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Introduction

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Every year, more than 100 000 people die from the consequences of a cancer caused by exposure at work (Takala, 2015). All of these cases are avoidable. Occupational cancers could be eliminated by alternative means of production, by a systematic implementation of preventative measures and by an organisation of work that accommodates these requirements.

The majority of these cancers are caused by exposure to chemical substances. The available data on the current levels of exposure for workers confirms that in the absence of adequate legislation there can be no significant improvement of the situation.

The fact is cancer costs practically nothing to the companies that cause it. Instead the costs fall to the victims, to social security provisions and to public health systems. Without strict regulation, no prevention measures can have a serious impact across the sectors. The present European legislation concerning the prevention of workplace cancers has to be profoundly reformed. Currently, its purview is far too narrow; the number of substances for which limit values are defined constitute less than 20% of the situations where workers are actually exposed. Furthermore, the legislation does not provide for continued health monitoring after the period of exposure.

Further regulations need to be imposed to reduce the amount of commercially produced carcinogenic substances available on the market. For this purpose, the European regulation on chemicals (REACH) must function far more effectively, in particular by substantially increasing the number of carcinogenic substances covered by the authorisation procedure. Moreover, considering the pressure received from industry lobbyists during its development, the specific legislation related to pesticides and cosmetics needs to be reviewed.

This publication presents a critical appraisal of the principal EU legislation adopted so far. In so doing, it identifies significant gaps in the central feature of this legislation, which is the directive concerning the protection of workers against carcinogens.

The aspects of this directive which most require attention and revision are discussed in each of the different contributions to this paper. First and foremost, binding limit values for workplace exposure need to be redefined in order to cover the principal situations of exposure. Another key point is the necessity of expanding the directive's scope to cover other toxic substances, some of the most worrying being those that present risks to reproduction.

Finally, it is crucial that health checks continue to be organised for workers beyond the periods in which they are exposed to carcinogens. In fact, the latency period between exposure and the development of a cancerous disease may last many decades. Timely detection can save countless lives.

In terms of political context, this working paper is published at an interesting moment. Various Member States, the European Parliament and the trade union movement have come together to work towards an ambitious reform of the directive on carcinogens. The European Commission had announced such a revision in 2002, but then made a volte-face under pressure from industry lobbyists. As it has a monopoly on the legislative initiative, the commission effectively blocked other EU institutions by refusing to put forward a legislative proposal.

Working in the context of the Dutch EU presidency, this unusual cooperation between a large number of Member States, the European Parliament and the European Trade Union Confederation managed to push through the impasse. The European Commission finally announced that it would present a proposal for legislative reform. It is still too early to evaluate the impact of this proposal; but whatever the outcome may be, opening up the legislative process has paved the way for an essential public debate to take place.

This publication contributes to that debate by shedding light on the specific issues under review and by offering its own concrete proposals.

European legislation and prevention of occupational cancers

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The ESENER survey conducted by the Bilbao Agency emphasises the importance of precise and comprehensive legislation in order to organise prevention (Rial et al., 2010). According to this survey, which was conducted on the basis of a sample of 36 000 enterprises, the main factor encouraging enterprises to develop a prevention policy is the existence of legislation. Ninety percent of enterprises state that fulfilment of legal obligations is what spurs them on to act. In 22 of the 27 countries, this factor heads the responses. In the field of prevention of occupational cancers, the importance of a precise and detailed legislative framework is strengthened by the weakness of the economic incentives within enterprises. The cost of occupational cancers is almost totally externalised to social security and public health structures.

This contribution will make a brief analysis of the following elements: the development of Community legislation concerning the marketing of carcinogens and the protection of workers' health. It will also address the main obstacles encountered in the application of these rules in different Member States. It will be restricted to cancers caused by chemicals. Other factors likely to cause cancers such as night working, exposure to solar radiation, ionising radiation or biological agents will not be examined here.

1. Development of market regulation

For a long time, the European Union has ignored the importance of occupational cancers and failed to establish a coherent legislative framework with a view to preventing them. In this field, Community developments have not been very different from national developments in its Member States.

The question of harmonisation of legislations concerning the marketing of chemicals first arose at the time of creation of the European Economic Community. In fact, the diversity of national legislations was considered a potential obstacle to the creation of the common market. Community rules were adopted with the priority objective of free circulation of goods. It was only quite slowly that other worries were taken into account: public health, occupational health and protection of the environment. It is therefore not surprising that, on the basis of the Treaty of Rome (1958), the first legislative developments concerned market rules.

1.1 The 1967 Directive: illusion of self-regulation by industry

The first Directive adopted goes back to 27 June 1967 (Directive 67/548/EEC). It laid down rules relating to the classification, labelling and packaging of chemicals. It instituted self-regulation by producers and did not originally establish any counterbalance to this principle. It was for the chemical industry to determine the intrinsic dangers associated with the substances they were producing. Classification therefore depended mainly on data gathered and selected by the industry, even though the Directive gradually opened up the way to harmonised classification for the most dangerous substances. Such an approach ignores the conflict of interests between correct evaluation of the dangers and the economic profit associated with marketing the substances.

In view of the obvious inadequacy of this legislative framework, three strategies were possible with respect to the level of regulation: strengthen national regulation (this is what France did with the law of 12 July 1977 on the control of chemical products), count on reform of the Community legislation (main option of Germany, being mindful of guaranteeing access to the European market for its chemical production) or wait for hypothetical international agreements (there were lengthy negotiations under the auspices of the OECD, which resulted in 1982 in a purely optional text concerning the data which States *could* require from producers prior to marketing[1]).

Reform of Community law took place piecemeal. It multiplied the legislative instruments with respect both to the general market in chemicals and to specific uses (pesticides, cosmetics, etc.) or the safety of dangerous installations (first Seveso Directive 82/501/EEC adopted on 24 June 1982). REACH, the European legislation currently in force for the marketing and use of chemicals, only partially dealt with the drawbacks of a highly fragmented legislative framework. In fact, there are still specific legal systems in different fields.

The 1967 Directive has had to be amended many times and supplemented by other legislative instruments intended to mitigate the shortcomings of a self-regulation by the chemical industry limited to the classification and labelling of substances.

In 1976, Directive 76/769/EEC provided for the possibility of restrictions on the marketing of certain dangerous substances through restrictive measures. Fifty-nine measures have been adopted in 33 years[2]. The asbestos ban, only decided in 1999, shows the slowness of this process.

In 1979, the sixth amendment of the 1967 Directive (Directive 79/831/EEC of 18 September 1979) imposed a distinction between existing substances (about

1. Decision of 8 December 1982 of the Council of the OECD concerning the minimum pre-marketing set of data in the assessment of chemicals [C(82)196(Final)].
2. Since the adoption of REACH, the rate of restrictions has slowed down. There has been a move from two new measures a year on average to one measure a year (Musu, 2013).

100 000 substances present on the European market as at 18 September 1981) and new substances (marketed after 18 September 1981). As regards the latter, the manufacturer was required to submit a pre-marketing notification to the competent authorities of one of the Member States. The procedure provided for four elements: a technical dossier supplying the (eco)toxicological data necessary for evaluating the risks which the substance may entail for man and the environment; a statement concerning the unfavourable effects of the substance in terms of the various uses envisaged; proposed classification and labelling if the product is dangerous according to the criteria in the Directive; proposals concerning the precautions to be taken for the safe use and disposal of the substance. The information required was variable depending on the production volume calculated individually (per producer or importer and per year) and independently of a global estimate of the production volumes on the European market. This shortcoming was mitigated by the fact that the production volume from which notification was required was 10 kg per year per producer. On this point, the combined rules of REACH and the new CLP Regulation[3] represent a regression illustrated by their inability to provide an adequate framework for the regulation of nanomaterials[4]. Henceforth, the data on substances supplied through the registration dossiers in REACH are only required from a production volume of 1 tonne per year. The notification of classification required by the CLP regulation can be after marketing (within 30 days) and it comprises a classification rather than a proposed classification.

The notification obligation introduced for new substances from 1981 was formulated in a particular context. In 1976, the United States adopted the federal TSCA legislation (Toxic Substances Control Act) after five years of intensive debate, which was in many respects reminiscent of the polemic surrounding the REACH negotiations. At the time, the United States were tending towards a more ambitious policy than the European Union with regard to chemical risks. The reform taking place in Europe in 1979 appeared to be a reaction to this regulatory activity in the United States, which provoked hostility on the part of the European chemical industry (Brickman, Jasanoff and Ilgen, 1985). The debate at that time gave a kind of inverse image of what had occurred at the time of development of REACH, at least with respect to the positions of the state players.

The 7th amendment of the Directive adopted on 30 April 1992 (Directive 92/32/EEC) introduced the obligation for the manufacturer, importer or distributor to provide professional users with a safety data sheet containing the information needed for the protection of human health and the environment.

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3. Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures.

4. For numerous nanomaterials, the production volumes are less than one tonne per year per producer. In this case, no registration is obligatory under the terms of REACH. Also, producers tend to under-estimate the fact that the physico-chemical properties of nanomaterials differ appreciably from those of larger particles with the same chemical composition.

Rules concerning dangerous preparations were put in place from 1988 with the adoption of Directive 88/379/EEC[5], which has been amended several times. It was completely revised with the adoption of Directive 1999/45/EC.

In 1993, Regulation (EEC) No 793/93 provided for evaluation by the public authorities of the risks presented by existing substances. The evaluation process only produced disappointing results. The inadequate resources allocated to the public toxicological expert bodies combined with the reluctance of the chemical industry to communicate all of the relevant data made it impossible to overcome the enormous shortage of knowledge concerning the effects of substances on the market. Barely 141 substances were entered on the list of priority substances to be evaluated. Thirty-nine evaluations were effectively performed before this Regulation was repealed following the entry into force of the REACH reform in 2007.

As time went by, different European Regulations were adopted for more specific categories such as medicines, food additives, biocides, waste, cosmetic products, pesticides, detergents, etc. These regulations will not be examined in this article.

The interplay between the provisions of REACH and those of the specific Regulations sometimes gives rise to problems. As regards the European Regulations on biocides and pesticides, their application has been severely hampered by the European Commission, which has not met its obligations to define criteria concerning endocrine disruptors. These substances play an important role in the increase in hormone-dependent cancers such as breast cancer in women and prostate cancers in men. The Commission's inertia has resulted in open conflict with the Member States. It was caused by an intensive lobbying action of the chemical industry (Horel, 2015 and CEO, 2015). In May 2014, Sweden decided to bring a legal action against the European Commission owing to a failure to meet the obligation to define criteria for the definition of endocrine disruptors for December 2013. The Swedish complaint received the support of several Members States and of the Council of Ministers and the European Parliament. On 16 December 2015, in an unprecedented decision, the General Court of the European Union ruled that the Commission breached EU law by failing to publish the criteria of definition of endocrine disruptors.

1.2 The need for deep reform

By 1995, with the accession of Sweden, Finland and Austria[6], the need for radical reform had been acknowledged. The candidates for accession (mainly Sweden) had far more advanced regulation than the Community Regulation. Their public opinion would not have allowed alignment pure and simple with

5. In this text, a preparation is defined as a mixture or solution comprising two substances or more. In the current terminology, reference is made to mixtures.

6. The negotiations for enlargement also involved Norway. Norway's accession was rejected by referendum in the Autumn of 1994.

the Community rules. During the negotiations in preparation for this enlargement of the European Union, the need for global reform of the legislation in force was acknowledged. The act of accession included provisions allowing Austria and Sweden to maintain, for a transitional period of four years, stricter conditions with regard to certain aspects of regulation of the chemicals market. Highly symbolically, the first Swedish Commissioner in the European Commission, Ms M. Wallström, was given the environment portfolio between 1999 and 2004. She was to play a very important role in giving impetus to REACH.

Preparation for the reform was undertaken gradually during 1998. The Environment Ministers of the Member States held an informal Council in April 1998 in Chester and acknowledged the need for reform. On 18 November 1998, the Commission adopted a report on the application of the existing rules[7]. This report showed that regulation was incoherent, incomplete and poorly applied. It may however be noted that the European Commission was far from adopting a unanimous point of view on this matter. The careful wording of the 1998 report performed the diplomatic function of concealing a certain number of fundamental differences of opinion. Meeting on 20 and 21 December 1998, the Council of Ministers approved the Commission's report and backed a thorough reform.

The differences within the Community institutions came to the fore during 1999. The Commission decided to support a Swedish businessman who was challenging his national legislation. The case involved the general prohibition on the use of trichloroethylene for industrial purposes. The Swedish enterprise Toolex Alpha AB manufactured compact discs and used trichloroethylene to remove the grease originating from production residues. The Swedish chemical product inspectorate refused it authorisation to continue to use this substance since the enterprise had not submitted a plan for the substitution of trichloroethylene.

In July 2000, the European Court of Justice rejected the Commission's point of view and justified its support for the Swedish legislation by means of a general principle of substitution established in Community law (Toolex Alpha AB judgment, 11 July 2000, Case C-473/98). Despite the legal arguments, this trial showed that the Commission remained divided on the imperative need for reform of the Regulation on chemical products and on its content. The support given by the Commission to the Swedish businessman was all the more surprising in that, on 10 May 1999, Parliament and the Council had adopted Directive 1999/33/EC, which extended for a period of two years the derogation allowing Sweden and Austria to apply stricter national rules with regard to certain aspects of the marketing of chemicals. This Directive restated in its recitals the need to undertake a revision of all of the Community rules. Recital 6 stated in particular: 'whereas, during that period [the two years granted for extension of the derogation], coherence of the marketing conditions of dangerous substances and preparations should be sought'. According to the

7. Document SEC (1998)1986 final.

evidence we have gathered from former officials of the European Commission, the Commission's intervention had given rise to deep misgivings in different Directorates-General, which considered that DG Enterprise was aligning itself with the positions of the chemical industry.

