandjean and Landrigan, 2006).

Altered physiology and toxicokinetics (e.g. reduced renal clearance) make also elderly people potentially more sensitive due to reduced capacity for elimination. However, elderly people may also be less sensitive to some effects including nasal and eye irritation indicating that aging may also decrease the susceptibility (IPCS 1993).

Addittionally, people suffering from cardiovascular diseases are more vulnerable to particles (WHO 2003 and persons suffering from asthma and other respiratory diseases are more susceptible to several air pollutants (WHO 2004a, 2005b). For example, sensory irritation may occur at lower exposure level in persons with allergic rhinitis (WHO 2005b).

Currently within Europe and other industrialized countries as well as international bodies, vulnerable groups are considered on a case-by-case basis in general. However, a major gap in identification of vulnerable groups is the lack of data, but several ongoing activities are attempting to extend e.g. reproductive toxicity testing to better address immunological and neurological differences. Additionally, physiological-based pharmacokinetic models can offer insight in intraindividual variability in pharmacokinetics (TNO and RIVM 2006).

With regard to (outdoor) air pollution, a recent study has linked it to increased mental illness in children, even at low levels of pollution (A. Oudin et al., 2016). The new research found that relatively small increases in air pollution were associated with a significant increase in treated psychiatric problems. While this is the first study that establishes a link of this kind, it has also to be noted that the latter is consistent with a growing body of evidence that air pollution can affect mental and cognitive health and that children are particularly vulnerable to poor air quality. The research in question examined the pollution exposure of more than 500,000 under-18s in Sweden and compared this with records of medicines prescribed for mental illnesses, ranging from sedatives to anti-psychotics. There

have also been several earlier studies that found associations between air pollution and autism spectrum disorders and learning and development in children (S. Wang et al., 2009). However, this study adds to evidence that air pollution may have detrimental effects on the brains of children and adolescents.

2.3 SKIN CONTACT

Chemicals can also enter the body through skin contact. The skin consists of two layers, a thin, outermost layer called the epidermis and a much thicker under layer called the dermis. The external part of the epidermis is called the keratin layer, and is largely responsible for resisting water entry into the body as well as weak acids, but is much less effective against organic and (some) inorganic chemicals (Canadian OSH website, 2016). Organic and caustic (alkaline) chemicals can soften the keratin cells in the skin and pass through this layer to the dermis, where they are able to enter the veins and thus the blood stream. Areas of the body such as the forearms, which may be particularly hairy, are most easily penetrated by chemicals since they can enter down the small duct containing the hair shaft. Chemicals can also enter through cuts, punctures or scrapes of the skin since these are breaks in the protective layer. Contact with some chemicals, such as detergents or organic solvents, can cause skin dryness and cracking, as well as hives, ulcerations or skin flaking. All of these conditions weaken the protective layer of the skin and may allow chemicals to enter the body (Canadian OSH website, 2016).

Chemicals can vary enormously in the degree to which they can penetrate the skin. Some solvents such as trichloroethylene, naphtha and toluene may soften the keratin layer but are not believed to penetrate much further unless there is prolonged skin contact. On the other hand, chemicals such as benzene, carbon tetrachloride, carbon disulphide and methyl alcohol can readily pass through the epidermis and subsequently enter the blood stream. Other chemicals are so corrosive that they burn holes in the skin, allowing infection or other chemicals to enter. In some instances, chemicals may enter by accidental injection through the skin. This may occur in hospital settings or in industrial hole-punching or injection processes. Once in the blood stream, the chemicals can be transported to any site or organ of the body where they may exert their effects (Canadian OSH website, 2016).

Chemicals are capable of acutely irritating or burning the skin and, after repeated exposure, may chronically damage the skin. They can also systematically, after percutaneous absorption, cause poisoning or diseases such as cancer. Sensitising substances may cause allergic reactions following skin contact, such as from activities in the health service (e.g. disinfectants in general and methacrylates in dental laboratories) and in the construction sector (e.g. dichromate, cobalt, nickel of cements and epoxy resins) (EU-OSHA, 2008). Female adolescents, pregnant women, children and workers are particularly vulnerable to chemical absorption through the skin.

2.4 EXPOSURE THROUGH THE PLACENTA AND UMBILICAL CORD

According to Prouillac and Lecoeur (2010) the placenta is a key organ for the growth and development of the embryo and fetus during pregnancy. The placenta has traditionally been considered as a highly permeable organ for a large variety of substances with diverse molecular structures that are readily able to cross it from the maternal blood to reach the fetus. Indeed, proof of fetal exposure to maternal intake occurred for the first time with the thalidomide disaster in 1957 to 1961. The thalidomide crisis of the mid-twentieth century established the vulnerability of the fetus during the prenatal period and provided evidence that the placenta was not an impervious barrier against toxic exposures. Doctors prescribed thalidomide to pregnant women for morning sickness for four years before determining in 1961 that it caused many of the women's babies to be born without arms or legs (McBride WG, 1961).

After the thalidomide crisis, researchers soon found that low levels of chemicals with more subtle effects than thalidomide—for instance, lead, mercury, polychlorinated biphenyls (PCBs), and nicotine—also could cross the placenta and enter the fetal blood supply, causing damage. Once inside the placenta, researchers

speculated that these chemicals had direct access to the fetal brain and other developing tissues (Almond D., & Currie J., 2011). Moreover, findings offer evidence that phthalates and possibly other endocrine-disrupting chemicals may be able to affect fetal development indirectly by altering placental function. Like direct effects, these indirect effects may influence disease development later in life (Konkel 2016).
Additionally, associations between preeclampsia and placental levels of metals including cadmium has been bound (Laine 2015). Preeclampsia is a pregnancy complication that results in decreased oxygenation and metabolic stress for the fetus, hypertension for the mother, and later risk for heart disease and stroke in the child. This condition affects about 3–7% of pregnancies (Roberts & Cooper 2016).

Prouillac and Lecoeur (2010) also pointed out that, in addition to drug exposure, which can be voluntarily limited during pregnancy, fetal exposure to food contaminants is characterized by chronic exposure to low doses. They also outlined that very little information is available on fetal exposure to these pollutants and their long-term effects. Drug transporters are involved in the regulation of the chemical environment of the fetus by selectively transporting and removing toxic substrates. Thus, placental epithelia expressing xenobiotic metabolism enzymes and protein transporters are very helpful models for the in vitro study of quantitative and qualitative transfers of molecules to the fetus.

An analysis of National Health and Nutrition Examination Survey data from 2003–2004 found that virtually every pregnant woman in the United States is exposed to at least 43 different chemicals (Woodruff 2011). Chemicals in pregnant women can cross the placenta, and in some cases, such as with methyl mercury, can accumulate in the fetus, resulting in higher fetal exposure than maternal exposure (Rollin 2009). Prenatal exposure to environmental chemicals is linked to various adverse health consequences, and patient exposure at any point in time can lead to harmful reproductive health outcomes. For example, prenatal exposure to certain pesticides has been documented to increase the risk of cancer in childhood; adult male exposure to pesticides is linked to altered semen quality, sterility, and prostate cancer; and postnatal exposure to some pesticides can interfere with all developmental stages of reproductive function in adult females, including puberty, menstruation and ovulation, fertility and fecundity, and menopause (Sutton et al. 2013). Moreover, endocrine disrupting chemicals has been shown to interfere with the role of certain hormones, homeostasis, and developmental processes (Bergman et al. 2013).

HBM studies have also shown that the prenatal exposure to chemicals in infants could result in some adverse health effects. For example, findings from the South Korean MOCEH study suggested that prenatal exposure to phthalates may be inversely associated with the neurodevelopment of infants (Kim et al., 2011b). In the Flanders' FLEHS study, a strong correlation for Pb, As, and Tl was found between levels in cord blood and maternal blood, suggesting that these metals are transported to the fetus from the mother (Baeyens et al., 2014), and it appears that prenatal exposure to metals have adverse effects on newborns. The MOCEH study indicated a negative relationship between maternal Pd and Cd levels during late pregnancy period and neurodevelopment (Kim et al., 2013b). The EU-wide DEMOCOPHES project showed elevated levels of methyl mercury in fish eating subgroups of the investigated populations (i.e. mothers), and the Norwegian MoBa cohort study reported negative association between maternal exposure to mercury (via reported dietary intake during pregnancy) and birth weight (Vejrup et al., 2014). The Japanese Tohoku HBM study also reported a negative relationship between maternal hair mercury level and motor abilities of infants (Suzuki et al., 2010). Aside from phthalates and metals, the MoBa study also showed that maternal exposure to dioxins, PCBs, or benzo(a)pyrene resulted in decreased birth weight (Duarte-Salles et al., 2013a;), and the Japanese Hokkaido HBM study observed lower birth weight, higher risk of infections in infants, and reduced motor development due to maternal exposure to PFOS, 2,3,4,7,8-PeCDF, and PCDDs, respectively (; Miyashita et al., 2011;). Collectively, these studies emphasised the importance tomonitor the chemical levels in pregnant women in order to reduce chemical exposure and health risks in newborns.

2.5 EXPOSURE THORUGH BREAST MILK

While breast milk is considered the best source of nutrition for infants, its contamination is widespread and is the consequence of decades of inadequately controlled pollution of the environment by toxic chemicals. Polychlorinated biphenyls (PCBs), DDT and its metabolites dioxins, dibenzofurans, polybrominated diphenyl ethers (PBDEs), and heavy metals are among the toxic chemicals most often found in breast milk (Landrigan et al 2002).
The level of risk to infants and children of exposure to chemical residues in human milk depends on each mother's food consumption patterns, the nature and levels of chemical residues in her milk, and the toxicologic potency of those chemicals. Infants and children may exhibit unique susceptibilities to the toxic effects of chemicals because they are undergoing rapid tissue growth and development (Landrigan, 1999). Infants and children also consume much greater quantities of milk fat and certain foods than do adults on a body weight basis, and thus they may be subjected to proportionately higher levels of exposure to certain chemicals. Furthermore, these exposures occurring earlier in life may predispose infants and children to a greater risk of chronic toxic effects than exposure occurring later in life (Landrigan et al 2002).

Mogensen et al (2015) also demonstrated that Perfluorinated alkylate substances (PFASs) occur in breast milk, and the duration of breastfeeding is associated with serum-PFAS concentrations in children. To determine the time-dependent impact of this exposure pathway, they examined the serum concentrations of five major PFASs in a Faroese birth cohort at birth, and at ages 11, 18, and 60 months. The trajectory of serum-PFAS concentrations during months with and without breastfeeding was examined by linear mixed models that accounted for the correlations of the PFAS measurements for each child. The models were adjusted for confounders such as body size. The duration of exclusive breastfeeding was associated with increases of most PFAS concentrations by up to 30% per month, with lower increases during partial breast-feeding. In contrast to this main pattern, perfluorohexanesulfonate was not affected by breast-feeding. After cessation of breastfeeding, all serum concentrations decreased. This finding supports the evidence of breastfeeding being an important exposure pathway to some PFASs in infants.

2.6 OCCUPATIONAL EXPOSURE

Many occupations involve the use or generation of substances that can be harmful to human health. Health effects can range from relatively mild (e.g. eye irritation) to serious diseases (e.g. cancer) (Ekenga, 2015). Adverse effects can occur as a result of a single episode of high exposure or from sustained, lower level, long-term exposure. Workers can be exposed to harmful chemicals capable of causing health effects, such as cancer and chronic obstructive pulmonary disease, for many years with no obvious ill effects. This can also mean that by the time symptoms will appear, irreversible harm has already been caused. Certain chemicals can be easily recognised as dangerous substances, while for others this is not always as straightforward. For instance, exposure to some substances, such as flour dust, may result in various adverse health outcomes from conjunctivitis to baker's asthma (Stobnicka A & Górny RL, 2015).

The types of industry where the risk to chemical exposure is highest include (Keen C, 2016a):

- primary extraction such as mining, quarrying, oil and gas drilling (risk of exposure to respirable crystalline silica, as well as lubricants and drilling muds);
- manufacturing industries, including food production (risk of exposure to dangerous process chemicals such as isocyanates, solvents, and end products such as paints and lubricants);
- farming (risk of exposure to pesticides, organic dusts and bioaerosols);
- service industries (risk of exposure to cleaning products, asbestos, bioaerosols and process chemicals such as paint strippers and adhesives);
- healthcare sector (risk of exposure to biohazards, pharmaceuticals and disinfectants);

- hairdressing sector and beauty salon industry (risk of exposure to a wide range of hazardous chemicals used in products such as sprays and paints);
- construction industry (risk of exposure to dangerous substances such as mineral dusts, paints and glues);
- recycling industry (risk of exposure to a wide range of hazardous materials, including dusts, toxic metals and biohazards).

2.7 FURTHER INFORMATION

Nanomaterials
Given their extremely small size, nanomaterials, depending on their use, may enter the body through inhalation (e.g. work place air), ingestion (e.g. food) or skin contact (e.g. sunscreens).

Inhaled nanoparticles can cross the pulmonary epithelium, enter into the bloodstream and spread to other organs. Research with animal models has shown that silver nanoparticles in particular may reach the liver and brain through these routes (Ji, J.H., et al., 2007). Moreover, increased manganese levels can be detected in the brain of rats after inhalation of manganese oxide (Elder, A., et al., 2006). Inhaled particles may also migrate to the brain via the olfactory nerve (Oberdörster, G., et al., 2004). Additionally, inhaled gold nanoparticles have shown to accumulate in the olfactory bulb, and have also been detected in the lung, oesophagus, tongue, kidney, aorta, spleen, septum, heart and blood in rats (Yu, L. E., et al., 2007).

Particles may also disperse into the body through other routes, like crossing intestinal epithelium after ingestion (Oberdörster, G., et al., 2004). Ingestion may happen accidentally or as a result of poor hygiene (e.g. eating with contaminated hands). Moreover, ingestion is possible as a "secondary" effect of inhalation (deposition on the lips, nose and throat membranes and ingestion of secretions).

The possible penetration of nanoparticles through the skin is currently a subject of debate, especially regarding the hazards associated with the use of cosmetics and sunscreen protection. Recent studies reported that titanium dioxide nanoparticles do not penetrate beyond the epidermal level (Butz, T., et al., 2011) but the debate is still ongoing (Gratieri, T., et al., 2010).

Occupational exposure stemming from nanomaterials
Occupational exposure to nanomaterials is of particular concern, as workers may be exposed at much higher levels than the general public and on a more consistent basis (IOM, 2004). In particular, workers may experience nanoexposure in the production, manufacturing, packaging or transport of products that contain nanomaterials, or during cleaning or maintenance work.

Processes during which dry nanomaterial powders are generated, handled or used are particularly likely to lead to significant occupational exposure. Furthermore, lending, reloading, drying or vacuum cleaning are operations that may increase the level of exposure to airborne nanomaterials. The same applies for sprayed colloidal suspensions, whereby the hazards of the dispersant should also be considered. Furthermore, measurements of airborne nanomaterials have shown higher levels where processes such as extrusion and cutting of bags containing nanomaterials, or dry-sawing of nanomaterial-containing composites took place (Möhlmann, C., et al., 2011). Whether exposure can occur when handling, processing or using nanomaterials embedded into a solid matrix or products containing nanomaterials is currently a subject of debate and needs further investigation (Göhler, D., et al., 2010).

It is also worth underling that if information on the presence of nanomaterials are not available down the user chain employers and workers may not be aware that they handle products containing nanoparticles or nanomaterials. Therefore, significant exposure is more likely in situations of this kind,

since employers and workers do not have the necessary information to implement adequate protection and prevention measures (ACLI, 2009).

Pesticides

Pesticides can enter your body during mixing, applying, or clean-up operations. There are generally three ways a chemical can enter the body: through the skin (dermal), through the lungs (inhalation), by mouth (ingestion), or through injection.

With regard to absorption through skin, in most work situations, it is the most common route of pesticide exposure. People can be exposed to a splash or mist when mixing, loading or applying the pesticide. Skin contact can also occur when a piece of equipment, protective clothing, or surface that has pesticide residue on it is touched.

Inhalation may occur through breathing contaminated air. This situation is particularly common in working places where gases as well as vapours can contaminate the air. In some instances, contamination may happen through mists which are the result of an industrial process that produce tiny liquid droplets that are able to float in the air. Other workplace processes can generate tiny solid hazardous particles which are light enough to float in the air, and these are referred to as dusts, fumes and smoke.

While ingestion (by mouth) is a less common way to be exposed, it can result in the most severe poisonings. Chemicals may be swallowed accidentally if food or cigarettes (or hands) are contaminated (OSH, 2009).

Injection is the fourth way chemicals may enter the body. While uncommon in most workplaces, it can occur when a sharp object (e.g., needle) punctures the skin and injects a chemical directly into the bloodstream.

In addition, the exposure to pesticides can be direct (e.g., industrial workers who produce pesticides and the operators – especially farmers – who use them) and indirect. In particular, residents and bystanders can be indirectly exposed to pesticides as a result of spray drift. So can consumers through residual amounts in agricultural products or water (ibid).

3 WHICH CHEMICALS CAN CAUSE ADVERSE HEALTH EFFECTS IN VULNERABLE POPULATIONS?

3.1 REPRODUCTIVE TOXINS

Since the mid-20th century, numerous studies have reported an increasing incidence of human reproductive diseases and a consequent decline in reproductive function worldwide (Woodruff, 2011). The following trends, related to changes of the reproductive system, have been described in literature (Balabanic *et al*., 2011; UNEP & WHO, 2013):

- Data from the United States show that the percentage of women who have difficulty in achieving and maintaining pregnancy has increased between 1982 to 2002, and is slightly lower in 2006-2010 (though still higher than 1995 and earlier). While some of this increase is likely due to people starting families later in life (fertility decreases with age and miscarriage rates increase with age), this does not explain why the sharpest increase in reported infertility is seen in younger women between 1982 and 2002.
- In the United States, United Kingdom and Scandinavia, the preterm birth rate has increased by more than 30% since 1981. Since 1990, the percentage of infants born in the USA with low birth weight also rose 16% to 8.1% of births in 2004.
- There is a secular trend toward earlier onset puberty among American and European girls. Premature puberty can lead to reduced adult height and is also associated with a higher risk of breast cancer and polycystic ovary syndrome. It can also have psychological consequences such as greater likelihood of engaging in risky behaviours (smoking, unprotected sex, alcohol and drugs.

Given the short time frame, the above described developments cannot be explained by genetic changes alone. Environmental and other non-genetic factors, including nutrition, age of mother and viral diseases are also at play, and the exposure to environmental substances may also be accountable for the observed trends.

A large body of research exist showing the adverse effects of EDCs on the reproductive system. This, together with the consistent detection of endocrine-disrupting residues in human serum, seminal plasma and follicular fluid, has raised concern that environmental exposure to EDCs is affecting human fertility (Younglai *et al*., 2002). EDCs may affect the development and functioning of the reproductive system in both sexes, particularly in foetuses, causing developmental and reproductive disorders, as well as infertility. As male sexual differentiation is androgen-dependent (and potentially oestrogen-dependent) and female differentiation occurs largely independently of oestrogens and androgens, it is expected that different disorders are seen in males and females as a result of EDC effects (Diamanti-Kandarakis *et al*., 2009).

Most EDCs are known to act as agonists of oestrogen receptors, e.g. bisphenol A and alkylphenols, and only a few antagonise androgen receptor such the dicarboximide fungicides. Progesterone receptors are also a potential target for many chlorinated EDC, such as DDT and derivatives (D. Caserta, 2008). Other examples of endocrine disrupting chemicals that have shown to have an effect on the reproductive system are: Diethylstilbestrol (DES), Tributyltin, Phytestrogens, Alkylphenolethoxylates, Phthalate esters (DEHP, BBP, DiNP, DBP), Dioxins, Polychlorinated biphenyls, Herbicides, Lead, Cadmium, and Manganese (UNEP & WHO, 2013).

Experimental studies with rodents have widely studied the adverse effects of EDCs on the reproductive system. These animal studies, which enable the investigator to measure hormone action at various times during development and thus to accurately interpret the relationship between exposure and all of the effects on the endocrine system, indicate that early prenatal and/or perinatal exposure to EDCs can lead to long-term effects on reproduction and development which can become evident later,

even at sexual maturity and/or at adulthood. The identification and characterisation of this 'early exposure—late effect' pattern of EDCs represents a challenge for scientists and risk assessors (Caserta, 2008). Additionally, endocrine-disrupting compounds can have varying effects throughout development because of variations in tissue hormone receptor isoforms and concentrations at different developmental stages (Crain et al., 2008).

As explained by WHO (2014), human and wildlife health depends on the ability to reproduce and develop normally. This is not possible without a healthy endocrine system. Three strands of evidence fuel concerns over endocrine disruptors:

1. the high incidence and the increasing trends of many endocrine-related disorders in humans;
2. observations of endocrine-related effects in wildlife populations;
3. the identification of chemicals with endocrine disrupting properties linked to disease outcomes in laboratory studies.

Close to 800 chemicals are known or suspected to be capable of interfering with hormone receptors, hormone synthesis or hormone conversion. However, only a small fraction of these chemicals have been investigated in tests capable of identifying overt endocrine effects in intact organisms. The speed with which the increases in disease incidence have occurred in recent decades rules out genetic factors as the sole plausible explanation. Environmental and other non-genetic factors, including nutrition, age of mother, viral diseases and chemical exposures, are also at play, but are difficult to identify. Numerous laboratory studies support the idea that chemical exposures contribute to endocrine disorders in humans and wildlife. The most sensitive window of exposure to EDCs is during critical periods of development, such as during foetal development and puberty.

Significant knowledge gaps exist as to associations between exposures to EDCs and other endocrine diseases, as follows (WHO, 2014):

- There is very little epidemiological evidence to link EDC exposure with adverse pregnancy outcomes, early onset of breast development, obesity or diabetes.
- There is almost no information about associations between EDC exposure and endometrial or ovarian cancer.
- High accidental exposures to PCBs during foetal development or to dioxins in childhood increase the risk of reduced semen quality in adulthood. With the exception of these studies, there are no data sets that include information about foetal EDC exposures and adult measures of semen quality.
- No studies exist that explore the potential link between foetal exposure to EDCs and the risk of testicular cancer occurring 20–40 years later.

Wildlife populations have been affected by endocrine disruption, with negative impacts on growth and reproduction. These effects are widespread and have been due primarily to POPs. Bans of these chemicals have reduced exposure and led to recovery of some populations.

Internationally agreed and validated test methods for the identification of endocrine disruptors capture only a limited range of the known spectrum of endocrine disrupting effects. This increases the likelihood that harmful effects in humans and wildlife are being overlooked. Disease risk due to EDCs may therefore be significantly underestimated (WHO, 2014).

WHO (2014) states that, despite substantial advances in our understanding of EDCs, uncertainties and knowledge gaps still exist that are too important to ignore. These knowledge gaps hamper progress towards better protection of the public and wildlife. An integrated, coordinated international effort is needed to define the role of EDCs in current declines in human and wildlife health and in wildlife populations. An important focus should be on reducing exposures by a variety of mechanisms. Government actions to reduce exposures, while limited, have proven to be effective in specific cases

(e.g. bans and restrictions on lead, chlorpyrifos, tributyltin, PCBs and some other POPs). This has contributed to decreases in the frequency of disorders in humans and wildlife.

Diamanti-Kandarakis *et al.* (2009) explain that EDCs can be classified in the following two ways:

1. Those that occur naturally.
   - Natural chemicals found in human and animal food (e.g. phytoestrogen: genistein and coumestrol) and
2. Those that are synthesized. These can be further grouped as follows:
   - Synthetic chemicals used as industrial solvents or lubricants and their byproducts (e.g. polychlorinated biphenyls (PCBs), polybrominated biphenyls (PBBs), dioxins)
   - Plastics (e.g. bisphenol A (BPA))
   - Plasticizers
   - Pesticides (e.g. dichlorodiphenyltrichloroethane (DDT))
   - Fungicide (e.g. vinclozolin) and
   - Some pharmaceutical agents (e.g. diethylstilbestrol (DES)).

EDCs can also be grouped according to their origins:

- Natural and artificial hormones (e.g. fitoestrogens, 3-omega fatty acids, contraceptive pills and thyroid medicines).
- Drugs with hormonal side effects (e.g.naproxen, metoprolol and clofibrate).
- Industrial and household chemicals (e.g.phthalates, alkylphenoletoxilate detergents, fire retardants, plasticizers, solvents, 1,4-dichloro-benzene and polychlorinated bis-phenols (PCBs).
- Side products of industrial and household processes (e.g., polycyclic aromatic hydrocarbons (PAHs), dioxins, pentachlorobenzene).

DDT has a long history as an endocrine disruptor. The compound was once used randomly as a pesticide in the agricultural sectors, in production of crops and livestock, in household, gardens, public places and institutions, but because of its hazardous nature it was banned few years back. However, the compound is still in use in some countries. DDT can interfere with thyroid, oestrogen, androgen, rennin-angiotensin, insulin and neuroendocrine systems which can directly influence the reproductive, cardiovascular and metabolic systems of human body. These have obviously made it one of the most potential candidates of endocrine disruptors (Gore *et al*., 2014).

As explained by Gore *et al.*, EDCs are present in the products that we use in our day to day life, starting from the products that include children products, electronics, personal care products, textile/clothing to building contact materials. However, in most of the cases, we are not aware of these facts since it is not always included in their chemical compound list. This is a matter of concern since there is a huge possibility of these chemicals to be released into the environment and come in contact with us. Also in the children's product where EDCs are mainly found, it is always seen that the children might pick up those products and put them into their mouth. Apart from these, EDCs are frequently found in personal care products starting from toothpaste, the products that we apply on our skin, soaps, in which antimicrobial agents are used. However for ease of understanding we may subclass this class into two groups: children's product and electronics.

Brominated flame retardants (BFR) are now being widely used in different products that we use regular in our daily life. These products may range from computers, electronics and electronical equipment, textiles, foam furniture, insulating foams and other building materials. The product is selected as a potential source of endocrine disruptors, since the compound is not bound to the products, and as a result they are easily released into the environment. However, although the compound has been prohibited in many countries, it is still being considered as a vulnerable source, since high half-life of the compound makes it to persist in the environment for longer period of time (Gore *et al.*, 2014).

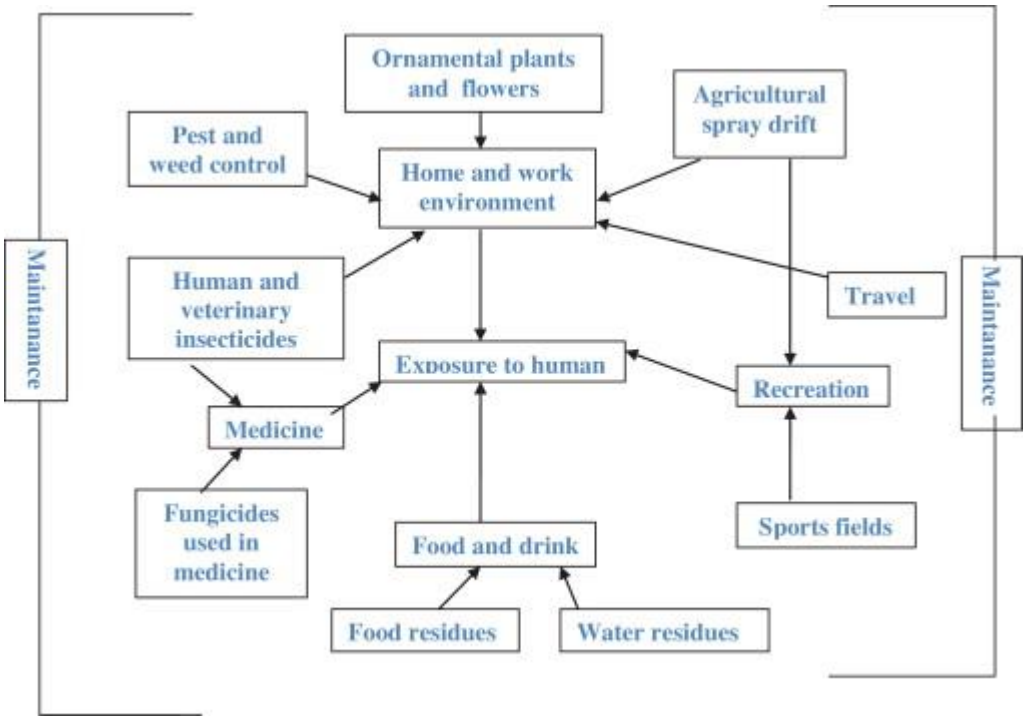
Bisphenol A was once used frequently in plastic based containers, and also in the epoxy based lining of canned food. However, because of the hazardous effects on human being, the compound is no longer used in baby bottles. The compound is still found in use in many containers, especially in epoxy based lining canned foods which are used for soups, vegetables etc. The lining is used to give protection from pathogens. But since it is in direct contact with the food, they may find their way into food and finally into human being (Gore *et al.*, 2014).

Considering the structural features of EDC, it is very difficult to establish a relationship between them. This is because of the diverse mechanism of action of EDC in the human body. Additionally, sometimes, it is the metabolites of EDC that is more hazardous than the parent compound itself. Although, there are some structural features that are indicative of endocrine disruption, it is also generally not possible to determine whether a compound is an EDC based on its structure.

The sources of EDC exposure are usually diverse and widely distributed all over the environment and society of the world. But the situation is neither constant nor can be predicted easily since there is a significant usage difference of these substances among the countries. The whole scenario becomes more complicated as some of these chemicals have been banned in some countries while others remain the same in other countries.

The following pictures summarises the exposure route of human to EDCs (Cristina *et al.*, 2012).

Figure 1: Different exposure routes of human to EDCs



Endocrine-disrupting chemicals (EDCs) represent a unique kind of toxicity. They are referred to by WHO as *"exogenous substances or mixtures that alter function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub) populations"* (WHO/IPCS, 2002).

The chemical disrupts hormone action, and can do so in three different ways (NIEHS, n.d.):

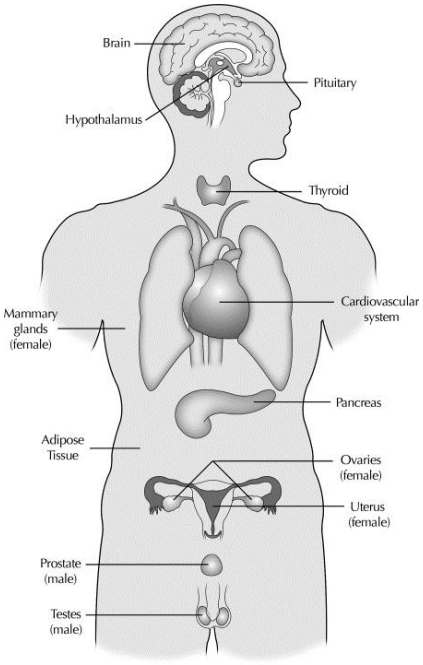
- Mimic or partly mimic naturally occurring hormones in the body like estrogens, androgens, and thyroid hormones, potentially producing overstimulation.