For 15 years, we have consistently noted a far more determined political will on the part of DG Environment in favour of policies favourable to human health and the environment[8]. DG Enterprise (recently renamed DG Growth) tends to see its own role as a kind of spokesperson for the interests of private enterprises and it wishes to be considered the central decision-making body for chemical products[9]. DG Social Affairs remains passive. The resources available to it are derisory in comparison with the challenge of chemical risks for workers in Europe. It has fewer than five people working on these matters. The internal tensions have been evident many times both during the negotiations for REACH and during its implementation. Over the two terms of the Commission under the presidency of Mr Barroso, DG Enterprise was able to consolidate its positions thanks to alliances between two successive Commissioners (the German socialist G. Verheugen between 2004 and 2009 and the Italian conservative A. Tajani between 2009 and 2014) and the President of the European Commission. These alliances have sometimes damaged the principle of collective responsibility on the basis of which the Commission should adopt positions.

The Commission's White Paper of 27 February 2001 – Strategy for a future chemicals policy (COM(2001)88 final) conducted a critical evaluation of the arrangements put in place and proposed significant changes. The different stages of the negotiations were marked by bitter conflicts. Lively debate also took place in the European Trade Union movement. The European Trade Union Confederation emphasised the need for fundamental reform while the European Mine, Chemical and Energy Workers' Federation (EMCEF) adopted positions close to those of the chemical industry.

Eventually, the most innovative aspects of the White Paper were watered down. It was not just in Europe that there was an offensive against REACH. The Bush administration in the United States racked up the pressure on the European Union not to adopt a regulation increasing the safety obligations for producers of chemical products. In October 2003, the Commission presented its proposal for a regulation. Known by the acronym REACH (Registration, Evaluation, Authorisation of CHemicals), this text was less ambitious than the initial proposals in the White Paper and the draft submitted for public consultation in May 2003. The final compromise, covered by an agreement between

8. With the formation of the new Commission chaired by J.-Cl. Juncker in 2014, the role of DG Environment in European policies concerning chemical risks has been greatly reduced. The biocides dossier has been removed from it. This reversal was criticised by environmental protection associations, which detected a sign of strengthening of the role of industry lobbies.

9. Mr Geert Dancet, the first director of the European Chemicals Agency (ECHA) based in Helsinki came from the ranks of DG Enterprise and Industry. After the end of a first term of five years, he was reappointed in 2012.

Parliament and the Council in December 2006, is a second-rate version in comparison with the initial drafts. It allows industry only to supply highly fragmentary data for two thirds of the 30 000 substances covered by REACH (for production volumes below 10 t per year per producer). It sets over-lax conditions for the authorisation of substances of very high concern. It excludes polymers from the scope of application of the main provisions concerning the registration and evaluation of substances.

REACH was supplemented by Regulation (EC) No 1272/2008 on the classification, labelling and packaging [abbreviated to CLP] of substances and mixtures. This Regulation supersedes Directives 67/548/EEC and 1999/45/EC. It establishes a new system based on the globally harmonised system negotiated at international level and should provide, at worldwide level, for equivalent rules for chemical substances and mixtures with regard to their classification, labelling and packaging. The globally harmonised system does not require the states implementing it to create public control mechanisms which would make notification by producers, examination of the content of the notification and the creation of a stringent harmonised classification determined by the public authorities mandatory. The principles of notification and harmonised classification have clearly been upheld within Europe.

1.3 A few elements for an initial assessment of REACH

REACH entered into force on 1 June 2007. All Carcinogenic, Mutagenic and Toxic for Reproduction (CMR) substances produced in Europe in quantities exceeding one tonne per year had to be registered before the deadline of 1 December 2010. Furthermore, whatever their production volumes, all substances marketed in Europe and classified as hazardous by their manufacturers had to be notified to ECHA (European Chemicals Agency) before 3 June 2011. Of the 1 300 CMR substances with a harmonised classification in Annex VI to the CLP Regulation, only 67% of them have been registered or notified to the ECHA (ECHA 2015)[10].

According to those ECHA data from 2014, 5 675 substances have been notified as CMR (categories 1A, 1B or 2) under the terms of the CLP Regulation, although they are not deemed to be CMR in the harmonised classification (ECHA, 2015). Of these substances, 1 169 have been registered under the terms of REACH (which means that they are manufactured or imported above one tonne per year per manufacturer or importer). These data lead to three conclusions. First, the harmonised classification probably includes significant gaps with respect to the reality of the substances marketed. Second, the fact of limiting the registration of CMRs to substances for which the annual production volume per producer is one tonne constitutes an obstacle to prevention since, according to producers' notifications, there are more than 4 000 different CMRs with production volumes of less than one tonne. Finally,

10. https://echa.europa.eu/documents/10162/13562/cmr_report_2014_en.pdf

it should be stated that the mechanisms put in place by REACH are too slow and inadequate to rid the market of CMRs.

An additional problem concerns the relative multiplicity of manufacturers (or importers) which register CMRs. The ratio between the number of substances registered and the total number of registration dossiers is of the order of 1 to 10: 419 substances registered as carcinogenic for 3 964 registrations, 223 mutagens registered for 1 642 registrations and 121 reprotoxic substances for 1 451 registrations. The same CMR substance is therefore produced by numerous different manufacturers in the EU and is covered by dossiers that may include significant differences as regards the preventative measures to be adopted[11].

The current period corresponds to the gradual implementation of REACH, which is to continue until 2018. This is a decisive stage, during which vital future trends will be decided. Evaluation of the quality of registration dossiers must definitely be restored. An initial sort is undertaken electronically by ECHA. This is restricted to verifying that all the relevant headings contain information, regardless of its content. The quality of the content of numerous dossiers seems highly problematical. According to ClientEarth, which has reviewed the dossiers for different substances whose effects as endocrine disruptors are known, much of the available and relevant scientific information is not mentioned in the dossiers. The list of candidate substances likely to be subjected to authorisation procedures remains very limited in comparison with all of the substances of great concern on the basis of the REACH criteria. It included 161 substances or groups of substances in December 2014.

This figure is still far from the 334 substances or groups of substances which are particularly dangerous for workers and which are included in the list of priority substances drawn up by the European Trade Union Confederation (Musu, 2011).

The central role played by ECHA also gives rise to legitimate concerns (Schaible and Buonsante, 2012). To what extent will it adopt a line of conduct independent of the pressures exerted by industry? Does the interpretation it adopts with regard to the content of REACH meet the objectives of all of the text? Three examples illustrate the urgency of these questions.

1. There have already been great controversies with regard to the very restrictive definition which ECHA proposes for the concept of article[12]. The number of articles subject to notification owing to the presence of a

11. REACH provided for different methods for the exchange of data. As part of a forum for the exchange of information on a single substance, several producers (and/or importers) may decide to establish a consortium to submit a single registration dossier. The formation of a consortium resulting in the submission of a single registration dossier is just an option and not an obligation.

12. This conflict pits ECHA, supported by the European Commission, against six states that interpret the concept of article more in conformity with the aims of REACH: Belgium, Denmark, France, Germany, Norway and Sweden.

particularly dangerous substance included in the list of candidate substances is very small. Less than 40 substances of extremely great concern had been notified in November 2014. In the great majority of cases, the number of notifications for each substance is limited to less than five different articles. A whole section of the system envisaged by REACH does not work. To a certain extent, the criteria defined by the Agency have contributed to this paralysis. On 10 September 2015, the European Court of Justice ruled that the ECHA interpretation of the concept of article was too restrictive. For the Court, each of the articles incorporated as a component of a complex product is covered by the duties to notify and to provide information when they contain a substance of very high concern in a concentration above 0,1% of their mass.

2. Environmental protection organisations like Client Earth and ChemSec consider that ECHA is not complying with freedom of information, as established by Community law and by different international instruments such as the Aarhus Convention of 1998. On 23 September 2015, the General Court of the European Union stated that they did not consider the case presented by ChemSec and Client Earth to be strong enough when discussing why disclosure of tonnage data was in the public interest.

3. The introduction of a concept of derived minimal effect level (DMEL) is in no way justified in the text of REACH. The Agency has developed this concept in 'guidance documents'. An examination of DMELs determined by producers with regard to CMRs shows that the levels of health protection they provide are very variable and that the concept of 'tolerable risk' they reflect is clearly less favourable than the OELs [Occupational Exposure Limits] defined in Germany for the same substances (Püringer, 2011).

The proper functioning of REACH also depends on the active involvement of the public authorities in the different Member States. This involves both a matter of political will and the mobilisation of resources making it possible to develop public toxicological expertise. Otherwise, the information available under the terms of REACH depends excessively and dangerously on the data supplied by industry. In the current stage, a limited number of states are really cooperating in the proper functioning of REACH. This can be measured quantitatively. Thus, of 173 substances proposed for possible inclusion in the list of candidate substances for authorisation, a little fewer than 100 have been proposed by states[13]. The very great majority of proposals originate from just 7 states: Germany (40 substances), France (17), Sweden (13), the Netherlands (12), Austria (11), Denmark (9) and Norway[14] (7). Other states with a large chemical industry only collaborate marginally: the United Kingdom (2 substances proposed), Belgium (3), Poland (1) and Italy (0).

13. Data available in December 2014.
14. REACH is also applied in the countries of the European Free Trade Association, which includes Norway, Iceland and Liechtenstein.

2. Development of European rules for the protection of workers

The European legislation concerning the protection of workers has been put in place more slowly than the market rules. Paradoxically, the question has been addressed on the basis of a highly specific situation. In the late 70s, a scandal broke with respect to vinyl chloride monomer (Soffritti, 2013; Markovitz and Rosner, 2013). It was able to be established that the chemical industry had intentionally concealed essential information concerning the risks of cancer among exposed workers. This explains why, as of 1976, the first Directive adopting measures to limit marketing included vinyl chloride. In 1978, Directive 78/610/EEC was adopted for the protection of workers. Since the legal basis for such a Directive remained uncertain under the terms of the Community Treaty in force at that time, justification for the Directive rested on the assertion that unequal levels of protection for workers had a direct impact on the functioning of the common market.

Framework Directive 80/1107/EEC of 27 November 1980 defined a new approach to health and the safety at work. It was centred on industrial hygiene. It provided for the adoption of a set of occupational exposure limits (OELs) which would be binding in nature for Member States, while allowing them to adopt rules ensuring better protection for workers. These OELs were to be regularly updated so as to take account of the experience acquired and technical and scientific progress. The Directive provided for the short-term adoption of OELs for nine chemical agents or families of agents: acrylonitrile, asbestos, arsenic and its compounds, benzene, cadmium and its compounds, mercury and its compounds, nickel and its compounds, lead and its compounds, chlorinated hydrocarbons (chloroform, paradichlorobenzene and carbon tetrachloride). Between 1980 and 1988, only two OELs were defined for chemical agents. They concerned lead (1982) and asbestos (1983). The inability to reach agreement on a proposed directive concerning benzene brought the whole process to a halt. In 1988, the Framework Directive of 1980 was revised by Directive 88/642/EEC. Henceforth, indicative limit values were adopted, without any binding effect for Member States. The development of indicative OELs has been laborious. On the basis of the 1980 Directive, two lists have been produced (Directives 91/322/EEC and 96/94/EC). Following the adoption of the Directive on chemical risks (Directive 98/24/EC), three lists have been adopted on this new legal basis: the first in 2000, the second in 2006, the third in 2009. In all, there are 121 substances for which an indicative Community OEL has been defined.

It is also on the basis of Directive 80/1107/EEC that Directive 88/364/EEC was adopted, banning four aromatic amines. This Directive was more general in scope. It provided for the ban of certain agents or certain activities. The four prohibited carcinogenic substances were included in a list designed to be supplemented gradually. In reality, this was the swan song for this period of legislative development.

Fortunately, the political will to improve working conditions was reflected in the adoption of Article 118a of the Treaty under the terms of the provisions of

the Single European Act. This made it possible to move on without excessive delay to a new stage in the production of Community legislation. This involved defining, first of all, the essential aspects in undertaking prevention in enterprises, whatever the risk in question and, next, legislating on the different risks by developing more specific texts. This concept formed the basis for Framework Directive 89/391/EEC of June 1989, which extensively updated occupational health law in most of the Member States.

2.1 Impetus provided by the Framework Directive of 1989

Since the adoption of Framework Directive 89/391/EEC of 1989, the matter of prevention of cancers has been addressed more systematically. In 1990, a specific Directive was adopted (Directive 90/394/EEC). This text remains the basis for the legislation currently in force. It was very partially amended in 1997 and 1999[15].

At the time it was adopted, this Directive constituted a positive contribution for the great majority of Member States, which only had highly fragmented and ineffective regulations in the field of protection of workers against carcinogenic chemicals. The Directive went beyond the basic requirements of Framework Directive 89/391 by formulating a general obligation to substitute for any carcinogenic agent in so far as it is technically possible. If this is not possible, the production and use of a carcinogenic agent must take place in a closed system in so far as this is technically possible. Otherwise, exposure must be reduced to the lowest technically possible level. Other preventative measures are envisaged. None of these measures depends on a risk evaluation but on the intrinsic danger characteristics presented by any carcinogenic agent. The Directive clearly sets out the role played by OELs. Its recitals specify that, even if current scientific knowledge does not make it possible to set a level below which the health risks cease to exist, a reduction in exposure to carcinogenic agents will nonetheless reduce the risks. They emphasise the need to define OELs for all carcinogenic agents: 'limit values and other directly related provisions should be established for all those carcinogens for which the available information, including scientific and technical data, make this possible'.

This important Directive, however, included problematic elements. The experience acquired over the last 24 years shows that these weaknesses have significantly reduced the efficacy of prevention.

The current scope of application of the Directive concerns workers exposed to carcinogenic and mutagenic substances or preparations[16]. When substances have been subject to harmonised classification in categories 1 or 2 (since 2008, the new terminology is 1A and 1B, the Directive has been amended on this point by Directive 2014/27/EU of 26 February 2014), the scope of application of the

15. The version currently in force is Directive 2004/37 of 29 April 2004, which represents a consolidation of the original Directive with the amendments adopted in 1997 and 1999.

16. Mutagenic substances were added to the scope of application by Directive 1999/38/EC.

Directive is clearly determined. When they meet the criteria for possible classification, the legal uncertainty is major. This is reflected in considerable differences in preventative practices between countries and, in each country, between enterprises. The Directive does not address the question of substances which have been classified or meet the criteria for classification as suspected carcinogens (former category 3, now category 2). In practice, there is sometimes a difference between the evaluations made by the International Agency for Research on Cancer and those used for Community classification. This is the case in particular for formaldehyde, which the IARC considers to be a confirmed carcinogen for humans (group 1), while it is only considered to be a suspected carcinogen in the Community classification (current class 2) and therefore does not fall within the scope of application of the Directive for the protection of workers[17]. But the major difference is to be found elsewhere: the purpose of the Community classification is to facilitate the market while the IARC classification has public health objectives in identifying carcinogenic agents. This means that exposure to carcinogens resulting from the degradation of a substance or, generally, produced by an industrial process, are not to be incorporated into the Community classification.