- Bind to a receptor within a cell and block the endogenous hormone from binding. The normal signal then fails to occur and the body fails to respond properly.
- Interfere or block the way natural hormones or their receptors are made or controlled, for example, by altering their metabolism in the liver or by acting directly on the proteins that control the delivery of a hormone to its normal target cell or tissue.

Most of the research conducted studying the impacts of endocrine disruptors have so far focused predominantly on the interaction of EDCs with the reproduction and thyroid hormone systems (UNEP & WHO, 2013). However, a growing number of studies indicate that endocrine disruptors can also affect other systems that can, for example, result in weight gain, insulin sensitivity and glucose tolerance. This indicates a potentially important role for endocrine disruptors in immune, digestive, and cardiovascular systems, as well as the development of obesity, type 2 Diabetes and metabolic syndromes.

The following image (from Diamanti-Kandarakis et al., 2009) shows the different systems that can be affected by endocrine-disrupting chemicals. The figure demonstrates that all hormone-sensitive physiological systems are vulnerable to EDCs, including brain and hypothalamic neuroendocrine systems; pituitary; thyroid; cardiovascular system; mammary gland; adipose tissue; pancreas; ovary and uterus in females; and testes and prostate in males.

Figure 2: Endocrine systems targeted by endocrine-disrupting chemicals



The hazardous effects of endocrine-disrupting chemicals depend on a range of factors, such as level and timing of exposure. As described by Diamanti-Kandarakis et al. (2009), some of the key elements that are key to the full understanding of mechanisms of action and consequences of exposure to EDCs include:

- **Age at exposure**: There are particularly vulnerable periods during foetal and postnatal life when EDCs alone, or in mixtures, have strong and often irreversible effects on developing organs, resulting in disorders or diseases later in life. There is a growing probability that maternal, foetal and childhood exposure to chemical pollutants play a larger role in the etiology of many endocrine diseases and disorders than previously thought possible (UNEP & WHO, 2013).
- **Latency from exposure**: There may be a delay between the time of exposure and the manifestation of the disorder or disease, which means that the exposure early in life may not be

immediately apparent but manifests later in life (e.g. during adulthood or ageing).

- **Mixtures**: Endocrine disruptors can work together to produce additive, combination effects, even when combined at low doses that individually do not produce observable effects. There is, however, a limited understanding of the types of mixtures that humans are exposed to and how they affect the endocrine system (National Research Council, 2008). Moreover, the effects of EDCs may be blocked or enforced in combination with certain environmental, biological or physical stressors, which makes it even more difficult to identify definite evidence linking exposure to chemicals with endocrine disruptions. Not merely because the majority of disorders and diseases are probabilistic and multicausal (UNEP & WHO, 2013).
- **Non-traditional dose-response dynamics**: Very low levels of exposure may cause endocrine or reproductive abnormalities, particularly if exposure occurs during a critical developmental window (Sheehan et al., 1999). Surprisingly, low doses may even exert more potent effects than higher doses. Moreover, EDCs may exert nontraditional dose-response curves, such as inverted-U or U-shaped curves (vom Saal et al., 2007). Both of these concepts have been known for hormone and neurotransmitter actions, but only in the past decade have they begun to be appreciated for EDCs.
- **Transgenerational, epigenetic effects**: Research suggests that EDCs may not only be causing mutations to DNA sequences, but also modify factors related to the germline that regulate gene expression (e.g. DNA methylation and histone acetylation). This means that not only the exposed person will be affected, but also the children and subsequent generations (Anyway et al., 2006).

UNEP and WHO explain in their report of 2013 that we are beginning to understand the importance of certain events during development and throughout the lifespan that interact with genetic background to increase susceptibility to a variety of diseases. It is clear that a large number of all non-communicable diseases have their origin during development. It is also clear that one of the important risk factors for disease is exposure to EDCs during development. Exposure to EDCs during development can, as demonstrated in animal models and in an increasing number of human studies, result in increased susceptibility to, and incidence of, a variety of diseases. These include some of the major human diseases that are increasing in incidence and prevalence around the world. The incidence of these diseases and dysfunctions is increased at current levels of exposure to EDCs in normal populations. It is also clear from human studies that we are exposed to perhaps hundreds of environmental chemicals at any one time. It is now virtually impossible to identify an unexposed population around the globe. There is an increasing burden of disease across the globe in which EDCs are likely playing an important role, and future generations may also be affected.

Regarding future needs, UNEP & WHO (2013) calls for better information on how and when EDCs act in order to reduce exposures during development and prevent disease from occurring. A clear example of the success of primary prevention through exposure control is lead. The following needs were identified to take advantage of current knowledge to improve human and wildlife health by prevention of environmentally induced diseases.

- *Strengthening knowledge of EDCs*: It is critical to move beyond the piecemeal, one chemical at a time, one disease at a time, one dose approach currently used by scientists studying animal models, humans or wildlife. Understanding the effects of the mixtures of chemicals to which humans and wildlife are exposed is increasingly important. Assessment of EDC action by scientists needs to take into account the characteristics of the endocrine system that are being disrupted (e.g. low-dose effects and non-monotonic dose–response curves, tissue specificity and windows of exposure across the lifespan). Interdisciplinary efforts that combine knowledge from wildlife, experimental animal and human studies are needed to provide a more holistic approach for identifying the chemicals that are responsible for the increased incidence of endocrine-related disease and dysfunction. The known EDCs may not be representative of the full range of relevant molecular structures and properties due to a far too narrow focus on halogenated chemicals for many exposure assessments and testing for endocrine disrupting effects. Thus, research is needed to identify other possible EDCs. Endocrine disruption is no longer limited to estrogenic,

androgenic and thyroid pathways. Chemicals also interfere with metabolism, fat storage, bone development and the immune system, and this suggests that all endocrine systems can and will be affected by EDCs. Together, these new insights stress a critical need to acquire a better understanding of the endocrine system to determine how EDCs affect normal endocrine function, how windows of exposure may affect disease incidence (particularly for childhood respiratory diseases) and how these effects may be passed on to generations to come.

Furthermore, new approaches are needed to examine the effects of mixtures of endocrine disruptors on disease susceptibility and etiology, as examination of one endocrine disruptor at a time is likely to underestimate the combined risk from simultaneous exposure to multiple endocrine disruptors. Assessment of human health effects due to EDCs needs to include the effects of exposure to chemical mixtures on a single disease as well as the effects of exposure to a single chemical on multiple diseases. Since human studies, while important, cannot show cause and effect, it is critical to develop cause and effect data in animals to support the studies on humans.

- *Improved testing for EDCs*: Validated screening and testing systems have been developed by a number of governments, and it requires considerable time and effort to ensure that these systems function properly. These systems include both in vitro and in vivo endpoints and various species, including fish, amphibians and mammals. New approaches are also being explored whereby large batteries of high-throughput in vitro tests are being investigated for their ability to predict toxicity, the results of which may be used in hazard identification and potentially risk assessment. These new approaches are important as one considers the number of chemicals for which there is no information, and these high-throughput assays may provide important, albeit incomplete, information. An additional challenge to moving forward is that EDC research over the past decade has revealed the complex interactions of some chemicals with endocrine systems, which may escape detection in current validated test systems. Finally, it will be important to develop weight-of-evidence approaches that allow effective consideration of research from all levels—from in vitro mechanistic data to human epidemiological data.

- *Reducing exposures and thereby vulnerability to disease*: It is imperative that we know the nature of EDCs to which humans and wildlife are exposed, together with information about their concentrations in blood, placenta, amniotic fluid and other tissues, across lifespans, sexes, ethnicities (or species of wildlife) and regions. Many information gaps currently exist with regard to what is found in human and wildlife tissues, more so for developing countries and countries with economies in transition and for chemicals that are less bioaccumulative in the body. Long-term records to help us understand changes in exposures exist only for POPs and only for a few countries.

  In addition, there is a need to continue expanding the list of chemicals currently examined to include those contained in materials and goods as well as chemical by-products; it is impossible to assess exposure without knowing the chemicals to target. The comprehensive measurement of all exposure events during a lifetime is needed, as opposed to biomonitoring at specific time points, and this requires longitudinal sampling, particularly during critical life stages, such as fetal development, early childhood and the reproductive years. Wildlife and humans are exposed to a wide variety of EDCs that differ greatly in their physical and chemical properties. Further, these compounds are generally present at trace concentrations and in complex matrices, requiring highly selective and sensitive analytical methods for their measurement. The wide range of different compound classes requires a variety of analytical approaches and techniques, making it challenging to understand all of the different chemicals in the environment and in human and wildlife tissues. There is a growing need to develop new analytical techniques and approaches to prioritize the assessment of EDCs. There is global transport of EDCs through natural processes (ocean and air currents) as well as commerce, leading to worldwide exposures. New sources of exposure to EDCs, in addition to food, have been identified and include indoor environments and

electronics recycling and dumpsites (of particular concern in developing countries and countries with economies in transition). The sources and routes of exposure to EDCs need to be further investigated.

- *Identifying endocrine active chemicals*: Identifying chemicals with endocrine disrupting potential among all of the chemicals used and released worldwide is a major challenge, and it is likely that we are currently assessing only the "tip of the iceberg". It is possible to trace high production volume chemicals, but that is not the case for the numerous additives and process chemicals. Adding greatly to the complexity, and to the number of chemicals in our environment, are the unknown or unintended byproducts that are formed during chemical manufacturing, during combustion processes and via environmental transformations. While the active ingredients in pharmaceuticals and pesticides have to be documented on the final product, this is not the case for chemicals in articles, materials and goods. Personal hygiene products and cosmetics require declarations of the ingredients, and the number of chemicals applied in this sphere of uses counts in the thousands. Many sources of EDCs are not known because of a lack of chemical constituent declarations in products, materials and goods. We need to know where the exposures are coming from.

- *Creating enabling environments for scientific advances, innovation and disease prevention*: Exposure to EDCs and their effects on human and wildlife health are a global problem that will require global solutions. More programmes are needed that foster collaboration and data sharing among scientists and between governmental agencies and countries. To protect human health from the combined effects of EDC exposures, poor nutrition and poor living conditions, there is a need to develop programmes and collaborations among developed and developing countries and those in economic transition. There is also a need to stimulate new adaptive approaches that break down institutional and traditional scientific barriers and stimulate interdisciplinary and multidisciplinary team science.

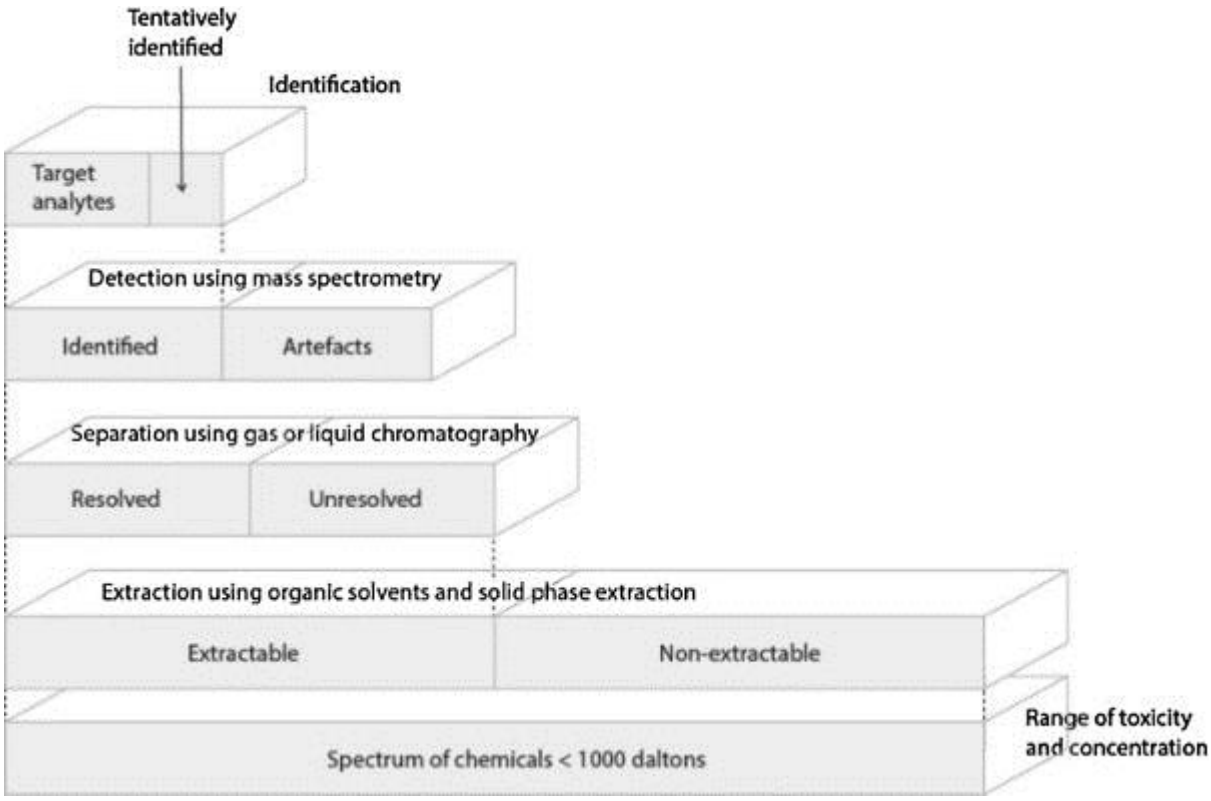
- *Methods for evaluating evidence*: There is currently no widely agreed system for evaluating the strength of evidence of associations between exposures to chemicals (including EDCs) and adverse health outcomes. A transparent methodology is also missing. The need for developing better approaches for evaluating the strength of evidence, together with improved methods of risk assessment, is widely recognized. Methods for synthesizing the science into evidence-based decisions have been developed and validated in clinical arenas. However, due to differences between environmental and clinical health sciences, the evidence base and decision context of these methods are not applicable to exposures to environmental contaminants, including EDCs. To meet this challenge, it will be necessary to exploit new methodological approaches. It is essential to evaluate associations between EDC exposures and health outcomes by further developing methods for which proof of concept is currently under development.

Even though wildlife and human matrices are available for extraction and analysis these days, the measured levels that are to be translated into an internal dose is not as simple. It is not always possible to do detailed comparisons between studies or assessments of effects of mixtures, since chemical analyses and exposure assessments still lack standardization. It is necessary to take into consideration that it is not the mass-based concentrations but the number of molecules that count when mixture doses are assessed. Therefore, the level of contaminants in humans and wildlife can only be currently compared on a molar basis (UNEP and WHO, 2013).

There is also a high demand for developing screening analytical methods that will accommodate a wide variety of analytical functional groups of the EDCs at low detection levels. Existing methodologies for chemical analyses of the EDCs having variable persistence, short half-lives in vivo and highly different structures need to be improved. The analytes need to be pure compounds as well as characterized in detail to promote methodological advances. The analysis of target analytes can be viewed as a top-down approach that only scratches the surface of the number of chemicals that can be

measured. This is shown in the figure below. Authentic standards are ultimately needed, although larger numbers can be tentatively identified based on mass spectra. Larger numbers cannot be readily identified, even if they can be isolated by the conventional extraction and separation technology widely employed in trace organics analysis laboratories. Furthermore, the analyst has to make a decision about how to best allocate analytical resources for this task. While the "spectrum of the EDC chemicals" (not isomers or congeners) is very large, only a subset can be extracted and separated by chromatography, and even less numbers identified. The use of effects directed analysis (EDA) and quantitative structure-activity relationship (QSAR) directed non-target analyses are two techniques that are currently being used to address this challenge (UNEP and WHO, 2013).

Figure 3: An illustration of the possibility of complexity of measuring potential EDCs in environmental media



3.2 THYROID DISRUPTORS

Compared with 2002, increased but still limited evidence exists showing associations between thyroid related disorders and chemical exposures. There is, however, very little direct evidence that effects on thyroid hormone action mediate these associations. There is currently no direct approach to test this hypothesis on human populations (UNEP & WHO, 2013).

Some epidemiological studies report associations between chemical exposures (PCBs, PBDEs, phthalates, BPA and perfluorinated chemicals) and thyroid function, including in pregnant women, but few of these report associations with thyroid measures in the cord blood of their offspring or with abnormal function in these offspring. Laboratory experiments with rodents show that there are many chemicals that can interfere with thyroid function. For example, exposure to PCBs clearly reduces serum thyroid hormone levels in rodents.

Similarly, there are chemicals that can interfere directly with thyroid hormone action in a manner that will not be captured by measuring serum hormone levels only. The variability of effects seen is interpreted by some to indicate that there is no convincing evidence that chemicals can interfere with

thyroid hormone action in humans. Evidence of relationships between exposure to chemicals and thyroid hormone disruption in wildlife species has increased in the last decade, especially in relation to exposure to the flame retardant PBDEs and PCBs, but other chemicals are inadequately studied.

The strength of evidence supporting a role for EDCs in disrupting thyroid function in wildlife adds credence to the hypothesis that this could occur in humans. Thyroid disruption is acknowledged to be poorly addressed by the chemical tests currently listed in the OECD conceptual framework. Genetic lines of mice are now widely available that could help clarify the mechanisms by which chemical exposures can interfere with thyroid hormone action (UNEP & WHO, 2013).

Other than neurotoxicants, a large variety of pervasive chemicals, such as dioxin-like compounds, certain flame retardants, PCBs, bisphenol A (BPA), perchlorate, pentachlorophenol and several other common contaminants have been shown to have thyroid-disrupting properties. Thyroid hormones play a significant role in the development of the CNS, pulmonary system, cardiovascular system, and other organs. Small modifications in thyroid serum levels during pregnancy – particularly during the first trimester - have been associated with cognitive deficits and other damaging effects on neurological outcome. Various studies have shown that hypothyroidism in the mother can result in impaired intellectual development in her children, as well as hearing loss. Perinatal exposure to thyroid-disrupting chemicals such as PCBs has also been associated with poorer neurodevelopment in neonates, toddlers and school-aged children.

Studies have shown that BPA and high levels of flame-retarding chemicals (polybrominated diphenyl ethers) can alter pregnant women's thyroid hormones, which are essential for normal foetal growth and brain development.

A study among elderly women found they were almost two-and-a-half times more likely to develop myocardial infarction and over one-and-a-half times more likely to develop aortic atherosclerosis in those with hypothyroidism, indicating that changes in thyroid function can impact the cardiac health of the elderly (Hak AE *et al.*, 2000).

3.3 NEUROTOXICANTS

According to Grandjean & Landrigan (2013) disorders of neurobehavioural development affect 10–15% of all births, and prevalence rates of autism spectrum disorder and attention-deficit hyperactivity disorder seem to be increasing worldwide. All these disabilities can have severe consequences: they diminish quality of life, reduce academic achievement, and disturb behaviour, with profound consequences for the welfare and productivity of entire societies.

The root causes of the present global pandemic of neurodevelopmental disorders are only partly understood. Although genetic factors have a role, they cannot explain recent increases in reported prevalence, and none of the genes discovered so far seem to be responsible for more than a small proportion of cases. Overall, genetic factors seem to account for no more than perhaps 30–40% of all cases of neurodevelopmental disorders. Thus, according to them, non-genetic, environmental exposures are involved in causation, in some cases probably by interacting with genetically inherited predispositions.

Strong evidence exists that industrial chemicals widely disseminated in the environment are important contributors to what it is called the global, silent pandemic of neurodevelopmental toxicity (Grandjean, 2013). The developing human brain is uniquely vulnerable to toxic chemical exposures, and major windows of developmental vulnerability occur in utero and during infancy and early childhood. During these sensitive life stages, chemicals can cause permanent brain injury at low levels of exposure that would have little or no adverse effect in an adult. In particular, five industrial chemicals have been classified as developmental neurotoxicants: lead, methylmercury, arsenic,

polychlorinated biphenyls, and toluene. Moreover, 201 chemicals had been reported to cause injury to the nervous system in adults, mostly in connection with occupational exposures, poisoning incidents, or suicide attempts. Additionally, more than 1000 chemicals have been reported to be neurotoxic in animals in laboratory studies.

In a famous review published in 2006, Grandjean & Landrigan expressed concern about additional developmental neurotoxicants that might lurk undiscovered among the 201 chemicals then known to be neurotoxic to adult human beings and among the many thousands of pesticides, solvents, and other industrial chemicals in widespread use that had never been tested for neurodevelopmental toxicity. Furthermore, since then, new data have emerged about the vulnerability of the developing brain and the neurotoxicity of industrial chemicals. Particularly important new evidence derives from prospective epidemiological birth cohort studies. For instance, cross-sectional data from Bangladesh show that exposure to manganese from drinking water is associated with reduced mathematics achievement scores in school children (Khan K, 2012). A meta-analysis of 27 cross-sectional studies of children exposed to fluoride in drinking water, mainly from China, suggests an average IQ decrement of about seven points in children exposed to raised fluoride concentrations (Choi, et al 2012).

The occupational health literature suggests that solvents can act as neurotoxicants, but the identify cation of individual responsible compounds is hampered by the complexity of exposures. In a French cohort study of 3000 children, investigators linked maternal occupational solvent exposure during pregnancy to deficits in behavioural assessment at 2 years of age (Pele et al. 2013). Clinical data suggest that also acute pesticide poisoning during childhood might lead to lasting neurobehavioural deficits (Kofman et al., 2006). Herbicides and fungicides might also have neurotoxic potential. Propoxur, a carbamate pesticide, and permethrine, a member of the pyrethroid class of pesticides, have recently been linked to neuro developmental deficits in children (Bjorling-Poulsen et al, 2008). The group of compounds known as polybrominated diphenyl ethers (PBDEs) are widely used as flame retardants and are structurally very similar to the polychlorinated biphenyls. Experimental evidence now suggests that the PBDEs might also be neurotoxic (Dingemans et al 2011)

3.4 CARCINOGENS

As shown by UNEP & WHO (2013):

- The increase in incidence of endocrine-related cancers in humans cannot be explained by genetic factors; environmental factors, including chemical exposures, are involved, but very few of these factors have been pinpointed.
- For breast, endometrial, ovarian and prostate cancers, the role of endogenous and therapeutic oestrogens is well documented; this makes it biologically plausible that xeno-oestrogens might also contribute to risks. However, chemicals shown to be associated with breast (dioxins, PCBs and solvents) or prostate (unspecified agricultural pesticides, PCBs, cadmium and arsenic) cancer either do not have strong estrogenic potential or are unspecified. The possibilities of involvement of EDCs in ovarian and endometrial cancers have received little attention.
- For thyroid cancer, there are indications of weak associations with pesticides and 2,3,7,8-tetrachlorodibenzo-p-dioxin, but there is no evidence that hormonal mechanisms are involved.
- Models of hormonal cancers are not available for regulatory testing. This makes the identification of hormonal carcinogens very difficult and forces researchers to rely on epidemiological studies. However, epidemiological studies cannot easily pinpoint specific chemicals and can identify carcinogenic risks only after the disease has occurred.
- Similar types of cancers of the endocrine organs, particularly reproductive organs, are also found in wildlife species (several species of marine mammals and invertebrates) and in domestic pets. In wildlife, endocrine tumours tend to be more common in animals living in polluted regions than in those inhabiting more pristine environments.

Other facts presented by the report include:

- Global rates of endocrine-related cancers (breast, endometrial, ovarian, prostate, testicular and thyroid) have been increasing over the past 40–50 years
- There is a trend towards earlier onset of breast development in young girls in all countries where this has been studied. This is a risk factor for breast cancer.
- The prevalence of obesity and type 2 diabetes has dramatically increased worldwide over the last 40 years. WHO estimates that 1.5 billion adults worldwide are overweight or obese and that the number with type 2 diabetes increased from 153 million to 347 million between 1980 and 2008
- High exposures to polychlorinated dioxins and certain PCBs (in women who lack some detoxifying enzymes) are risk factors in breast cancer. Although exposure to natural and synthetic oestrogens is associated with breast cancer, similar evidence linking estrogenic environmental chemicals with the disease is not available.
- Prostate cancer risks are related to occupational exposures to pesticides (of an unidentified nature), to some PCBs and to arsenic. Cadmium exposure has been linked with prostate cancer in some, but not all, epidemiological studies, although the associations are weak.

As shown by Carpenter DO & Bushkin-Bedient S (2013), the early life onset of a lifelong exposure to mixtures of multiple environmental chemical carcinogens and radiation contributes significantly to the etiology of cancer in later life. Because cells are rapidly dividing and organ systems are developing during childhood and adolescence, exposure to carcinogens during these early life stages is a major risk factor for cancer later in life. Because young people have many expected years of life, the clinical manifestations of cancers caused by carcinogens have more time in which to develop during characteristically long latency periods. Many chemical carcinogens persist in the body for decades and increase risk for all types of cancers. Carcinogens may act via mutagenic, non-mutagenic, or epigenetic mechanisms and may also result from disruption of endocrine systems. The problem is magnified by the fact that many chemical carcinogens have become an integral part of our food and water supply and are in air and the general environment.

Yet, few studies exist on human exposure to chemical carcinogens during early life, with most concerning animal studies. One such study showed that acute exposure of juvenile animals to eight different carcinogens resulted in at least a twofold greater sensitivity than a similar acute exposure to adult animals. This finding applied to cancers of the liver, lung, kidney, breast, blood, and nervous system. Some chemicals, such as benzo[a]pyrene, showed a nine-fold increase in risk for liver cancer when administered to neonatal animals than when administered to adult animals.

Also during adolescents, the developing tissues and functions of organ systems are particularly sensitive to the effects of carcinogenic and EDCs (Anderson LM *et al*., 2000; Soto AM & Sonnenschein C, 2010). Another factor that increases the risks in adolescence is their life expectancy. More years of life allows for greater acquisition and bioaccumulation of environmental chemicals, including persistent organic pollutants (POPs). An example is dioxin, a known human carcinogen, which has a half-life of about seven years (Flesch-Janys D *et al*., 1996). As humans are unable to detoxify and excrete dioxin-like chemicals efficiently, the daily intake exceeds elimination under most circumstances. Therefore, levels for background exposures in humans increase with age (ATSDR, 2000).

Pregnant women can be particularly vulnerable to toxicants absorbed through the skin. In fact, chemicals used in cosmetics and personal-care products have been shown to have endocrine-disrupting properties. Ethanolamine compounds, commonly found in shampoos, soaps and facial cleaners, have been demonstrated to be carcinogenic; exposure to synthetic 'fragrances' has been shown to affect the CNS; heavy metals like lead, arsenic and mercury that can be found in personal care products including lipstick, whitening toothpaste and nail polish can also cause various adverse health effects (EWG, 2007).

3.5 METABOLIC DISRUPTORS

As explained by UNEP & WHO (2013), Obesity, diabetes and metabolic syndrome are due to disruption of the energy storage–energy balance endocrine system and thus are potentially sensitive to EDCs. Exposures of animal models to a variety of chemicals during early development have been shown to result in weight gain, revealing the possibility of an origin for obesity early in development. Because they are disrupting many components of the endocrine system involved in controlling weight gain (adipose tissue, brain, skeletal muscle, liver, pancreas and gastrointestinal tract), these chemicals constitute a new class of endocrine disruptors called "obesogens".
Obesity is also correlated with type 2 diabetes, and chemicals that have been shown to cause obesity in animal models also result in altered glucose tolerance and reduced insulin resistance. There are no compelling animal data linking chemical exposures with type 1 diabetes, although some chemicals can affect the function of insulin producing beta cells in the pancreas, including BPA, PCBs, dioxins, arsenic and phthalates. Many of these chemicals are also immunotoxic in animal models, and so it is plausible that they could act via both immune and endocrine mechanisms to cause type 1 diabetes.

Limited epidemiological data exist to support the notion that EDC exposure during pregnancy can affect weight gain in infants and children. Limited epidemiological data show that adult exposures to some EDCs (mainly POPs, arsenic, BPA) are associated with type 2 diabetes, but there are no data for type 1 diabetes, there is insufficient evidence of endocrine mechanisms and there is insufficient study of this area in general (UNEP & WHO, 2013).

Casals-Casas & Desvergne (2011) show that bisphenol A (BPA) is an EDC in part because it can act through the oestrogen-related receptor- to alter insulin production and release, thus contributing to the pathogenesis of insulin resistance and type 2 diabetes. The pancreatic -cell as a target of oestrogens and xeno-oestrogens: implications for blood glucose homeostasis and diabetes.

3.6 IMMUNOTOXICANTS AND ALLERGENS

It is clear from both laboratory data and human and wildlife samples that EDCs can play a role in the development of immune-related disorders and are at least partially responsible for their rise in recent years (UNEP & WHO, 2012). Since 2002, molecular mechanisms connecting a variety of nuclear receptors to NF-κB (one of the master regulators of inflammation and immunity) have been elucidated, and developmental immunotoxicity studies link compounds such as DES and the phytoestrogen genistein to postnatal immune disorders. Oestrogen exposure has been shown to cause prostate inflammation, and BPA caused allergic sensitization, antibody production and type 2 helper T cell immune responses.

Systemic inflammation, immune dysfunction and immune cancers such as lymphoma and leukaemia in humans have been associated with EDC exposures. These chemicals may exert their effects through nuclear receptor signalling pathways that have well established ties with the immune system through crosstalk with inflammatory pathways.

There are good epidemiological data associating exposure to polycyclic aromatic hydrocarbons, PCBs and other persistent POPs with autoimmune thyroid disease, exposure to phthalates and dioxins with endometriosis and allergies, and exposure to phthalates with asthma and other airway disorders. Endocrine mechanisms are not, however, clear. Together, these new insights stress a critical need to better understand how EDCs affect normal immune function and immune disorders and how windows of exposure may affect disease incidence (particularly for childhood respiratory diseases) (UNEP & WHO, 2013).

3.7 COMBINED EFFECTS

Throughout life, the population is exposed to a variety of chemicals, contained in food, water, medicines, air, cosmetics, health care products, shoes, clothing and other consumer products at the same time (European Commission, DG ENV, official webpage, 'combination effects of chemicals'). In recent years, there has been an increasing focus on the effects on human health and on the environment arising from exposure to many different chemicals. These effects are variously referred to as combination effects, mixture effects or cocktail effects.

In particular, research has highlighted that, under certain conditions, chemicals present in a mixture will act jointly in a way that the overall level of toxicity is influenced. In particular, chemicals with common modes of action may act jointly to produce toxic combination effects that are larger than the effects of each of the mixture components applied singly (SCHER, SCENIHR, SCCS, 2012). Moreover, an increasing number of scientific studies have suggested that endocrine disrupting chemicals (EDCs), particularly in combination, play a role in both chronic diseases, including hormone related cancers (such as breast and testicular cancer), obesity, diabetes, cardiovascular disease and also in reproductive problems, including low sperm counts and birth defects in baby boys, such as un-descended testes (Schug, et al. 2011). Vulnerable groups are also exposed to chemical mixtures. For instance, a study by the Danish Environmental Protection Agency showed that pregnant women have a number of different endocrine disrupting chemicals in their bodies, and these EDCs are known to be capable of passing through the placenta and thus reaching the fetus during a uniquely sensitive developmental phase in life (Danish Environmental Protection Agency, 2012).

Current risk assessments (RA) of chemicals mainly focus on exposure to individual chemicals (Kienzler, et al. 2016). As such, the EU legislative framework does not provide for a comprehensive and integrated assessment of cumulative effects of different chemicals taking into account different routes of exposure. In the case where a mixture of concern is identified and where such a mixture contains chemical substances regulated under different pieces of EU legislation, no mechanism currently exists for promoting an integrated and coordinated assessment across the different pieces of legislation.

Acknowledging these concerns, on 22 December 2009, the Council of Environment Ministers adopted conclusions on the combination effects of chemicals. In its conclusions, the Council invited the Commission to assess how and whether existing legislation addresses this problem and to suggest appropriate modifications and guidelines (Council of the European Union, 200).

On 31 May 2012 the Commission reported to the Council in its Communication from the Commission on Combination effects of Chemicals (Chemical mixtures). In this report, the Commission expressed concerns about the current limitations of assessing compounds individually and proposing a path forward to ensure that risks associated with chemical mixtures are properly understood and assessed. The Communication states that EU laws set strict limits for the amounts of particular chemicals allowed in food, water, air and manufactured products, but that the potential risks of these chemicals in combination are rarely examined (Communication from the Commission to the Council, 2012). The new Commission approach draws heavily on the opinion of the three non-food scientific Committees, "Toxicity and Assessment of Chemical Mixtures", adopted in 2012 (SCHER, SCENIHR, SCCS, 2012).

With regard to the Scientific Committees, they have remarked that, the number of potential combinations of the toxic substances currently in commerce is astronomical and the attention of the risk assessors should be focussed on those situations where the potential for negative impacts is highest. In this regard, the Committees pointed out that an initial filter to allow a focus on mixtures of potential concern is necessary. The criteria proposed for consideration are the following: (SCHER, SCENIHR, SCCS, 2012)

- Human and/or environmental exposure at significant levels.
- Chemicals that are produced and/or marketed as multi-constituent substances or commercial mixtures with several components and/or active ingredients and/or substances of concern.
- Potential serious adverse effects of one or more chemicals at the likely exposure levels.
- Likelihood of frequent or large scale exposure of the human population or the environment.
- Persistence of chemicals in the body and/or in the environment.
- Known information of potential interaction at levels of human and environmental exposure.
- Predictive information that chemicals act similarly.
- Particular attention should be paid to mixtures for which one or more components are assumed to have no threshold for its effects.

The Committees also underlined there are extensive knowledge and data gaps (mainly related to the mode of action and exposure data) that limit the extent to which mixtures can be properly assessed. In addition, they stressed that information being collected in the context of EU legislation, in particular the REACH Regulation, will contribute to reducing current uncertainties. However, notwithstanding the knowledge and data gaps, it is possible to assess mixture toxicity in a more systematic manner in the context of EU legislation. When information regarding the mode of action and dose/response is not available, or inconclusive, a default assumption of dose/concentration addition provides a higher level of protection but may also overestimate negative effects. This limitation and the additional costs it might imply shall be taken into account in the case where possible management measures are being considered (SCHER, SCENIHR, SCCS, 2012).

In addition to the Committee's framework for the assessment of chemical mixtures, others frameworks have been developed by international bodies in recent years. For instance, a widely accepted framework for the RA of combined exposure to multiple chemicals was developed in a WHO/IPCS workshop. This framework describes a general approach for RA of combined exposure to multiple chemicals that could be adapted to the needs of specific users. However, its use is often hampered by large data gaps on exposure as well as hazard information (Meek, et al., 2011).

Thus, although methodologies for assessing the combination effects of chemicals are being developed and applied by scientists and regulators in specific circumstances, so far there is no systematic, consistent, comprehensive and integrated approach across different pieces of legislation. Yet, frameworks as the ones described above may provide high-level guidance as well as tiered approaches for screening level assessments and further refinements. A limitation in their application arises however due to the lack of data for performing higher tier assessments. Therefore, there is now a need to build on these frameworks to develop a robust and transparent approach not only for conducting, but also reporting a chemical mixture RA (Kienzler, et al. 2016).

3.8 FURTHER INFORMATION

Nanomaterials

Nanomaterials are chemical substances or materials that are manufactured and used at a very small scale (down to 10,000 times smaller than the diameter of a human hair). Nanomaterials are developed to exhibit novel characteristics (such as increased strength, chemical reactivity or conductivity) compared to the same material without nanoscale features.

The special properties of nanomaterials also led to their use in many applications, including medical and technical ones. However, while nanomaterials have the potential to improve the quality of life and to contribute to industrial competitiveness, they may also pose risks to the human health.

Sources of nanoparticles can be natural (e.g., volcano emissions), anthropogenic, unintentional (e.g., Diesel particles) or engineered (intentionally produced with specific properties). The information

described in this chapter solely focuses on engineered nanoparticles and manufactured nanomaterials, as these are most relevant to the scope of the study.

Uses

Nanomaterials are used in a variety of products, such as such as batteries, coatings, and anti-bacterial clothing (Shand, H., Wetter, K., 2006). A few examples of applications are presented in the following table:

Table 4: Examples of uses of nanomaterials for different types of applications

Applications	Nanomaterial used
Electronics, ICT and photonics	Carbon nanotubes, fullerenes
Pharmaceuticals and medicine	Nanomedicines and carriers (nanobiotechnology)
Cosmetics and personal care	Titanium dioxide, zinc oxide, fullerenes, gold
Catalysts and lubricants	Cerium oxide, platinum, molybdenum trioxide
Paints and coatings	Titanium dioxide, gold, quantum dots
Environmental and water remediation	Iron, polyurethane, carbon nanotubes
Agrochemicals	Silica as carrier
Food packaging	Gold, nanoclays, titanium dioxide, silver

Source: Senjen, 2009

The international on-line inventory of nanotechnology-based consumer products contains, as of October 2013 a number of 1628 products or product lines. Between 2006 and 2010, the inventory grew 521% (Pen project, 2011). Some materials, as shown in the following table, are well known nanomaterials (like carbon black), others, like fullerenes or nanotubes, are more recent discoveries.

Table 5: Non-exhaustive list of nanomaterials either currently used commercially or being produced in significant quantities for research or development purposes

Aluminium	Dimethyl siloxide	Polyethylene
Aluminium oxide	Dysprosium oxide	Polystyrene
Aluminium hydroxide	Fullerenes	Praseodymium oxide
Antimony oxide	Germanium oxide	Rhodium
Antimony pentoxide	Indium oxide	Samarium oxide
Barium carbonate	Iron	Silanamine
Bismuth oxide	Iron oxides	Silicon dioxide
Boron oxide	Lanthanum oxide	Silver
Calcium oxide	Lithium titanate	Single and multi-walled carbon nanotubes
Carbon black	Manganese oxide	Tantalum
Cerium oxide	Molybdenum oxide	Terbium oxide
Cluster diamonds	Nanoclays	Titanium dioxide
Cobalt	Neodymium oxide	Tungsten
Cobalt oxide	Nickel	Yttrium oxide
Colloidal gold	Niobium	Zinc oxide
Copper(II) oxide	Palladium	Zirconium oxide
Dendrimers	Platinum	

Source: JRC, 2010

Potential risk to human health

The available information on adverse effects to health of nanomaterials is generally based on animal and cell laboratory studies (in vivo and in vitro), as well as on epidemiological and toxicological studies. In the latter field, research mainly focuses on the health effects after exposure to ultrafine particles (e.g. Diesel exhaust), which are substances that are similar to engineered nanomaterials (Oberdörster, G., 2005). These studies have shown that Diesel exhaust exposures and PM10 concentrations (which is inhalable particulate matter of less than 10 µm aerodynamic diameter) are linked to higher mortality rates in the general population. Exposure to ultrafine particles such as carbon black (Niwa, Y., 2007) is also linked to cardiovascular effects (NIWL, 2003).

Nanomaterials may also cause pulmonary effects, including inflammation, cytotoxicity (cell toxicity), fibrosis (formation of excess connective tissue) and tumour generation. Moreover, the scientific literature stresses that cytotoxicity and oxidative stress of cells is observed in different in vitro studies like those involving zinc oxide and cadmium sulfide in kidney cells or silver nanoparticles in brain cells (Rahman, M.F., 2009).

It is generally acknowledged that the activity and toxicity of nanomaterials are influenced by various parameters such as size, chemical composition, surface area, surface charge, coating, reactivity, shape, solubility, etc. At present, the way each of these properties influence the penetration of nanomaterials into the body, their mobility, reactivity, accumulation or elimination is not totally understood.

Size in particular is a distinctive feature of nanoparticles. Studies have shown that for the same chemical composition, nanoparticles prove a higher toxicity compared to coarse particles. For example, after respiratory exposure of mice to titanium dioxide, the lung inflammatory reaction proved to be more important for particles at nanoscale compared to the micrometric scale (Oberdörster, G., et al., 2004). However, size alone does not always determine the behaviour of nanoparticles. For example, particles of the same size (20 nm) but consisting of different chemical nature (titanium dioxide and carbon black), have different rates of penetrating the alveolar interstitium (which is a network of thin connective tissue fibres within the walls of lung alveoli) in the respiratory zone of the lungs: about 50% for the titanium dioxide and 4% for the carbon black (AFSSET, 2008).

With regard to the surface composition of nanomaterials, several studies have underlined that this may also be an element influencing toxicity. For example, the presence of sodium citrate impurities on the surface of gold nanoparticles might play a pivotal role in inducing cytotoxicity to human alveolar cells (Uboldi, C., et al., 2009).

The shape of nanoparticles may also influence their toxicokinetics and their possible effects on human health. Carbon nanotubes have a length-to-diameter ratio similar to that of fibres, and are insoluble and biopersistent. These characteristics are also encountered in asbestos, another well-known lung toxicant, which was initially considered to be harmless. Moreover, some studies have shown that carbon nanotubes also have the same length-dependent pathogenicity as asbestos, concluding that the longer, straighter and more fibre-like the nanotube, the more pathogenic it is likely to be (Donaldson, K. 2011). Studies investigating toxicity of carbon nanotubes in mice showed that they induced epitheloid granulomas (tumour-like nodules) and in some cases inflammation of the lungs (Ryman-Rasmussen,J.P., et al., 2009). Surface contaminants are also of concern, because they may contribute to the induced health effects.

There are thus a large number of variables that may influence toxicity, which means that it is difficult to generalise about health risks associated with exposure to nanomaterials. It is therefore important to assess each nanomaterial individually, and all material properties must be taken into account during health and safety assessments.

Nanomaterials and vulnerable groups

Compared to the general population, there is less literature available that specifically focus on the health impacts of nanomaterials on vulnerable groups, such as infants and children (Tang, S., et al., 2015; Quadros ME, et al., 2013). The issue, however, has been generally taken into account in some articles, especially in the sections dealing with occupational exposure (Hristovski, D., K., 2012). The lack of scientific evidence concerning the effects of nanomaterials on specific groups of the population can be explained as a direct consequence of the limited scientific information about nanomaterials and their effects on the general population.

Among the articles that have tackled the issue, the conclusions of the SCENIHR report are particularly relevant as they single out certain categories of vulnerable groups. According to the opinion, "the available evidence suggests that certain subpopulations, particularly those with pre-existing disease such as asthma and cardiovascular disease may be more susceptible to the adverse effects of nanoparticles, which again should be considered in the assessment of human health hazards" (SCENIHR opinion, 2007).

The SCENIHR opinion also stresses that the human exposure to nanomaterials might have consequences for both the general public and potentially vulnerable subpopulations, including the embryo, the very young, and the elderly, beyond that associated with the exposure of workers. The particular vulnerability of specific categories of the population vis-à-vis nanomaterials was also highlighted by Hristovski, who wrote that "vulnerable population groups, such as children or elderly, can often be indirectly exposed to nanomaterials released in the environment and may respond differently to nanomaterial exposure than a healthy, middle-aged person" (Hristovski, D., K., 2012).

As far as children are concerned, they are among the vulnerable groups that have been studied more extensively. According to the literature, nanomaterials interact with children in various ways that differ from adults. Children eat more food, drink more water and inhale more air than adults based on body weight. Children also have greater dermal exposure to nanomaterials in sunscreens/cosmetics than adults as they have lower body weights but an increased ratio of body surface area to weight. Additionally, their anatomy is different: the thinner and under-keratinized epidermis of children may increase the absorption of nanomaterials through the skin. (Landrigan PJ, 2004).

Infants and children are prone to enhanced deposition of inhaled nanomaterials in the lung because of the relative smaller caliber airway and higher ventilation requirements. Moreover, infants and children are biologically susceptible and at an increased risk of toxicant injury because of the developmental immaturities of vital organs, which present unique targets not accessible in adults (Sly P.D., 2012)

Furthermore, in infants and children, the growth and development of organ systems are not well adapted at repairing damage caused by toxicants, which increases vulnerability where the resulting dysfunction in development can be permanent. Hence, the delicate developmental processes of fetuses or children may be easily altered by nanomaterials; if their central nervous system (CNS) is injured, respiratory system damaged, reproductive development disrupted, or immune system development destroyed, the consequential dysfunction could be irreparable. (Bearer CF, 1995)

Finally, numerous diseases initiated by toxicants require many years to develop, thus toxic exposures that occur early in life are more likely to cause lasting effects than exposures that occur later in life. Nevertheless, despite these evidences, the article concludes that knowledge about actual nanomaterial exposure and nanotoxicity in infants and children remains largely unknown (Tang, S., et al., 2015).

Pesticides

Pesticides are chemical or biological substances (such as a virus, bacterium, antimicrobial, or disinfectant) designed to prevent, destroy, or retard the growth of harmful organisms ('pests'). The most common use of pesticides is as plant protection products which aim at protecting plants from damaging influences such as weeds, fungi, or insects. However, pesticides is a broader term which also covers non-agricultural products. The term pesticide includes all of the following: herbicide,

insecticide, insect growth regulator, nematicide, termiticide, molluscicide, piscicide, avicide, rodenticide, predacide, bactericide, insect repellent, animal repellent, antimicrobial, fungicide, disinfectant (antimicrobial), and sanitizer (Randall, C., et al., 2013).

Although pesticides help to improve the quality of agricultural products, they may also pose health risks to humans. According to the Stockholm Convention on Persistent Organic Pollutants, 9 of the 12 most dangerous and persistent organic chemicals are organochlorine pesticides (Gilden, RC., et al., 2010).

Potential risks to human health

While pesticides safeguard and improve the quality of agricultural products, they can also have an adverse impact on human health. The likelihood of developing health effects depends by the type of the pesticide, the duration of the exposure as well as the frequency of the exposure.

Pesticides have been linked to a wide range of human health hazards, ranging from short-term impacts to chronic ones. According to literature, the most common adverse effects of pesticides include acute headaches, vomiting, stomach-aches, and diarrhoea (Bal-Price, A. K., et al., 2011).

Pesticide exposure can also cause various neurological health effects such as memory loss, loss of coordination, reduced speed of response to stimuli, reduced visual ability, altered or uncontrollable mood and general behavior, and reduced motor skills (Ibid).

Moreover, low but constant exposure levels may lead to long-term and chronic health impairment (e.g. cancer, birth defects, reproductive problems, and endocrine disruption). It is important to notice that some health effects may occur right after the exposure. Some other symptoms may occur several hours after exposure. Other effects instead may not be noticed for years, for example cancer. As a result, it is problematic to understand the connection between exposure to pesticides and the disease (Miligi, L., et al., 2006)

The table below highlights the most frequent symptoms that might indicate pesticide poisoning.

Table 6: General Symptoms that Might Indicate Pesticide Poisoning

Mild Poisoning	Moderate Poisoning	Severe Poisoning
Any of the following: ■ irritation of the nose, throat, eyes or skin ■ headache ■ dizziness ■ loss of appetite ■ thirst ■ nausea ■ diarrhea ■ sweating ■ weakness or fatigue ■ restlessness ■ nervousness ■ changes in mood ■ insomnia	Any of the mild symptoms, plus any of the following: ■ vomiting ■ excessive salivation ■ coughing ■ feeling of constriction in throat and chest ■ abdominal cramps ■ blurring of vision ■ rapid pulse ■ excessive perspiration ■ profound weakness ■ trembling ■ muscular incoordination ■ mental confusion	Any of the mild or moderate symptoms, plus any of the following: ■ inability to breathe ■ extra phlegm or mucous in the airways ■ small or pinpoint pupils ■ chemical burns on the skin ■ increased rate of breathing ■ loss of reflexes ■ uncontrollable muscular twitching ■ unconsciousness ■ death

Source: OSH Answers Fact Sheet, 2016.

With particular regard to cancer, scientific evidence increasingly links it to pesticides exposure. Some of the most prevalent forms include leukemia, non-Hodgkins lymphoma, brain, bone, breast, ovarian, prostate, testicular and liver cancers (Steliarova-Foucherb, E., et al., 2006).

There is also mounting evidence that exposure to pesticides disrupts the endocrine system, wreaking havoc with the complex regulation of hormones, the reproductive system, and embryonic development. Endocrine disruption can produce infertility and a variety of birth defects and developmental defects in offspring, including hormonal imbalance and incomplete sexual development, impaired brain development, as well as behavioural disorders (Orton F., et al., 2011)

The consequences highlighted above can be even worse for highly vulnerable population groups.

Vulnerable groups
The entire population is vulnerable to contaminants circulating in the environment, but to varying degrees. The literature indicates that three categories of the population are especially vulnerable to the presence of pesticides. The first group is composed by women and children, who, because of their body types, are more sensitive to contaminants. The second group comprises people in poor health (including older people), who are likely to have reduced defences against chemical stresses. The third group is the one in more frequent contact with pesticides; it includes workers who handle pesticides on the job and people who live in areas where pollutants accumulate, and who also fish, hunt and collect fruit to feed themselves (Bal-Price, A. K., et al., 2011).

Children and women
Children are particularly vulnerable to the risks posed by pesticides because:

- they eat more food, drink more water and breathe more air per kilogram of body weight than adults and can thus absorb larger quantities of the pollutants present in the environment;
- their diets are appreciably different from those of adults (consisting largely of fruits, vegetables and mother's milk), and the younger they are, the more limited their ability to metabolize and eliminate residual toxic substances;
- have significantly lower levels of a key enzyme ("paraoxonase") that protects against the toxic effects of certain pesticides;
- they have a lower capacity to assess risks;
- have different habits (for instance, more exploratory behaviour, more frequent outdoor activities) which expose them to pollutants to a greater degree than adults;
- they often cannot read warning labels on pesticides (Huen, K., et al, 2009).

The following table outlines sources of exposure relevant to children:

Table 7: Sources of exposure relevant to children

1. The Home (in the child's home & homes of playmates)	■ Applications of pesticides ■ Indoor commercial application of pesticides to control rodents, cockroaches, ants, termites, earwigs, etc. ■ Homeowner/resident use of insecticide sprays, strips, baits ■ Application of insect repellents directly on skin or scalp (e.g. personal bug sprays, shampoos for lice, scabies) ■ Collars or powders to treat household pets for fleas, ticks, etc. ■ Commercial application of lawn and garden insecticides, herbicides and fungicides ■ Insecticides, herbicides and fungicides used in the garden or on the lawn by the homeowner or resident ■ Storage and handling of pesticides ■ Storage of household pesticides in areas accessible to children ■ Disposal of pesticides in household garbage ■ Pesticide life cycle and pathways ■ Pesticide residues in house dust and in soil tracked in from outdoors ■ Pesticide residues on furniture, drapes, toys, pet fur, absorbent items
2. Public Places (schools,	■ Commercial applications of pesticides for rodents, cockroaches, termites, etc. ■ Storage of pesticides in areas accessible to children ■ Disposal of pesticides and pesticide containers in regular school garbage

daycare, etc.)	■ Commercial applications of pesticides to maintain playgrounds, playing fields ■ Wood preservatives on play structures ■ Pesticide application in other public places, e.g. airplanes, restaurants, malls, offices, etc.
3. Via Air & Water	■ Pesticides in indoor air (from uses above for household and public places) ■ Pesticides in outdoor air ■ Pesticide drift from spraying (agricultural, municipal, household) ■ Long range transport of persistent pesticides (e.g. DDT) ■ Pesticides in drinking water -- treated tap water or well water ■ Pesticides in swimming water -- lake and river sediments, algicides in swimming pools
4. Via Food	■ Food crops that are routinely sprayed and form a significant part of juvenile diet, e.g. fruits, vegetable, grains ■ Foods prepared from agricultural products, e.g. baby foods ■ Bioaccumulation in other animals and their products e.g. meat, fish, eggs, dairy products ■ Mother's intake and body burden transferred across placenta ■ Mother's intake and body burden transferred to breast milk

Source: Canadian Environmental Law Association, Draft -- Regulating Pesticides to Protect Children's Health, 94 p., December 1, 1999.

The health effect of pesticides on children can be acute (immediate poisoning) and chronic (more subtle, longer term harm such as cancer or damage to hormone and immune systems) arising from continued or repeated exposure to lower doses of pesticides. Chronic effects, in particular, are harder to measure as it is extremely difficult to assess the multiple causes of chronic diseases.

Researches also suggest that exposure to chemical pollutants acting as hormone disruptors can affect the development of the foetus and the child. It has been stressed that from the moment of conception, the foetus comes into contact with pollutants from the mother's body that pass through the placenta. In particular, pesticides can be absorbed by a fetus through the placenta, the skin and the lungs. (Schwartz, S., 1999).

With regard to women, whose bodies contain greater proportions of fatty tissue, they are more likely to accumulate persistent organic pollutants (POPs). Some researchers assume on the basis of this fact that women exposed to pesticides may run a higher risk of developing breast cancer (Hoyer, P., et al., 1998). Another study showed that women living in a farm setting displayed a high rate of pre-menopausal breast cancer. Nevertheless, although a number of studies were cited in support of this hypothesis, according to other studies, it remains difficult to link breast cancer directly with pesticides. A study carried out in Hawaii in 1997, for example, suggests that volcanic soil and acid rain can aggravate the effects caused by pesticide contamination of drinking water and ground water by dieldrin. In particular, it has been stressed that a host of parameters can influence the impact of contaminants, making it almost impossible to demonstrate a cause-and-effect relationship (Allen, R.H., et al., 1997).

People in poor health

People who suffer from asthma or allergies, people with multiple chemical sensitivity (MCS) and older people can have more violent reactions following contact with pesticides than other people who are in better health. For example, people with MCS can suffer a wide of range of symptoms including burning eyes, breathing problems, muscular weakness, headaches, fatigue, asthma, allergies and chronic infections (Nova Scotia Environmental Health Centre). However, other studies pointed out that the impacts of pesticides on this population group are still poorly understood (Maes, G.E., 2013).

Workers

Workers are among the primary victims of chronic illnesses caused by pesticides (Morrison, H.I, 1992). In particular, people who handle pest control products as part of their work (farmers and their families, forestry workers, exterminators, grounds keepers, municipal and railway employees, employees in pesticide manufacturing plants, etc.) are exposed to very high doses of pesticides. In

addition to suspected long-term effects, these workers are likely to suffer from chronic effects of pesticides if they do not follow handling precautions. According to the scientific literature pesticides can persist on the skin for many months after exposure and some studies indicate that the children of adults exposed can be affected by the residues. It has been also noted that non-Hodgkin's lymphoma seems to be observed principally among people who are most exposed to pesticides, namely those who work with them. Some researchers have succeeded in demonstrating a significant dose-response relationship between fields sprayed with herbicides and the risk of contracting non-Hodgkin's lymphoma (Wigle, D.T., et al., 1990), while others have not succeeded in statistically demonstrating this link between the presence of pesticides and the various illnesses observed (Blair, A., et al., 1997). Moreover, it has to be stressed that children and women can be exposed to pesticides not only as consumers, but also as workers since they constitute a significant rural labour force in particular in developing countries and countries with an economy in transition. According to the international Labour Organization (ILO), about 60% of the estimated 215 million child labourers worldwide work in agriculture. As such, by working on family and commercial farms and plantations they are exposed to dangerous chemicals on a daily basis.

Plastics

Plastics are polymers, which, in turn, are chains of molecules. Each link of the chain is usually made of carbon, hydrogen, oxygen, and/or silicon. To make the chain many links are hooked or polymerized together. To create polymers, petroleum and other products are heated under controlled conditions and broken down into smaller molecules called monomers. Different combinations of monomers produce plastic resins with different characteristics, such as strength or molding capability (U.S. Environ. Prot. Agency, 2009).

Early uses of plastics date back to 1600 B.C when natural rubber was shaped by human hands and polymerized into objects of utility in prehistoric Mesoamerica (Hosler, D., et al., 1999). The exploitation of plastics started in 1839 with the discovery of vulcanized rubber and polystyrene (Andrady, AL., 2009). Mass production of plastics began in the 1940s and has continued to expand ever since. The success of plastics is due to the versatility of the materials combined with an extremely low cost. This is particularly true for the health care sector where the use of plastics has enabled the mass production of disposable single-use health care products that are functional and hygienic. The societal value of plastics is immense and has also been examined in greater depth (Andrady, AL., 2009).

However, while plastics improve modern life, they may also pose a number of potential human health risks. (Halden, R.U., 2010). Some of them appear to be universally accepted, whereas others are subject to an intense debate (Thompson, RC, et al., 2009).

Health risks for the general population and vulnerable groups

The chemical additives contained in plastics pose a number of potential human health and environmental risks. The following paragraphs focus on plastics components and additives of principal concern such as bisphenol A and phthalates.

- *Bishphenol A*

Bisphenol A (BPA) is a chemical that is mainly used in combination with other chemicals to manufacture plastics and resins. For example, BPA is used in polycarbonate, a high performance transparent, rigid plastic. Polycarbonate is used to make food containers, such as returnable beverage bottles, infant feeding (baby) bottles, tableware (plates and mugs) and storage containers. Residues of BPA are also present in epoxy resins used to make protective coatings and linings for food and beverage cans and vats. BPA can migrate in small amounts into food and beverages stored in materials containing the substance.

While food is considered the major exposure source (e.g., up to 99% of the total exposure in school

children), additional environmental exposures can occur primarily via inhalation (Wilson NK, et al., 2007). Additional airborne exposures can occur during off-gassing of the substance from consumer products and volatilization from contaminated water. The body burden of BPA is routinely assessed in blood serum and urine as either the free, unconjugated BPA level or the combined total concentration. Elevated exposure of women of childbearing age and of children are of particular concern because of known windows of vulnerability to BPA that put the developing foetus and children at elevated risk, compared with adults exposed to identical levels of the contaminant (Vandenberg LN, et al., 2009). Information on long-term trends in BPA exposure is still lacking.

The health risks of BPA are fiercely debated and, after more than 70 years of study, are still not fully understood. Estrogenic properties of BPA had been described as early as 1936 (Dodds EC, Lawson W. 1936). Today, monomeric BPA is classified as an estrogen mimic, which binds to both estrogen receptor α (ERα) and ERβ (Vandenberg LN, et al., 2009). These data have led to an initial classification of BPA as a very "weak estrogen and endocrine disruptor" (vom Saal FS, Hughes C. 2005); however, this classification has been called into question by a number of studies, including one report (Wozniak AL, et al., 2005) demonstrating BPA-mediated stimulation of calcium influx in MFC-7 breast cancer cells in culture at levels of 0.023 µg/L (vom Saal FS, Hughes C. 2005).
Adverse effects recorded in animal studies included:

- increased postnatal growth in both sexes after maternal doses between 2.4 and 500 µg/kg/day;
- early onset of sexual maturation in females after maternal doses between 2.4 and 500 µg/kg/d;
- altered plasma luteinizing hormone levels and decreased plasma testosterone in males at maternal doses of 2 µg/kg/d;
- increased prostate size in male offspring following a maternal dose of 2–50 µg/kg/d;
- decreased sperm production and fertility in males at maternal doses of 0.2 to 20 µg/kg/d from developmental and adult exposure;
- stimulation of the development of the mammary gland in female offspring at a maternal dose of 0.025 µg/kg/d;
- during meiosis in oocysts, a significant disruption of chromosome alignment during puberty caused by doses of 15–70 µg/kg/d;
- increased mortality of embryos following a maternal dose of 25 µg/kg/d;
- disruption of adult estrous cycles following maternal doses of 100–500 µg/kg/d;
- alterations in immune function at doses of 2.5–30 µg/kg/d;
- decreases in antioxidant enzymes of adult males at doses of 0.2 µg/kg/d;
- effects on the brain such as increases in levels of progesterone receptor mRNA following a dose of 400 µg/kg/d;

Additionally, observed were behavioural effects such as:

- hyperactivity at 30 µg/kg/d;
- increased aggressiveness at 2–40 µg/kg/d;
- alterations in response to pain and threat stressors at 40 µg/kg/d;
- impaired learning at 100 µg/kg/d;
- reversal of normal sex differences and elimination of differences between the sexes in behaviour via changes in the locus coeruleus induced at 30 µg/kg/d;
- decreases in maternal behaviour following developmental exposure at 10 µg/kg/d;
- alterations in play and sociosexual behaviors at 40 µg/kg/d;
- altered behavioural response to amphetamine following a BPA dose of 40–300 µg/kg/d (vom Saal FS, Hughes C. 2005).

Moreover, additional studies reported binding of BPA to several membrane steroid receptors including a membrane-bound form of ERα (mER) and a transmembrane ER, termed G protein–coupled receptor 30 (GR30) (Vandenberg LN, et al., 2009). New studies also point to BPA's ability to affect vertebrate development in vivo by inhibiting T3 pathways (Heimeier RA, et al., 2009). This finding adds to more

than 100 previous in vivo studies and lends further credibility to a previously proposed effect of BPA on thyroid hormone homeostasis (Moriyama K, et al., 2002).

In contrast to the conclusions drawn from feeding studies considered by the National Toxicology Program (NTP, 1982), a recent study of the effects of BPA exposure onprostate cancer showed that neonatal BPA exposure (10 μg/kg/d) followed by treatment with hormones in adulthood (testosterone and estrogen) caused a significant increase in the incidence and severity of prostatic intraepithelial neoplasias in male Sprague-Dawley rats (Ho SM, et al., 2006). A recent review article discusses six controversies in the assessment of BPA health risks, and the authors also conclude that a possible connection is strengthening between perinatal BPA exposure and mammary cancer in rodents (Vandenberg LN, et al., 2009).

Finally, epidemiological studies have found associations between blood levels of BPA in women and impaired health, including obesity, endometrial hyperplasia, recurrent miscarriages, sterility, and polycystic ovarian syndrome (Warner M, et al., 2002.). However, these types of studies are not suited to drawing conclusions about the causality of these outcomes.