The Directive also applies to specific substances, preparations or processes subject to a list (Annex I to the Directive). This list is limited to five elements. The discrepancy in scientific knowledge is far more considerable here. As an example, the list mentions hardwood dust, while there are data concerning the carcinogenic nature of all wood dust. It mentions neither crystalline silica nor diesel particulate emissions, never mind leather dust or rubber dust and fumes, etc. The inadequacies of Annex I also give rise to huge inequalities with regard to prevention. The terminology used is more restrictive than for substances and preparations. Unlike what happens for substances for which a Community classification would be possible, there is no provision for the inclusion of processes meeting the criteria identifying an occupational risk of cancer. Since this is a Directive that formulates minimum requirements, the inclusion of other processes depends on national legislations.

The binding OELs determined by the Directive only concern three substances: vinyl chloride monomer, benzene and hardwood dust (to which asbestos and lead should be added, for which binding limit values have been defined in other Directives). This causes two problems. First, these limit values are far from prevention requirements that techniques make it possible to implement today. They need to be revised. Second, the catalogue of binding Community OELs only covers a very small proportion of workers exposed to carcinogenic or mutagenic substances. Referring to the data from the SUMER 2010 survey[18],

17. A harmonised classification of formaldehyde as carcinogen 1B came into force in the EU in April 2015.

18. There are no European data comparable with SUMER. The CAREX programme intended to evaluate the number of workers exposed to carcinogenic substances in Europe supplied data for the ’90s (Kauppinen, 2010). It was then interrupted. Since 2000, the European Commission has no longer supplied any statistical data on this matter. The European survey on working conditions does not draw any distinction between exposure to carcinogenic agents and other exposure to chemical risks.

it can be seen that, of the 10 carcinogenic chemicals corresponding to the most massive exposure in France, only two are subject to a binding Community OEL. These are wood dust (the Community OEL only concerns hardwoods) and lead (which is not considered carcinogenic in the Community classification and is subject to far too high a limit value from the point of view of health protection). Extending the sample to the 20 agents corresponding to the most frequent exposures, the list of Community OELs hardly makes a contribution to prevention. Asbestos and benzene may be added to the two OELs already mentioned. A calculation performed on the basis of SUMER data indicates that the binding Community OELs cover less than 20% of the exposure situations registered for carcinogenic agents[19]. At the national level, there are very great disparities between the number of carcinogenic substances subject to a national OEL and the levels of health protection taken into account. A comparative study by the European Agency for Safety and Health at Work in Bilbao on OELs concerning CMRs shows that the accumulated logjams at Community level have resulted in highly divergent occupational cancer prevention policies in the Member States (Schneider and Kosk-Bienko, 2009).

2.2 Solving the legislative paralysis: essential revision of the Directive on the protection of workers

Revision of the Directive on occupational exposure to carcinogenic agents has been on the agenda for more than 12 years. This objective had already been included in the Community strategy for health at work for the period 2002-2006. As part of the gradual implementation of REACH, it would have been logical to consider this revision to be a central priority for the 2007-2012 strategy.

In accordance with the procedures laid down by the Treaty, trade union and employers' organisations were consulted on two occasions in 2004 and in 2007. For its part, the Scientific Committee for the definition of OELs at European level (SCOEL) [Scientific Committee on Occupational Exposure Limits] carried out some important work and formulated recommendations for several tens of CMRs.

The main points to address revision of the Directive are as follows:

1. Extension of its scope of application to reprotoxic substances. This is already the case in the national legislation of five Member States: Germany, Austria, Finland, France and the Czech Republic. This situation shows that the argument whereby such an extension would represent an unbearable burden for enterprises is devoid of any relevance. Such an

19. Of 3 316 000 exposure situations recorded by SUMER 2010, about 600 000 are covered by a binding Community OEL. The actual percentage is lower if it is considered that the Community OEL only concerns hardwood dust, while SUMER lists all of the situations of exposure to wood dust.

extension would make the legislation on the protection of workers more coherent with the concept of substances of very high concern which is used by REACH. It would make it possible to incorporate into the prevention policy knowledge concerning the transgenerational risk of certain occupational exposures, in particular with regard to cancers (Schmidt, 2013). Eventually, it would make sense to include endocrine disruptors in the scope of application of the Directive.

2. Revision of OELs already defined at Community level. Most of them go back more than 15 years (more than 30 years in the case of lead). The experience of different European states shows that OELs which are far more effective from the point of view of prevention are technically possible and have never given rise to the economic catastrophes claimed by consultants in the business world.

3. Definition of new Community OELs for the CMRs of most concern (in particular, for those to which large numbers of workers are exposed, such as crystalline silica, diesel fumes, formaldehyde, refractory ceramic fibres, chromium VI, trichloroethylene, etc.). Taking account of the delays that have accumulated, a minimum short-term objective could be to cover at least 50 CMRs corresponding to the exposures of most concern (taking account of their frequency and health impact). In March 2016, the European Trade Union Institute published a report identifying 71 substances and processes for which a European binding OEL should be defined (Wriedt, 2016). Another list was proposed by the Dutch government on the basis of a study carried out by the National Institute for Public Health and Environment (Puts, ter Brug, 2015). It identified a short list of 50 substances and processes. There is a strong convergence between the two lists.

4. Definition of more coherent criteria for the determination of binding OELs in the Community legislation. Up to now, each OEL has been defined case by case, with no overall coherence in terms of health protection. In its impact evaluations, the European Commission favours a cost-benefit approach which gives rise to great inequalities[20]. In fact, the real or presumed cost of preventative measures can vary enormously from one substance to another depending on the usages. Hence, the economic argument results in toleration of far higher health risks for certain OELs than for others.

5. Extension of the health surveillance after the end of the workplace exposure. Cancer may not develop until a very long time after exposure,

20. The European Commission has entrusted a private body with the task of performing impact studies on the adoption of new OELs. This body (Institute for Occupational Medicine) followed the Commission's instructions and applied a cost-benefit model where extrapolations are decisive with respect to very few data. These extrapolations are noted for considerable margins of uncertainty. The Commission's official impact study should have been presented in early 2014. At the time of writing (February 2015), it had not yet been finished!

which makes it vital for workers who have been exposed to a carcinogen to continue getting health surveillance throughout their lives. Early detection of tumours is key to surviving most cancers.

A majority of Member States are in favour of revision of the Directive. They consider that it would be dangerous to organise competition between the different national economies to the detriment of protection of workers' lives. They are also aware of the extent of public health expenditure associated with cancers and of the particularly effective nature of prevention targeted on occupational exposure.

Even a large proportion of employers have eventually softened their opposition to revision. Employers' organisations in countries where there is more advanced legislation consider that they are suffering a competitive disadvantage on the European market. This is what explains the very firm position of employers in the Netherlands in favour of revision of the Directive. In 2013, the Dutch Ministry of Labour sent a letter to the European Commission to request that the new Community strategy for the period 2013-2020 include revision of the Directive on the protection of workers against the risks of mutagenic and carcinogenic agents. This letter reflected a joint position adopted at a tripartite meeting between the government, employers' organisations and trade union organisations in the Netherlands. The joint position stated in particular: 'We are of the view that we should make every effort to establish before 2020 limit values at the European level which are more numerous and more ambitious for a substantial number of substances. This also contributes to defining an equal playing field at the European level with the objective of adequate protection of the entire workforce in Europe and avoiding distorted competition'[21].

On 4 March 2014, the Ministers of Labour of Germany, Belgium, Austria and the Netherlands took the unusual initiative to send a joint letter to the European Commission. The tone was particularly urgent. The letter stated that more than 30 million workers in Europe were exposed to carcinogenic and mutagenic substances with exposure levels which were not acceptable. It requested urgent revision of the Directive and recommended the establishment of binding OELs for 50 substances corresponding to the very great majority of exposure situations. It provided criteria for the establishment of these OELs.

In both cases, the Commission made just a dilatory response. The strategic action programme for health and safety adopted by the Commission in June 2014 for the period 2014-2020 remained silent on revision of the existing legislation and on the definition of binding OELs at the European level, while implicitly noting the failure of Community policies by stating that 100 000 workers were dying every year of cancer caused by inadequate prevention at workplaces.

21. Letter from the Dutch Minister of Social Affairs and Employment, L. F. Asscher, to European Commissioner L. Andor, 28 August 2013.

The shift in employers' positions has enabled the consultative committee for health and safety to adopt positions favourable to revision of the Directive. These opinions also reflect certain divergences with regard to the actual content of such revision (in particular with respect to the need to include reprotoxic substances and crystalline silica in the scope of application of the Directive). There is already a consensus on about 20 OELs that could be adopted[22]. The European Parliament several times came out strongly in favour of revision of the Directive.

It was the Commission that produced the surprise. On 2 October 2013, it announced that it would not submit any proposal for revision of the Directive before the end of its term of office (Communication 2013 (685) final). This position was only supported very vaguely by the concern not to increase the 'regulatory burden on enterprises'. President Barroso saw fit to make this decision part of a programme for the future: according to him, 'the REFIT programme foreshadows with pragmatism the future of regulation in Europe'. The burden represented by about 100 000 deaths per year attributable to cancers caused by working conditions is not even raised by this Commission European communication. Community law grants the European Commission a monopoly on legislative initiatives. In the final analysis, neither a majority of European parliamentarians, nor a majority of Member States, nor a citizens' petition can force it to act. In political terms, this exceptional situation with respect to the usual principles of parliamentary democracies should encourage the Commission not to consider it a simple privilege and to act with a major sense of its responsibilities.

The future of Community legislation on the protection of workers against occupational cancers is uncertain. A majority of Member States want the existing rules to be strengthened. They are not unaware of the immense costs which cancers caused by work represent for public health and social security. Trade union organisations have made revision of the Directive and the adoption of binding OELs covering the majority of occupational exposure situations a strategic priority. This element was reaffirmed with particular force in a resolution adopted by the Executive Committee of the European Trade Union Confederation in December 2014. On the other hand, the Commission remains very reticent to put this dossier forward. Revision of the Directive is not even mentioned in the working programme of the new Juncker Commission for 2015. At the time of writing (February 2016), the Commission had still not published an official proposal for the revision of the Directive.

22. Three opinions were adopted by the ACSH in December 2012, May 2013 and November 2013. See www.etui.org > Topics > Health & Safety > Occupational cancers.

3. Elements for a global assessment: obstacles to the prevention of occupational cancers in Member States

The prevention of occupational cancers implies a set of conditions influencing the efficacy of any prevention policy. These play an enhanced role with respect to risks which are both extremely diffuse and not very socially visible. The experience acquired in the field of prevention makes it possible to identify two central elements in a global assessment, going beyond the extreme variety of national practices. They relate to the need for collectivisation procedures and to better understanding of the great diversity of activities involving dangerous exposure.

A coherent legislative framework is an initial condition. Research conducted by the European Agency for Safety and Health at Work shows that, as a driving force for prevention, the existence of legislation is the factor most often cited by employers to explain the implementation of prevention measures (Rial Gonzalez et al., 2010). As a general rule, both at Community level and in the different countries, the legislation enacted essentially concerns the first circle of prevention. It formulates obligations on employers and provides a framework for prevention activities in enterprises. Beyond this essential dimension, questions should be asked about the weakness of public structures, mainly with respect to collectivisation and control.

Sparse data originating from different Member States suggest that substitution is only implemented by a small number of enterprises and with respect to a limited number of substances. It is more frequent for substances identified as CMRs because they form part of the production cycle than for CMRs which are process-generated as a result of the production cycle. One of the obstacles to substitution is the weakness of public structures providing access to precise data on the alternatives which could be put in place. At Community level, the legislation has never been supplemented by such collectivisation structures. In the Member States, experiences are varied but remain globally inadequate. Public collectivisation procedures are just one aspect in the field of substitution. They are called upon to play a role in all prevention measures: better knowledge of the risks associated with processes, OEL usefulness and limits, actual performance of personal protection equipment, methods for integrating the prevention of cancers into the evaluation of risks, role of prevention services and contribution of a multidisciplinary approach, in particular through ergotoxicology.

The status of prevention services in almost all of the Community countries also gives rise to problems. Only a few very large enterprises have in-house prevention specialists with all the skills needed for the fight against occupational cancers. The majority of services are inter-enterprise services working in a competitive market. They generally design their interventions in a contractual framework with enterprises which are seen as ‘clients’. The control exerted over their independence with respect to employers and over

the quality of their work both by workers' organisations and by the labour inspectorate is weak. The services tend to neglect their role in public health (or, worse, they confuse this role with a vague promotion of individual health in a context totally foreign to their mission to transform working conditions). They contribute little to the implementation of collective monitoring systems, whether involving toxicovigilance or mapping actual exposures in relation to work activities. Also, in numerous European countries, there has been a significant weakening of occupational medicine within the prevention services.

The public authorities also have a responsibility in these shortcomings. They have access to a set of information defined by the Community Directive but take few initiatives for information to be effectively gathered, analysed and used in order to improve prevention. There is no real interaction between the prevention services at workplaces and the public health structures involved in the fight against cancer. Apart from the Nordic countries (Pukkala et al., 2009), the national cancer registers are not used systematically to establish links between the occupational activities undertaken throughout their lives by patients and the locations of cancer. There is generally no monitoring of post-employment health.

The implementation of public information systems is an important issue. Practice shows that numerous enterprises which use chemical products often only have fragmented, and sometimes contradictory information. The data they obtain from suppliers only partially meet their needs for prevention. Some data are inaccurate; others are formulated in too non-specific terms. An improvement in the information supplied is one of the anticipated consequences of the implementation of REACH but this is not enough. A more effective fight against occupational cancers therefore also involves prevention strategies able to overcome the shortcomings of a fragmented approach, enterprise by enterprise. A European strategy in this field would make it possible to achieve greater efficacy but, in the current political context, it is unlikely. National strategies, accompanied by cooperation between the public prevention institutions in different countries, are more likely to be put in place.