It is also worth noticing that, in January 2015 the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) issued a Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs. The CEF Panel concludes that the dietary exposure to BPA for the highest exposed groups, which includes infants, children and adolescents, is below the t-TDI of 4 μg/kg bw per day, indicating that there is no health concern for BPA at the estimated levels of exposure. These conclusions also apply to prenatally exposed children and to the elderly. In addition, the CEF Panel concludes that the central estimates for aggregated exposure to BPA via the dietary and non-dietary sources (dust, toys, cosmetics and thermal paper) for the highest exposed groups, which includes infants, children and adolescents, is also below the t-TDI of 4 μg/kg bw per day, indicating that the health concern for BPA is low at the estimated levels of exposure. However, the CEF Panel noted that there is a considerable uncertainty in the exposure estimate for the non-dietary sources (EFSA CEF Panel, 2015).

- *Phthlates*

Phthalates are a diverse group of compounds which are produced in large quantities since the 1930s. They can be found in industrial plastics, household items, paints, medical devices, children's toys, and personal care products including cosmetics, lotion, sunscreen, and perfumes. (Sathyanarayana S, et al. 2008). Phthalates are incorporated into plastics to impart flexibility, pliability, and elasticity to otherwise rigid polymers, such as PVC (Chou K, Wright RO. 2006). Di-(2-ethylhexyl) phthalate (DEHP), produced at annual quantities of 2 million tons and widely used in medical devices, is one of the principal phthalates causing human health concerns (Latini G., 2005). Attention to DEHP was first drawn in the late 1960s, when reports showed leaching of the compound from medical plastic devices into body fluids and subsequent migration into human tissues (Jaeger RJ, Rubin RJ., 1970.). Forty years after discovery of this chemical leaching process, the scientific and regulatory communities are still struggling to define and manage potential human health risks posed by DEHP in medical devices.

Migration of plasticizers and ensuing human exposures have been demonstrated for many additional phthalates and plastics products. Important other additives include di-isononyl phthalate (DINP), dibutylphthalate (DBP), butylbenzyl phthalate (BBP), di-isododecyl phthalate (DIDP), di-n-octyl phthalate (DnOP), and di-n-hexyl phthalate (DnHP) (Kavlock R, et al., 2002).

Among the nonmedical applications of phthalate-containing plastics, usage in children's toys and baby care products stand out as being most controversial. Di-ethyl phthalate (DEP), di-methyl phthalate (DMP), and DBP are also heavily used in cosmetics, in personal care products, and as enteric coatings of oral medications (Sathyanarayana S, et al. 2008).

Important routes of human exposure to phthalates include, most notably, medical exposures caused by direct release of phthalates into the human body, e.g., through dialysis, blood transfusions, and extracorporeal membrane oxygenation (ECMO); ingestion of contaminated materials, including contaminated food, house dust, or food that has been in contact with food packaging; dermal uptake of phthalates from personal care products; and inhalation exposure from outdoor and indoor air containing phthalate off-gassing from paints, as well as from covering materials for walls, ceilings, and floors (Sathyanarayana S, et al. 2008; Latini G., 2005).

Exposure of the developing foetus occurs in utero, from phthalates crossing the placental barrier, from blood and amniotic fluid, and in the early developmental period after birth from ingesting breast milk, infant formula, and cow's milk and from contact with mouthing toys and baby care products (Sathyanarayana S, et al. 2008).

Once incorporated into the human body, phthalates are short-lived and rapidly metabolized with half-lives on the order of hours to several days (Frederiksen H, et al., 2007). Despite the rapid metabolism of phthalates, single measurements provided fairly reliable estimates of steady-state concentrations in the human body (Silva MJ, et al., 2004). However, more work is needed to understand better the trajectory of phthalate exposure levels over time in the general population. The occurrence of this body burden in the general population is a cause of concern because phthalates are endocrine-disrupting compounds (Sathyanarayana S, et al. 2008; Latini G., 2005).

With regard to the suspected adverse health effects there are reproductive outcomes, including testicular dysgenesis syndrome comprising male genital abnormalities that can cause atypical sperm characteristics, which later may develop into testicular cancer (vom Saal F, et al., 2001). Moreover, laboratory studies in animals showed phthalates including DBP, DEHP, and BBP to produce malformations of the male reproductive system, cryptorchidism, and testicular injury together with permanent feminization evidenced by the retention of nipples/areolae and demasculinization of the growth of the perineum resulting in a reduced anogenital distance (AGD) (Fromme H, et al., 2009).

Additional human studies (Sathyanarayana S, et al. 2008) reported other adverse outcomes associated with elevated phthalate body burden, including a positive association between premature onset of the larche in young girls and their serum levels of the phthalates DMP, DEP, DBP, DEHP and the monoester of DEHP (Colon I, et al., 2000), an inverse relationship between phthalate exposure and human sperm quality observed in two (Hauser R, et al., 2007) of three studies conducted (Jonsson BAG, et al., 2005), and a positive association between increased phthalate levels and waist circumference as well as an inverse association of phthalate levels with insulin resistance (StahlhutRW, et al., 2007). A limited number of reports suggest an effect of phthalates on the thyroid hormone axes and on human immune response (Sathyanarayana S, et al. 2008). The observed development of liver tumors in adult rodents following dosing with high concentrations of DEHP initially suggested DEHP to represent "probable carcinogen"; however, in 2000 the International Agency for Research on Cancer (IARC) downgraded the designation to "cannot be classified as to its carcinogenicity in humans" because the identified pathway involving the peroxisome proliferation receptor and its response elements in rodents was deemed by the agency as a mechanism that is not relevant to humans (IARC, 2000).

4 LEGAL FRAMEWORK

4.1 EU LEGAL FRAMEWORK

4.1.1 Relevant legislation with references to vulnerable groups

- *Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)*

REACH is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals.

Pursuant to recital 69, the REACH Regulation shall ensure a sufficiently high level of protection for human health, having regard to relevant human population groups and possibly to certain vulnerable sub-populations.

With regard to the Annexes, point 1.4.1. of Annex I (general provisions for assessing substances and preparing chemical safety reports) focus on the identification of the derived no-effect level (DNEL), which is the level of exposure to a substance above which humans should not be exposed. Pursuant to point 1.4.1., "(a) DNEL(s) shall be established for the substance, reflecting the likely route(s), duration and frequency of exposure. →M10 For some hazard classes, especially germ cell mutagenicity and carcinogenicity, the available information may not enable a toxicological threshold, and therefore a DNEL, to be established. ←If justified by the exposure scenario(s), a single DNEL may be sufficient. However, taking into account the available information and the exposure scenario(s) in Section 9 of the Chemical Safety Report it may be necessary to identify different DNELs for each relevant human population (e.g. workers, consumers and humans liable to exposure indirectly via the environment) and possibly for certain vulnerable sub-populations (e.g. children, pregnant women) and for different routes of exposure".

With regard to Annex IX (standard information requirements for substances manufactured or imported in quantities of 100 tonnes or more), its point 8.7 – reproductive toxicity - specifies that if a substance is known to have an adverse effect on fertility, meeting the criteria for classification as toxic for reproduction category 1A or 1B: may damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for developmental toxicity must be considered. Moreover, if a substance is known to cause developmental toxicity, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.

Point 30 of Annex XVII (restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixture and articles) highlights that some reproductive toxicant category 1A may cause adverse effects on sexual function and fertility or on development (Table 3.1) or reproductive toxicant category 1 with R60 (May impair fertility) or R61 (May cause harm to the unborn child).

- *Regulation (EC) No 1223/2009 on cosmetic products*

This Regulation establishes rules to be complied with by any cosmetic product made available on the market, in order to ensure the functioning of the internal market and a high level of protection of human health.

Pursuant to recital 34, the assessment by the Scientific Committee for Consumer Safety (SCCS) of the use of substances classified as CMR 1A and 1B in cosmetic products should also take into account the exposure to those substances of vulnerable population groups, such as children under three years of age, elderly people, pregnant and breast-feeding women and persons with compromised immune responses.

In this regard, pursuant to Article 15(2), the use in cosmetic products of substances classified as CMR substances, of category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited. However, such substances may be used in cosmetic products by way of exception where, subsequent to their classification as CMR substances of category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008, several conditions are fulfilled, among which letter (d) specifies that "they have been evaluated and found safe by the SCCS for use in cosmetic products, in particular in view of exposure to these products and taking into consideration the overall exposure from other sources, taking particular account of vulnerable population groups".

With regard to the Annexes, Annex I (cosmetic product safety report), part A (cosmetic product safety information), specifies at point 3 (microbiological quality) that the microbiological specifications of the substance or mixture and the cosmetic product. Particular attention shall be paid to cosmetics used around the eyes, on mucous membranes in general, on damaged skin, on children under three years of age, on elderly people and persons showing compromised immune responses.

Moreover, Annex II lists of substances prohibited in cosmetic products, among which there is also Safrole which may have hazardous consequences on the health of children.

Finally, Annex III (list of substances which cosmetic product must not contain), specifies that boric acid, borates and tetraborates should not be used in products for children under 3 years of age.

- *Directive 2009/48/EC on the safety of toys*

The objective of this Directive is that of ensure a high level of safety of toys with a view to ensuring the health and safety of children whilst guaranteeing the functioning of the internal market by setting harmonised safety requirements for toys and minimum requirements for market surveillance.

Recital 21 stresses that in order to ensure a high level of protection of children against risks caused by chemical substances in toys, the use of dangerous substances, in particular substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR), and allergenic substances and certain metals, should be subject to careful attention. The recital also underlines that it is therefore necessary to complete and update the provisions on chemical substances in toys to specify that toys should comply with general chemicals legislation, in particular Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency. Moreover, the recital specifies that hose provisions should, however, also be adapted to the particular needs of children, who are a vulnerable group of consumers. Therefore, the recital explains, new restrictions on CMR substances, in accordance with applicable Community legislation on the classification, labelling and packaging of substances and mixtures, and on fragrances in toys should be provided for on account of the special risks that these substances may entail for human health.

Recital 24 of this Directive emphasises that in order to ensure adequate protection in the case of toys involving a high degree of exposure, it should be possible to adopt implementing measures establishing specific limit values for chemicals used in toys intended for use by children under 36 months and in other toys intended to be put in the mouth, taking into account the requirements of Regulation (EC) No 1935/2004 and the differences between toys and materials which come into contact with food.

Recital 25 stresses again that the general and specific chemical requirements laid down by this Directive should aim at protecting the health of children from certain substances in toys.
As far as the Articles are concerned, pursuant to Article 46(2) of this Directive, the Commission may adopt specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth, taking into account the packaging requirements for food as laid down in Regulation (EC) No 1935/2004 and the related specific measures for particular materials, as well as the differences between toys and materials which come into contact with food. The Commission shall amend Appendix C to Annex II to this Directive accordingly.

Moreover, according to Article 46(3), the Commission may decide upon the use in toys of substances or mixtures that are classified as carcinogenic, mutagenic or toxic for reproduction of the categories laid down in Section 5 of Appendix B to Annex II and have been evaluated by the relevant Scientific Committee, and may amend Appendix A to Annex II accordingly.

It is also worth stressing that Appendix C sets out the specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth adopted in accordance with Article 46(2) of the Directive in question.

- *Regulation (EU) No 1169/2011 on the provision of food information to consumers*

The provision of food information aim at pursuing a high level of protection of consumers' health and interests by providing a basis for final consumers to make informed choices and to make safe use of food, with particular regard to health, economic, environmental, social and ethical consideration.

Annex I point 5.1.5 of the Regulation specifies that foods or food ingredients with added phytosterols, phytosterol esters, phytostanols or phytostanol esters must include an easily visible statement that the food may not be nutritionally appropriate for pregnant or breastfeeding women and children under the age of 5 years.

- *Regulation (EC) 1333/2008 on food additives*

This Regulation lays down rules on food additives used in foods with a view to ensuring the effective functioning of the internal market whilst ensuring a high level of protection of human health and a high level of consumer protection, including the protection of consumer interests and fair practices in food trade, taking into account, where appropriate, the protection of the environment.

Article 16 of this Regulation specifies that food additives shall not be used in foods for infants and young children as referred to in Directive 89/398/EEC, including dietary foods for infants and young children for special medical purposes, except where specifically provided for in Annex II to this Regulation.

- *Regulation (EC) No 1107/2009 on plant protection products*

Recital 8 stresses that the purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture. The recital also adds that particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children.

Furthermore, recital 24 underlines that the provisions governing authorisation must ensure a high standard of protection. In particular recital 24 stresses that when granting authorisations of plant protection products, the objective of protecting human and animal health and the environment should take priority over the objective of improving plant production. Therefore, pursuant to the recital, it should be demonstrated, before plant protection products are placed on the market, that they present a

clear benefit for plant production and do not have any harmful effect on human or animal health, including that of vulnerable groups, or any unacceptable effects on the environment.

It is worth noting that Article 3(14) of this Regulation specifies the notion of vulnerable groups, namely 'persons needing specific consideration when assessing the acute and chronic health effects of plant protection products. These include pregnant and nursing women, the unborn, infants and children, the elderly and workers and residents subject to high pesticide exposure over the long term'.

Article 4, which establishes the approval criteria for active substances, specifies that an active substance shall be approved in accordance with Annex II if it may be expected, in the light of current scientific and technical knowledge, that, taking into account the approval criteria set out in points 2 and 3 of that Annex, plant protection products containing that active substance meet the requirements provided for in paragraphs 2 and 3. Moreover, its paragraph 2 stresses that the residues of the plant protection products, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall not have any harmful effects on human health, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available, or on groundwater.

With regard to the Annexes, point 2.A of Annex IV (comparative risk assessment) specifies that significant difference in risk shall be identified on a case-by-case basis by the competent authorities. The properties of the active substance and plant protection product, and the possibility of exposure of different population subgroups (professional or non-professional users, bystanders, workers, residents, specific vulnerable groups or consumers) directly or indirectly through food, feed, drinking water or the environment shall be taken into account.

- *Regulation (EU) No 528/2012 biocidal products*

Article 1 states that the purpose of this Regulation is to improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment. The Article also stresses that the provisions of this Regulation are underpinned by the precautionary principle, the aim of which is to safeguard the health of humans, the health of animals and the environment and that particular attention should be paid to the protection of vulnerable groups (see also recital 3).

In this regard, Article 19, which establishes the conditions for granting an authorisation for the biocidal product, specifies that the latter should not have no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects.

As far as the Annexes are concerned, point 8.10 of Annex II – title I (chemical substances) specifies that if a substance is known to cause developmental toxicity, meeting the criteria for classification as Reproductive toxicity Cat 1A or 1B: may damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, point 8.10 of the annex also underlines that testing for effects on fertility must be considered.

Annex VI, which establishes common principles for the evaluation of dossiers for biocidal products, at the point 24 stresses that, as far as the assessment is concerned, in considering the different groups of the populations, particular attention should be given to the need to protect vulnerable groups within these populations. Furthermore, point 32 of Annex VI specifies that an exposure assessment shall be carried out for each of the human populations (professional users, non-professional users and humans exposed directly or indirectly via the environment), for which exposure to a biocidal product occurs or

can reasonably be foreseen, with particular attention paid to the pathways of exposure relevant for vulnerable groups. In addition, point 59 emphasises that evaluating body shall consider possible effects on all human populations, and particular attention shall be paid to vulnerable groups among the different populations.

- *Directive 2001/83/EC on the Community code relating to medicinal products for human use*

The aim of this Directive is laying down rules governing the production, distribution and use of medicinal products whilst safeguarding the general public health.

Pursuant to Article 59(1) of this Directive the package leaflet shall be drawn up in accordance with the summary of the product characteristics; it shall include, inter alia, a list of information which is necessary before the medicinal product is taken. According to Article 59(2)(a), this list shall take into account the particular condition of certain categories of users (children, pregnant or breastfeeding women, the elderly, persons with specific pathological conditions).

Moreover, point 5.2.5.1 of Annex I (analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products) stresses that any patients or patient groups at increased risk should be identified and particular attention paid to potentially vulnerable patients who may be present in small numbers, e.g., children, pregnant women, frail elderly, people with marked abnormalities of metabolism or excretion etc.

- *Directive 98/24/EC - risks related to chemical agents at work*

The objective of this Directive is to lay down minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents.

Article 3 establishes the occupational exposure limit values and biological limit for chemical risks. It stresses that the Commission shall evaluate the relationship between the health effects of hazardous chemical agents and the level of occupational exposure by means of an independent scientific assessment of the latest available scientific data. On the basis of the evaluation described Article 3 specifies that the Commission, after first consulting the Advisory Committee on Safety, Hygiene and Health protection at Work, shall propose European objectives in the form of indicative occupational exposure limit values for the protection of workers from chemical risks, to be set at Community level.

Article 6, which describes the specific protection and prevention measures, specifies at paragraph 4 that the employer shall carry out on a regular basis, and when any change occurs in the conditions which may affect workers' exposure to chemical agents, such measurements of chemical agents which may present a risk to worker's health at the workplace as are necessary, in particular in relation to the occupational exposure limit values.

- *Directive 2004/37/EC carcinogens or mutagens at work*

The objective of this Directive is the protection of workers against health and safety risks from exposure to carcinogens or mutagens at work.

Recital 13 specifies that occupational exposure limit values must be regarded as an important component of the general arrangements for the protection of workers. Also, it stresses that such limit values must be revised whenever this becomes necessary in the light of more recent scientific data.

Furthermore, Annex III(A), through a table, specifies the limit for occupational exposure.

- *Directive 92/85/EEC pregnant workers*

The purpose of this Directive is to implement measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or who are breastfeeding.

Article 6 highlights the cases in which exposure is prohibited. In particular, pregnant workers may under no circumstances be obliged to perform duties for which the assessment has revealed a risk of exposure, which would jeopardize safety or health, to the agents and working conditions listed in Annex II, Section A; workers who are breastfeeding, within the meaning of Article 2 (c), may under no circumstances be obliged to perform duties for which the assessment has revealed a risk of exposure, which would jeopardize safety or health , to the agents and working conditions listed in Annex II, Section B.

Pursuant to Article 4 of the Directive in question, for all activities liable to involve a specific risk of exposure to the agents, processes or working conditions, the employer shall assess the nature, degree and duration of exposure, in the undertaking and/ or establishment concerned, of workers in order to:
— assess any risks to the safety or health and any possible effect on the pregnancys or breastfeeding of workers;
— decide what measures should be taken.

As far as the chemicals are concerned, point A3 of Annex I established that the employer shall assess the nature, degree and duration of exposure of the following chemical agents in so far as it is known that they endanger the health of pregnant women and the unborn child and in so far as they do not yet appear in Annex II :
(a) substances labelled R 40 , R 45 , R 46, and R 47 under Directive 67 / 548 /EEC (2) in so far as they do not yet appear in Annex II;
(b) chemical agents in Annex I to Directive 90 / 394 / EEC (3);
(c) mercury and mercury derivatives;
(d) antimitotic drugs;
(e) carbon monoxide;
(f) chemical agents of known and dangerous percutaneous absorption.

- *Directive 94/33/EC young people at work*

The aim of this Directive is to ensure that Member States takes the necessary measures to prohibit work by children. Accordingly, they shall also ensure that the minimum working or employment age is not lower than the minimum age at which compulsory full-time schooling as imposed by national law ends or 15 years in any event.

In this regard, Article 7(2) of the Directive specifies that Member States shall prohibit the employment of young people for, *inter alia*: work involving harmful exposure to agents which are toxic, carcinogenic, cause heritable genetic damage, or harm to the unborn child or which in any other way chronically affect human health; work involving harmful exposure to radiation. Furthermore, the Article specifies that the work which is likely to entail specific risks for young people includes work involving harmful exposure to the physical, biological and chemical agents referred to in point I of the Annex.

Point 3 of Annex I lists all the chemical agents which are toxic, carcinogenic, cause heritable genetic damage, or harm to the unborn child or which in any other way chronically affect human health:

a)
— acute toxicity, category 1, 2 or 3 (H300, H310, H330, H301, H311, H331);
— skin corrosion, category 1A, 1B or 1C (H314);
— flammable gas, category 1 or 2 (H220, H221);

— flammable aerosols, category 1 (H222);
— flammable liquid, category 1 or 2 (H224, H225);
— explosives, categories 'Unstable explosive', or explosives of Divisions 1.1, 1.2, 1.3, 1.4, 1.5 (H200, H201, H202, H203, H204, H205);
— self-reactive substances and mixtures, type A, B, C or D (H240, H241, H242);
— organic peroxides, type A or B (H240, H241);
— specific target organ toxicity after single exposure, category 1 or 2 (H370, H371);
— specific target organ toxicity after repeated exposure, category 1 or 2 (H372, H373
— respiratory sensitisation, category 1, subcategory 1A or 1B (H334);
— skin sensitisation, category 1, subcategory 1A or 1B (H317);
— carcinogenicity, category 1A, 1B or 2 (H350, H350i, H351);
— germ cell mutagenicity, category 1A, 1B or 2 (H340, H341);
— reproductive toxicity, category 1A or 1B (H360, H360F, H360FD, H360Fd, H360D, H360Df).

(d) Substances and mixtures referred to in point (ii) of point (a) of Article 2 of Directive 2004/37/EC of the European Parliament and of the Council (1); ▼B
(e) Lead and compounds thereof, inasmuch as the agents in question are absorbable by the human organism;
(f) Asbestos.

- *Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)*

Appendix 3 of the Regulation lays down the criteria for hazard Category 5 which are intended to enable the identification of test substances which are of relatively low acute toxicity hazard but which, under certain circumstances may present a danger to vulnerable populations. These substances are anticipated to have an oral or dermal LD50 in the range of 2 000-5 000 mg/kg or equivalent doses for other routes. Test substances could be classified in the hazard category defined by: 2 000 mg/kg < LD50 < 5 000 mg/kg (Category 5 in the GHS) in the following cases:
(a) if directed to this category by any of the testing schemes of Appendix 2, based on mortality incidences
(b) if reliable evidence is already available that indicates the LD50 to be in the range of Category 5 values; or other animal studies or toxic effects in humans indicate a concern for human health of an acute nature;
(c) through extrapolation, estimation or measurement of data if assignment to a more hazardous class is not warranted;
and
— reliable information is available indicating significant toxic effects in humans, or
— any mortality is observed when tested up to Category 4 values by the oral route, or
— where expert judgement confirms significant clinical signs of toxicity, when tested up to Category 4 values, except for diarrhoea, piloerection or an ungroomed appearance, or
— where expert judgement confirms reliable information indicating the potential for significant acute effects from the other animal studies.

- *Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom*

This Directive establishes uniform basic safety standards for the protection of the health of individuals subject to occupational, medical and public exposures against the dangers arising from ionising radiation.
Article 10, entitled "Protection of pregnant and breastfeeding workers", stresses that Member States

shall ensure that the protection of the unborn child is comparable with that provided for members of the public. As soon as a pregnant worker informs the undertaking or, in the case of an outside worker, the employer, of the pregnancy, in accordance with national legislation the undertaking, and the employer, shall ensure that the employment conditions for the pregnant worker are such that the equivalent dose to the unborn child is as low as reasonably achievable and unlikely to exceed 1 mSv during at least the remainder of the pregnancy. Furthermore, as soon as workers inform the undertaking, or in case of outside workers, the employer, that they are breastfeeding an infant, they shall not be employed in work involving a significant risk of intake of radionuclides or of bodily contamination.

Pursuant to Article 15(1) Member States shall require the undertaking to inform exposed workers on, inter alia:
(a) the radiation health risks involved in their work;
(b) the general radiation protection procedures and precautions to be taken;
(c) the radiation protection procedures and precautions connected with the operational and working conditions of both the practice in general and each type of workstation or work to which they may be assigned;

According to Article (15)2 Member States shall require the undertaking or, in case of outside workers, the employer, to inform exposed workers on the importance of making an early declaration of pregnancy in view of the risks of exposure for the unborn child. Moreover, paragraph 3 of Article 15 stresses that Member States shall require the undertaking or, in case of outside workers, the employer, to inform exposed workers on the importance of announcing the intention to breast-feed an infant in view of the risks of exposure for a breast-fed infant after intake of radionuclides or bodily contamination.

With regard to Article 62(1), it specifies that Member States shall ensure that the referrer or the practitioner, as appropriate, inquire, as specified by Member States, whether the individual subject to medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure. In addition, Article 62(2) underlines that if pregnancy cannot be ruled out and depending on the medical radiological procedure, in particular if abdominal and pelvic regions are involved, special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the expectant individual and the unborn child.

- *Regulation No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control*

This Regulation establishes compositional and information requirements for the following categories of food: infant formula and follow-on formula; processed cereal-based food and baby food; food for special medical purposes; total diet replacement for weight control.

According to recital 21, the use of pesticides can lead to pesticide residues in food that is covered by this Regulation. Such use should, therefore, be restricted as much as possible, taking into account the requirements of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market. Recital 21 specifies that, however, a restriction on, or a prohibition of, use would not necessarily guarantee that food covered by this Regulation, including food for infants and young children, is free from pesticides, since some pesticides contaminate the environment and their residues can be found in such food. Therefore, the maximum residue levels in such food should be set at the lowest achievable level to protect vulnerable population groups, taking into account good agricultural practices as well as other sources of exposure, such as environmental contamination.

- *Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain*

contaminants in foodstuffs

The aim of this regulation is to protect public health by keeping contaminants at levels which are toxicologically acceptable.

In this regard recital 4 stresses that maximum levels for certain contaminants in foodstuffs should be set at a strict level which is reasonably achievable by following good agricultural, fishery and manufacturing practices and taking into account the risk related to the consumption of the food. In the case of contaminants which are considered to be genotoxic carcinogens or in cases where current exposure of the population or of vulnerable groups in the population is close to or exceeds the tolerable intake, maximum levels should be set at a level which is as low as reasonably achievable (ALARA). Such approaches ensure that food business operators apply measures to prevent and reduce the contamination as far as possible in order to protect public health. Furthermore, recital 4 specifies that it is appropriate for the health protection of infants and young children, a vulnerable group, to establish the lowest maximum levels, which are achievable through a strict selection of the raw materials used for the manufacturing of foods for infants and young children.

Recital 23 highlights that it is appropriate to set maximum levels for cereals, cereal products, dried vine fruit, roasted coffee, wine, grape juice and foods for infants and young children, all of which contribute significantly to general human exposure to OTA or to the exposure of vulnerable groups of consumers such as children.

Moreover, recital 43 emphasises that in addition to the setting of maximum levels, targeted consumer advice is an appropriate approach in the case of methylmercury for protecting vulnerable groups of the population.

Finally, recital 45 underlines that in order to protect public health from this health risk it is necessary to set maximum levels for inorganic tin in canned foods and canned beverages. It also stresses that until data becomes available on the sensitivity of infants and young children to inorganic tin in foods, it is necessary on a precautionary basis to protect the health of this vulnerable population group and to establish lower maximum levels.

- *Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin*

This Regulation affirms the need to ensure a high level of consumer protection and harmonised Community provisions relating to maximum levels of pesticide residues in or on food and feed of plant and animal origin.

Recital 5 stresses that one of the most common methods of protecting plants and plant products from the effects of harmful organisms is the use of active substances in plant protection products. However, recital 5 recalls that a possible consequence of their use may be the presence of residues in the treated products, in animals feeding on those products and in honey produced by bees exposed to those substances. According to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, public health should be given priority over the interests of crop protection, thus it is necessary to ensure that such residues should not be present at levels presenting an unacceptable risk to humans and, where relevant, to animals. In addition, recital 5 underlines that maximum residue levels (MRLs) should be set at the lowest achievable level consistent with good agricultural practice for each pesticide with a view to protecting vulnerable groups such as children and the unborn.

With regard to Article 3, it lays down the relevant definition of this Regulation. In particular, speaking about "acute reference dose" and "acceptable daily intake", Article 3 specifies that: (i) 'acute reference dose' means the estimate of the amount of substance in food, expressed on a body weight basis, that

can be ingested over a short period of time, usually during one day, without appreciable risk to the consumer on the basis of the data produced by appropriate studies and taking into account sensitive groups within the population (e.g. children and the unborn); (j) 'acceptable daily intake' means the estimate of the amount of substances in food expressed on a body weight basis, that can be ingested daily over a lifetime, without appreciable risk to any consumer on the basis of all known facts at the time of evaluation, taking into account sensitive groups within the population (e.g. children and the unborn).

- *Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety*

The purpose of this Directive is to ensure that products placed on the market are safe.

Recital 8 stresses that the safety of products should be assessed taking into account all the relevant aspects, in particular the categories of consumers which can be particularly vulnerable to the risks posed by the products under consideration, in particular children and the elderly.

With regard to Article 2, it lays down all the relevant definition for the purpose of this Directive. In particular, defining 'safe product', Article 2 stress that the latter shall mean any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account *inter alia*: (iv) the categories of consumers at risk when using the product, in particular children and the elderly.

- *Directive 93/42/EEC on medical devices*

The main objective of this Directive is to safeguard the safety of medical devices and their free movement within the internal market.

Annex I (essential requirements [of medical devices]), part II (requirements regarding design and construction), point 7 (chemical), sub-point 7.5 specifies that the devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Sub-point 7.5 also specifies that if parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates. The sub-point also emphasises that if the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.

- *Directive 2008/50/EC on ambient air quality and cleaner air for Europe*

This Directive lays down measures aimed at the following:

- defining and establishing objectives for ambient air quality designed to avoid, prevent or reduce harmful effects on human health and the environment as a whole;

- assessing the ambient air quality in Member States on the basis of common methods and criteria;
- obtaining information on ambient air quality in order to help combat air pollution and nuisance and to monitor long-term trends and improvements resulting from national and Community measures;
- ensuring that such information on ambient air quality is made available to the public;
- maintaining air quality where it is good and improving it in other cases;
- promoting increased cooperation between the Member States in reducing air pollution.

Article 23 stresses that where, in given zones or agglomerations, the levels of pollutants in ambient air exceed any limit value or target value, plus any relevant margin of tolerance in each case, Member States shall ensure that air quality plans are established for those zones and agglomerations in order to achieve the related limit value or target value specified in Annexes XI and XIV. The Article also underlines that in the event of exceedances of those limit values for which the attainment deadline is already expired, the air quality plans shall set out appropriate measures, so that the exceedance period can be kept as short as possible. The air quality plans may additionally include specific measures aiming at the protection of sensitive population groups, including children.

Moreover, Article 24 specifies that where, in a given zone or agglomeration, there is a risk that the levels of pollutants will exceed one or more of the alert thresholds specified in Annex XII, Member States shall draw up action plans indicating the measures to be taken in the short term in order to reduce the risk or duration of such an exceedance. Where this risk applies to one or more limit values or target values specified in Annexes VII, XI and XIV, Member States may, where appropriate, draw up such short-term action plans. Article 24 also emphasises that the short-term action plans may, depending on the individual case, provide for effective measures to control and, where necessary, suspend activities which contribute to the risk of the respective limit values or target values or alert threshold being exceeded. Those action plans may include measures in relation to motor-vehicle traffic, construction works, ships at berth, and the use of industrial plants or products and domestic heating. Furthermore, Article 24 underlines that specific actions aiming at the protection of sensitive population groups, including children, may also be considered in the framework of those plans.

Finally, Annex XV (Information to be included in the local, regional or national air quality plans for improvement in ambient air quality), part B (Information to be provided under article 22(1)), point 3, specifies that the information on all air pollution abatement measures that have been considered at appropriate local, regional or national level for implementation in connection with the attainment of air quality objectives must be included in air quality plans, including, inter alia, where appropriate, measures to protect the health of children or other sensitive groups.

- *Regulation (EC) No 850/2004 on Persistent Organic Pollutants (POPs)*

The objective of this Regulation is to protect human health and the environment from persistent organic pollutants by prohibiting, phasing out as soon as possible, or restricting the production, placing on the market and use of substances subject to the Stockholm Convention on Persistent Organic Pollutants, hereinafter "the Convention", or the 1998 Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants, hereinafter "the Protocol", and by minimising, with a view to eliminating where feasible as soon as possible, releases of such substances, and by establishing provisions regarding waste consisting of, containing or contaminated by any of these substances.

Recital 19 highlights that public awareness of the hazards that persistent organic pollutants pose to the health of present and future generations as well as to the environment, particularly in developing countries, is often lacking, and wide-scale information is therefore needed to increase the level of caution and gain support for restrictions and bans. In accordance with the Convention, public awareness programmes on these substances, especially for the most vulnerable groups, as well as training of workers, scientists, educators, technical and managerial personnel should be promoted and

facilitated, as appropriate.

Pursuant to Article 10(1) of this Regulation, the Commission and the Member States shall facilitate and undertake the exchange within the Community and with third countries of information relevant to the reduction, minimisation or elimination, where feasible, of the production, use and release of persistent organic pollutants and to alternatives to those substances, specifying the risks and the economic and social costs related to such alternatives. According to Article 10(2), the Commission and Member States, as appropriate, shall promote and facilitate with regard to persistent organic pollutants:

- awareness programmes, including relating to their health and environmental effects and their alternatives and on the reduction or elimination of their production, use and release, especially for:
  - policy and decision makers,
  - particularly vulnerable groups.

4.1.2 Legislation in specific areas

Nanomaterials

In the EU nanomaterials are defined by the Recommendation on the definition of a nanomaterial (European Commission, 2011). The Commission has taken the ISO (International Organisation for Standardisation) term "nanomaterial" as the basis for its definition but has made a number of modifications which were deemed necessary to ensure its practical application in a regulatory context. According to the Recommendation a nanomaterial means:

"[a] natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.By derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials".

The scope of the Recommendation covers nanomaterials when they are substances or mixtures, but not when they are final products. This means that if a nanomaterial is used amongst other ingredients in a formulation the entire product will not become a nanomaterial. This is in line with the definitions proposed by the Organisation for Economic Co-operation and Development (OECD) and the ISO (2015).

Moreover, seeing the fast pace of technological development and scientific progress, it was envisaged that the scope of the European Recommendation on the definition of a nanomaterial will be reviewed by December 2014, in particular with regard to whether the number size distribution threshold of 50 % should be increased or decreased, and whether to include materials with internal structure or surface structure in the nanoscale (such as complex nano-component nanomaterials, including nano-porous and nano-composite materials that are used in some sectors). However, until now, the definition of nanomaterials has not been reviewed yet.

Pesticides

Existing policies and legislation on pesticides were first introduced at EU level in 1979 and have evolved considerably over the years, culminating in the adoption of Directive 91/414/EEC concerning the placing of plant protection products on the market, followed by Directive 98/8/EC on the placing of biocidal products on the market. Currently, the Directive 91/414/EEC has been replaced by the

Regulation (EC) No 1107/2009 which sets out sets out the requirements, procedure and timeframes for authorisation of Plant Protection Products. The Regulation requires pesticide not to have unacceptable effects on plants, or damaging effects on human and animal health. In order to reach this scope, all pesticides need to be evaluated and authorised before they can be placed on the market.

Active substances are approved by the European Commission through implementing acts, following a risk assessment carried out by the European Food Safety Authority (EFSA) (section n. 5.4). A dual system is in place, under which the EFSA evaluates active substances used in plant protection products and Member States evaluate and authorise the products at national level. The EU pesticides database list the approved active substances, the non-approved ones, as well as the substances for which approval is pending.

Moreover, all matters related to legal limits for pesticide residues in food and feed are covered by Regulation (EC) No 396/2005. This regulation also contains provisions on official controls of pesticides residues in food of plant and animal origin that may arise from their use in plant protection.

Furthermore, the Directive 2009/128/EC establishes a framework for the sustainable use of pesticides. It aims to reduce the risks and impacts of pesticide use on human health and environment and promote the use of integrated pest management and of alternative approaches, such as non-chemical ones. Furthermore, Members States must develop national action plans and communicate them to the European Commission. Action plans must include quantitative objectives, measures and timetables, as well as indicators to monitor the use of dangerous plant protection products and targets for the reduction of their use (see more in detail section 5.3).

In addition, a number of other pieces of EU legislation and policies also affect the use of pesticides. In particular: the Common Agricultural Policy (CAP); the Directive 200/127/EC concerning the machinery for pesticide application; the Regulation (EC) No 1272/2008 concerning the classification, packaging and labelling of dangerous preparations, including pesticides; the Commission Regulation (EC) No 889/2008 which allows the use of pesticides in organic agriculture only when other methods of pest and disease control are ineffective; the Directive 2000/60/EC (Water Framework Directive), which sets the limits to the levels of particular chemicals in the aquatic environment, including pesticides; the Directive 2006/12/EC (Waste Framework Directive); the Council Directive on Hazardous Waste 91/698/EE; the Council Directive 98/83/EC (Drinking Water Directive), which fixes the maximum pesticides concentration in drinking water; and the Directive on Health and Safety of Workers 98/24/EC.

Plastics

Despite the consequences that might have on human health (see section 6.4), in the EU there is no legislation that focuses solely on plastic considered as a chemical. Nevertheless, the issue of plastics and their effects on human health is addressed in various pieces of EU legislation.

In particular, plastic is defined by Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation). The REACH Regulation was adopted in order to improve the protection of human health and the environment from the risks that can be posed by chemicals. In principle REACH applies to all chemical substances, including plastics. The REACH regulation places the burden of proof on companies which must identify and manage the risks linked to the substances they manufacture and market in the EU. They have to demonstrate to the European Chemicals Agency (ECHA) how the substance can be safely used, and they must communicate the risk management measures to the users. If the risks cannot be managed, authorities can restrict the use of substances in different ways. Moreover, in the long run, the most hazardous substances should be substituted with less dangerous ones. Pursuant to Article 3(5) of the Regulation in question "plastic" is a polymer which in turn is a substance consisting of molecules characterised by the sequence of one or

more types of monomer units. Such molecules are distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. "Monomer" means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process.

With regard to the Classification, Labelling and Packaging Regulation 1272/2008/EC (CLP Regulation), it allows the identification of hazardous chemicals and informs users about these hazards through standard symbols and phrases on the packaging labels and through safety data sheets. These information are used for stimulating the production of less hazardous plastics in Europe.

Furthermore, in the EU plastic is one of the most common food contact materials. Food contact materials are all materials and articles intended to come into contact with food, such as packaging and containers, kitchen equipment, cutlery and dishes. These may be made exclusively of plastic or they may consist of a plastic layer on top of another material such as metal or paper. Recycled plastic may also under certain conditions be used in food contact materials. The safety of food contact materials requires evaluation as chemicals can migrate from the materials into food. The materials shall be manufactured in compliance with EU regulations, including good manufacturing practices, so that any potential transfer to foods does not raise safety concerns, change the composition of the food in an unacceptable way or have adverse effects on the quality of foods (for instance, taste and/or odour).

General requirements for all food contact materials are laid down in Framework Regulation EC 1935/2004. Good Manufacturing Practice for materials and articles intended to come in contact with food is described in Regulation EC 2023/2006. In 2011, existing EU legislation for plastics used in food contact materials was consolidated into a single instrument: the Regulation EU 10/2011. This regulation sets an overall migration limit and includes a list of authorised substances for the manufacture of plastic food contact materials with their corresponding specific migration limits:

- Overall Migration Limit - 10mg of substances/dm² (square decimetre) of the food contact surface for all substances that can migrate from food contact materials to food. In some cases the overall migration limit is expressed as 60 mg/kg food;
- Specific Migration Limit (SML) for individual authorised substances fixed on the basis of a toxicological evaluation and a default exposure assumption

These limits assume daily exposure throughout a lifetime for a person weighing 60 kg, to 1 kg of food packed in plastics containing the substance in the maximum permitted quantity.

Bisphenol A (BPA), a chemical mainly used to manufacture plastics, for instance, is permitted for use in food contact materials in the European Union under Regulation EU 10/2011. However, it is worth noticing that, in January 2011, the European Commission adopted Directive 2011/8/EU, prohibiting the use of BPA for the manufacture of polycarbonate infant feeding bottles (for the health risks that BPA may pose on human health see section 6.4.1).

As far as the recycled plastics is concerned, materials and articles made either entirely or partially from recycled plastics and used in contact with food should only be obtained from processes which have been assessed for safety by EFSA and authorised by the European Commission. Regulation EC 282/2008 establishes rules for the authorisation of processes used to recycle such materials. In an initial authorisation phase, once EFSA has published all its opinions on these recycling processes, the Commission and Member States will decide whether or not to grant or refuse authorisation of the evaluated recycling processes. After that, recycled plastics used in food packaging, food containers and other food contact materials may only be obtained from processes which have been assessed for safety by EFSA and authorised by risk managers. The European Commission will then prepare a Register of authorised processes.

The Directive 2008/98/EC on waste (Waste Framework Directive) also addresses the issue of plastics. In particular, the Directive sets a separate plastic waste collection target to be reached in 2015, as well as the 50% household waste collection target to be reached by 2020. In this respect, the Directive 94/62/EC (Packaging and Packaging Waste Directive), which was adopted in order to prevent or reduce the impact of packaging and packaging waste on the environment, also set a specific plastic waste target (see Article 6). Nevertheless, although the plastic carrier bags constitute packaging within the meaning of that Directive, the latter did not contain specific measures on the consumption of such bags. For this reason, given that the consumption of plastic carrier bags has several negative impacts on the environment, the Directive 94/62/EC was amended in 2015 by the Directive (EU) 2015/720 whose aim is reducing the consumption of lightweight plastic carrier bags.

4.1.3 Legislation that could consider references to vulnerable groups

The EU legislation considered in this section, although do not contain any direct references to vulnerable groups, may however include general provisions that can be applicable to vulnerable groups. Hence, the following legislation might fit within the scope of our report:

- Regulation (EC) 648/2004 on detergents;
- Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food;
- Directive 98/79/EC on in vitro diagnostic medical devices;
- Directive 2008/68/EC on inland transport of dangerous goods;
- Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals (recast);
- Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances (SEVESO-III);
- Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control);
- Directive 2008/105/EC on environmental quality standards in the field of water policy as amended by Directive 2013/39/EU;
- Decision 2015/495/EC establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC;
- Directive 2008/98 on waste;
- Directive 2006/66/EC on batteries & accumulators;
- Regulation (EC) No 1013/2006 shipments of waste;
- Directive 1999/31/EC on the landfill of waste;
- Directive 2004/10/EC on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version);
- Regulation (EU) No 1007/2011 on textile fibre names and related labelling and marking of the fibre composition of textile products;
- Regulation (EC) 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Reg 2232/96;
- Regulation (EC) No 2003/2003 relating to fertilisers;
- Directive 2009/142/EC appliances burning gaseous fuels;
- Directive 2004/107/EC relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air;
- Regulation (EU) No 517/2014 on fluorinated greenhouse gases;
- Regulation (EC) No 1005/2009 on substances that deplete the ozone layer;
- Council Directive 91/271/EEC concerning urban waste water treatment;
- Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast);
- Directive 2009/148/EC protection of workers from the risks related to exposure to asbestos at work.

4.1.4 Legislation considered, but less relevant and no references to vulnerable groups

The EU legislation which appears in this section do not show any references to vulnerable groups and do not contain any specific provisions that might be applicable to them. Therefore, the following EU legislation falls outside the scope of our report.

- Directive 2014/40/EU on manufacture, presentation and sale of tobacco;
- Council Directive 75/324/EEC on aerosol dispensers;
- Regulation (EC) No 66/2010 on the EU Ecolabel;
- Regulation (EC) No 450/2009 on active and intelligent materials;
- Directive 2014/68/EU on pressure equipment;
- Regulation (EU) No 305/2011 laying down harmonised conditions for the marketing of construction products;
- Directive 2001/82/EC on the Community code relating to veterinary medicinal products;
- Directive 2004/35/CE on environmental liability;
- Directive 2000/60/EC establishing a framework for Community action in the field of water policy;
- Directive 2000/53/EC on end-of-life vehicles;
- Directive 92/58/EEC on H & S signs at work;
- Directive 2015/1535 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services;
- Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes;
- Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (Codified version);
- Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code;
- Directive 87/357/EEC concerning products which, appearing to be other than they are, endanger the health and safety of consumers;
- Directive 78/142/EEC on materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs;
- Directive 84/500/EEC relating to ceramic articles intended to come into contact with foodstuffs;
- Directive 93/11/EEC concerning the release of the N-nitrosamines and N- nitrosatable substances from elastomer or rubber teats and soothers;
- Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food;
- Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients;
- Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC;
- Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption;
- Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed;
- Directive 2002/46/EC food supplement;
- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;
- Regulation (EC) No 1829/2003 on genetically modified food and feed;
- Regulation (EC) No 1830/2003 traceability and labelling of genetically modified organisms and

the traceability of food and feed products produced from genetically modified organisms;
- Regulation (EC) No 1831/2003 additives for use in animal nutrition;
- Directive 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs;
- Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods;
- Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings;
- Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes;
- Commission Regulation (EC) No 1895/2005 restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food;
- Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to food;
- Regulation (EC) No 767/2009 on the placing on the market and use of feed;
- Regulation (EU) No 234/2011 establishing a common authorisation procedure for food additives, food enzymes and food flavourings;
- Regulation (EC) No 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation;
- Regulation (EC) No 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin;
- Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food;
- Directive 2014/28/EU on the making available on the market and supervision of explosives for civil uses (recast);
- Directive 2013/29/EU on pyrotechnic articles (recast);
- Directive 2009/125/EC setting ecodesign requirements for energy-related products;
- Directive 2006/42/EC on machinery, and amending Directive 95/16/EC (recast);
- Directive 2014/34/EU on equipment and protective systems intended for use in potentially explosive atmospheres (recast);
- Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93;
- Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State
- Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC;
- Directive 2009/105/EC relating to simple pressure vessels;
- Directive 90/385/EEC relating to active implantable medical devices;
- Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;
- Directive 2009/41/EC on the contained use of genetically modified micro-organisms (Recast);
- Directive 2009/32/EC extraction solvents used in the production of foodstuffs and food ingredients;
- Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists;
- Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment;

- Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture;
- Directive 2001/18/EC deliberate release into the environment of genetically modified organisms;
- Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT);
- Directive 2006/118/EC protection of groundwater against pollution and deterioration ;
- Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive);
- Regulation (EU) No 525/2013 on a mechanism for monitoring and reporting greenhouse gas emissions and for reporting other information at national and Union level relevant to climate change;
- Directive 2006/7/EC of the European Parliament and of the Council of 15 February 2006 concerning the management of bathing water quality;
- Directive 94/63/EC on the control of volatile organic compound (VOC) emissions resulting from the storage of petrol and its distribution from terminals to service stations;
- Regulation (EC) No 443/2009 setting emission performance standards for new passenger cars as part of the Community's integrated approach to reduce CO 2 emissions from light-duty vehicles;
- Regulation (EC) No 1497/2007 establishing, pursuant to Regulation (EC) No 842/2006 of the European Parliament and of the Council, standard leakage checking requirements for stationary fire protection systems containing certain fluorinated greenhouse gases;
- Implementing Regulation (EU) 2015/2067 establishing, pursuant to Regulation (EU) No 517/2014 of the European Parliament and of the Council, minimum requirements and the conditions for mutual recognition for the certification of natural persons as regards stationary refrigeration, air conditioning and heat pump equipment, and refrigeration units of refrigerated trucks and trailers, containing fluorinated greenhouse gases and for the certification of companies as regards stationary refrigeration, air conditioning and heat pump equipment, containing fluorinated greenhouse gases;
- Implementing Regulation (EU) 2015/2066 establishing, pursuant to Regulation (EU) No 517/2014 of the European Parliament and of the Council, minimum requirements and the conditions for mutual recognition for the certification of natural persons carrying out installation, servicing, maintenance, repair or decommissioning of electrical switchgear containing fluorinated greenhouse gases or recovery of fluorinated greenhouse gases from stationary electrical switchgear;
- Regulation (EC) No 306/2008 establishing, pursuant to Regulation (EC) No 842/2006 of the European Parliament and of the Council, minimum requirements and the conditions for mutual recognition for the certification of personnel recovering certain fluorinated greenhouse gas-based solvents from equipment;
- Regulation (EC) No 307/2008 establishing, pursuant to Regulation (EC) No 842/2006 of the European Parliament and of the Council, minimum requirements for training programmes and the conditions for mutual recognition of training attestations for personnel as regards air-conditioning systems in certain motor vehicles containing certain fluorinated greenhouse gases;
- Regulation (EC) No 308/2008 establishing, pursuant to Regulation (EC) No 842/2006 of the European Parliament and of the Council, the format for notification of the training and certification programmes of the Member States;
- Regulation (EC) No 1102/2008 of the European Parliament and of the Council of 22 October 2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury;
- Directive 94/62/EC of 20 December 1994 on packaging and packaging waste;
- Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE);
- Decision 2000/532/EC establishing list of wastes;
- Directive 92/91/EEC on safety and health of workers in the mineral-extracting industries;
- Directive 89/391/EEC on measures to encourage improvements in the safety and health of

workers at work;
- Directive 92/57/EEC on minimum safety and health requirements at construction sites;
- Directive 92/104 minimum requirements for improving the safety and health protection of workers in surface and underground mineral-extracting industries;
- Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors.

4.2 INTERNATIONAL FRAMEWORK

4.2.1 International framework which contains reference to vulnerable groups

- *Stockholm Convention*

The Stockholm Convention is a global treaty to protect human health and the environment from persistent organic pollutants (POPs). POPs are chemicals that are persistent, bioaccumulative, subject to long-range environmental transport and that are toxic to humans and the environment. Governments have to take measures to eliminate or reduce the release of POPs into the environment. At its adoption, the Convention targeted 12 particularly toxic POPs for reduction and eventual elimination. Nine further POPs have been added to the Convention based on a consensus decision by the Parties in May 2009. The Convention also provides support to developing countries and countries with economies in transition to phase out and clean up stockpiles of certain chemicals. The Stockholm Convention entered into force in 2004 and had 168 Parties as of November 2009.

- *Rotterdam Convention*

The Rotterdam Convention creates legally binding obligations for the implementation of the PIC procedure for pesticides and industrial chemicals that have been banned or severely restricted for health or environmental reasons by the Parties. The Convention builds on the voluntary PIC procedure, which was initiated by UNEP and FAO in 1989 and came to an end on 24 February 2006. The Rotterdam Convention had 130 Parties as of November 2009. Its objectives are:

- to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm;
- to contribute to the environmentally sound use of those hazardous chemicals by facilitating information exchange and by providing for a national decision-making process on the import and export of those hazardous chemicals.

- *Strategic approach to international chemicals management (SAICM)*

Adopted by the International Conference on Chemicals Management (ICCM) on 6 February 2006 in Dubai, United Arab Emirates, the Strategic Approach to International Chemicals Management (SAICM) is an international voluntary policy framework to foster the sound management of chemicals. Its aim is to support the achievement of the goal agreed at the 2002 Johannesburg World Summit on Sustainable Development of ensuring that, by the year 2020, chemicals are produced and used in ways that minimize significant adverse impacts on the environment and human health. A major driving force for the establishment of the Strategic Approach has been the recognition of the growing gaps between the capacities of different countries to manage chemicals safely, the need to improve synergies between existing instruments and processes and the growing sense of urgency regarding the need to assess and manage chemicals more effectively to achieve the 2020 goal articulated in the Johannesburg Plan of Implementation.

- *ILO Chemicals Convention 1990, No. 170*

The Convention represents one of the most far-reaching international agreements in the area of chemicals management and specifically addresses the protection of workers from harmful effects of chemicals at the workplace. It applies to all branches of economic activity in which chemicals are used, covers all chemicals and provides specific measures in respect of hazardous chemicals. The Convention requires that classification systems be established and that all chemicals should be marked to indicate their identity. Hazardous chemicals should be labelled to provide essential information on their classification, their hazards and safety precautions to be observed. Because of the tri-partite composition of the ILO under whose jurisdiction the Convention was negotiated, governments, suppliers, employers and workers all have responsibilities for the safe management and handling of chemicals. Governments are required to develop national policies on safety in the use of chemicals at work and that may include measures to prohibit and/or restrict the use of certain chemicals. Suppliers, which may include manufactures, importers and distributors, are required to ensure that chemicals are properly classified and labelled and that safety data sheets are provided to employers.

Employers have an obligation to ensure that workers are not exposed to chemicals exceeding national or international limits, that they are provided with safety data sheets and that they are trained on all aspects of safety in the use of chemicals in the workplace. Employers are also required to assess the risks associated with use the use of chemicals and identify options to protect workers throughout all stages of the life-cycle of the chemical. Workers have an obligation to co-operate with their employers and to take all reasonable steps to minimize or avoid risk.

- *Minamata Convention on Mercury*

The Minamata Convention on Mercury is a global treaty to protect human health and the environment from the adverse effects of mercury. It was agreed at the fifth session of the Intergovernmental Negotiating Committee on mercury in Geneva on 19 January 2013 and adopted later that year on 10 October 2013 at a Diplomatic Conference held in Kumamoto, Japan.

The Convention draws attention to a global and ubiquitous metal that, while naturally occurring, has broad uses in everyday objects and is released to the atmosphere, soil and water from a variety of sources. Controlling the anthropogenic releases of mercury throughout its lifecycle has been a key factor in shaping the obligations under the Convention.

Major highlights of the Minamata Convention include a ban on new mercury mines, the phase-out of existing ones, the phase out and phase down of mercury use in a number of products and processes, control measures on emissions to air and on releases to land and water, and the regulation of the informal sector of artisanal and small-scale gold mining. The Convention also addresses interim storage of mercury and its disposal once it becomes waste, sites contaminated by mercury as well as health issues.

- *UN Convention on the rights of the child*

The United Nations Convention on the Rights of the Child is a human rights treaty which sets out the civil, political, economic, social, health and cultural rights of children. The UN General Assembly adopted the Convention and opened it for signature on 20 November 1989. It came into force on 2 September 1990, after it was ratified by the required number of nations. Currently, 196 countries are party to it. According to article 24 (1) of the Convention "states Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health". This provision can be considered a legal basis to protect children from the harmful effects of chemicals.

5 TEST METHODS AND RISK ASSESSMENT METHODOLOGIES

5.1 RISK ASSESSMENT

Definition

The classification of a substance or a mixture reflects the type and severity of the intrinsic hazards of a substance or mixture. It should not be confused with risk assessment which relates a given hazard to the actual exposure of humans or the environment to the substance or mixture displaying this hazard. Nevertheless, the common denominator for both classification and risk assessment is hazard identification and hazard assessment (ECHA, 2015).

The risk assessment of chemical contaminants in food is based on the integration of two aspects: knowledge about the human exposure to these substances via food and other routes, and their potential to cause adverse health effects. The safety of chemicals is assessed following the four steps of risk assessment, namely hazard identification (genotoxic, carcinogen, endocrine disruptive, etc.), hazard characterisation (dose-response relationship, mechanisms/mode of action, kinetics, etc.), exposure assessment (external, internal), and risk characterisation. Important considerations in risk assessment include windows of susceptibility. Human exposure is a key element in risk assessment (Alexander et al., 2012).

Hazard is the inherent capacity of a chemical or mixture to cause adverse effects in man or the environment under the conditions of exposure. *Risk* is the probability of an adverse effect on man or the environment occurring as a result of a given exposure to a chemical or mixture. *Risk assessment* is a process which entails some or all of the following elements: hazard identification, effects assessment, exposure assessment and risk characterization. *Hazard identification* is the identification of the adverse effects which a substance has an inherent capacity to cause, or in certain cases, the assessment of a particular effect. *Effects assessment*, or more precisely, dose-response assessment is the estimation of the relationship between dose or level of exposure to a substance, and the incidence and severity of an effect. *Exposure assessment* is the determination of the emissions, pathways and rates of movement of a substance and its transformation or degradation in order to estimate the concentrations/doses to which human populations or environmental compartments are or may be exposed. *Risk characterization* is an estimate of the incidence and severity of the adverse effects likely to occur in a human population or environmental compartment due to actual or predicted exposure to a substance, and may include "risk estimation", i.e., the quantification of that likelihood. *Risk management* is a decision-making process that entails weighing political, social, economic, and engineering information against risk-related information to develop, analyse and compare regulatory options and select the appropriate regulatory response to a potential health or environmental hazard (Van Leeuwen & Vermeire, 2007).

Depending on the nature and dimension of hazards and the exposure situations involved, risk management measures are taken directly based on the identified hazard classification using generic risk considerations justifying a direct risk management consequence, or based on a specific risk assessment. Direct mechanisms applying measures to classified substances based on generic risk considerations without further specific assessment of the risk may be justified by specific considerations, such as the characteristics of the hazard, the vulnerability of certain parts of the population (e.g. children), non-controllable or widespread exposure. Examples of risk management and communication measures based on generic risk considerations include coverage of industrial sites by the Seveso Directive, labelling requirements under CLP, EU Ecolabel eligibility under the Ecolabel Regulation and cut-off criteria under the Plant Protection Products Regulation. A specific risk assessment assesses the probability of occurrence of an adverse effect on man or the environment resulting from a given exposure to a chemical or mixture. The assessment takes into account both the hazards and the potential specific exposures of humans and the environment. An example of

legislation providing for such specific risk assessments is the Cosmetics Regulation as regards CMR10 categories 1A, 1B and 2 substances. In addition, in some cases, risk management measures may take into account other factors, such as socioeconomic considerations and the precautionary principle (European Commission, 'Evaluation and Fitness Check (FC) Roadmap: Fitness check on the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries', 2016).

According to a European Commission Communication on the precautionary principle, the precautionary principle should be considered within a structured approach to the analysis of risk which comprises three elements: risk assessment, risk management, risk communication. The precautionary principle is particularly relevant to the management of risk. The precautionary principle, which is essentially used by decision-makers in the management of risk, should not be confused with the element of caution that scientists apply in their assessment of scientific data (Communication from the Commission on the precautionary principle, 2000).

Risk assessment

A process intended to calculate or estimate the risk to a given target organism, system, or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system. The risk assessment process includes four steps: hazard identification, hazard characterization (related term: *Dose–response assessment*), exposure assessment, and risk characterization. It is the first component in a risk analysis process (IPCS, 2004).

There is a need to expand risk assessment paradigms to evaluate exposures relevant to children from preconception to adolescence, taking into account the specific susceptibilities at each developmental stage. The full spectrum of effects from childhood exposures cannot be predicted from adult data. Risk assessment approaches for exposures in children must be linked to life stages.

Establishing causal links between specific environmental exposures and complex, multifactorial health outcomes is difficult and challenging, particularly in children. For children, the stage in their development when the exposure occurs may be just as important as the magnitude of exposure. Very few studies have characterized exposures during different developmental stages. Examples have shown that exposures to the same environmental chemical can result in very different health outcomes in children compared with adults.

While research has addressed the impact of environmental chemicals on children's health, typically investigators have focused on exposure to a particular environmental chemical, such as heavy metals or pesticides, and a particular organ system or end-point. Noticeably absent are prospective longitudinal studies capturing exposures over key developmental windows or life stages. Virtually no studies have captured periconceptional exposures either alone or in addition to other life stage exposures. Advancing technology and new methodologies now offer promise for capturing exposures during these critical windows. This will enable investigators to detect conceptions early and estimate the potential competing risk of early embryonic mortality when considering children's health outcomes that are conditional upon survival during the embryonic and fetal periods.

While substantial knowledge has been gained on the effects of exposure to environmental agents on children's health, much remains to be learned. Child-protective risk assessment approaches must be based on a better understanding of the interactions of exposures, biological susceptibility, and socioeconomic and cultural (including nutritional) factors at each stage of development. In order to gain a better understanding, further research is needed in the following areas:

- Design and implement prospective cohort studies of pregnant women, infants, and children with longitudinal capture of exposures at critical windows and sensitive health end-points along the

continuum of human development. Efforts to recruit couples prior to conception are needed to address critical data regarding periconceptional exposures and children's health.

- Continue to develop and enhance population-based surveillance systems for the real-time capture of sentinel health end-points. This includes current surveillance systems such as vital registration for birth size and gestation and birth defects registries for capture of major malformations. Consideration of emerging sentinel end-points such as fecundability, as measured by time to pregnancy and sex ratios, should receive added research consideration.
- Strengthen exposure monitoring efforts in children during different developmental stages, including efforts to assess aggregate and cumulative exposures.
- Strengthen exposure monitoring efforts in developing countries.
- Identify subpopulations with the highest exposure levels.
- Develop validated, sensitive, and cost-effective biomarkers of exposure, susceptibility, and effects, particularly during early developmental stages.
- Improve characterization of the differences in toxicokinetic and toxicodynamic properties of xenobiotics at different developmental stages. Develop databases of developmental stage–specific physiological and pharmacokinetic parameters in both human and animal studies.
- Conduct studies focusing on mechanisms of action during different developmental stages by which exposures may cause adverse outcomes.
- Develop end-points that can be used to assess organ system functions in both humans and animal species and to identify analogous periods of development across species.
- Examine the utility of newer molecular and imaging technologies to assess causal associations between exposure and effect at different developmental stages.
- Improve characterization of the windows of susceptibility of different organ systems in relation to structural and functional end-points.
- Develop and validate biological models and animal testing guidelines that can address health outcomes at different developmental stages.
- Determine which exposure reductions will have the greatest overall impact on children's health (WHO, 2006).