The development of research is also an important element. The prevention of occupational cancers is still largely modelled through knowledge and representations essentially going back to the '70s and '80s. It does not coherently incorporate new scientific data on carcinogenesis (Clapp et al., 2008) and, in particular, epigenetic research and study of the role played by endocrine disruptors along with the transgenerational effects of certain occupational exposures. Beyond the incorporation of new scientific data, questions should also be asked about the social construction of prevention practices and the representations underlying them. In particular, the representation whereby working conditions only play quite a marginal role for cancers in women merits critical analysis. Although it is true that the gender apportionment of work has concentrated a major percentage of men in certain activities where exposure is very high (in particular in construction), this still does not mean that women are sheltered from other types of exposure which give rise to a risk of occupational cancer. It is likely that there is a vicious circle

between the priority given to male groups in the epidemiology of occupational risks of cancer, the weakness of the prevention systems in highly feminised activities and the particularly dramatic levels of under-recognition of occupational cancers in women. Recent studies have highlighted important risks of breast cancer among women in different occupational groups (Engel and Rasanayagam, 2015). For some occupations, exposures to chemicals are the main explanatory factor. For instance, the risk of breast cancer is 5 times higher in the hairdressing and cosmetics sectors, as also among food and beverage production workers. It is 4.5 times higher among dry cleaning and laundry workers. It is 4 times higher among workers in the paper and printing industry and among those making rubber and plastic products.

Another important element in improving prevention strategies must be based on the fact that the legislation, both at the European level and in the different countries, formulates the basic essentials of the obligations imposed on the employer. In numerous cases, the reality of risks is more complex. They tend to be concentrated and, in any case, to be subject to less systematic prevention throughout the subcontracting chains. A broadened approach not limited to the employer and formulating prevention obligations with regard to clients could considerably improve the efficacy of prevention. Among the significant data in the results of the SUMER 2010 survey, it may be noted that the two areas of occupational activity where employees are most exposed to carcinogenic agents are maintenance (43%) and building and public works (32%). These are areas in which the apportionment of risks is associated with subcontracting. As a complement to this, a sector approach could also make a useful contribution, in particular by developing prevention measures which take account of the frequency of multiple exposures and the identification of ‘cocktails’ that are relatively typical for certain activities.

4. Conclusions

In such a complex field, market rules are in constant interaction with the health at work rules. Regulation must be based on public research in numerous different fields and collectivisation tools are essential in order to improve prevention practices. The added value of a Community policy seems obvious. Suffice to note that, before the adoption of the Directive on occupational exposure to carcinogenic agents of 1990, the national legislations were piecemeal and purely reactive. They addressed, without any overall coherence, a few specific risks (asbestos, vinyl chloride, benzene, etc.). In 1990, the majority of Member States of the European Union had not yet ratified Convention No 139 adopted by the ILO in 1974 even though its provisions were minimalist[23].

23. As of January 2015, 13 Member States of the European Union had not yet ratified this convention. These are Austria, Bulgaria, Cyprus, Spain, Estonia, Greece, Latvia, Lithuania, Luxembourg, Malta, Poland, Romania and the United Kingdom.

The obstacles to a Community policy are considerable. This is what is shown by more than 40 years experience. The challenge is far more antagonistic than for occupational accidents. Effective prevention of occupational cancers would bring to the fore an important factor in social health inequalities and would run contrary to the currently dominant trend towards an increase in inequalities in most fields. Beyond this challenge for society, it may also be stated that there are few economic incentives pushing employers to make efforts in prevention. The morbidity and mortality caused by occupational cancers only involve marginal costs for enterprises, in particular owing to the often very long latency periods between exposure and the appearance of pathologies. In the great majority of cases, exposure to carcinogens is not associated with a dysfunction in the production process and does not disrupt it. The pressure exerted by the trade union movement is also less strong than in other fields of prevention. Different factors are contributing to this situation: lesser social visibility, great differentiations in the levels of risk depending on the sectors, difficulties in supporting collective intervention at an appropriate level of expertise, the tendency to delegate the most complex questions of prevention to specialists.

It may be added that, although in some countries, including France, the question of asbestos triggered an acute awareness of the importance of prevention of occupational cancers (Henry, 2007), the European Union has an institutional culture which makes it far more distant with respect to societal expectations. The health catastrophe was no less severe in the other countries of Europe but, on the European political scene, there is no significant trace of the asbestos scandal. Suffice it to note the relative indifference which has accompanied the European Commission's decision to make it still possible even now to import several tens of tonnes of asbestos each year into two Member States (Germany and Sweden). Discrete lobbying by the enterprises involved (mainly Dow Chemical) was enough for the European Commission to postpone *sine die* the date of total ban initially planned for 2005 [24] and to turn a blind eye to the clear illegality of the exemption granted by the German authorities to Dow Chemical [25]. The possible health impact of this measure is no doubt minor (except, of course, for asbestos mine workers located in Brazil and in transport activities from the mine to the ports) but its symbolic impact is considerable: it is hampering efforts aimed at the worldwide ban on asbestos.

Apart from questions of health at work, another factor is increasingly involved. The Community institutions share, to varying degrees, the ideology whereby the ultimate legitimacy of the law lies in its economic efficacy. This is a common base for the beliefs of different institutions from the Commission to the European Court of Justice. This instrumental vision of the law expresses a

24. ECHA supports the maintenance of this derogation until 31 December 2025. This position reflects the intense lobbying conducted by the multinational Dow Chemical. The final decision should be adopted by the Commission during 2016.

25. On the basis of Community law, Germany was able to grant an exemption concerning the import of membranes containing asbestos fibres. The exemption has been extended to the import of fibres.

convergence between the apologists for market laws in the liberal tradition and the political and economic elites of central and eastern Europe formed in the Stalinist tradition. Of course, it does not exclude debate between different political options but it considerably impoverishes it and above all makes it closed to social mobilisations and debates on social projects. This tendency can be seen, often like a caricature, in the implementation of regulation strategy whose watchwords are impact assessment, the reduction of 'administrative burdens' and the simplification of enterprises' obligations (Vogel and Van den Abeele, 2010). The legitimacy of legislation on occupational cancers lies in the reduction of social health inequalities and in the coherence of rules intended to reduce employees' life, body and health to a status of goods to be exchanged for a salary. Such legitimacy justifies significant limitation of the freedom to engage in enterprise and employers' prerogatives in technological choices and the organisation of work. This is one of those fields where it seems obvious that the sum of individual egos never results in collective happiness whatever trust is put in the invisible hand of the market.

The logjam in European policy concerning occupational cancers implies a clear risk of renationalisation of this central element of any prevention strategy. This has two major drawbacks: a loss of efficacy associated with the dispersion of efforts among the 28 Member States (this is already visible in the production of OELs and in the campaigns in favour of substitution) and a negative spiral of competition that would hamper the efforts made in the countries that have made most progress over the last 10 years. Eventually, the question is whether the European Union, which, in the '90s, was a stimulating factor in prevention policies for health at work, is risking becoming an obstacle to new progress in this field.

The medium-term perspective: a single OSH Directive for all chemical substances

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1. Introduction

Workers in the EU are protected against carcinogenic substances by a special EU occupational safety and health (OSH) directive, the 2004 Carcinogens and Mutagens Directive (CMD, Directive 2004/37/EC). It was originally based on the 1990 Carcinogens Directive (Directive 90/394/EEC), which came into force before the 1998 EU Chemical Agents Directive (CAD, Directive 98/24/EC). The CMD is also partly based on two International Labour Organization (ILO) agreements from 1974: the Occupational Cancer Convention (C139) and the Occupational Cancer Recommendation (R147).

Many EU Member States turned the CMD and CAD directives into national law with a single regulation, which might in itself be an argument for consolidating them. More important, though, is the effect of the CMD since it came into force, in particular the way carcinogens were substituted by less hazardous substances and the degree of exposure reduction. Another issue is whether the CMD can still keep up with the state of scientific knowledge.

These concerns are illustrated by the following observations:

— Recent attempts to develop more binding occupational exposure limits (BOELs) for the CMD have revealed the very slow progress in reducing exposure levels. These efforts depend on enforcement by authorities, which is often lacking.

— No comprehensive employer data is currently available on the nature, degree and duration of worker exposure to carcinogens and mutagens, even though it is one of the CMD's fundamental obligations and EU Member State authorities have the right to request it. This lack of data both hampers scientific research on occupational cancer and restricts the development of regulation.

— Although OSH regulation on respiratory risks has always been seen as more important than dermal exposure, there are many chemicals in the workplace that can be absorbed through the skin, suggesting this issue deserves more attention.

— The occupational exposure limit (OEL) concept underlying the CMD is outdated as it does not take account of the risk-based limits introduced in the Netherlands in the mid-1990s and Germany in 2008. Also, only

three carcinogens – benzene, hardwood dust, and vinyl chloride monomer – have been given BOELs in the past 25 years.

— Recent drafting of recommendations for additional BOELs for carcinogens revealed a disturbing fact: no methodology has yet been developed to set BOELs in the CMD.

— The CMD is still based on 1970s and early-1980s assumptions that effect thresholds (the point at which the agent has no adverse health effect) do not exist for carcinogens with genotoxicity (the ability of chemical agents to damage a cell's genetic information) as the mode of action. But since the mid-1980s, evidence has emerged that effect thresholds are likely to exist for some carcinogens with inflammation-induced modes of action.

— The CMD's scope conflicts with the REACH regulation's scope of substances of very high concern (SVHCs). All carcinogens and mutagens placed on the market are covered by the CMD and, at the same time, are eligible to be SVHCs according to article 57 of REACH. Yet substances with a toxic effect on reproduction (reprotoxicants) or other substances of 'equivalent concern' used at the workplace are also eligible as SVHCs under REACH but outside the scope of the CMD. There has been no progress in the regulatory efforts that began ten years ago to extend the scope of the CMD to reprotoxicants.

— There are possible overlaps between the REACH and OSH legislation, for example, when it comes to workers' health under the REACH processes of authorisation (REACH Title VII) and restriction (Title VIII). A recent restriction proposal on 1-Methyl-2-pyrrolidone (NMP) revealed conflicts between them. Solutions are needed to prevent the two regulatory processes interfering with one another. This is not a hypothetical issue: NMP, which can be absorbed through the skin, is a reprotoxic solvent used at work. The proposed restriction under REACH aims at introducing regulatory measures, notably to protect pregnant women and the unborn, but it is not currently suited for such occupational health and safety issues.

— The BOELs in the CAD and in the CMD are supposed to reflect both feasibility factors and health considerations. In other words, BOELs are designed to both include technical and socio-economic considerations on top of health aspects. However, there are no details elaborated on how these considerations should be practically applied when deriving limit values. By contrast, guidance on socio-economic analysis does exist in the REACH regulation.

These observations show that the EU OSH directives on hazardous chemicals need to be modernised and aligned with the REACH regulation.

The following chapter explains how this could be achieved with a consolidated OSH Directive for chemical substances. This would retain the successful parts

of the two current directives, while revising or amending the more troubling portions.

2. Approach

The consolidated, single OSH Directive for chemical substances should not be rewritten from scratch. Rather, the revision should take account of approaches from across Europe that might serve as starting points. One such example is the German Hazardous Substance Ordinance, which was the single regulatory instrument used to transpose both the CAD and the CMD into German law.

2.1 The German Hazardous Substance Ordinance

The 1986 German Hazardous Substance Ordinance, which sets rules on the use of carcinogens in the workplace, was adapted to take account of the EU's 1990 Carcinogens Directive (90/394/EEC). The Ordinance was overhauled when it took on the provisions of the Chemical Agents Directive (98/24/EC). This 2004 revamp set general obligations for all chemical substances within the scope of the CAD, and additional obligations – as laid down in the CMD – for carcinogenic and mutagenic substances.

Talks on extending the CMD to cover reprotoxic substances have gone on since the turn of the millennium. During that time, Germany has broadened rules on carcinogenic and mutagenic substances to include reprotoxic ones. Most reprotoxic substances have effect thresholds for reprotoxicity. In such situations, if the exposure is below a health-based OEL, the Ordinance's section on carcinogenic, mutagenic, and reprotoxic (CMR) substances limits the employer's obligations to those for non CMR-substances.

The substitution obligation is not affected by that qualification: it applies to all CMR substances, irrespective of the existence of an effect threshold. The serious concerns about these substances mean that substitution or use in a closed system are considered as safer solutions than exposure minimisation.

One consequence of Germany's extension of the CMD to cover reprotoxic substances was that existing OELs were checked to see if their values were below the effect threshold. OELs were then derived for relevant reprotoxicants that did not as yet have them. Ten years without complaints from employers about this approach suggests it is a viable solution.

2.2 Outline of a single OSH Directive for chemical substances

2.2.1 Structure

The experience applying the German Hazardous Substance Ordinance can help guide efforts to turn the existing CAD and CMD into a single OSH Directive for chemical substances. This single directive could be based on the structure

of the current CAD. It would have a section on substances of very high concern that includes any CMD obligations that transcend those in the CAD (for details cf. section 2.2.3.below).

The new directive would keep the two obligations establishing an inherent safety: the substitution obligation and the obligation of use in a closed system if technically possible. The remaining additional obligations would be waived for uses of a substance under certain conditions:

— a health-based OEL exists;
— exposure at the workplace is below that OEL;
— the effects posed by simultaneous exposure to different substances are taken into account;
— for substances with a skin notation (when it says that a substance can be absorbed through the skin) and when use does not include manual handling that could lead to repeated or prolonged skin contact.

In addition to a mere consolidation of the current contents of both the CAD and the CMD, certain aspects of both the REACH regulation itself and its outcome could also be utilised in a single OSH Directive. Main examples would be information generated by the registration process, the notion of SVHCs, and the authorisation process.

2.2.2 Scope

The scope of the single OSH Directive should be identical to the existing CAD and CMD. It should thus cover substances on the market, substances generated through work activities (so-called process-generated substances) and substances contained in products or in the work environment which are no longer produced or put on the market, such as asbestos ('legacy substances'). By contrast, the scope of the REACH regulation is limited only to substances on the market.