Although substantial knowledge has been gained on the prevention of environmental hazards to children, much remains to be learned. Further research is needed in the following areas:

- design and implement prospective cohort studies of pregnant women, infants, and children with a longitudinal capture of exposures at critical windows and sensitive health end-points along the continuum of human development. Efforts to recruit couples prior to conception are needed to address critical data regarding periconceptional exposures and children's health
- continue to develop and enhance population-based surveillance systems for the real-time capture of sentinel health end-points. This includes current surveillance systems such as vital registration for birth size and gestation and birth defects registries for capturing major malformations. Also, the consideration of emerging sentinel end-points such as fecundability, as measured by time to pregnancy and sex ratios, should receive added research consideration
- strengthen exposure monitoring efforts in children during different developmental stages, including efforts to assess aggregate and cumulative exposures
- strengthen exposure monitoring efforts in developing countries
- identify subpopulations with the highest exposure levels
- develop validated, sensitive, and cost-effective biomarkers of exposure, susceptibility, and effects, particularly during early developmental stages
- improve characterization of the differences in toxicokinetic and toxicodynamic properties of xenobiotics at different developmental stages. Also, to develop databases of developmental stage–specific physiological and pharmacokinetic parameters in both human and animal studies.
- conduct studies focusing on mechanisms of action during different developmental stages by which exposures may cause adverse outcomes
- develop end-points that can be used to assess organ system functions in both humans and animal species and to identify analogous periods of development across species

- examine the utility of newer molecular and imaging technologies to assess causal associations between exposure and effect at different developmental stages. Also, to improve characterization of the windows of susceptibility of different organ systems in relation to structural and functional end-points
- develop and validate biological models and animal testing guidelines that can address health outcomes at different developmental stages
- determine which exposure reductions will have the greatest overall impact on children's health (WHO, 2011)

Systematic review in chemical risk assessment
The European Food Safety Authority (EFSA) considers that current levels of exposure to BPA present a low risk of harm to the public (European Food Safety Authority, 2015a). The French food regulator ANSES takes a seemingly different stance on the risks to health posed by BPA (French Agency for Food, Environmental and Occupational Health, and Safety, 4/7/2014), determining there to be a "potential risk to the unborn children of exposed pregnant women". On this basis, ANSES has proposed classifying BPA as toxic to reproduction in humans (French Agency for Food, Environmental and Occupational Health, and Safety, 2013), a proposal which has contributed to the French authorities' decision to implement an outright ban on BPA in all food packaging materials (France, 12/24/2012). While the ban has been challenged by some stakeholders as being disproportionate under EU law (Tošenovský, 2014, Tošenovský, 2015 and Plastics Europe, 2015), the Danish National Food Institute has argued that EFSA has overestimated the safe daily exposure to BPA and that some populations are exposed to BPA at levels higher than can be considered safe (National Food Institute, Denmark, 2015); a view reflected in the conclusions of some researchers, e.g. (Vandenberg et al., 2014) but not others, e.g. (US Food and Drug Administration, 2014).

Vulnerable groups

Meeting the needs of vulnerable populations
A major challenge in risk assessment is the protection of vulnerable populations, considering vulnerability as the combination of higher susceptibility (i.e. the presence of biological intrinsic factors affecting the response to a chemical), higher levels of exposure and additional factors that include social and cultural parameters (e.g. socio-economic status and location of residence but also risk awareness and risk education of each member of the population) that can contribute to an increased health risk. The exposure shows large variations as a function of life stage, due to changing physiology but also due to different lifestyles resulting in different behaviour. Exposure in early life may produce epigenetic changes that may not result in a risk but late-life exposure to the same or a different compound may result in an adverse effect. The evaluation of exposure to chemicals and the related health risk requires population specific information that may vary significantly, depending on geography and cultural practices. In addition, exposure scenarios and response factors may vary for different populations based on age and life-stage changes in behaviour and physiology, which can determine critical windows of susceptibility. Although experiencing the same level of external exposure, some individuals can be more susceptible due to developmental stage or age, pathological status, or to genetic features affecting any individual's ability to withstand harm from a variety of chemical exposures. The internal dose, which determines the toxicological outcome, can be affected by the genetic polymorphism and differential expression of active transporters or enzymes involved in the toxicokinetics of a given chemical.

The ability to identify vulnerable populations is increased by the knowledge of the mechanism of action of chemicals, allowing to consider the impact of factors such as age, genetics, environment, exposure, pathophysiological conditions or combinations of these and other factors on risk assessment protecting the overall populations, including vulnerable groups.

Human risk assessment
Human risk assessment has traditionally consisted of 4 steps: hazard assessment, doseresponse

extrapolation (hazard characterisation), exposure assessment and inter and intraspecies species-transposition (risk assessment). The approach to human risk assessment used has been usually hazard driven with a strong reliance on the use of laboratory animals as surrogates for humans. The selection of rats and mice for this purpose was based primarily on animal husbandry considerations (e.g. ease of breeding, housing and maintenance) rather than scientific evidence that such rodents responded to chemical exposure in a very similar manner to humans. Other animal species such as dogs are only used in hazard assessment and determination of dose-response relationships for chemicals with intended human exposures (e.g. food additives, pharmaceuticals) or for chemicals with specific applications (e.g. plant protection products). For specific cases, such as pharmaceuticals, non-human primates have sometimes been used. In these cases, it is hoped that the use of an additional animal species (selected based on the expected similarity of toxicokinetics of the specific chemical in the experimental animal to that in humans) will reduce the uncertainty in transposition of effects in animals to humans. Histopathology is to date the accepted primary determinant for effects assessment along with changes in organ and body weight and some selected biochemical and haematological parameters. Over time, these tests have been increasingly standardised by the introduction of good laboratory practice and ICH or OECD test guidelines.

Some *in vitro* tests, in particular for genotoxicity and topical effects have been added. Many of the tests in current use are written into legislative requirements for the approval of various types of products. To reduce the number of animals used and to enhance the likelihood of identifying an adverse effect, it has been common practice to dose animals at much higher exposure levels than humans would ever be likely to be exposed to under normal circumstances. To address uncertainties due to the need for transposition, when using data obtained in rats and mice to characterise effects that may occur in humans, conservative standard default values (also called assessment factors, uncertainty factors or default factors) have come into common use (EFSA 2011). The current approach uses default safety factors of 10 to account for species transposition between responses observed in experimental animals and those potentially expected in humans. An additional factor of 10 is used to cover inter-individual differences in response over the human population. This factor is also considered sufficient to cover potentially vulnerable subgroups, but in some specific cases the application of additional safety factors may be considered on the basis of experimental data, to allow for particularly vulnerable population groups. In case of an insufficient database, or of factors which may modify the responses, the default factors can be adjusted. For a very limited number of chemicals or groups of chemicals, mode of action studies have been used to characterise the soundness of the scientific basis for the transposition of data to man (e.g. organophosphorous pesticides and phthalate plasticisers).

Conclusions on priorities for change and their rationale

A third priority is to develop improved understanding of modes of action of toxicologically important chemicals. This will provide an essential scientifically justified base for characterising thresholds for adverse effects and identifying vulnerable population groups. It would also enable a sound basis for read-across, a relevant framework for the grouping of chemicals and for the risk assessment of mixtures.

Modelling of external exposure

TK represents an essential piece of information for the appropriate design of any toxicity tests and for data interpretation. The use of physico-chemical data allied with some simple *in vitro* tests for the estimation of uptake from various routes of exposure, metabolic fate and persistence of chemicals in man is particularly important for tier 1 exposure assessments. Such data will also be needed for tier 2 assessments. This would enable the application of SAR. The production of *in vitro* kinetic data in tier 2 *in vitro* toxicity testing is essential for the *in vitro-in vivo* extrapolation for which PBPK modelling is considered as the most appropriate tool. PBPK modelling is likely to be also a very important component of tier 3: for a refined exposure assessment, for the estimate of effects in vulnerable populations and for the evaluation of mixture effects. Considerable uncertainties still exist on the applicability of such models for certain categories of chemicals such as polar or ionised and/or

nanoparticles.

Biomarkers are anticipated to play an increasingly important role in (SCHER, 2013):

- The validation of test systems including the appropriateness of various *in vitro* models for specific toxicity testing purposes;
- The early detection of effects that in the longer term may result in marked adverse effects.
- Identification of vulnerable populations
- Analysing risk of aggregate exposures – multiple sources and pathways.

Workplace exposure

The workplace exposure scenario
In risk assessments carried out under health and safety legislation, the term "exposure scenario" (ES) has commonly been used to describe the particular situation that is the focus of the risk assessment. This may vary from a general assessment of the use of a chemical in an industry sector or activity, to one that is specific to a workplace. According to the OECD/IPCS definition, the scenario would tend to include consideration of all key variables that affect the risk (including non-chemical hazards and measures in-place to control such risks). This contrasts with the definition under REACH which describes a control strategy for substances, giving realistic operational conditions for manufacture of a substance or identified use(s) of a substance, a group of substances or a preparation. The REACH exposure scenario prescribes appropriate measures that serve to effectively manage health, environmental and safety risks from the chemical during its manufacture or use for a given set of operational conditions. The appropriateness of these measures for a specific workplace can vary, however. For local reasons, the measures identified may be invalid and equivalent or better approaches available. Thus there is a need to use the information contained within the REACH exposure scenario as one information source when determining (and documenting) the adequacy of worker health protection strategies in the workplace.

It should be further noted that in workplace exposure assessments, special consideration is not generally given to vulnerable groups. The assumption is made that children and elderly people do not form part of the workforce. A further assumption made is that the requirements for pre-employment medical examinations and routine health surveillance serve to manage the "additional concerns" represented by sensitive working groups, such as asthmatics on medication. As such, acceptable workplace exposure levels are not generally determined by the vulnerability of the workers. The exception to this rule, however, is in the case of reprotoxic and teratogenic risks when particular consideration needs to be given to pre, in utero and post-natal exposures but where specific European legislation to manage such risks has only existed since 1992 (Van Leeuwen, 2007).

Tools and methodologies

Hazard assessment
Respondents were asked if they perform specific hazard assessments for children, and, if so, to specify for which hazard endpoints. Five respondents provided total six endpoints: developmental toxicity, carcinogenicity, neurotoxicity, generic alterations, reproductive toxicity and endocrine disruption, in addition, they were asked if they had any guidance or tools on methodologies for hazard assessment, and, if so, to provide the name of the guidance and references containing the methodology. Ten respondents reported that they perform specific hazard assessments for children and gave the titles of existing guidance or methodologies, as well as suggesting journal papers. Note that some of the guidance is not specific to children.

Exposure assessment
Respondents were asked if they perform specific exposure assessments for children and, if so, whether they have developed specific exposure scenarios for children and whether they focus on specific

exposure pathways or media (such as air, water, soil, food or contact with articles) in those exposure scenarios.

Respondents were also asked to provide the names (and a brief description) of any guidance or tools on methodologies. Twenty-five respondents reported that they perform specific exposure assessments for children, and, of these, 22 reported that they use specific exposure scenarios for children. The existing exposure assessment programmes reported a relatively balanced distribution of target pathways (such as air, water, soil, food and contact with articles) in exposure assessments for children: around 13% to 20% of the total respondents focused on each pathway. More specific exposure pathways that were reported included paints, glazed earthenware, (accidental) contact with biocidal products, residential contact with pesticides ("mouthing" – mouth or tongue contact), house dust, noise, use of household products, contact with pets, grass and foliage, contact with treated surfaces (carpets, bedding), incidental oral digestion, and personal care products. Twenty respondents listed guidance documents or methodologies for assessing exposure to children.

Risk characterisation
Respondents were asked if they perform specific risk characterisation for children and, if so, if they had guidance or tools on methodologies for risk characterisation for children. 19 respondents reported that they perform specific risk characterisations for children and 13 indicated that there are guidance documents or tools on methodologies for risk characterisation for children.

Additional information (cohort study and combined exposure)
Respondents were asked if they perform children *cohort studies* and if they assess the risks to children from combined exposure to multiple chemicals. If they responded 'yes' to either question, they were invited to provide the name of any guidance or tools used. Nine programmes perform cohort studies of children and seven have existing guidance or tools on performing child cohort studies. Twelve programmes assess the risks to children from *combined exposure* to multiple chemicals; six have existing guidance or tools on performing risk assessment from combined exposure to multiple chemicals.

Other guidance or tools relevant to risk assessments for children
Part I of the questionnaire concluded by asking if respondents had any other guidance or tools relevant to risk assessment for children which had not yet been mentioned; eight programmes responded. Besides those mentioned above, the US EPA's *Exposure Factors Handbook* (US EPA, 2011) was suggested, as well as the SPIN Exposure Toolbox (Use Index), a tool on the Danish Environmental Protection Agency's SPIN online database (OECD, 2013).

Part II: Need for additional guidance or tools on risk assessment for children
In the second part of the questionnaire, respondents were asked to identify for which areas of children's risk assessment additional guidance or tools are needed. The responses for each area are summarised below.

Definition of terms
A total of 11 responses suggested the need for harmonised definitions for assessing the risks of chemicals to children's health.

Hazard assessment
A total of 17 specific responses were provided inputs on hazard assessment. It should be noted that one response suggested that it is too soon to develop guidance on hazard assessment.

Exposure assessment
A total of 20 responses provided inputs on exposure assessment. Based on these responses, it appears that there is a significant need for tools for exposure assessment. But the *types* of need or tools varied by respondents, including:

- 1) General exposure scenarios for children
- 2) Specific exposure behaviour or situations for children
- 3) Exposure scenarios from specific sources
- *4)* Specific exposure factors, data or models

5.2 RISK ASSESSMENT IN SPECIFIC CONTEXTS

EDCs

Experimental studies with rodents have widely studied the adverse effects of EDCs on the reproductive system. These animal studies, which enable the investigator to measure hormone action at various times during development and thus to accurately interpret the relationship between exposure and all of the effects on the endocrine system, indicate that early prenatal and/or perinatal exposure to EDCs can lead to long-term effects on reproduction and development which can become evident later, even at sexual maturity and/or at adulthood. The identification and characterisation of this 'early exposure—late effect' pattern of EDCs represents a challenge for scientists and risk assessors (Caserta, 2008). Additionally, endocrine-disrupting compounds can have varying effects throughout development because of variations in tissue hormone receptor isoforms and concentrations at different developmental stages (Crain et al., 2008).

A. *Improved testing for EDCs*: Validated screening and testing systems have been developed by a number of governments, and it requires considerable time and effort to ensure that these systems function properly. These systems include both in vitro and in vivo endpoints and various species, including fish, amphibians and mammals. New approaches are also being explored whereby large batteries of high-throughput in vitro tests are being investigated for their ability to predict toxicity, the results of which may be used in hazard identification and potentially risk assessment. These new approaches are important as one considers the number of chemicals for which there is no information, and these high-throughput assays may provide important, albeit incomplete, information. An additional challenge to moving forward is that EDC research over the past decade has revealed the complex interactions of some chemicals with endocrine systems, which may escape detection in current validated test systems. Finally, it will be important to develop weight-of-evidence approaches that allow effective consideration of research from all levels—from in vitro mechanistic data to human epidemiological data.

A. *Methods for evaluating evidence*: There is currently no widely agreed system for evaluating the strength of evidence of associations between exposures to chemicals (including EDCs) and adverse health outcomes. A transparent methodology is also missing. The need for developing better approaches for evaluating the strength of evidence, together with improved methods of risk assessment, is widely recognized. Methods for synthesizing the science into evidence-based decisions have been developed and validated in clinical arenas. However, due to differences between environmental and clinical health sciences, the evidence base and decision context of these methods are not applicable to exposures to environmental contaminants, including EDCs. To meet this challenge, it will be necessary to exploit new methodological approaches. It is essential to evaluate associations between EDC exposures and health outcomes by further developing methods for which proof of concept is currently under development.

Nanomaterials

The EU's risk assessment system consists of various independent bodies, which give scientific advice to decision makers. In addition to three Scientific Committees managed by DG SANTE (the Scientific Committee on Consumer Products (SCCP), the Scientific Committee on Health and Environmental

Risks (SCHER) and the Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR)), the EU Risk Assessment system also includes the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), The European Chemicals Agency (ECHA), the European Centre for Disease Control and Prevention (ECDC), the European Environment Agency (EEA) and the Scientific Committee on Occupational Exposure Limits (SCOEL), managed by DG Employment.

Currently, the safety of nanomaterials is assessed through the standard procedure applicable for chemicals which is specified in the EU Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH Regulation). In order to understand whether the existing risk assessment measures can properly tackle the health risks stemming from nanomaterials, in 2007, the SCENIHR issued an opinion on "*the appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials*". The opinion specifies that even though nanomaterials are not per se dangerous, there is still scientific uncertainty about the safety of nanomaterials in many aspects. Therefore, given their special properties, nanomaterials cannot be assessed through standard procedures applicable to conventional chemicals. Instead, their safety assessment must be carried out on a case-by-case basis.

Based on scientific research, there is a general consensus according to which standard procedure of risk assessment should be modified in light of the special features of nanomaterials (Rocks, S., et al., 2008). In this regard, the adaptation of the REACH and its detailed guidance is an ongoing process (ECHA, 2012).

The main limitations of current procedures for the RA of nanomaterials can be summarised as it follows:

- The identification and definition of the term "nanomaterial" poses a challenge for framing a "substance class" with a high diversity (Commission Recommendation, 2011)
- Equipment and methods for characterization and detection of nanomaterials are often not appropriate and need further optimization. Furthermore, there is still no agreement about a concept for the dose or concentration of nanomaterials in test systems [Rocks, S., 2008].
- High quality exposure data is also largely missing. Many exposure related studies are published on occupational scenarios while much fewer studies are published on environmental and consumer exposure as well as about both acute and chronic exposures (Aschberger, K, 2011).
- There is still a need of standardized toxicological methods as well as appropriate controls.
- Studies that showed no significant (hazardous) effects are usually not published, even though they are crucial to relive nanomaterials from the suspicion of hazard (Krug, H. F., 2011).
- There is an ongoing debate on the significance of high-dose in vitro or in vivo studies conducted so far and whether or not the used methods are suitable for hazard characterization (Oberdörster, G., 2010).

It is also worth mentioning that, apart from the described knowledge gaps and methodological uncertainties, the most important challenge is the fact that nanomaterials share no common characteristics besides the nano-scale size. For this reason, the nanotoxicology community believes that it is appropriate to assess the safety of nanomaterials by adopting a "case-by-case" approach. (Krug, H. F., 2011).

Numerous studies indicate that, due to their special properties, nanoparticles are able to enter the human body through several routes (section 1.4.4.), and, consequently, they can damage human health in a range of different ways. However, there is currently scientific uncertainty about the exact health risks associated with exposure to nanomaterials (section 1.4.6.).

For this reason, nanomaterials require a risk assessment. In the EU, the safety of nanomaterials is

assessed through the standard procedure applicable for chemicals. However, there is a general consensus in the scientific literature according to which standard procedure of risk assessment should be modified in light of the special features of nanomaterials. Therefore, given their special properties, the safety assessment of nanomaterials must be carried out on a case-by-case basis (sections 1.4.6. and 1.4.7.).

The effects of nanomaterials on specific vulnerable groups have not been studied extensively (see section 1.4.8). Nonetheless, certain groups that may be particularly vulnerable to the effects of nanomaterials have already been identified. Among these groups are:

- people with pre-existing diseases (such as asthma, diabetes, among others), who may be more prone to the toxic effects of nanoparticles;
- children, as nanomaterials may interact with them in ways that differ from adults;
- workers, especially those working in nanotechnology related industries, who may be exposed at (much) higher levels than the general public and on a more consistent basis (section 1.4.5.).

Advanced analysis of the physical and chemical characteristics of nanoparticles will continue to be essential in revealing the relationship between their size, composition, crystallinity, and morphology and their electromagnetic response properties, reactivity, aggregation, and kinetics. Up until now, the lack of scientific knowledge on nanomaterials prevented us to understand whether standard health and safety measures that have been put in place are effective or not.

Importantly, assumptions about how chemicals behave once they have been used in final products, do not necessarily apply to nanomaterials. In this respect, it is important to note that fundamental properties of nanoparticles, such as magnetism in nanoparticles made of materials that are non-magnetic in bulk form, are still being discovered (Buzea, C., et al 2007). Therefore, more research is needed before we can fully understand the health risks that nanomaterials – nowadays used in hundreds of products world-wide - may pose to human health. As one the most recent study outlined: "*until we understand what realistic environmental concentrations [of nanomaterials] are likely to be, we don't really know what the impacts are*" (L. Garner, K., 2015).

Given the above, the following gaps can be identified:

- An EU specific Regulation establishing a common procedure to assess the safety of nanomaterials is deemed necessary;
- since fundamental properties of nanoparticles are still being discovered, further studies on kinetics and biochemical interactions of nanoparticles within organisms are needed;
- new risk assessments procedures must be adopted as nanomaterials behave different than standard chemicals;
- mandatory safety testing of nanomaterials must be adopted in order to assess their risk prior to their inclusion in commercial products;
- there is a need for a new discipline - nanotoxicology - that would evaluate the health threats posed by nanoparticles, and would enable safe development of the emerging nanotechnology industry;
- As the use of nanomaterials become more widespread, directed and focused studies seem necessary to determine adverse health consequences on specific vulnerable groups of the population, such as children, elderly, workers, and those with pre-existing disease.

Agricultural pesticides and biocides

Existing policies and legislation on pesticides were first introduced at EU level in 1979 and have evolved considerably over the years, culminating in the adoption of Directive 91/414/EEC concerning the placing of plant protection products on the market, followed by Directive 98/8/EC on the placing of biocidal products on the market. Currently, the Directive 91/414/EEC has been replaced by the Regulation (EC) No 1107/2009 which sets out sets out the requirements, procedure and timeframes for authorisation of Plant Protection Products. The Regulation requires pesticide not to have unacceptable

effects on plants, or damaging effects on human and animal health. In order to reach this scope, all pesticides need to be evaluated and authorised before they can be placed on the market.

Active substances are approved by the European Commission through implementing acts, following a risk assessment carried out by the European Food Safety Authority (EFSA) (section n. 5.4). A dual system is in place, under which the EFSA evaluates active substances used in plant protection products and Member States evaluate and authorise the products at national level. The EU pesticides database list the approved active substances, the non-approved ones, as well as the substances for which approval is pending.

Moreover, all matters related to legal limits for pesticide residues in food and feed are covered by Regulation (EC) No 396/2005. This regulation also contains provisions on official controls of pesticides residues in food of plant and animal origin that may arise from their use in plant protection.

Furthermore, the Directive 2009/128/EC establishes a framework for the sustainable use of pesticides. It aims to reduce the risks and impacts of pesticide use on human health and environment and promote the use of integrated pest management and of alternative approaches, such as non-chemical ones. Furthermore, Members States must develop national action plans and communicate them to the European Commission. Action plans must include quantitative objectives, measures and timetables, as well as indicators to monitor the use of dangerous plant protection products and targets for the reduction of their use (see more in detail section 5.3).

The risk assessment in the EU is performed by the EFSA. Its role is giving independent scientific advice to risk managers based on risk assessments. The European Commission and Member States take risk management decisions on regulatory issues, including approval of active substances and setting of legal limits for pesticide residues in food and feed (maximum residue levels, or MRLs).

Before an active substance can be used within a plant protection product in the EU, it must be approved by the European Commission. Active substances undergo an intensive evaluation process before a decision can be made on approval.

EFSA's Pesticides Unit is responsible for the EU peer review of risk assessments of active substances used in plant protection products, in close cooperation with EU Member States. The risk assessment of active substances evaluates whether, when used correctly, these substances are likely to have any direct or indirect harmful effects on human or animal health – for example, through drinking water, food or feed – or on groundwater quality. In addition, the environmental risk assessment aims to evaluate the potential impact on non-target organisms.

The Pesticides Unit also gives scientific advice to the European Commission on possible risks related to the presence of pesticide residues in food treated with plant protection products and makes proposals regarding the setting of MRLs. In addition, the Unit is responsible for preparing the Annual Report on Pesticide Residues in the EU. Furthermore, the Pesticides Unit provides administrative and scientific support to the Panel on Plant Protection Products and their Residues Panel.

EFSA's Panel on Plant Protection Products and their Residues (PPR) gives scientific advice on issues that cannot be resolved within the peer review of active substances, MRL applications/MRL reviews or when guidance is needed on more generic issues, commonly in the fields of toxicology, ecotoxicology, fate and behaviour and the development of risk assessment practice.

The PPR Panel and the Pesticides Unit have the task of developing and revising scientific methodologies, including guidance documents, for pesticides risk assessment. In this context, EFSA regularly outsources tasks to external organisations to assist with gathering scientific data and information or developing modelling tools. Stakeholder views on new guidance and methodologies are collected through public consultations. The guidance documents provide advice to applicants and

Member States on how to conduct a risk assessment for a particular area in the context of the peer review of active substances or national authorisations of plant protection products.

5.2.1 Risk assessment in legislation

REACH: With regard to Annex IX (standard information requirements for substances manufactured or imported in quantities of 100 tonnes or more), its point 8.7 – reproductive toxicity - specifies that if a substance is known to have an adverse effect on fertility, meeting the criteria for classification as toxic for reproduction category 1A or 1B: may damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for developmental toxicity must be considered. Moreover, if a substance is known to cause developmental toxicity, meeting the criteria for classification as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.

PPPR: With regard to the Annexes, point 2.A of Annex IV (comparative risk assessment) specifies that significant difference in risk shall be identified on a case-by-case basis by the competent authorities. The properties of the active substance and plant protection product, and the possibility of exposure of different population subgroups (professional or non-professional users, bystanders, workers, residents, specific vulnerable groups or consumers) directly or indirectly through food, feed, drinking water or the environment shall be taken into account.

BPR: As far as the Annexes are concerned, point 8.10 of Annex II – title I (chemical substances) specifies that if a substance is known to cause developmental toxicity, meeting the criteria for classification as Reproductive toxicity Cat 1A or 1B: may damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, point 8.10 of the annex also underlines that testing for effects on fertility must be considered.

5.3 BIOMONITORING

Definition

Human Biomonitoring (HBM) is a scientific technique that allows us to assess whether and to what extent these environmental substances have entered our bodies and how exposure may be changing over time. By measuring the concentration of natural and synthetic compounds in body fluids (blood, urine, and breast milk) or tissues (hair, nails, fat, and bone), biomonitoring can provide valuable information on environmental exposures and, in some cases, help, identifying potential health risks (COPHES)

HBM is a scientifically-developed approach for assessing human exposures to natural and synthetic compounds from the environment, occupation, and lifestyle. It relies on the analyses of human tissues and fluids and provides the only direct method of determining whether people have been exposed to particular substances, the magnitudes of such exposures, and how the exposures may change over time. HBM is a growing discipline used for exposure and risk assessment in environmental and occupational health and has become a more useful tool in recent years as the result of advancements in the capability to measure more minute amounts of chemicals in the human body. HBM focuses on the use of biomarkers as measurable indicators of changes or events in biological systems. Biomarkers are measurements of the concentrationsof chemical substances, their metabolites, or reaction products in human tissues or specimens such as blood, urine, hair, adipose tissue, teeth, saliva, breast milk, and semen. The main advantage of using biomarkers is that they are intrinsic in their nature, representing an integrative measurement of exposure to a given agent (i.e., the internal dose), that results from

complex pathways of human exposure and also incorporates toxicokinetic information and individual characteristics such as a genetically-based susceptibility. Through the use of biomarkers, it is not only possible to monitor exposure but also to detect early health effects. For population studies, biomarkers should be sensitive, specific, biologically relevant, feasible, practical, and inexpensive (Choi et al. 2015

Human biomonitoring (HBM), defined as systematic standardized measurement of concentration of a substance or its metabolites in human tissues (such as blood, urine, milk) has become an important tool in evaluating exposure to chemicals in the general population and specific subgroups (Angerer et al., 2007). The measured concentrations are commonly referred to as "body burdens" of these substances, and biomarkers are indicators of the chemical burden in the human body.

HBM have been applied in exposure assessment to evaluate human exposures to chemical contaminants acquired through the environment, including food consumption. Over the years, many emerging chemicals of concern, such as brominated flame retardants (BFRs), perfluorinated compounds (PFCs), phthalates and phenols [including bisphenol A (BPA)] have been identified through HBM, measuring their increasing presence in populations (Casas et al., 2013; Llop et al., 2011). Modern analytical methods make it possible to measure a wide range of chemicals in the human body even at very low levels. HBM can thus be used to monitor combined or mixed exposure, an issue of increasing concern in risk assessment (Silins & Hogberg, 2011).

HBM can identify (i) new chemical exposures, trends and changes in exposure; (ii) establish distribution of exposure among the general population; and (iii) identify vulnerable groups and populations with higher exposures. It is generally recognised that HBM data have the advantage in providing information on: (i) the internal exposure of humans to chemicals or their metabolites; (ii) exposure from all sources including food; (iii) the whole body burden of a chemical taken up by ingestion and other routes. However, it should be noted that HBM by itself does not provide information on the source(s) or route(s) of exposure, and environmental exposure data are rarely collected at the same time as HBM. Additional research studies to identify the relative contribution of the numerous sources and routes by which humans are exposed to environmental chemicals are often needed.

HBM can be used also to estimate a biological effect if a relationship has been established between the biological measurement and the health outcome. In this case, the associated effect to chemical exposure is quantified by measuring reaction products in human tissues or specimens. For a few chemicals only, such as lead, human data from occupational and other clinical studies allow the identification of body burdens for a chemical that may result in an adverse effect. For most chemicals, however, there are no adequate human data to be certain about health effects, particularly at very low chemical concentrations. In addition, most environmental exposures involve multiple substances, and attributing cause to a single hazard can often be difficult (Paustenbach & Galbraith, 2006). Thus, HBM studies can only provide information on correlations between health effects and internal exposure, but not a causal correlation (Choi et al, 2015).

HBM is a scientific technique for assessing human exposures to natural and synthetic compounds in the environment. It is based on analysis of human tissues and fluids and provides the only direct method of determining if people have been exposed to particular substances, what the magnitudes of their exposures are, and how these may be changing over time.

The National Research Council of the United States of America in 2002 defined HBM "as a method for assessing human exposure to chemicals by measuring the chemicals or their metabolites in human tissues or specimens such as blood or urine" (CDC, 2005).

According to (Kamrin, 2004), HBM is a growing discipline used for exposure and risk assessment in environmental and occupational health, and has become a more useful tool in recent years as the result

of advancements in the capability to measure more and more minute amounts of chemicals in the human body.

HBM relies on the use of biomarkers, measurable indicators of changes, or events in biological systems. Biomarkers are measurement of the concentrations of chemical substances, their metabolites, or reaction products in human tissues or specimens, such as blood, urine, hair, adipose tissue, teeth, saliva, breast milk, and sperm.

WHO defined biomarkers in 1993 in relation to risk assessment, where the term "biomarker" is used in a broad sense to include almost any measurement reflecting an interaction between a biological system and an environmental agent, which may be chemical, physical or biological. Three classes of biomarkers are identified:

- **Biomarker of exposure:** an exogenous substance or its metabolite or the product of an interaction between a xenobiotic agent and some target molecule or cell that is measured in a compartment within an organism;
- **Biomarker of effect:** a measurable biochemical, physiological, behavioural or other alteration within an organism that, depending upon the magnitude, can be recognized as associated with an established or possible health impairment or disease;
- **Biomarker of susceptibility** - an indicator of an inherent or acquired ability of an organism to respond to the challenge of exposure to a specific xenobiotic substance.

The main advantage of using biomarkers is intrinsic in their nature, representing an integrative measurement of exposure to a given agent (i.e., the internal dose), that results from complex pathways of human exposure and also incorporates toxicokinetic information and individual characteristics such as a genetically based susceptibility (Choi et al 2015).

Strengths and limitations
HBM is the only available tool that integrates exposures from all sources and provides data to epidemiology enabling studies of strengths of associations, dose response relationships. Biomonitoring data reflect the internal dose at a point in time.
However, HBM data does not differentiate the exposure by source, and HBM alone cannot provide information about the source of exposure or how long a chemical has been in the body. For translation of HBM data into daily exposure estimates there is need of a detailed understanding of the potential analytical/methodological pitfalls and of the toxicokinetics of the individual chemical (Choi et al 2015).

Human biomonitoring data can be used by governments, researchers and health practitioners in a wide variety of ways:

- To establish baseline levels of chemicals in the Canadian population.
- To compare exposure to environmental chemicals among different populations.
- To help identify priority chemicals for which further action should be taken to protect the public's health.
- To assess the effectiveness of health and environmental risk management actions intended to reduce exposure to specific chemicals and the associated health risks.
- To support future research on potential links between exposure to certain chemicals and specific health effects.
- To contribute to international monitoring programs.

Human biomonitoring is an important tool; however, there are certain limitations in its use. Although technological advances in laboratory methods have improved our ability to measure chemicals and generate biomonitoring data, our ability to interpret biomonitoring results in relation to the risks the levels pose to health is limited. More work needs to be done to assess the sources of exposure and to

evaluate the toxicological and health impacts of exposure to chemicals. For many chemicals, further research is needed to understand what health effects may be related to exposure at different levels (Health Canada).

One of the strengths of HBM is that it can give very precise information on the total internal exposure of an individual at a given time, as it adds together exposure from multiple sources and routes (e.g. air, water, food). Yet, the risks these exposures may pose to human health, in which combination and at what levels, remain difficult to evaluate. A combination other methods is needed for this.

HBM is much more than undertaking many chemical analyses. As well as quantitative chemical data, health professionals and policy-makers need to know where the chemicals come from, how they enter our bodies and what the possible health effects might be. For this, depending on the aims of the particular study, sample collection from volunteers is accompanied by carefully designed interviews and by questionnaires that investigate a range of factors that can reveal sources and pathways for exposure, such as: lifestyle (e.g. smoking, use of personal care products, living surroundings) and diet (food preferences) and other personal characteristics such as gender, age and medical history.

For a given chemical, HBM surveys can highlight spatial trends, help uncover cultural and lifestyle contributing factors, and indicate specific at-risk groups, such as given age cohorts. Surveys can also be repeated to reveal which chemical levels are increasing or decreasing with time and thus provide a focus for policy driven action or for policy evaluation.

The vital importance of HBM lies in its preventative nature and its ability to track the results of policy initiatives (COPHES).

Use in risk assessment
HBM is the only available tool that integrates exposures from all sources and provides data to epidemiology enabling studies of strengths of associations, dose response relationships. Biomonitoring data reflect the internal dose at a point in time.

However, HBM data does not differentiate the exposure by source, and HBM alone cannot provide information about the source of exposure or how long a chemical has been in the body. For translation of HBM data into daily exposure estimates there is need of a detailed understanding of the potential analytical/methodological pitfalls and of the toxicokinetics of the individual chemical.

As the human body burden and the development of potential health effects depend on many factors, such as fluid/tissue type, time of collection, containers used, preservatives and other additives, storage temperature, transport means and length of transit time, may affect the quality and stability of the samples and the measurement of biomarkers (Manno et al., 2010b), and the linking to specific sources can be very difficult, results from HBM studies needs proper and careful interpretation and clarification by experts in order to serve as a policy tool. Finding a chemical does not imply that it will cause a disease to develop.

In spite of all limitations, it is worthwhile to aim for the ultimate summit of HBM because it is the only way to identify and quantify human exposure and risk, to elucidate the mechanism of toxic effects and to ultimately decide if measures have to be taken to reduce exposure. Risk assessment and risk management without HBM could lead to wrong risk estimates and cause inadequate measures. In some countries like in the USA and in Germany, thousands of inhabitants are regularly investigated with respect to their internal exposure to a broad range of environmentally occurring substances. For the evaluation of HBM results, the German HBM Commission elaborates the use of reference- and HBM-values (Angerer et al., 2007).

The risk assessment of chemical contaminants in food is based on the integration of two aspects: knowledge about the human exposure to these substances via food and other routes, and their potential

to cause adverse health effects.

The safety of chemicals is assessed following the four steps of risk assessment, namely hazard identification (genotoxic, carcinogen, endocrine disruptive, etc.), hazard characterisation (dose-response relationship, mechanisms/mode of action, kinetics, etc.), exposure assessment (external, internal), and risk characterisation. Important considerations in risk assessment include windows of susceptibility. Human exposure is a key element in risk assessment (Alexander et al., 2012). In conventional exposure assessment to contaminants from food, occurrence levels in food are linked with consumption patterns across European populations (available in a database due to national surveys etc.). Whenever possible, the CONTAM Panel sets an exposure level where there is no appreciable health risk. This is known as a health-based guidance value (HBGV) such as an ADI or TDI or Tolerable Weekly Intake (TWI). If human exposure to the substance from food and other sources is below the HBGV, the CONTAM Panel usually concludes that such exposure does not pose an appreciable risk to human health. However, the HBGV approach is not suitable for genotoxic substances. For unintentionally-occurring substances, no additional toxicological information is provided by the manufacturer, and databases are often incomplete and limited (e.g. for certain marine biotoxins and many mycotoxins). For substances that cause genotoxicity by a mechanism involving reaction with DNA, the EFSA Scientific Committee proposed the margin of exposure (MOE) approach as a harmonised approach for the risk assessment of substances that are both genotoxic and carcinogenic.

However, the CONTAM Panel seeks to find ways to improve and refine its human and animal risk assessments. They rely on further integration of prospective data, and there is increasing evidence that HBM could play an important role in future exposure assessment. There are still considerable uncertainties to translate findings in selected experimental model systems to an understanding of human toxicology (e.g. various routes of exposure).

According to the risk management paradigm as formulated by the EU, both the dose-response relationship and the exposure data is required to characterise the health risk of a specific chemical hazard to subsequently decide whether the risk is such that management is required. In the standard European Union risk assessment process, the risks for industrial operators, for consumers and for 'man through the environment' are assessed. The last category relates to health risks of the general public potentially caused by exposure from chemical substances in the environment. For a comprehensive risk management, more qualitative and quantitative data related to toxicokinetics, toxicological endpoints, and the strength of evidence are requested.

HBM data is strengthened with the knowledge of the kinetics and toxicological effect levels of a substance of interest. Often information of the toxicokinetics is gained from animal studies, and interspecies extrapolation is necessary. The toxicokinetics together with sufficient toxicological knowledge (e.g. reproductive or carcinogenic effects) complement the HBM data and increases the weight of evidence for risk assessments and risk-based decision making.

Based on but not limited to occupational risk assessment, Manno et al. (2010) identified potential of HBM in the different steps of the classic, general definition of risk assessment by the USA's National Research Council (Choi et al 2015).

Hazard identification

HBM has a role in exposure assessment and for some toxicological studies where the actual in vivo exposure can only be found from biological monitoring. In addition, HBM can provide the observation of an increased individual or group level of a potentially toxic chemical, or its metabolite(s), in blood, urine or other biological samples from exposed populations as compared to those of control individuals. According to the ECHA guidance on Derivation of DNEL/DMEL from Human Data, human data can be used in hazard assessment under the obligation to derive limit or guidance values (DNEL/DMEL) (ECHA, 2010) and as part of the Chemical Safety Assessment. Forward or reversed

dosimetry comparing human and experimental animal concentrations bridge toxicology and human effects (Clewell et al., 2008).

Hazard characterisation
HBM can contribute to estimate either side of the dose-response equation, i.e. it may help to measure the dose (as the biological level of a chemical or its metabolite(s) corresponding to a given level of exposure) or to detect the response (the proportion of individuals showing some early adverse effect at a given level of exposure) or both (Manno et al., 2010b).

Risk characterisation
Risk characterisation combines the information from hazard identification and exposure assessment. Based on but not limited to occupational risk assessment (Manno et al., 2010b), HBM can be used to perform or validate risk assessment when environmental monitoring and health surveillance are unavailable or inadequate due to an intrinsically low sensitivity and/or specificity. HBM also allows assessing specific, otherwise inaccessible, components of risk, such as metabolic polymorphism, enzymatic inhibition or induction of the metabolizing enzymes and other susceptibility factors which may be responsible for a different response to chemicals.
In addition, the results of HBM surveys can be used for risk management. As internal dose (biomarkers of exposure) are determined by lifestyle factors, environment and personal factors, elevated levels in certain subgroups allow to trigger policy interpretation and remediation measures, public information and sensibilisation and the definition of vulnerable subgroups (Choi et al 2015).

Exposure assessment
Whereas the potential of HBM in hazard identification and hazard characterisation is limited, HBM has a critical role in exposure assessment as HBM will provide the ultimate data on actual exposure. HBM has the advantage that it integrates exposures from all sources: environmental exposure, lifestyle exposures and individual susceptibility (see Figure 4). HBM provides the summary impact of environmental pollution, lifestyle factors such as dietary habit, smoking or consumer products use and personal susceptibility determined by gender, age, genetic background, and body composition.

In combination with questionnaire information, HBM data may provide information about sources such as patterns of dietary habits. Higher levels of acrylamide adducts in haemoglobin, for example, have been observed in populations with high intake of fried food (Vikstrom et al., 2012).

It has been emphasised that HBM data is particularly valuable for establishing baseline measures of human exposure, but that the evaluation of potential health risk remains a difficult and uncertain task (Clewell et al., 2008).

Due to the fact that HBM data reflect internal exposure whilst the traditional risk assessment and the resulting estimates of safe exposure are generally based on external exposure, health HBM data need to be interpreted by means of forward or reverse dosimetry. PBPK models provide a useful way of accounting for the various factors controlling overall compound elimination and how variations in the various factors are translated into concentrations of compound/metabolite in blood and tissues (Aylward et al., 2014).

HBM survey data can be interpreted for risk management purposes by means of HBM-related guidance values, which are currently developed only in the USA and in Germany. In Germany, these type of HBM-related guidance values are called HBM values (HBM-I and HBM-II). In the United States, they are called Biomonitoring Equivalents (BE) (Choit et al 2015).

Major advantages of HBM in risk assessment are the analysis of contamination levels and trends, the personalisation of exposure and potential risks (awareness raising effect), and the verification of exposure and risk estimates.

One strength and advantage of HBM in exposure assessment is the fact that it reveals the actual body burden of an individual person independent from the source and route of exposure by summing up and integrating the combined effect and taking into account processes like metabolism, bioaccumulation and excretion. Another advantage is that it is closer to health effects than environmental monitoring, that it getting pollution personal, and having a strong awareness raising and educational effect. Finally, it can show geographical and socio-economic differences in exposure and body burdens.

HBM can support monitoring/surveillance of control the efficiency of political risk reduction measures or substitution of regulated substances, it can provide data for identification of needs & priority setting in policy, and contribute to a decision basis for management measures such as the establishment of limit values. Findings from HBM surveys may also encourage initiation of further investigations and identifications of potential substances of very high concern (SVHC) or chemicals of equivalent concern. The major limitations of HBM in risk assessment include the inability to differentiate by source, the variability of results and the difficulty to trace back past exposure for short-lived substances (Choit et al 2015).

Table 8: Benefits and limitations of human biomonitoring for each step in the process

Step in process	Benefits of HBM	Limitations of HBM
Hazard identification	May contribute from epidemiological studies bridging exposures and adverse effects	BM is not performed in all experimental toxicological studies, thus not enabling comparison to human levels
Hazard characterisation	May contribute from epidemiological studies bridging exposures and adverse effects	If BM is a part of the experimental toxicological studies, the species-specific toxicokinetics have to be taken into account
Exposure assessment Post-Market-Monitoring	HBM provides the ultimate proof of human exposure	Analytical limitation (insufficient sensitivity) may develop false negatives
Risk characterisation	The size and power of the HBM study may specify the human risk if epidemiological data can confirm	The biomarkers may not reflect the risk

Relevance for vulnerable groups

History in occupational risk assessment

In occupational medicine, HBM plays an important role within the measurement of the body burden of toxic substances and their metabolites for more than a century. HBM is also used in particular for detection of exposure and adverse health risk and for assessing the efficiency of preventive measures and for controlling working place limit values set. For certain industries and professions testing is mandatory. HBM as a surveillance tool in occupational medicine is regulated by legislation on health and safety in the workplace. Health surveillance in occupational medicine besides other is performed in the context of Occupational Exposure Limit Values (OELVs) for chemicals in the workplace established on European scale based on scientific recommendations of the Scientific Committee on Occupational Exposure Limit Values (SCOEL).

Relevance for other groups

Possibly higher exposed sub-groups or specifically vulnerable groups of a population with higher susceptibility are of special interest in HBM programmes because they are at higher risk of adverse health effect upon exposure of chemicals. Many HBM programmes stratify the data according to various factors in order to determine the potential risk factors of higher body burden.

HBM programmes, such as France's ESTEBAN or the USA's NHANES, collect participants of all ages; hence, age stratification analyses are often conducted to determine the chemical levels among different age groups. In addition, emerging HBM programmes are starting to focus only on specific populations. For example, the German GerES has performed the last 2 survey cycles focusing on children and adolescents, and the French ELFE cohort study intends to follow up on the children in

France until adulthood. In Norway, South Korea, and Japan, there are also multiple HBM studies determining the exposure of chemicals in pregnant women and following up on the exposure in their newborns. On the European level, programmes such as NewGeneris and PHIME reported HBM data from birth cohorts, and such data has been included in the HELIX program, providing information about fetal exposures from measurements in cord blood. The first harmonised European cross-sectional survey DEMOCOPHES included school children and their mothers and was able to demonstrate age differences in body burdens (Choit et al 2015).

Pregnant women and newborns:
Numerous HBM studies have already shown that the prenatal exposure to chemicals in infants could result in some adverse health effects. For example, it was observed from the French ELFE study that pregnant women have a significant exposure to phthalates, reflecting a potential high exposure in the hospitals (Zeman et al., 2013), and findings from the South Korean MOCEH study suggested that prenatal exposure to phthalates may be inversely associated with the neurodevelopment of infants (Kim et al., 2011b). In the Flanders' FLEHS study, a strong correlation for Pb, As, and Tl was found between levels in cord blood and maternal blood, suggesting that these metals are transported to the fetus from the mother (Baeyens et al., 2014), and it appears that prenatal exposure to metals have adverse effects on newborns. The MOCEH study indicated a negative relationship between maternal Pd and Cd levels during late pregnancy period and neurodevelopment (Kim et al., 2013b). The EU-wide DEMOCOPHES project showed elevated levels of methyl mercury in fish eating subgroups of the investigated populations (i.e. mothers), and the Norwegian MoBa cohort study reported negative association between maternal exposure to mercury (via reported dietary intake during pregnancy) and birth weight (Vejrup et al., 2014). The Japanese Tohoku HBM study also reported a negative relationship between maternal hair mercury level and motor abilities of infants (Suzuki et al., 2010).

Aside from phthalates and metals, the MoBa study also showed that maternal exposure to dioxins, PCBs, or benzo(a)pyrene resulted in decreased birth weight (Duarte-Salles et al., 2013a; Papadopoulou et al., 2013), and the Japanese Hokkaido HBM study observed lower birth weight, higher risk of infections in infants, and reduced motor development due to maternal exposure to PFOS, 2,3,4,7,8-PeCDF, and PCDDs, respectively (Konishi et al., 2009; Miyashita et al., 2011; Nakajima et al., 2006; Washino et al., 2009). Collectively, these studies emphasised the importance to monitor the chemical levels in pregnant women in order to reduce chemical exposure and health risks in newborns

Children:
Among the existing HBM studies, phthalates have shown to be a major concern for children as HBM studies and programmes from Denmark, Germany (GerES), and the USA (NHANES) all showed that children had higher body burden of several phthalate metabolites than adults (Becker et al., 2009; Calafat et al., 2011; Frederiksen et al., 2014). In addition, the GerES found that levels of organochlorine pesticides (such as HCB, HCH, and DDE) in children decreases with increasing age (Kolossa-Gehring et al., 2008), and data analysis from the NHANES survey showed that children aged 6-11 had the highest urinary level of the PAH metabolite 1-hydroxypyrene compared to adolescents and adults (Huang et al., 2006; Li et al., 2008). Other scientific HBM studies also indicated higher levels of PBDEs and fluorocarbons (PFOA/PFDA/PFNA) in children aged 1.5-9 than other subjects aged 9 or older (Lunder et al., 2010; Toms et al., 2009). These studies emphasise the need of HBM in children in order to generate the data appropriate for accurate risk assessment and management regarding children's exposure to chemicals.

Socioeconomic, regional and gender factors
Aside from age, study designs of many HBM programmes often include data collection of multiple factors from participants such as gender, living environment (urban vs. rural), SES, lifestyle habits (e.g. smoking, vegetarians), medical history (e.g. diabetes), etc. These factors have been proven useful for determining additional risk factors of higher body burden of chemicals. Table 21 shows a brief overview of the HBM findings associating different factors with chemical exposure (Choit et al 2015).

Older adults

Among the HBM programmes, it has been observed that several metals appear to accumulate in the elderly population. FLEHS findings showed that the highest levels of total Hg in blood were found in the elderly (aged 50-65) (Croes et al., 2014), and the PROBE study also showed that both blood lead and palladium concentrations increased with age (Alimonti et al., 2011). The Slovenian HBM study found that the blood cadmium, blood lead, and hair mercury levels were the highest among the older women (aged 50-60) compared to children or adults (Tratnik et al., 2013). Aside from metals, urinary levels of phthalates also appeared to be higher among subjects with older age in the South Korean KorSEP study (Lee et al., 2011), and a scientific HBM study from Australia observed the highest level of PFOS in the serum of subjects aged 60 or older (Toms et al., 2009). These findings suggest slower clearance of these chemicals out of the body. Therefore, it is likely that the elderly is at a higher risk of developing adverse effects from exposure to chemicals, making it important to monitor the chemical levels in the elderly within a HBM programme.

Even though national HBM surveys have differences among the study design and approaches, the results generated from these surveys can often be stratified by various factors such as age, sex, and socioeconomic status (SES). Among these factors, age is observed to be one of the key determinants in identifying vulnerable populations upon chemical exposure in HBM programs, particularly children and the older adults.

Phthalates have been observed to be a major concern for children based on HBM findings as both the GerES and NHANES previously showed that children appeared to have higher body burdens of phthalates and PAH metabolites than adults. In addition, GerES IV found that levels of organochlorine pesticides such as hexachlorobenzene (HCB), hexachlorocyclohexane (HCH), and dichlorodiphenyldichloroethylene (DDE) in children decreased with increasing age, and data analysis from the NHANES showed that children aged 6-11 had the highest urinary level of the PAH metabolite 1-hydroxypyrene compared to adolescents and adults. Other scientific HBM studies also indicatedhigher levels of PBDEs and PFCs in children aged 1.5-9 than other subjects aged 9 or older. These findings emphasize the need of HBM in children in order to generate the data appropriate for accurate risk assessment and management regarding children's exposure to chemicals.

From the reviewed HBM programs, it is observed that several metals accumulate in the older adult population. FLEHS findings showed that the highest levels of total Hg in blood were found in older adults (aged 50-65), and the PROBE study also showed that both blood Pb and Pd concentrations increased with age. Aside from metals, urinary levels of phthalates appeared to be higher among subjects with older age in the KorSEP study, and a scientific HBM study from Australia observed the highest level of the PFC perfluorooctane sulfonate (PFOS) in the serum of subjects aged 60 or older. These findings suggest slower clearance of these chemicals out of the body. Therefore, it is likely that the older adults are at a higher risk of developing adverse effects from exposure to chemicals, making it important to monitor the chemical levels in older adults within a HBM program.

Identification of vulnerable groups by way of HBM

Factors other than age such as sex, SES, region of residence, and lifestyle habits such as smoking can also lead to increased health risk from chemical exposure, and HBM data can be used to identify such vulnerable populations. Table 4 shows the overview of vulnerable populations due to other risk factors than age identified from HBM. This table not only provides information on the risk factors identified from individual HBM programs but also information that can serve as a reference for the design of future HBM programs. For example, in addition to increasing age, body burden of lead is higher in males (observed in both Europe and North America), people with low household income, and smokers. Future studies can be designed to investigate the association between these factors and lead exposure (Choit et al 2015).

Examples of existing HBM studies

United States of America: National Health and Nutrition Examination Survey (NHANES)
NHANES is an ongoing cross-sectional program aimed to assess the health and nutritional status of adults and children in the United States. Developed in the early 1960s, NHANES is a major program of the National Center for Health Statistics and a part of the Centers for Disease Control and Prevention (CDC). Since 1999, NHANES has been a continuous yearly program. For recruitment of participants, sampling is performed to represent the American population (non-institutionalized civilians) of all ages. Self-reported information on demographics, socioeconomic status, and health is supplemented with physical examination to collect medical, dental and physiological measurements as well as laboratory tests (e.g., for chemical analyses). Since 2002, NHANES collects dietary intake data with the "What We Eat in America" survey that uses the "Automated Multiple-Pass Method", a 5-step dietary interview involving 24-hr recalls.

As one of the components of NHANES, analysis of chemical exposure in the general American population is performed using blood and urine samples collected from the participants. The chemicals or classes of chemicals analyzed in the recent NHANES include acrylamide and its metabolite glycidamide, dioxins (polychlorinated dibenzo-p-dioxins; PCDDs), furans (polychlorinated dibenzofurans; PCDFs), polychlorinated biphenyls (PCBs), polybrominated diphenyl ethers (PBDEs), pesticides (e.g., carbamates, organophosphorus, pyrethroids) and metabolites, metals (e.g., As, Cd, Co, Cu, Pb, Hg, Se, Tl, W, U, Zn), phenols such as bisphenol A (BPA) and parabens, trihalomethanes, tobacco smoke (e.g., cotinine as a metabolite of nicotine), perchlorate, perfluorinated compounds (PFCs), phthalate metabolites, polycyclic aromatic hydrocarbons(PAHs) metabolites, phytoestrogens and metabolites, and volatile organic compounds (VOCs) and metabolites.

NHANES is considered the most extensive HBM program with much emphasis devoted to the development of sensitive and specific analytical methods and the refinement of all of the tools serving as references for other HBM programs.

Canada: Canada Health Measures Survey (CHMS)
CHMS is an ongoing cross-sectional survey carried out in 2-year cycles including study participants aged 3 to 79 and living in Canada. CHMS was launched in 2007 by Statistics Canada in partnership with Health Canada and the Public Health Agency of Canada, and 4 cycles have already been performed. Information regarding lifestyle habits, medical history, demographics, socioeconomic status, etc. of the recruited participants is collected during home interviews and questionnaires. For food intake data collection, a semi-quantitative food frequency questionnaire (FFQ) is administered, particularly collecting data on the consumption frequency of various food groups (e.g., meat, dairy, vegetables consumed per day, week, month, or year). The participants also report to one of the CHMS collection sites for direct health measures, and blood and urine samples from the participants will be collected for testing health and nutritional markers as well as chemical levels from environmental exposure. Small amounts of blood and urine from consenting participants are also frozen and stored anonymously in a biobank at the National Microbiology Laboratory in Winnipeg for use in future health studies.

As of July 2015, chemical analyses from CHMS cycles 1-3 have been published. In particular, 48 substances including acrylamide and its metabolite glycidamide, environmental phenols such as BPA and triclosan, metals (e.g., As, Cd, Fl, Pb, Hg), cotinine, PAH metabolites, VOCs such as benzene have been analyzed in blood and urine in CHMS cycle 3 (2012-2013), and the results are published in the *Third Report on Human Biomonitoring of Environmental Chemicals in Canada*. Additionally, other classes of chemicals such as PBDEs, PCBs, chlorophenols, PFCs, phthalate metabolites, and pesticides such as carbamate, organochlorines, organophosphates, and pyrethroids had been analyzed in previous CHMS cycles. CHMS aims to achieve the following objectives: (1) establish nationally-representative blood and urine concentrations for environmental chemicals, (2) provide baseline data to track temporal trends, (3) facilitate data comparisons among sub-populations in Canada and with other countries, and (4) provide data to explore relationships between environmental chemicals, other

physical measures, and self-reported information (Doug Haines, personal communication). A strategy has been developed to communicate results to survey participants with the expert opinion of CHMS Laboratory Advisory Committee, the Physician Advisory Committee, l'Institut national de santé publique du Québec, and Health Canada's Research Ethics Board.

Germany: German Environmental Survey (GerES)
GerES is an ongoing nationwide cross-sectional human biomonitoring program that has been periodically conducted in Germany since the mid-1980s. The survey is conducted by the German Federal Environmental Agency (Umweltbundesamt; UBA) in close collaboration with the Robert Koch Institute, who is responsible for the health examination part of the survey. Each survey focuses on specific population of people living in Germany such as residents of East or West Germany and children, and the study populations are recruited from resident registries to represent age, sex, community size, and locations.

There are three key features to the GerES: (1) human biomonitoring, (2) environmental biomonitoring, and (3) standardized interview-based questionnaires. Multiple questionnaires are administered to the study participants during home visits to retrieve information on exposure conditions (e.g., lifestyles/hobbies, housing conditions, quality of the residential environment, exposure-relevant behavior). For dietary data (namely the food selection of the participants), a specialized FFQ is given to collect consumption data of 50 food groups. Blood and urine specimens are taken from the participants, and extended monitoring of the subjects' environment (e.g., analyses of tap water, house dust, and indoor air) is conducted. For the ongoing GerES V (2014-2017), children and adolescents aged 3-17 are the target population, and the following substance classes are measured in urine samples: cotinine, metals (namely As and Hg), mercaptobenzothiazole (MBT), organophosphate metabolites, PAH metabolites, parabens, phthalate metabolites, and pyrrolidones.

These chemicals are selected because of the likelihood of exposure of these chemicals from the environment in children and adolescent. For example, phthalates and their substitutes are measured because of the use as plasticizers in food packaging, toys, etc., and MBT is measured because of its use in the manufacturing of rubber and can be found in toys. The previous cycles of GerES had analyzed other substances in urine, blood, or hair such as several classes of pesticides (e.g., organochlorines and pyrethroids), BPA, chlorophenols, and PCBs. Every participant is informed about the concentrations of the analyzed substances in his/her biological (e.g., blood and urine), drinking water, and indoor air samples. Additionally, an environmental-medical assessment of these data is supplied.

GerES has major impact on the environmental health in Germany with much focus on consumer safety and establishment of reference values. GerES has demonstrated temporal trends (e.g., decline in blood lead levels over time, decline in prohibited phthalates after regulation, rise in alternatives to prohibited substances) and regional differences with lower exposure levels to some industrial chemicals in the former East Germany compared with West Germany. Also, age and sex differences have been found providing data for more targeted concepts of intervention, reduction and prevention. GerES is considered the most extensive HBM program in Europe and served as the basis for the protocols developed and the reference values used for the COPHES/DEMOCOPHES study.

Belgium (Flanders): The Flemish Environment and Health Study (FLEHS)
FLEHS is a cross-sectional survey initiated in 2003 that measures selected pollutants and certain health effects in humans (mainly via the detection of biomarkers) living in Flanders. The FLEHS is implemented by the Flemish Centre of Expertise for Environment and Health and is funded and steered by the Flemish government. Study participants are categorized into groups: mothers and newborns, adolescents (aged 14-15), adults (aged 20-40), and older adults (aged 50-65). They are selected in urban, rural, and industrial areas and only qualify if they have resided for at least 10 years in Flanders. Recruited participants (and parents if the participants were children or adolescents) are asked to fill out extensive questionnaires regarding personal background, lifestyle factors, and food

intake. Blood (including cord and maternal blood from mothers and their newborns), urine, and hair (only from mothers and adolescents) samples are also collected from the participants.

The following substances were analyzed in FLEHS I (2002-2006) and FLEHS II (2007-2009): chlorophenols, cotinine, dioxins, fluorocarbons, furans, the herbicide 2, 4-dichlorophenoxyacetic acid (2, 4-D), metals (e.g., As, Cd, Cu, Pb, Mn, Hg, and Tl), organochlorine pesticides, organophosphate metabolites, PAH metabolites, PBDEs, PCBs, phenols such as BPA, phthalate metabolites, and pyrethroid metabolites. Also, measurements of 8-hydroxydeoxyguanosine (8-OHdG; a biomarker of oxidative DNA damage) and the single cell gel electrophoresis were conducted in FLEHS I/II to determine the amount of DNA damage. The ongoing FLEHS III survey (2012-2015) is further exploring the Flemish exposure levels to improve risk assessment and communication, and reference values will be established. High-throughput measurements such as transcriptomics have been included in the program. The Flemish program has currently engaged sociologists in developing a dissemination and communication strategy targeting the population.

France: The French National Survey on Nutrition and Health (ENNS)
ENNS is an ongoing cross-sectional survey aimed to describe the patterns of food consumption, nutritional status, and physical activity and to measure nutritional and environmental biomarkers in the general population (aged 3-74) in France. The French National Institute for Public Health Surveillance, along with the French National Program on Health and Nutrition, is responsible for carrying out the ENNS study. ENNS comprises 3 parts: (1) data collection (e.g., of socioeconomic and demographic information) of the participants using both face-to-face interview and self-administered questionnaires, (2) a food consumption survey using 24-h dietary recalls, and (3) a clinical examination including urine, blood, and hair samples. A total of 42 substances including chlorophenols, metals (e.g., As, Cd, Co, Pb, Hg, Ni, U), PCBs, and several classes of pesticides (e.g., organochlorines, organophosphates, and pyrethroids) have been measured. The findings from the first survey have generated reference values of exposure to various metals and chemicals in the French adult population. The clinical results are communicated to participants within two months after the examination with a letter to his/her own usual physician if results are abnormal. A comparison of the food consumption with the French nutritional recommendations is conducted and sent to the participants, who also receive information on how to eat well.

Spain: BIOAMBIENT.ES
BIOAMBIENT.ES was the first nationwide cross-sectional study with a stratified cluster sampling designed to cover all geographical areas, sex, and occupational sectors in order to obtain a representative sample of the Spanish workforce. The recruitment of the participants of the cross sectional study took place through the annual occupational medical check-ups in various health facilities. Study persons aged 16 or older were recruited and successfully participated in the study between March 2009 and July 2010. A short self-administered epidemiological questionnaire was given to selected participants to collect basic individual information on socio-demographic data and environmental- and lifestyle-related exposure. A health exam was provided for each participant, who agreed to provide the results for the BIOAMBIENT.ES study, and blood and urine specimens were collected for analyses of pollutants. BIOAMBIENT.ES analyzed the levels of the following substances: PBDEs, cotinine, metals (Cd, Pb, and Hg), organochlorine pesticides, PAH metabolites, and PCBs. This survey was conducted to generate reference values of chemical exposure (namely PCBs, Pb, and Hg) and confirmed high mercury levels attributable to fish intake. An information leaflet including individual levels of the results for each participant as well as general information on each toxicant was provided to the participants.