The REACH regulation should be the template for the SVHC section of the single OSH Directive, irrespective of the overall wider scope of the latter directive. Coverage should be extended by aligning it with art. 57 of the REACH regulation, thus ironing out the differences between the two, while creating new synergies.

It would also mean the reprotoxic substances in categories 1A and 1B should be included in the SVHC section of the single OSH Directive irrespective of whether they are in the SVHC candidate list under art. 59 of REACH. Substances that are not classified as CMR 1A or 1B yet raise equivalent concerns could be included in a separate annex similar to Annex I of the current CMD - but only after they have been added to the same REACH candidate list related to concerns over workers' health. This last condition is needed to avoid including SVHCs based on consumer health or environmental aspects rather than workers' health, as those concerns are outside the scope of OSH legislation.

2.2.3 Control measures

Section 2.2.1 refers to specific obligations under the CMD that go beyond the CAD. They include:

— the tiered approach on protection from exposure by substitution, using of a closed system, or exposure minimisation;
— providing information on exposure and related issues to competent authorities upon request;
— training, informing and consulting workers;
— health surveillance both during and after employment;
— keeping records of exposed workers and their health surveillance.

The three elements of the tiered approach on protection from exposure have helped improve workers' exposure to carcinogens since the mid-1980s, when the content of the CMD was first developed. The ECHA website (available at: http://echa.europa.eu/information-on-chemicals/registered-substances), which gathers information on chemicals registered under REACH, shows that some carcinogens have not been registered at all, even though Germany gave them OELs in the 1980s. It is not clear why they disappeared from the European market, but it could in part be due to a successful substitution process. Another possible explanation is a relocation of production and use sites outside the EU, or a phasing-out of uses due to changes in markets and technology. Other carcinogens with technical-based OELs have been registered for use as intermediates only, or under strict control conditions like a closed system. In other words, exposure should have stopped completely or should have been reduced considerably.

2.2.4 Exposure minimisation and action plan

The absence of reliable exposure information across industry means it is harder to assess the third tier, exposure minimisation. Data, although scarce, indicate falling exposure levels in some sectors. However, that cannot be extrapolated across industry as a whole. Given both the absence of a specific regulatory strategy on exposure minimisation and the precarious level of enforcement in a number of EU Member States, some sectors have probably seen little progress on reducing exposure to carcinogens. The Netherlands and Germany have addressed this concern by introducing an additional tool: an action plan in which employers have to describe their intentions on how, by when, and to what extent, they plan to further reduce exposure levels[1]. This action plan takes the form of an addendum to the documentation of the risk assessment. It allows worker representatives and labour inspectors to monitor employer compliance on reducing exposure. The obligation to provide such an action plan as part of the risk assessment should be specified in the SVHC section of the single OSH Directive.

1. For further details, see p. 57: H. Wriedt, *Reducing carcinogens in the workplace: lessons from Germany on how to complement substitution*.

2.2.5 Dermal exposure and uptake

For substances that can be absorbed through the skin, certain conditions of use can result in dermal exposure with a higher risk than respiratory exposure, especially with repeated or prolonged skin contact. These substances are tagged with a skin notation, which provides key information for the employer's risk assessment.

The skin notation is usually available for substances assessed by scientific committees, in particular when it comes to setting an OEL. This information is not part of the classification under the CLP regulation, nor is it easily accessible in the database of REACH-registered substances.

Skin contact with hazardous substances is particularly relevant for manual tasks like construction, handicrafts, hospital work, cleaning, maintenance and repair work. Manual tasks are more widespread amongst SMEs, which find risk assessment for hazardous substances particularly challenging. So when it comes to specific guidance on protection against dermal exposure, the new OSH directive should provide employers, particularly SMEs, with adequate support to help them comply with their mandatory obligations. One example of such guidance comes from Germany's Technical Rule on risks resulting from skin contact (electronically available at: http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/TRGS-401.html).

Dermal absorption is relevant for many SVHCs as the body can take in the most serious carcinogens and reprotoxicants through this route.

2.2.6 Compilation of exposure information by EU Member States

The current CMD allows EU Member State authorities to request exposure information from employers. However, as no government seems to have made use of this possibility, Member State reporting duties to the Commission should be added to a single OSH Directive, thus forcing authorities to collect exposure data for SVHCs. This information would serve two purposes. Firstly, it would help identify sectors or uses with particularly high exposure levels, and could in turn initiate targeted support and enforcement measures. Secondly, it would shed light on progress in exposure reduction, and could thus lead to evidence-based revisions if necessary.

As for SVHCs with an effect threshold, the aim is to keep exposure levels below that limit. Substances should be exempted from the obligation to be covered by an action plan on exposure reduction if a health-based OEL exists and the exposure at the workplace is below that OEL. Those uses should also be excluded from reporting duties by Member States to limit their additional burden.

2.3 SVHCs and risk management instruments

As this publication focuses specifically on carcinogens, the following sections look more closely at the different types of carcinogens and other SVHCs and

suggest appropriate instruments to manage their risks. These include instruments like OELs, the authorisation mechanism of uses foreseen under the REACH regulation, and guidance on specific tasks and uses. The best instrument for the respective exposure situation depends, at least partly, on the characteristics of the SVHCs involved.

2.3.1 Relevant SVHCs

Three types of SVHCs were addressed in section 2.2.2, above: substances which are on the market, process-generated substances and legacy substances. CMR substances (classes 1A or 1B) produced or imported at volumes over one tonne per year have to be registered under REACH before being put on the market. This rule allows regulators to prioritise further action on CMRs according to their production volumes, while letting worker representatives check if CMRs at the workplace are on the market legally.

From a chemical perspective, SVHCs can be present as individual substances or as mixtures of substances. Mixture examples include petroleum and coal stream substances, and several process-generated substances (for further details, see section 2.4.4 below).

SVHCs might have an effect threshold (a point below which the substance does not trigger an adverse health effect) from a toxicological perspective. Current scientific opinion says reprotoxicants have an effect threshold unless they also have carcinogenic properties. By contrast, not having an effect threshold means no exposure threshold has been identified below which the adverse health effect does not occur. Current scientific opinion suggests most carcinogens have no effect threshold.

However, these definitions do not account for the broad range of scientific complexities. Scientific propositions are based on the current state of knowledge: any regulation that uses them will be affected by potential scientific uncertainties. They will also be affected by the influence that interest groups wield over the regulatory process.

2.3.2 SVHCs with an effect threshold

These provisos should be borne in mind as we take a closer look at the scientific propositions. The European Commission's Scientific Committee on Occupational Exposure Limits (SCOEL) is currently trying to assign carcinogens to one of four categories: without a threshold, situation not clear, practical threshold and true threshold. The German scientific committee looking into exposure-risk-relationships (ERRs) for carcinogens takes a similar route, but with a nuance. Instead of a 'practical threshold' category, it uses a 'non-linear exposure-risk-relationship' one. For carcinogens in that category, no threshold is assumed: it only has slowly increasing risks below a certain concentration value and a much steeper increase above that value. Thus, the resulting ERR is not a linear one but takes the shape of a hockey stick.

These two scientific bodies have different assignations for a number of carcinogens. SCOEL says some carcinogens have either a true or a practical

threshold, which the German committee does not support. These include cadmium compounds, ceramic fibres, nickel compounds and trichloroethylene. By contrast, the German committee assumes a linear ERR for cadmium compounds and ceramic fibres, but a non-linear one for nickel compounds and trichloroethylene.

The two committees agree that there is a threshold for carcinogenicity for at least three substances, namely formaldehyde, propylene oxide, and naphthalene (naphthalene is still classified as C2, being therefore outside the scope of the CMD). The German committee has so far identified 24 carcinogens or groups of carcinogens without a threshold: a linear ERR was derived for 18 of them, a non-linear ERR for two and no ERR could be derived for another four. By contrast, thresholds were assigned and health-based OELs were derived for only five carcinogens. Of these, two are considered as threshold ones (formaldehyde, isoprene), whereas for the other three (beryllium, butylene oxide, propylene oxide), the additional cancer risk at the OEL is considered to be so small (i.e. at or below an additional cancer risk of 4:100 000 over 40 years of exposure) that any further exposure reduction would not result in meaningful risk reduction.

2.4 Risk management instruments

2.4.1 OELs

General considerations

OELs serve two main functions as tools for respiratory exposure risk assessment:

1. They define the level of protection which should at least be achieved for the design of control measures.
2. They are the yardsticks to assess the effectiveness of control measures and their improvement if need be.

Different types of OELs are defined in the CAD (both indicative and binding ones, or IOELs and BOELs, respectively), in the CMD (binding ones, BOELs), and in the REACH regulation (so-called derived no-effect levels, or DNELs).

The OEL can be set differently according to the health hazards of the substance it has been set for. The OEL can be set either for short-term exposure, typically as an average value for 15 minutes (for some substances, it can be a ceiling value that should not be exceeded at all). Or it can be set for long-term exposure, typically as an average value for the duration of a whole shift, i.e. for eight hours. For some substances, both long and short-term OELs have been derived. For substances where only an eight-hour OEL has been derived, some EU Member States have stated that by default, no short-term exposure should exceed the long-term OEL by a factor of eight. But the eight-hour OEL is relevant for most of them since OELs refer to detrimental long-term health effects.

While some OELs for dermal exposure might be of scientific and regulatory interest, the absence of suitable instruments for monitoring dermal exposure at the workplace means they are not always practical.

OELs for SVHCs

From a scientific point of view, there are obvious ways to set OELs for SVHCs. For SVHCs with an effect threshold, the instrument of choice is a health-based OEL below the effect threshold.

For SVHCs without an effect threshold, like most carcinogens, a risk-based OEL could be the preferred option. This would assume that a consensus could be reached on introducing an overall, substance-independent, risk value for the additional cancer risk on which each OEL were to be based, and the regulatory consequences if it is exceeded. One obvious action if an OEL is exceeded is mandatory use of respiratory protective equipment (RPE). By contrast, compliance should not impact the overall obligations to minimise the exposure and to write an action plan on the future steps in the minimisation process.

But the way forward is more complex from a regulatory context and requires adaptations to current instruments. Although no major changes to the SCOEL methodology are needed to set health-based OELs, Member States should no longer be allowed to set higher values than those derived by SCOEL. In other words, health-based values have to be binding, but unlike the current BOELs, technical or socio-economic factors should not be considered.

A new methodology for BOELs is needed anyway for carcinogens without a threshold, as the prototype of non-threshold SVHCs, as the current situation is unsatisfactory. The obvious though challenging way forward under the outline listed above would be a new approach, like the Dutch and the German one, that includes risk-based OELs.

This regulatory approach would leave no room for BOELs set using technical feasibility or socio-economic considerations. These issues should be covered instead by the REACH regulation's authorisation mechanism. For carcinogens outside the scope of REACH, such as process-generated crystalline silica, a corresponding regulatory mechanism should be set up. Additional details are sketched out in section 2.4.3 below.

2.4.2 Number of OELs needed

It should be possible to set OELs for the most relevant CMR substances, even if the classification and labelling information on notified and registered substances (C&L Inventory) on the ECHA website (http://echa.europa.eu/information-on-chemicals/cl-inventory-database) suggests otherwise with its huge list of such substances.

However, the information from the C&L Inventory should not be taken at face value. A single OEL would suffice to cover all the compounds in certain groups

of substances, such as the different carcinogenic metals and their compounds: arsenic, cadmium, chromium (VI) compounds, cobalt, and nickel. By contrast, an OEL would be futile for the coal and petroleum-related products that account for most of the carcinogen entries in the C&L Inventory: other approaches would be needed (see section 2.4.5, below). Of the remaining carcinogenic substances or groups of substances, about 40 are registered under REACH with a full registration of uses that might result in workers' exposure. Another 25 are registered for intermediate use only, or for use under strictly controlled conditions, which is comparable to the way the CMD refers to use in a closed system.

Similarly, the number of OELs needed to cover relevant reprotoxic substances can be estimated. Again, a single OEL might suffice for two groups of substances, lead compounds and boric acid derivates. A number of substances are also classified as carcinogens (C 1A / C 1B) and thus do not need to be considered a second time. Of the remaining substances or groups of substances, about 30 have a full REACH registration and about another ten are registered for intermediate use only.

Eight of the reprotoxicants on the list now have OELs at EU level or have been suggested by SCOEL. SCOEL is still working on a recommendation for another two. An OEL has been derived for a further four reprotoxicants in the German list of health-based OELs. The German MAC Commission has made OEL recommendations for an additional four reprotoxicants. In other words, health-based OELs or recommendations for them are already available for the majority of the most relevant reprotoxicants. However, this has to be qualified as the scientific committee has warned that there is no certainty an unborn child would be protected under half the OELs or recommended OELs.

Only CMRs or groups of CMRs which are registered under REACH should be considered as relevant in Europe as their annual production or import volume exceeds one tonne. An OEL should be urgently considered only for those of them with a full registration.

2.4.3 Authorisation of SVHCs

There will be important consequences as a result of the introduction of health and risk-based BOELs regardless of their technical or socio-economic feasibility: for some SVHCs there will be certain uses that will not comply with the respective BOEL, while the BOEL will be complied with by other uses of the same SVHC, or where identical or similar uses of different SVHCs will comply with their respective BOELs.

This situation, where different uses of the same substance result in different exposure levels, given that control measures of the same level of technical feasibility are applied, cannot be reconciled with the current technical-based OELs. These OELs do not distinguish between different uses of a substance. Instead, the resulting BOEL will most likely be based on a use that creates the highest exposure level over the whole use spectrum. For all other uses, the BOEL will apply in spite of lower exposure levels already achieved.

A better regulatory approach in such a situation could be to use the authorisation mechanism of the REACH regulation. That mechanism would allow differentiation between different uses of the same substance. It would also facilitate monitoring of company-level efforts on substitution, using closed systems and minimising exposure. The specific authorisation conditions (cf. art. 60 of the REACH regulation) could serve a similar purpose to the action plan (cf. section 2.2.4, above), allowing not only labour inspectorates but also workers and their representatives to closely monitor employer compliance with those conditions.

Different scenarios could be established depending on the type of OEL and on compliance with its value:

— For substances with a health-based OEL, the risk of uses with an exposure below the OEL should be qualified as 'adequately controlled'. Such uses should thus be exempted from the authorisation mechanism.