Italy: Program for Biomonitoring the Italian Population Exposure (PROBE)
PROBE was a cross-sectional population study to determine the exposure to metals of the healthy general population in Italy. It was commissioned and funded by the Italian National Institute of Health (Istituto Superiore di Sanità; ISS) and ran from 2008 to 2010. The recruited participants (aged 18-65) were residents of one of the five urban regions which were selected to establish representative data for

South, Central, and North Italy without medical conditions (e.g., cancer). Questionnaire was given to the participants to collect information regarding participant's general characteristics (i.e., sex, age, height, weight, etc.), medical history, lifestyle, food intake, and environmental exposure, and morning blood samples were collected from the participants who had fasted overnight. A total of 20 metals (i.e., Sb, As, Be, Cd, Cr, Co, Ir, Pb, Mn, Hg, Mo, Ni, Pd, Pt, Rh, Tl, Sn, W, U, and V) were analysed directly in the blood and serum samples. The 95th percentile values from this study were established as the reference values that can be used for comparisons with higher exposure scenarios in Italy. PROBE further analysed the data with the stratification of sub-groups of multiple variables (such as sex, age, place of residence, etc.) to find and launch new environment and health measures to reduce the exposure to environmental metals of the Italian population.

Czech Republic: Human Biomonitoring Project (CZ-HBM)
CZ-HBM was carried out as a limited representative cross-sectional study of the urban/suburban population in the Czech Republic and covered two time periods: (1) 1994-2003 and (2) 2005-2009. It was a part of the nationwide environmental health monitoring system funded by the Czech Ministry of Health. The purpose of CZ-HBM was (1) to document the extent, distribution, and determinants of population exposure to environmental pollutants, (2) to follow up long-term time trends and their possible changes as a result of preventive measures, (3) to establish a database from which to derive the reference values important for the characterization of the exposure of the general population, and (4) to use the available data for health risk assessment and management.

Three population groups were included in the CZ-HBM: adults aged 18-58, children aged 8-10, and breastfeeding primiparas. Information of each participant and biological specimens from the participants such as blood, urine, breast milk, hair, and teeth were collected. For food intake, data was collected via two 24-hour recall processes. Three groups of biomarkers were analysed: (1) selected heavy metals (Cd, Pb, and Hg) and essential elements (Cu, Se, and Zn), (2) indicator PCBs and organochlorine pesticides, and (3) cytogenetic changes in peripheral lymphocytes in blood. The reference values for Cd, Hg, and Pb levels as well as for PCBs and organochlorine pesticides in breast milk samples have been published in scientific journals.

South Korea: Korea National Survey for Environmental Pollutants in the Human Body (KorSEP)
KorSEP was a cross-sectional HBM survey initiated as a part of The Korea National Health and Nutrition Examination Survey (KNHANES) in 2005 and designed to measure the levels of environmental pollutants in the human body across the general population in South Korea and to identify human exposure to toxic substances from the environment. Three cycles had been conducted: KorSEP I (2005), KorSEP II (2007), and KorSEP III (2008). For KorSEP III, the participants comprised non-institutionalized citizens aged 20 or older. The study entailed questionnaire-based interviews (for data collection regarding sociodemographic information, socioeconomic data, family history, indoor and outdoor environments, lifestyle (i.e., exposure to smoking, alcohol and drug consumption, and physical activity), occupational history and dietary information) and sample collection. Blood and urine specimens were collected, and the following substances were measured: BPA, cotinine, metals (As, Cd, Pb, Mn, and Hg), and metabolites of PAHs, phthalates, and pyrethroids. Some findings from the KorSEP III study have been published as scientific articles.

In summary: The participants of the reviewed HBM programs mainly consist of randomly selected and voluntary adults (i.e., aged 18 and over) living in the respective countries. Besides PROBE and KorSEP, children and adolescents (i.e., aged 3-12 and 13-17, respectively) have also participated in the programs. In addition, pregnant women and their newborns were recruited in FLEHS and CZ-HBM.

Harmonisation of HBM methodologies at EU level

In 2004, the Commission launched the Environment and Health Action Plan 2004-20102 which recognises the value of HBM and the relevance and importance of coordinating HBM programmes in

Europe. In some countries, HBM is already used extensively at national and regional level, but the results cannot be easily compared across projects and programmes. Improved comparability would allow for a clearer understanding of exposure of the population to pollutants across Europe and would help identify potential highexposure populations and relations to possible sources, thus supporting the development of better regulations and preventive actions (DEMOCOPHES).

In the feasibility study DEMOCOPHES, 17 European countries tested a common approach for human biomonitoring surveys which was developed by Consortium to Perform Human Biomonitoring on a European Scale (COPHES). They produced data on the distribution of specific biomarkers and related lifestyle data among defined study populations which, for the first time, are comparable on a European scale.

These comparable data are a step towards European reference values. Now that the feasibility of an EU-harmonised approach has been demonstrated, policy-makers can start to envisage a European survey programme using the lessons learned. To ensure a sustainable way forward, Europe needs a structure that will enable suitable coordination and decision-taking.

Teams in Belgium, Cyprus, Czech Republic, Denmark, Germany, Hungary, Ireland, Luxembourg, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom studied exposure to mercury, cadmium, tobacco smoke and some phthalates and possible relations to lifestyle, using biomarkers and questionnaire data. Bisphenol A was added as an additional substance for a group of 6 countries.

The national teams translated the European common protocol, which describes in detail how to implement the study. Without compromising the comparability of the results, small adaptations were allowed to suit cultural differences and sometimes specific national needs. Before starting the study, ethics authorities in each country approved the necessary documents.

Participants in this study were children aged 6-11 years and their mothers aged 45 years and under. Fieldworkers in the participating countries collected hair and urine samples from a total of 3688 volunteers, half from urban areas and half from rural areas. Mothers provided details on their living environment, nutrition, smoking behaviour, and other information that could help to explain the levels of the biomarkers measured in hair and urine (DEMOCOPHES).

6 POLICY MEASURES AND STAKEHOLDER INITIATIVES

6.1 EU POLICY MEASURES

7th Environmental Action Programme

Priority objective 3 of the 7th EAP focuses on safeguarding the Union's citizens from environment-related pressures and risks to health and well-being. Paragraph 45 highlights the issue of indoor air pollution and notes that action is especially needed in areas, such as cities, where people, particularly sensitive or vulnerable groups, and ecosystems, are exposed to high levels of pollutants. Paragraph 50 notes the potential of endocrine disrupting chemicals to cause adverse effects on health, including the development of children. To this effect, efforts need to be stepped up to ensure that, by 2020, all relevant substances of very high concern, including those with EDC properties, are placed on the REAH candidate list. According to para. 54, the 7th EAP shall also ensure that by 2020 the combination effects of chemicals and safety concerns related to endocrine disruptors are effectively addressed in all relevant Union legislation, and risks for the environment and health, in particular in relation to children, associated with the use of hazardous substances, including chemicals in products, are assessed and minimised.

Priority objective 5, to improve the knowledge and evidence base for Union environment policy, contains paragraph 71(3) pointing out that there are still uncertainties surrounding human health and environmental implications of endocrine disruptors. Suggested methods to fill in the knowledge gaps include the establishment of a Union-wide database for nanomaterials and targeted human biomonitoring to provide a more comprehensive view of actual population exposure to pollutants, especially sensitive population groups such as children.

Paragraph 71(4) states that in order to develop a comprehensive approach to minimising exposure to hazardous substances, in particular for vulnerable groups, including children and pregnant women, a chemical exposure and toxicity knowledge base will be established. The same provision also suggests that guidance documentation on test methods and risk assessment will be developed to support decision-making (European Parliament and the Council, Decision No 1386/2013/EU of the 20 November).

Community Strategy for Endocrine Disruptors

In 1999 the Commission adopted the Communication 'Community strategy for endocrine disrupters – A range of substances suspected of interfering with the hormone systems of humans and wildlife. As a short-term action the document indicated that the Commission intends to establish a priority list of substances for further evaluation of their role in endocrine disruption – the so-called "ED priority list". The priority list was meant to be used, inter alia, to identify specific cases of consumer use, for example, the case of potentially more vulnerable groups of consumers such as children, for special consideration from a consumer policy point of view. In such cases, as far as the substances are not covered by the methodology agreed under existing legislation, the Commission would consult the relevant Scientific Committees for independent scientific advice and consider potential restrictions on use through Community legislative instruments. The possibility of using existing instruments, such as Directive 92/59/EEC, for short-term emergency action was also mentioned.

A Communication on the implementation of the Community strategy was adopted in 2001, and a number of Staff Working Documents thereafter – the most recent one dating to August 2011. The 2011 Staff Working Document mentions ongoing large-scale projects in the field of endocrine disruption and food, relevant to vulnerable groups: NEWGENERIS focusing on the role of exposure to genotoxic substances (including endocrine disruptors) in the development of childhood cancer and immune disorders, PHIME focusing on public health impact of long-term, low level mixed element

exposure in susceptible population strata, and the NECTAR cluster (Network for Environment Chemical Toxicants Affecting Reproduction) comprising 4 projects and receiving over €10M from the EU, focusing on the impact of early life exposures to endocrine disrupting substances on foetal testes development and male reproductive disorders in newborns and young adults (DEER), the impact of fetal exposures to mixtures of endocrine disrupting substances on human reproductive health (CONTAMED), and the impact of such substances on female reproductive tissue and consequent effects on conception, maintenance of pregnancy, and hormonal processes that regulate reproduction (REEF).

Environment and health strategy

The European Environment and Health Strategy, adopted in 2003, includes a strong focus on children as a section of the population with particular susceptibility to environmental agents. Covering the first cycle of the European Environment and Health Strategy, the European Environment & Health Action Plan 2004-2010 integrates concerns related to children throughout the plan. The first cycle aims to establish a good understanding of the link between environmental factors and (1) childhood respiratory diseases, asthma, allergies; (2) neurodevelopmental disorders; (3) childhood cancer; (4) endocrine disrupting effects; and it aims to identify and to prevent new health threats caused by environmental factors. It also aims at reinforcing the institutional structure needed to strengthen policy-making and to integrate environment and health into other policy areas (Communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee - A European Environment and Health Strategy, 2003).

The items selected for the first cycle include the following:

1. European Integrated Environment & Health Monitoring and Response system, which includes:

- establishing an EU Bio-monitoring Framework, which aims to assess environmental and health linkages relative to children;
- pilot projects on dioxins, heavy metals and endocrine disrupters (the choice of the specific pollutants has been done on the basis of significant health effects in children)
- developing harmonised environment and health indicators

2. Research on environment and health issues, including:

- Application of research results, arising from activities funded under the EU RTD Framework Programmes and other sources such as progress in genomics research by the Joint Research Centre and the research by the European Science Foundation networks on genetic susceptibility to environmental toxicants and their impacts on human health with particular attention to the interaction between nutritional, environmental and genetic factors in early human development
- Annual research meetings and reports organised by the Commission, and research supported by the Policy Interpretation Network on Children's Health and the Enviroment which operates in the context of the European Health Forum
- Development of methodologies to help to identify exposures and to perform combined exposure analysis of environmental factors connected to particular diseases and risk assessment taking into account individual susceptibilities and genetic predisposition
- Strengthening the research base for the economic valuation of health impact of policies, measures and technologies, with a particular focus on environment and children's health

3. Reducing exposure, including:

- Improvement of air quality (indoors and outdoors), linked to the evidence showing that exposure to environmental smoke causes increased risks of several illnesses in children and reductions in foetal growth
- Adoption of a strategies and measures on heavy metals
- Studying possible health effects of exposure to electro-magnetic fields

- Adoption of a thematic strategy on the urban environment, including biomonitoring of children in an urban environment

Project HELIX: Building the early-life exposome

HELIX is a collaborative project funded through the European Commission Seventh Framework Programme. It is intended to exploit novel tools and methods for characterisation of early-life exposure to environmental hazards. The 'exposome' concept was coined to encompass the totality of human environmental exposures from conception onwards, complementing the genome. The objectives of Project HELIX include measuring a range of chemical and physical environmental hazards in food, consumer products, water, air, noise and the built environment, pre- and postnatal early-life periods, defining multiple exposure patterns and individual exposure variability, quantification of uncertainty in exposure estimates etc. Six prospective birth cohort studies are contributing to HELIX as "the only realistic and feasible way to obtain the comprehensive, longitudinal, human data needed to build this early-life exposome." The project is intended to lead to major improvements in health risk and impact assessments and thus to improved prevention strategies for vulnerable populations.

DEMOCOPHES

DEMOCOPHES is the first European-level human biomonitoring pilot study, co-funded by the European Commission LIFE+ programme and partners from 21 countries. During this project 17 European countries tested a common approach for human biomonitoring surveys, producing comparable data on the distribution of specific biomarkers and related lifestyle data among defined study populations. Participants in the study were children aged 6-11 years and their mothers aged 45 years or under. Hair and urine samples were collected from a total of 3688 volunteers, half from urban areas and half from rural areas. Additional details on the living environment, nutrition, smoking behaviour and other information were collected from the mothers by questionnaires.

FACET (Flavours, additives and food contact material exposure task)

The research project FACET, originally designed to create a food chemical exposure surveillance system, is intended to constitute a tool for post market monitoring. The concept for the project originated in an attempt to harmonise methods and to provide a scientific standardised approach for food chemical exposure assessment in Europe – an area where efforts tended to be orientated towards specific groups of chemicals in isolation. The FACET project draws on the scientific expertise in the three areas of food additives, flavourings and food contact materials together with expertise in food intake, exposure assessment methodologies and software development. A number of the food categories chosen for the study have relevance to children's health: e.g baby foods and fennel tea. Limitations in the amount of available data in certain countries were observed during the project, such as the lack of food consumption data on children under 5 years, younger adults between 18-25 years and older adults over 65 years.

Voluntary agreement between the European Commission and the Toy Industries of Europe

Under the Voluntary agreement between the European Commission and the Toy Industries of Europe, TIE agrees to engage its members in a programme of work including educational, enforcement and expertise activities.

- Voluntary agreement between the European Commission and Eurocommerce, the European Retail Round Table, Toy Traders of Europe and the European Promotional Products Association

The participants to the Voluntary agreement between the European Commission and Eurocommerce, the European Retail Round Table, Toy Traders of Europe and the European Promotional Products Association agree to engage their members in a number of listed activities, mostly related to spreading knowledge and best practice as well as supporting and collaborating on the work to ensure compliance with national and European safety legislation.

6.2 INTERNATIONAL LEVEL

Global Plan of Action for Children's Health and the Environment (2010-2015)

The Third WHO International Conference on Children's Health and the Environment in Busan, Republic of Korea (June 2009), resulted in the Busan Pledge, asking WHO to facilitate the development of a global plan of action to improve children's environmental health and regularly monitor and report on its progress. The Pledge recognised that the activities of the plan should be implemented in close interactive partnerships with all sectors. 5 target areas of work are included in the Global Plan of Action, including: (1) data collection and analysis; (2) collaborative research; (3) advocacy; (4) clinical service delivery; and (5) awareness raising and education. Among the more detailed actions listed in the Plan, those related to chemicals include promotion of human biomonitoring and human tissue measurements in order to enable better measurement of children's exposure to chemicals, as well as urging national and global efforts to clean the air, water and soil of contaminants and to properly manage chemicals in the environment.

Strategic Approach to International Chemicals Management (Comprising the Dubai Declaration on International Chemicals Management, the Overarching Policy Strategy and the Global Plan of Action)

The Strategic Approach to International Chemicals Management (SAICM) was adopted by the International Conference on Chemicals Management (ICCM) in 2006 in Dubai, as a policy framework to foster the chemical safety around the world. The overall objective is the achievement of the sound management of chemicals throughout their life cycle so that, by 2020, chemicals are produced and used in ways that minimise significant adverse impacts on human health and the environment. The 2020 goal was originally adopted by the World Summit on Sustainable Development in 2002. The Dubai Declaration on International Chemicals Management expresses high-level political commitment to SAICM. Paragraph 9 of the Declaration expresses a commitment to the protection of vulnerable groups by way of achieving chemical safety. Paragraph 24 further commits to protect children and the unborn child rom chemical exposures that impair their future lives.

The Overarching Policy Strategy, which sets out the scope, needs, objectives, financial considerations, underlying principles and approaches as well as implementation and review arrangements relating to SAICM, also mentions considerations relevant to vulnerable groups. These relate to risk reduction, and making scientific information available for risk assessment. Finally, the Global Plan of Action serves as a working tool and guidance document to support implementation of SAICM. Activities in the plan are to be implemented, as appropriate and applicable, by stakeholders. The plan clarifies further the Overarching Policy Strategy actions. It is noted, for example, that work under the risk reduction objective would include the development of action plans to address priority concerns in relation to groups with specific vulnerabilities and e.g. the development of new tools and methods for risk assessment related to vulnerable groups. Other relevant work areas include e.g. establishment of exposure monitoring systems, harmonisation of principles and methods for risk assessment, and consideration of potential enhanced exposures and vulnerabilities of children when setting nationally acceptable levels or criteria for chemicals.

FAO International Code of Conduct on the Distribution and Use of Pesticides (some references to children, pregnant women and workers)

The objectives of the Code are to establish voluntary standards of conduct for all public and private entities engaged in or associated with the distribution and use of pesticides, particularly where there is inadequate or no national legislation to regulate pesticides. The measures included in the Code include some that are relevant to vulnerable groups, such as ensuring that advertising of pesticides is not in conflict with any special precautions for children and pregnant women and does not contain any visual representation of potentially dangerous practices, such as mixing or application without sufficient protective clothing, use near food or use by or in the vicinity of children.

Global Alliance to Eliminate Lead Paint (references to children)

Adopted in 2011, the Global Alliance to Eliminate Lead paint is a voluntary partnership established to help achieve international goals to prevent children's exposure to lead paint and to minimise occupational exposures to lead paint. The focus on children is justified by the significant adverse health effects attributed to childhood lead exposure. The broad objective of the Alliance is to promote a phase-out of the manufacture and sale of paints containing lead. The Alliance is guided by an advisory group chaired by the United States of America through the Environmental Protection Agency (US EPA) and consisting of Government representatives from Colombia, Republic of Moldova, Kenya,Thailand, IPEN (International POPs Elimination Network), HEAL (Health and Environmental Alliance), IPPIC (International Paint and Print Ink Council), AkzoNobel (a paint company), United Nations Industrial Development Organization (UNIDO), the World Health Organization (WHO) and the United Nations Environment Programme (UNEP).

6.3 MS AND OTHER COUNTRIES

Danish Chemicals Action Plan 2010-2013

The Danish Chemicals Action Plan for 2010-2013 has as its starting point the goal agreed that the 2002 Johannesburg World Summit on Sustainable Development: to ensure that by the year 2020 there are no goods or products on the market which have significant adverse effects on human health and the environment. The plan consists of two parts: general initiatives, and challenges relating to specific target groups or specific substances and groups of substances. Vulnerable groups are explicitly considered in the context of a number of the listed initiatives. For example, continued efforts in the consumer field are foreseen to include more studies on consumer products, including product groups such as toys, cosmetics, hobby products and textiles, as well as a focus on the overall exposure of population groups such as children. The plan also mentions targeted information campaigns for particularly vulnerable or at-risk groups as well as institutions and parents. In addition, it includes a specific focus to combat endocrine disruptors and combination effects by way of knowledge acquisition and sharing as well as a voluntary phase-out of EDCs in medical equipment.

Swedish Action Plan for a Toxic-Free Everyday Environment 2015-2020

The previous Swedish Action Plan for a Non-toxic Everyday Environment (2011-2014) was focused on safeguarding the reproduction of human beings and child health, and this remains the focus for the current plan (2015-2020). The national-level measures in the plan include, for example, information campaigns on sustainable consumption targeted at pre-school and school pupils. The impact of chemicals on children and young people is listed as one of the main challenges, and the Swedish Chemicals Agency considers a national action plan for endocrine disrupters and a national action plan for allergenic substances to be an important part of the action plan for 2015-2020. The plan also foresees activities to influence chemicals policy at the EU and international level.

French strategy on EDCs (mentions vulnerable groups)

The French strategy on endocrine disruptors explicitly takes as its focus the prevention of health risks

and exposure of vulnerable populations, pregnant women and young children. The strategy makes reference to several research projects and the goal of increasing expertise and the amplification of measures evaluation the dangers and risks of EDCs through a programme of expertise entrusted to Anses and ANSM. Based on the conclusions, EDCs are stated to be subject to appropriate regulatory measures prioritised at the EU level and aiming to reduce exposure. France strongly promotes the adaptation of EU regulations to the specificities of EDCs. The strategy also envisages educational and information-sharing activities.

UK Children's Environment and Health Action Plan (CEHAP)

Adopted in 2010, the UK Children's Environment and Health Action Plan aims to identify a set of indicators that appropriately describes the burden and distribution of hazards and risks of childhood disease and injury due to environmental factors at a sub-national level. One of the indicators is the potential exposure to chemical incidents, defined as "an acute event in which there is, or could be, exposure of the public to chemical substances which cause, or have the potential to cause ill health". It is noted that the impact of such exposure will likely be acute and short-term rather than chronic. The numerator for the indicator is the number of uncontained chemical incidents occurring within the West Midlands between January and December 2007. The source of the information is the Chemical Incident Surveillance System hosted and managed by the CRCE of the HPA. Another indicator is the exposure to air pollutants, measured as the annual mean levels of nitrogen oxide (NO_2) and particles (PM_{10}) at background locations. It is noted that children living in the more urban/industrial areas experience poorer air quality, and that ambient air pollution is associated with a range of health impacts in children.

6.4 POLICY MEASURES IN SPECIFIC AREAS

Nanomaterials

The debate on nanotechnologies and nanosciences was first brought to the EU political level in 2004, when the European Commission published the Communication 'Towards a European Strategy for Nanotechnology' (European Commission, 2004). The integrated approach proposed in the Communication was further developed through the adoption of the 2005 Action Plan: 'Nanosciences and nanotechnologies: An action plan for Europe 2005-2009" (European Commission, 2005). In this framework, the Commission also adopted a code of conduct for responsible nanosciences and nanotechnologies research (European Commission, 2008), and implemented two regulatory reviews of nanomaterials, in 2008 and 2012 respectively. The objective of the regulatory reviews was to assess the legal coverage of nanomaterials within EU environmental legislation and to identify legislative and implementation gaps.

As part of the second regulatory review on nanomaterials, in 2013, the Commission launched an impact assessment to identify and develop the most adequate means to increase transparency and ensure regulatory oversight on nanomaterials (Commission, 2012). It was initiated in response to concerns raised about potential health and environmental risks of nanomaterials and possible lack of information on nanomaterials on the market. Over the course of the impact assessment exercise, a number of policy options were defined and assessed, such as a single nanoregistry at EU level, a nanomaterials observatory, and a recommendation on best practices for national registries.

Moreover, in 2012, the Commission adopted the Communication on the Second Regulatory Review on Nanomaterials (Commission, 2012). The Communication describes the Commission's plans to improve EU law and its application to ensure the safe use of nanomaterials. The Communication was accompanied by a Staff Working Paper on nanomaterial types and uses (Commission, 2012), which gives a detailed overview of available information on nanomaterials on the market, including their benefits and risks. As part of the impact assessment process, the Commission also launched a public

consultation between 13 May and 5 August 2014 in order to obtain stakeholder views on the available information on nanomaterials on the market, and, consequently, to elaborate policy options on the matter.

Despite the various developments at EU level, to date, no nanotechnology-specific regulation has been developed and implemented in the European Union. Today, nanomaterials are regulated only through specific measures spread in different pieces of EU legislation (e.g. CLP Regulation, Novel Food Regulation, Food Contact Materials Regulation, etc.). In particular, the safety of nanomaterials is assessed through the standard procedure applicable for chemicals that are specified in the EU Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) (see section 1.4.6).

Pesticides

Pesticides have been regulated in most Member States and in the EU since 1979. Yet, despite the solid regulatory framework aiming at limiting the health risks linked to their use, unwanted amounts of certain pesticides exceeding regulatory limits were still found in agricultural produce.

The European Parliament and the Council, recognising that the negative effects of pesticides on human health and the environment should have been further reduced, adopted in 2002 the 6th environment action programme (6^{th} EAP). They underlined the need to achieve a more sustainable use of pesticides as well as a significant overall reduction in risks and of the use of pesticides consistent with the necessary crop protection. Therefore, the 6^{th} EAP outlined a two-track approach based on i) a full implementation and revision of the relevant legal framework; ii) the development of a Thematic Strategy on the Sustainable Use of Pesticides (European Parliament and Council, 2002).

The EU regulatory framework has been analised in the section 5.2.2. With regard to the thematic strategy, in its Communication '*Towards a Thematic Strategy on the Sustainable Use of Pesticides'* of July 2002, the Commission launched a wide ranging consultation exercise (Commission, 2002). The Communication included extensive background information on the benefits and risks of using pesticides (which were discussed in the impact assessment submitted in parallel with this Communication), presented a list of essential points to be addressed as well as possible measures to reverse negative trends. The consultation encompassed the European Parliament, the Council, the European Economic and Social Committee, the Committee of the Regions, industry, consumer and farmer organisations and the general public. A detailed summary of the consultation process can be found in the impact assessment (Commission, 2006)

The Thematic Strategy on the Sustainable Use of Pesticides is composed of a number of individual measures, the impacts of which have been assessed from economic, social, health and environmental points of view. In particular, its objectives are:

- to minimise the hazards and risks to health and environment from the use of pesticides;
- to improve controls on the use and distribution of pesticides;
- to reduce the levels of harmful active substances including through substituting the most dangerous with safer (including non-chemical) alternatives;
- to encourage low-input or pesticide-free cultivation, among others through raising users' awareness, promoting the use of codes of good practices and promoting consideration of the possible application of financial instruments;
- to establish a transparent system for reporting and monitoring progress made in the fulfilling of the objectives of the strategy, including the development of suitable indicators.

In order to reach these objectives, they were included in the Framework Directive 2009/128/EC, which sets EU rules for the sustainable use of pesticides (see also section 5.2.2.). The directive in question sets out the following measures:

- Establishment of National Action Plans by the Member States which will have to set individual objectives to reduce hazards, risks and dependence on chemical control for plant protection (National Action Plans - NAP);
- Creation of a system of training of professional pesticide users in order to ensure that those who regularly use pesticides are fully aware of the risks linked to this use and take all appropriate measures to find the least harmful means for solving a plant protection problem. This system includes guidance for users on the best choices to make among different products available for the same treatment (substitution at user's level).
- Awareness raising of the general public (with particular attention to non-professional users of pesticides) through awareness raising campaigns and information passed on through retailers to ensure that it is better informed.
- Regular and compulsory inspection of application equipment in order to reduce adverse impacts of pesticides on human health (in particular as regards operator exposure) and the environment during application, and to ensure the most efficient use by guaranteeing the actual quantity applied equals the present dosage.
- Prohibition of aerial spraying to limit the risks of significant adverse impacts on human health and the environment, in particular from spray drift. Aerial spraying should only be used by way of derogation where it offers clear advantages and also environmental benefits compared to other spraying methods, or where there are no viable alternatives. Conditions for such derogations have to be established in order to minimise the risks of unwanted effects, e.g. through appropriate requirements for training of operators and standards of application equipment.
- Minimising or banning the use of pesticides in critical areas for environmental and health reasons;

The Sustainable Use Directive 2009/128/EC came into force on 25 November 2009 and had to be transposed by the Member States by 26 November 2011. The European Commission has also issued a survey which analyse the status of the implantation of the Directive in question (Commission, 2011).

Plastics

Until now there is no comprehensive policy framework of plastic in the EU. Specific aspects are addressed in various pieces of legislation (section 6.2), and policy documents. Among them, one of the most important is certainly the *Green Paper on a European Strategy on Plastic Waste in the Environment* (European Commission, 2013) which assesses the environmental and human health risk of plastic in products when they become waste. In fact, the inherent characteristics of plastic create specific challenges for waste management as it can persist in the environment for long time.

The aim of the Paper was to launch a public consultation on possible responses to the public policy challenges posed by plastic waste which were not specifically addressed in EU waste legislation. According to the results of the public consultation, the EU strategy should focus more on reuse and recycling of plastic products; moreover, the EU should participate in worldwide co-ordination actions to manage plastic waste. It was also recommended to have better implementation and enforcement of the current legislation. Finally, according to the public consultation plastic waste can be reduced by raising the awareness of citizens through education about sorting and collection (European Commission, 2013)

The Green Paper also stressed the importance to reduce the incidence and impacts of plastic in the marine environment. Specifically, it opened a reflection process on how to tackle the problem of uncontrolled disposal marine litter. While marine litter includes all types of waste, studies have shown that the majority of waste found in seas and oceans is plastic. According to the Green Paper, the successful implementation of waste policy is a key prerequisite to avoid plastic litter entering the marine environment.

Currently, the 7th Environmental Action Plan, which is a plant that will be guiding European environment policy until 2020, develop the reflection further to consider an EU-wide quantitative

reduction target for marine litter (European parliament and Council, 2013). In fact, marine litter can be prevented efficiently through improved waste, in particular plastic waste, management, increased recycling, avoidance of single use products and product eco-design (e.g. to minimise release of microplastics in the marine environment) and through intensive education and awareness actions and campaigns.

6.5 STAKEHOLDER INITIATIVES

HEAL: Chemicals Health Monitor

Chemicals Health Monitor is a project, launched by the non-profit organisation Health and Environmental Alliance (HEAL) in 2007. It aims to improve public health by encouraging more protective regulations of hazardous chemicals in Europe and beyond. The campaign is concerned with effective implementation of the EU chemicals law in general, as well as with certain specific issues relevant to vulnerable groups, such as EDCs.

BUND: Information leaflet about pregnancy and chemical exposure

The German organisation BUND (Friends of the Earth Germany) has produced a leaflet in German about pregnancy and how to avoid exposure to chemicals. It contains advice on where to find potentially harmful chemicals and what to look out for in everyday life. The guide highlights the potential presence of EDCs in many daily life products such as food, cosmetics and cleaning products.

TENDR Consensus Statement (signed by a number of scientific and medical experts and children's health advocates)

The TENDR Consensus Statement, signed by a number of scientific and medical experts and children's health advocates, is a call to action to reduce children's exposures to toxic chemicals in the US. The authors agree, based on their expertise in the topic area, that widespread exposures to toxic chemicals in the environment and consumer products can increase the risks for cognitive, behavioural or social impairment or specific neurodevelopmental disorders such as autism and ADHD. Examples of neurodevelopmental toxic chemicals are listed in the Statement and references are made to the need for a new approach to evaluating evidence as well as the need to avoid regrettable substitution.

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