— For substances with a risk-based OEL, uses with an exposure below the OEL should be granted a long-term authorisation if the applied occupational safety and health measures conform to good practice, and if the action plan specifies future measures for exposure reduction.

— For substances with a health-based or risk-based OEL, uses with an exposure that exceed the OEL should only be granted a short or medium-term authorisation if the occupational safety and health measures applied conform to best practice, and the action plan specifies future measures for exposure reduction. In addition, RPE has to be used by workers, which implies that additional breaks and recovery times have to be provided.

A similar approach should be taken for manual uses of substances that can be absorbed through the skin if they lead to repeated or prolonged skin contact. Those uses should also go through the authorisation mechanism: whereby authorisation should only be granted if the occupational safety and health measures for manual handling conform to best practice and future measures for further reducing or completely avoiding skin contact are specified in an action plan. In addition, personal protective equipment, in particular protective gloves, have to be worn by workers, which implies that additional breaks have to be given on a daily basis. Sufficiently long work phases also have to be foreseen without wearing gloves, so that the prolonged use of protective gloves does not damage the skin.

The approach sketched out here, replacing the use of technical-based BOELs with health-based or risk-based ones plus an authorisation mechanism, would increase pressure to comply with obligations to reduce exposure to SVHCs (which has worked poorly for carcinogens in the past).

One reservation has to be mentioned, though: during the first authorisations process under REACH, there were controversies on assessing the economic feasibility of alternative solutions. These controversies need to be resolved

before exploring the authorisation mechanism to replace the technical-based BOELs as referred to above.

2.4.4 Process-generated SVHCs

As mentioned in section 2.3.1, regulation of process-generated substances differs in key respects. Some of these, like diesel engine emissions (DEE), silica dust and hardwood dust, are dealt with in the same way as other substances with OELs. Others are seen as mixtures which large numbers of workers could be exposed to. These include polycyclic aromatic hydrocarbons and their nitro-derivatives (PAHs), used mineral oils, polychlorinated dibenzo dioxins and furans (dioxins) and N-nitrosamines.

The situation is more complex for the second group of process-generated mixtures thanks to the variable composition of their constituents and the differences in their carcinogenic potency. Although OELs have been derived for some individual substances from those groups - e.g. for benzo(a)pyrene and N-nitroso dimethylamine - there are no OELs for each of these groups as a whole. This is not surprising given the differences in the ERRs or the dose-effect curves of the individual substances in each group: the eventual results depend on the mixture's composition and the fractions of the individual substances in it. The composition depends not only on the nature of the process from which it is generated but also on key process parameters (temperature, composition of basic substances and presence of specific compounds). So it would be of little use to determine a key component and use it as a proxy for the mixture.

From a scientific point of view, any OEL derivation would have to start by identifying the individual constituents to determine their respective fractions in the specific mixture. The ERR (or the dose-effect curve) of that specific mixture could then be calculated without considering any potential interaction between constituents. However this approach is not viable in practice as the ERR (or the dose-effect curve) has not yet been determined for most of the individual substances in those mixtures. And given the large number of different constituents, it is highly unlikely they will be determined in the foreseeable future.

There is a further complication when it comes to substances for which the exposure risk is through the skin rather than by inhalation: specific solutions on dermal exposure assessment have to be developed for these four groups. This also applies to the petroleum and coal stream substances addressed above: they contain PAHs or other carcinogens to a variable extent, and dermal exposure is also a significant risk.

In other words, assessment tools based solely on scientific evidence, such as OELs, are not an option for such complex mixtures. A different approach is thus warranted.

2.4.5 Guidance

Such an approach could consist of guidance to improve both the operational conditions of the underlying process and to improve selection of the most effective control measures. It could be complemented by a more pragmatic assessment tool for the exposure generated during the process. This assessment tool should be scientifically informed by the ERR (or the dose-effect curve) of a representative substance for that type of mixture for which sufficient data is available (e.g. benzo(a)pyrene for PAHs, or N-nitroso dimethylamine for N-nitrosamines). But it should also be based on a scientifically informed convention on weight factors for adding up the contribution of the individual constituents.

The guidance for recommendations on the operational conditions and the control measures should be non-binding to help reduce the length of the regulatory process. To give it more legal weight, the Commission should be mandated to issue such guidance in the single OSH directive. Any guidance could also be complemented by the promotion of good practice on the website of the European Agency for Safety and Health at Work in Bilbao.

This guidance is already available for some processes in certain Member States: the UK has operational guidance on coke oven emissions and COSHH essentials on machining with metalworking fluids; Germany has technical rules on processes involving PAHs and N-nitrosamines. Guidance at EU level should make the best use of resources by building on existing guidance at Member State level.

2.4.6 Legacy SVHCs

Restricting certain substances like asbestos does not prevent them being present in the workplace today, nor does authorisation exclude them from tasks beyond those authorised. The past use of certain SVHCs, before restrictions or authorisations, means they are still present in all sorts of objects and products, from industrial sites to buildings to machinery, vehicles and appliances. A number of tasks involving those objects and products – like maintenance and repairs, demolition, or recycling – will mean exposure to 'legacy substances', such as asbestos, carcinogenic glass fibres, PAHs, lead or other heavy metal pigments, for the foreseeable future.

Although OELs for these substances can help in assessing the risks associated with different tasks, the manual nature of many of these tasks will result in high risks anyway, particularly if the legacy substances are present in relevant concentrations. As in the previous section, specific guidance for such tasks seems similarly warranted as a complementary regulatory tool.

3. Summary

A consolidated, single OSH Directive for chemical substances could do much to address the regulatory shortcomings and deficits outlined in the introduction. The enforcement of certain obligations would also be made easier.

The key aspects of such a consolidated directive are:

— extending the scope of the current CMD to align it with the scope of SVHCs under REACH;
— introducing an action plan as part of the risk assessment for uses of SVHCs with mandatory exposure minimisation;
— introducing regular monitoring and reporting duties by Member States to the Commission on SVHC exposure levels;
— putting a stronger focus on dermal exposure in risk assessment;
— mandating the Commission to issue non-binding guidance for certain processes and tasks, in particular those that involve legacy substances or create complex process-generated mixtures;
— modernising the outdated OEL concept and basing it solely on health-based and risk-based OELs;
— abandoning technical-based OELs and replacing them, when necessary, with a mechanism tailored to the REACH authorisation process;
— adapting the CMD to the current state of scientific knowledge, in particular by recognising the existence of different modes of actions for carcinogenicity.

A consolidated directive would be improved considerably by prioritising additional OELs for the SVHCs that are most relevant in the workplace. An initial survey of the relevant ECHA databases suggests a manageable number. Additional needs have been identified for specific assessment tools for certain process-generated carcinogens, such as PAHs, dioxins, and N-nitrosamines, that have a variable composition of constituents. In addition, specific guidance is needed for tasks involving complex mixtures and on protection against dermal exposure.

Occupational exposure limits: uses and limitations in worker protection

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Occupational exposure limits (OELs) are important tools for assessing and monitoring workers' exposure to hazardous substances. They have been used for decades in all industrialised countries to help prevent adverse effects on the health of people exposed to hazardous chemical agents in their workplace. The OEL can be defined as the concentration of a substance, most often in the working atmosphere, to which workers may be exposed repeatedly (throughout their working life) or acutely (for a short time) without any adverse effects on their health or that of their descendants at any time. Comparing the concentration of a hazardous substance measured in the atmosphere to its occupational exposure limit can help to assess the risks for exposed workers and to select appropriate measures to manage such risks. OELs can also be used to check and improve the effectiveness of risk management measures implemented.

We should make it clear from the start that complying with the exposure limits should under no circumstances be considered to be an end goal that will ensure effective prevention. Effective prevention requires a whole range of measures, the priority of which must be to eliminate hazardous chemical substances or replace them with safer processes or alternatives. If elimination or replacement is not possible, then workers' exposure level should be reduced to a minimum by application of a set of preventive and protective measures. Priority should be given to collective measures over individual measures. These principles are established and applied throughout Europe under the EU legislation in force on the protection of workers' health from chemical risks.

The substances for which OELs are determined, the methods used to determine the OELs, their legal status and the practices used to revise and implement them in workplaces vary from one industrialised country to another (Schenk et al., 2008; Schneider E. and Kosk-Bienko J., 2009; Walters et al., 2003). It is no surprise, then, that different countries apply different OELs for the same substance.

In this article, we will review the main types of OEL that exist for chemical substances and the different methods used to develop them. We will also discuss the influence of the REACH regulation on the use of exposure limits in Europe, as well as the general limitations of using OELs.

1. Health-based and risk-based exposure limits

The definition of OELs set out in the introduction to this article implies that it is possible, using the available scientific data, to identify a single exposure threshold below which exposure to a substance causes no adverse effects. In such cases, we talk about 'health-based OELs'. One substance with this kind of OEL is cyclohexane, a flammable liquid used mainly in nylon production. It is an irritant with low acute toxicity and can cause drowsiness or dizziness, but none of these effects are expected to be observed in human beings below its OEL of 700 mg/m³.

When the state of knowledge about a substance is not sufficient to determine a single threshold below which no adverse effects on health are observed, we must assume that every level of exposure, however low, brings with it risks of adverse effects. This is the case for 'non-threshold' substances such as genotoxic carcinogens, which damage DNA, and respiratory sensitisers. It is possible to develop OELs in such a situation, but they will necessarily be associated with a risk. This risk will have been determined in advance and considered low enough to be 'acceptable'. In such cases, we talk about 'risk-based OELs'. This method is currently applied in the Netherlands and Germany (Pronk, 2014). While the relationship between levels of exposure to a non-threshold carcinogen and the corresponding risks of developing cancer can be scientifically determined, the definition of what constitutes an 'acceptable' risk is a political decision that calls for a societal debate. For example, in the Netherlands, the government decided that no worker could be exposed to a carcinogen at an atmospheric concentration higher than that at which the risk of developing cancer is 4 additional cases per 1 000 workers exposed over a 40-year career. This concentration varies from one carcinogen to the next. For arsenic trioxide, which has been proven to be carcinogenic to humans and is used in the glass industry, this risk of 4×10^{-3} corresponds to an OEL of 7µg/m³. Additional details about the principles for establishing risk-based OELs are available in H. Wriedt's chapter, p. 59.

The progress made in recent years in understanding cancer risk and the behaviour of carcinogenic substances suggests that a distinction may be made between genotoxic and non-genotoxic substances (European Commission, 2013). For the latter, a no-observed-adverse-effect level may be determined because the cancer risk is dose-dependent and does not involve DNA damage or mutations. In practice, this means that a health-based OEL may be proposed for some carcinogens (such as chloroform or carbon tetrachloride). Similarly, some genotoxic substances could act in a dose-dependent way and a 'practical' no-observed-adverse-effect level could be calculated based on mechanistic studies. The following carcinogens could fall within this category: nickel, cadmium, formaldehyde and crystalline silica. It should be noted that this distinction between different types of carcinogens seems to be becoming an established feature of the regulatory landscape both in Europe (REACH Regulation) and elsewhere in the world, though it remains controversial (ETUI, 2012).

2. OELs: from scientific concept to social construct

The first stage in establishing an OEL is generally based on scientific knowledge. Experts collect all the relevant data available about the substance (intrinsic properties, studies on humans and/or animals describing the short- and long-term adverse effects, target organs, etc.) and determine whether the substance acts via a non-threshold mechanism or whether a traditional toxicological model (with a threshold) may be used. In the latter case, they establish the no-observed-adverse-effect level (NOAEL) which will be used as a basis for determining the OEL. As the experimental or epidemiological data available is often limited, uncertainty factors (sometimes known as 'assessment factors' or 'safety factors') are used to take into account inter- and intra-species variations and other necessary extrapolations. The final health-based OEL value for the workplace atmosphere is obtained by dividing the NOAEL value by the uncertainty factors. A public consultation is held during the procedure so that comments and/or information from third parties can be taken into consideration. The OEL is expressed in mg/m³ or parts per million (ppm). The value supplied is generally the time-weighted average (TWA), which is the average concentration of a substance in the air without adverse effects for workers over a normal working period of 8 hours per day or 40 hours per week. It is sometimes accompanied by a short-term exposure limit (STEL) to prevent adverse effects that may arise from brief exposure (typically 15 minutes).

This general methodology is used throughout the world. It is applied, for example, by the American Conference of Governmental Industrial Hygienists (ACGIH) in the United States and by the Scientific Committee on Occupational Exposure Limits (SCOEL) in Europe. Both these bodies set health-based OELs which are published in the form of recommendations.

There can then be a second stage of the process, in which the recommended values may be modified in order to take account of socio-economic factors or technical feasibility before they are used in workplaces. These changes may be made unilaterally by employers (United States) or negotiated between social partners (Europe). As a consequence, the limits used in practice are much less protective than those recommended by scientists based on the current state of scientific knowledge. The health of exposed workers is therefore sacrificed for the sake of profit (keeping equipment costs down, staying competitive, etc.). When the substance to which workers are exposed is a non-threshold carcinogen and an OEL is applied (regardless of the method used to establish its numerical value), there is risk, albeit a small one, of developing cancer. In this sense, we can say that occupational exposure limits are social constructs, compromises between worker protection and the economic interests of businesses. This is why some trade union organisations in Europe are reluctant to adopt OELs for carcinogens, calling instead, for ethical reasons, for such substances to be banished from workplaces altogether.

3. Different statuses in different jurisdictions

In the United States, the OELs developed regularly by the ACGIH since the 1940s and by the National Institute of Occupational Safety and Health (NIOSH) since 1974 are recommendations and therefore have no legal force. These limits have served, and continue to serve, as the basis for establishing OELs in various industrialised countries. However, the United States also has legally binding OELs. They are adopted by the federal Occupational Safety and Health Administration (US-OSHA). These limits, known as 'Permissible Exposure Limits' (PEL), mostly date back to the 1970s and are based on OELs developed by the ACGIH. As they have never been revised since, they are, by US-OSHA's own admission, outdated and inadequate for protecting workers' health.

In Japan, OELs are recommendations developed by a scientific institute, which may be converted into binding values by the authorities with responsibility for occupational health (Takahashi & Higashi, 2006). In Australia, the limits are known as 'Workplace Exposure Standards'. They are binding and must be implemented in all workplaces (Safe Work Australia, 2013).

In Europe, occupational exposure limits are developed and adopted at both EU and national level. They may be recommendations, or binding values. European legislation on occupational health imposes minimum requirements on all Member States, allowing for states to adopt more stringent measures if they so wish (Vogel, 2016).

The recommended OELs are adopted within the framework of the Chemical Agents Directive (98/24/EC), for 'threshold substances', and currently concern 121 substances. The substances are selected by the European Commission, which then asks the SCOEL to recommend one or more OELs for each of them. These limits are based solely on scientific considerations about health, and do not take account of socio-economic feasibility factors. The European Advisory Committee on Safety and Health at Work (ACSH), which comprises workers, employers and Member States, issues an opinion to the European Commission on the values proposed by the SCOEL before they are formally adopted. Once they have been annexed to the Chemical Agents Directive, all Member States must transpose them into their own legislation. However, they can still choose the final value that will be used at national level. It may be the same as, greater than or less than the OEL adopted at EU level. This is why the OELs are said to be 'indicative'. In some Member States, these OELs will remain recommendations, while in others they will be transposed into binding values.

For a limited number of substances, essentially carcinogens and mutagens, EU legislation also provides for binding OELs. Unlike the indicative OELs, they require socio-economic and technical feasibility factors to be considered. Thus far, binding OELs have only been adopted for five substances (see Table 1). These are asbestos (a carcinogen), through Directive 2009/148/EC; inorganic lead and its derivatives (reprotoxic substances) through Directive 98/24/EC; and benzene, vinyl chloride monomer and hardwood dust within the framework

Table 1 **Carcinogenic substances for which a binding OEL has been adopted in the EU**

Substance name	CAS number	Mandatory OEL in force (TWA 8h)
Metallic lead and its compounds		150 µg/m³
Asbestos	77536-66-4, 12172-73-5, 77536-67-5, 12001-29-5, 12001-28-4, 77536-68-6	0.1 fibre/cm³
Benzene	71-43-2	3.25 mg/m³
Vinyl chloride monomer	75-01-4	7.77 mg/m³
Hardwood dust		5.0 mg/m³

of the Carcinogens and Mutagens Directive (Directive 2004/37/EC). For these substances, EU countries do not have a choice; they must, at national level, apply the value defined at European level, or a more stringent value. The Carcinogens and Mutagens Directive has been undergoing revision since 2004 with a view to widening its scope to include reprotoxic substances and adopting binding OELs for an additional twenty-five carcinogenic substances (Musu, 2013). The Directive does not set out the method that must be used to develop the binding OELs, and this subject has been debated for many years in Europe, not least among the three interest groups represented within the ACSH. One solution could be to differentiate between threshold substances and non-threshold substances, and to attach different obligations to each of these categories, including different types of OEL[1]. In the absence of a predefined method for developing OELs for carcinogens at European level, the European Commission has, as part of the revision of the Carcinogens and Mutagens Directive, commissioned an analysis of the socio-economic, health and environmental impacts of adopting exposure limits for 25 carcinogens preselected based on the number of workers exposed to them and the existence of OELs for these substances at national level. For each of these carcinogens, the costs and benefits were assessed for different OEL values in order to determine the most cost-effective value. When the value is selected on a socio-economic basis, the risk of contracting cancer at work varies from one carcinogen to another depending on the value selected, meaning that this method has the disadvantage of leading to unequal protection of workers depending on the carcinogen to which they are exposed. The social partners and the Member States have nevertheless agreed, within the ACSH, on the carcinogens for which they recommend the adoption of a binding OEL and on numerical values of the OELs to be included in the Annex III of the Directive (see Table 2). Additional process-generated substances (crystalline silica, diesel engine exhaust emissions, rubber process dusts and fumes and used engine oils) should also be included in the Annex I to bring them in the scope of the Carcinogens & Mutagens Directive. It is now up to the Commission to propose a draft revised directive to incorporate these substances in EU legislation.

1. See p. 29: H. Wriedt, *The medium-term perspective: a single OSH Directive for all chemical substances*.

Unfortunately, the difficult economic climate in Europe and the REFIT programme being pursued by the Commission are likely to further delay the adoption of these new exposure limits (Vogel, 2010; Van den Abeele, 2014). Irritated by the huge delays incurred in the adoption of new OELs for carcinogens at European level, some Member States recently called upon the European Commission make progress in the revision of the Carcinogens Directive and recommended that it urgently adopt exposure limits for the 50 carcinogenic substances responsible for 80 to 90% of occupational exposure in the EU. This initiative was supported by the European Trade Union Confederation in its resolution on occupational health and safety adopted in December 2014 (ETUC, 2014).

Table 2 **Carcinogenic substances for which a binding OEL could soon be adopted in the EU**

Substance name	CAS number	Binding OEL proposed (8h TWA)
Acrylamide	79-06-1	70-100 µg/m³
Aluminium silicate fibres (Refractory ceramic fibres)	142844-00-6	0.1-0.3 fibre/ml
Bromoethylene (vinyl bromide)	593-60-2	1 ppm
1,3-butadiene	106-99-0	1 ppm
Chromium VI	7440-47-3, 1333-82-0	25 µg/m³
1,2-dibromoethane	106-93-4	0.8 mg/m³
1,2-dichloroethane	107-06-2	2 ppm
Diesel engine exhaust emissions		100 µg/m³
Epichlorohydrin	106-89-8	1.9 mg/m³
Ethylene oxide	75-21-8	1 ppm
Hardwood dust*		3 mg/m³
Hydrazine	302-01-2	13 µg/m³
4,4′-methylenebis (2-chloroaniline) - MOCA	101-14-4	5 µmol total MOCA in urine/mol creatinine**
4,4'-Methylenedianiline (MDA)	101-77-9	80 µg/m³
2-Nitropropane	79-46-9	5 ppm
Propylene oxyide (1,2-epoxypropane)	75-56-9	1 ppm
Respirable crystalline silica	14808-60-7, 14464-46-1, 15468-32-3	100 µg/m³
o-Toluidine	95-53-4	0.1 ppm
Trichloroethylene	79-01-6	10 ppm
Vinyl chloride monomer*	75-01-4	1 ppm

*update of an existing binding OEL
**biological limit value
Note: the numerical values are based on the opinions adopted by the ACHS in 2012 and 2013. Each interest group might have different views on the numerical values of the BOELs to be included in the annex III of the directive.

At national level, in addition to the (indicative or binding) OELs set at European level and transposed into their legislation, different EU Member States also have national OELs for many other substances (including carcinogens), adopted under rules specific to each country. In some countries,

the national OELs are binding, while in others they are recommendations. In total, if we add together all the hazardous substances for which an OEL has been developed in one of the industrialised countries, we are now looking at over 1800 substances (IFA, 2014).

4. REACH and exposure limits

The debate on OELs was recently revived in Europe by the implementation of the REACH regulation (**R**egistration, **E**valuation and **A**uthorisation of **CH**emicals), which has, since 2007, set the rules for the marketing and use of chemical substances in the European Economic Area. The main objectives of this legislation are to ensure a high level of protection for human health and the environment, as well as to promote innovation and the free movement of chemical substances within the EU. The cornerstone of the Regulation is the shifting of the burden of proof from the regulatory authorities to industry. Manufacturers and importers must now assess the health and environmental risks of their substances before they can market them. They must collect information about their substances and show, by compiling a registration dossier, that they can be used safely. Around 30 000 chemical substances already present on the European market in quantities in excess of 1 tonne per year must be registered with the new European Chemicals Agency (ECHA) at some point before 2018. Non-confidential data about these substances are publicly available on the ECHA website, which currently lists around 13 000 registered chemical substances (ECHA, 2015).

The registration system provided under REACH obliges registrants to acquire and then communicate information on the properties and uses of the substances they market. The 'no data, no market' principle applies. When the substance is classified as hazardous and is produced in quantities in excess of 10 tonnes per year, a chemical safety report is also demanded in the registration dossier. The system obliges businesses to establish the necessary risk prevention measures for safe use of the substance. This information must be produced for each identified use of the substance and be annexed to its safety data sheet.

5. DNELs and DMELs

In order to be able to determine the appropriate risk management measures when the chemical substance concerned has a no-observed-adverse-effect level, the registrant must develop a health-based reference value called the 'Derived No-Effect Level' (DNEL). This is the level of exposure above which humans should not be exposed. If the risk management measures implemented ensure a level of exposure (estimated or measured) lower than the DNEL, then the risk is considered, under REACH, to be adequately controlled. When the route of worker exposure is long-term inhalation, the DNEL is very similar in principle to an occupational exposure limit. It is also expressed using the same units.

When the toxicological data do not allow a no-observed-adverse-effect level to be established (typically for 'non-threshold' carcinogens), the registrant is encouraged to develop a value known as the 'Derived Minimum Effect Level' (DMEL). This is the level of exposure associated with a residual risk that is considered acceptable. The concept of the DMEL does not appear in the REACH regulation itself, but only in the non-binding guidelines published on the ECHA website to help registrants discharge their obligations. It is very similar in principle to the concept of risk-based OELs used in some European countries.

With the implementation of REACH, some substances for which an OEL already existed at national or European level were assigned DNELs (or DMELs) by their manufacturers when their registration dossiers were compiled.

Many questions have therefore inevitably been asked about the use of DNELs/DMELs and the relationship that should exist between the DNELs/DMELs developed under REACH and the existing (or future) OELs under legislation for the protection of workers' health. These questions, and the answers to them, are not always simple. Already, they have given rise to two seminars, organised by the European Chemicals Agency (ECHA, 2012) and the European Commission (European Commission, 2014), as well as various publications. A recent study compared the DNELs developed by businesses with the indicative OELs adopted at European level and the national OELs in Finland (Tynkkynen et al., 2015). The results show that the DNELs derived by manufacturers were identical to the indicative OELs adopted in the European legislation for the majority of the substances examined (64 cases out of 87). For some substances, the DNELs were lower than the European indicative OELs (18 cases out of 87) and for others they were higher (five cases out of 87). Examples of substances in each of these categories can be found in Table 3. The comparison of the DNELs with the corresponding national OELs in Finland shows that, while the values were identical or very similar in 49% of the 315 cases examined, they were different for the remaining substances. In 28% of cases, the DNELs were lower than the national OELs and in 23% of cases the DNELs were higher than the national OELs. Other studies report similar findings (Schenk, 2011; Schenk, 2014).

The cases in which the DNELs and the European indicative OELs are identical can be explained by businesses using the existing European OEL as a DNEL for workers in their registration dossier. This is indeed what the REACH guidelines for businesses recommend in such situations.

The cases in which the DNELs are lower than the European indicative OELs mean that the health-based limit calculated by the manufacturer of the substance is more protective than that recommended by the SCOEL experts. We can imagine two scenarios here. The first possibility is that the data used by the businesses are more recent than those used by the SCOEL. In such an eventuality, the SCOEL should update its OEL in the light of the results of the new epidemiological or animal studies available. The second possibility is that the studies used by the businesses and the SCOEL to develop their respective

Table 3 **Examples of substances for which the DNELs derived by companies are lower than, equal to or greater than the corresponding indicative OELs in the European legislation**

Substance	CAS number	IOEL (8h TWA) mg/m³	DNEL (workers, long-term exposure) mg/m³
Chloroform	67-66-3	10	2.5
1,2-Dichlorobenzene	95-50-1	122	10
2-Ethoxyethanol	110-80-5	8	0.083
Toluene	108-88-3	192	192
Cyclohexane	110-82-7	700	700
Ethylacrylate	140-88-5	21	21
Chlorobenzene	108-90-7	23	23/42.3*
Heptan-2-one	110-43-0	238	394
Oxalic acid	144-62-7	1	4.03

*two registration dossiers give two different DNELs
Source: adapted from Tynkkynen et al., 2015

limits are the same, but that the uncertainty factors used by the businesses are more conservative than those used by the SCOEL. As the details of the DNEL calculation are unfortunately not publicly available, it will be difficult to decide which scenario applies. In any event, we can assume that worker protection is assured in such cases.

The other situation, however, is more worrying. When the health-based limit calculated by the businesses is higher (and therefore less protective) than that calculated by the SCOEL, protection of workers' health is no longer assured. Exposure to the substance at levels lower than the DNEL but higher than the indicative OEL may be problematic. In this case, the ECHA responsible for checking the compliance of the data provided by the companies with the obligations of the REACH regulation should take action to assess the validity of the risk management measures proposed by these businesses.

6. Does REACH mean privatisation of exposure limits?

Situations in which a substance has been given a European or national OEL and a DNEL/DMEL under REACH are relatively limited. Eventually, the number of substances for which companies must calculate a DNEL/DMEL will be around ten times the number of substances for which an OEL has so far been developed. We might therefore wonder whether REACH amounts to a privatisation of the exposure limit development process. Some employers do not hesitate to request the abolition of worker protection legislation in Europe in order to avoid duplicating obligations also imposed under REACH. However, such employers are rather quick to forget that the regulation itself explicitly provides that it applies without prejudice to the provisions of worker

protection legislation. This means that businesses must comply with the obligations arising from both types of legislation. It should also be remembered that European worker protection legislation provides for many important aspects that are not covered by REACH, such as worker training, monitoring of worker health, and the development of OELs for by-products of manufacturing processes (e.g. crystalline silica, welding fumes), which fall outside of the scope of REACH because they are not marketed.

When a business develops a DMEL for a non-threshold substance, it sets the risk level it deems acceptable itself. For risk-based limits, such as in Germany and the Netherlands, in contrast, the acceptable risk is defined by discussion and consensus between social partners (Püringer, 2011).

We should also note that, while the numerical values of the DNELs/DMELs are publicly available on the ECHA website and in the safety data sheet of the substance, the details of the calculation used by the business to determine its DNELs/DMELs, and the reasoning behind it, are not. This lack of transparency contrasts with the practice of the various scientific committees (national or European), which make documents public when they develop a health- or risk-based OEL. For risk-based OELs, the underlying risk value should be made transparent and always communicated together with the numerical values of the OELs.

7. Conflict of jurisdiction

The restriction procedures for which provision is made in the REACH regulation limit marketing or use of a hazardous substance when the risks for human health or the environment are unacceptable. These restrictions, proposed by Member States or the Commission, often prohibit the use of the substance beyond a given concentration in certain items. For example, the presence of heavy metals in batteries or of certain phthalates in toys is restricted to a very low concentration. Recently, a new type of restriction has been proposed in the form of a binding DNEL to limit the risks from occupational exposure to N-methyl-2-pyrolidone (NMP), a reprotoxic solvent[2]. If the proposed restriction is adopted by the European Commission, European businesses using the solvent will have an obligation to apply the DNEL. The mandatory DNEL was proposed by the Netherlands and then developed by an ECHA scientific committee, whereas until now the OELs adopted at European level have always been adopted within the framework of worker protection legislation, with SCOEL involvement. The value proposed by the ECHA scientific committee is four times lower than that recommended by the SCOEL and adopted as an indicative OEL under the Chemical Agents Directive. The tripartite European Advisory Committee on Safety and Health at Work (ACSH), which advises the Commission on OELs, has adopted an opinion

2. http://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/1899/term

expressing its disapproval of REACH interference in the development of European OELs. It will be up to the European Commission to settle this dispute over jurisdiction.

8. Improper use and the limits of the limits

OELs must not be confused with air quality standards, which are designed to protect the general population. Neither must they be used to assess non-occupational exposure. They must not be used to compare the toxicity levels of different substances. It is also worth remembering that an OEL is developed for a specific substance and cannot be used for another substance

In the workplace, workers are rarely exposed to just one hazardous substance at a time. There are normally several. The risk management measures implemented to keep worker exposure below the OEL for a specific substance are therefore not necessarily effective in controlling the risks from exposure to the other substances present in the working atmosphere.

Another limitation of an OEL is the fact that its numerical value is, of course, dependent on the state of scientific and metrological knowledge at the time when it is developed, and must be revised if new data become available. Experience shows that the numerical values of OELs tend to decrease each time they are revised. Unfortunately, too many current OELs are outdated and can no longer be considered adequate for limiting risks of adverse effects on the health of workers and their descendants.

In all countries it is recognised that small companies generally have limited awareness and understanding of the meaning of OELs and therefore little capacity to apply them adequately in their risk management strategies. There can also be different meanings associated with compliance with OELs in different Member States (Walters, 2003).

Moreover, the DNELs introduced by REACH are creating some confusion for employers who are used to working with OELs. Despite the similarities mentioned above between a long-term inhalation DNEL for workers and an OEL, it is important to understand the differences between the two concepts. The OEL serves as a point of comparison when the concentration of the hazardous substance in the working atmosphere is measured. If the measured concentration is higher than the limit, measures must be taken to reduce the risks and improve worker protection. The DNEL developed under REACH is not intended to be compared with the concentration of the substance measured in the workplace. The DNEL is a stage in the REACH risk assessment process that serves to develop the exposure scenarios for each particular use of a substance. An exposure scenario establishes the risk management measures and the conditions for safe use of the substance. This information is intended for the various users of the substance and must be included in its safety data sheet. Under worker protection legislation, an inspector may check, for example, that the atmospheric concentration of a hazardous substance in a

workplace is lower than its OEL. Under REACH, an inspector will instead check whether the risk management measures indicated in the safety data sheet for the specific use of the substance are implemented in the workplace. The obligations under REACH concern compliance with the established risk management measures and conditions for use, and not compliance with the DNEL.

9. Conclusions

Occupational exposure limits are one possible tool for protecting workers against adverse effects of exposure to hazardous substances. However, effective prevention is based on a hierarchy of measures, the first of which is the elimination of the hazardous substance or its replacement with a safer process or alternative. If elimination or replacement are impossible, workers' exposure should be reduced to a minimum. For carcinogens, the use of a closed system is therefore recommended. The limits, then, are only a secondary tool for assessing risks and deciding on the measures to be implemented to minimise worker exposure when primary prevention measures cannot be taken. Like all tools, they have their limitations, but they have also been extremely useful in many working situations, including asbestos removal and monitoring and reducing workplace exposure to crystalline silica, wood dust and many man-made chemical compounds that are impossible to replace.

The OEL can differ for the same substance, depending on the country or organisation that sets it. There can be many reasons for these differences. For health-based OELs, variations may be due to the adverse effects considered, the uncertainty factors applied, or the state of scientific knowledge at the time when the OEL is developed. When OELs also take into account socio-economic or technical feasibility factors, the numerical value adopted is a compromise between the protection of workers' health and the economic interests of employers. The same goes for risk-based OELs, which will depend on the definition of 'acceptable risk'. That is why we can describe these occupational exposure limits as 'social constructs'.

In Europe, OELs are also a regulatory tool and efforts have been made over decades to harmonise the methods used to develop them and ensure that an equivalent level of protection is provided for all European workers. Greater harmonisation would also make it possible to avoid the relocation of businesses to countries where protection standards are lower and, thus, competition between businesses at the expense of their workers' health. Though the method applied for 'threshold substances' is widely accepted (health-based OELs), Europe is struggling to agree on a harmonised method for deriving OELs for non-threshold substances. The recent adoption of the REACH regulation is influencing this debate at various levels. There is still some confusion among businesses about the use of DNELs/DMELs developed by manufacturers and indicated on the safety data sheets of their substances. Eventually, through the efforts of the various stakeholders involved and greater transparency about the details of DNEL/DMEL calculations, these uncertainties should be cleared up

and worker protection strengthened. Indeed, the new data about the substances generated by the REACH system should make it possible to revise many obsolete OELs, as well as improving risk management measures for the large numbers of chemical substances for which no occupational exposure limits are used.

Reducing carcinogens in the workplace: lessons from Germany on how to complement substitution

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1. Introduction

The best way to protect workers from occupational cancer is by substituting carcinogens. This approach is prioritised in the EU Carcinogens and Mutagens Directive (CMD, Directive 2004/37/EC) ahead of other measures like use in a closed system and exposure reduction to as low a level as is technically feasible. However, progress with substitution in the workplace is slow. Even if substitution is used with perfect enforcement measures, it would not remove all carcinogens in the workplace. It will take a long time before viable substitution solutions can be developed and implemented for some substances. So a complementary approach to substitution is needed. This contribution outlines the approach developed and implemented for exposure reduction in Germany over the past ten years.

Although carcinogen substitution may at first glance seem like a silver bullet for worker protection, it is slow, does not deal with process-generated carcinogens comprehensively and does not solve the legacy issue of carcinogens used in the past when they come to light again in maintenance and demolition work.

Some carcinogenic metals and their compounds (beryllium, chromium VI, cobalt, nickel) cannot be replaced in the foreseeable future for a number of important uses, including stainless steel welding. Similarly, we do not yet have the technology to completely avoid creating process-generated carcinogens such as crystalline silica, hardwood dust, diesel engine emissions, polycyclic aromatic hydrocarbons (PAHs) and related compounds, or nitrosamines. And even some banned carcinogens like asbestos will remain in the work environment for decades to come, in particular in the maintenance and demolition sectors: millions of tonnes have been used, and are still embedded in buildings, tunnels, roads and other infrastructure.

2. The minimisation strategy

For most carcinogens, there is no exposure threshold below which cancer cannot be induced. The only truly safe level is zero exposure. However, the risk of contracting cancer depends heavily on the degree and duration of exposure to the carcinogen's incorporated dose. In other words, the risk is subject to the laws of statistics: the higher the dose, the higher the probability of contracting cancer. Limiting exposure reduces the risk of contracting cancer but does not rule it out completely.

The goal of any minimisation approach is therefore to reduce the number of cases of occupational cancer as much as possible. Minimisation is always limited by technical feasibility, which effectively means economic feasibility. Exposure can be reduced to virtually zero using current technologies for the closed systems in the nuclear industry, the pharmaceutical industry and parts of the chemical industry. But they come at a prohibitive cost for other industries such as construction, engineering and metallurgy.

Germany's initial minimisation strategy for exposure was based on technical-based occupational exposure limits (OELs) for relevant carcinogens. These OELs defined workplace concentration limits and complemented the general minimisation obligation. Respiratory protective equipment (RPE) had to be worn when it was not possible to comply with the OEL during a work task. The OELs helped establish an exposure ceiling level and thus set the maximum additional risk of contracting cancer. This system of technical-based OELs was first introduced in Germany in 1974. By the end of the 1990s, technical-based OELs were in use for more than 70 carcinogens.

Yet despite its success in limiting occupational cancer risks, the approach had major shortcomings and these became obvious in the late 1990s:

— No difference was made in many workplaces between technical-based OELs and the parallel, health-based OELs: no further carcinogen exposure reduction was sought once the workplace complied with the technical-based OEL. This hampered progress in exposure minimisation.

— The regulatory adaptation of existing technical-based OELs to technological advances was very tedious and time-consuming. By 2002, more than half of the technical-based OELs had not been updated for more than ten years.

— Such OELs were usually based on the processes and tasks with the highest exposure levels (and the lowest levels in technology). This meant there was little incentive to improve exposure situations for processes and tasks with better technical standards: the OELs applied across all processes and tasks, instead of differentiating according to the available technology levels for the different sectors.

— Calculations of the quantitative cancer risks associated with the different OELs showed that about one third of the OELs were associated with additional lifetime cancer risks of more than 1%, another third with additional risks between 0.1% and 1%, and the remaining third with additional risks below 0.1%. The difference between the OEL with the lowest and the highest associated risk was a factor of about 100 000. These huge differences in risk did not have any regulatory consequences, though: additional control measures, such as the use of RPE, had to be applied when the OEL was exceeded, irrespective of the resulting risk.

— In the Netherlands, a system of risk-based OELs had been in place since the mid-1990s, where the maximum risk associated with OELs for carcinogens was limited to 0.4%. By comparison, for half of the German technical-based OELs the associated risk exceeded the Dutch risk limit.

These problems contributed to Germany's 2004 decision to abandon the approach of technical-based OELs as a tool for exposure minimisation of carcinogens, which occurred when the EU's Chemical Agents Directive (CAD, Directive 98/24/EC) was implemented into German legislation after a long delay. However, the main reason the German approach was abandoned was that it was incompatible with a system of risk assessment that used health-based OELs.

No alternative approach was made at that time. This was mainly due to arguments amongst stakeholders that emerged during the heated debates over the EU's REACH regulation. Instead, a general risk-related approach was agreed and the tri-partite Committee on Hazardous Substances, set up in 2005, was asked to come up with a detailed concept.

3. The new, risk-related minimisation concept

The new concept addressed the problems of the previous approach. Its main aims were to:

— verify the minimisation requirement at company level;
— prioritise the minimisation of high risks;
— help companies carry out exposure minimisation.

A detailed framework was reached on the concept by the end of 2007. It is described in the Technical Rule on Hazardous Substances 910 (BAUA, 2014) TRGS 910, Risk-related concept of measures for activities involving carcinogenic hazardous substances), available in English at: http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/TRGS-910.html.

Since then, 43 carcinogens or groups of carcinogens relevant to workplaces have been or still are being considered for inclusion in that concept. By spring 2015, 20 carcinogens were already covered by the concept (or their coverage is imminent), and a health-based OEL had been derived for another five. Different solutions were found for a further seven, such as use in closed systems only, or use according to a Technical Rule (comparable to an Approved Code of Practice). Work is still ongoing for 11 carcinogens, including six from a second batch from 2014.

This process ensures that the most important occupational carcinogens in German workplaces will be covered by action on this cluster of less than 45 carcinogens or groups of carcinogens. There is less concern about certain carcinogens for which a technical-based OEL was in existence until 2004: they are either no longer used in Germany at all or dealt with in closed systems.

Indeed, some workplace carcinogens are not registered under the REACH regulation or are registered for use as intermediates only.

3.1 The conceptual framework

The conceptual framework has three main elements:

1. Three general risk bands (high, medium, and low risk), separated by two risk limits (upper and lower risk limit) to quantify the individual risk of contracting cancer.
2. A general tiered control scheme to reduce exposure, regardless of the risk substance. This has 14 individual control measures, each graded according to the three risk bands.
3. A comprehensive guide to help set exposure-risk relationships (ERR) for individual carcinogens.

The core of the concept concerns the additional quantitative cancer risk for the individual worker through exposure to occupational carcinogens. Additional individual cancer risks are calculated by assuming continuous exposure at the given exposure level during a 40-year working life. On that basis, the upper risk limit was set at 4:1 000 (0.4%) and the lower one at 4:100 000 (0.004%). For the concept's implementation period up until 2018, the lower risk limit is 4:10 000 (0.04%).

These figures, identical to those in the Netherlands in the mid-1990s, were formally agreed after extensive negotiations amongst the social partners. The upper limit used figures for the average risk of a fatal work accident across all sectors, which is currently 0.1% in Germany. No workplace-specific figure was set for the final value of the lower limit. Instead, it will apply the same figure for the workplace as environmental regulations do when calculating a target value for environmental cancers in the general population.

The two risk levels serve different functions. The upper one should not be exceeded at all. However, if this upper limit is temporarily exceeded, the use of RPE is mandatory and additional technical measures have to be implemented immediately to reduce exposure. By contrast, the lower risk limit is a target value for the medium-term or sometimes even in the long-term. To put the upper risk limit into perspective, it is worth noting that an additional cancer risk of 0.4% is about the same as the risk of lung cancer for a non-smoker.

The importance of the two risk limits can also be illustrated by looking at the corresponding concentration values of individual substances. For asbestos, the corresponding upper and lower concentration values are respectively 100 000 fibres/m³ and 10 000 fibres/m³. The same 100 000 fibres/m³ concentration level is defined in the EU directive on exposure to asbestos at work (Directive 2009/148/EC) as a limit that should not be exceeded. It corresponds to an additional cancer risk of 0.4% and is effectively a common denominator at the

level of the upper risk limit. In other words, both the Dutch and the German approaches limit the maximum additional cancer risk for any carcinogen at the same level as that set for asbestos at EU level.

The tiered control scheme at the heart of the concept is based on the hierarchy of preventive and protection measures (i.e. the TOP principle that prioritises technical measures over organisational ones over personal protection). It includes various control measures that should help reduce further exposure. For example, when it comes to grading measures, the use of RPE is mandatory in the high risk band. In the medium risk band, the employer has to supply RPE to the employees but use is left to the discretion of the individual worker. And in the low risk band, use of RPE is unnecessary. The employer has to tell employees the extent of risk exposure: this is part of the employer's general information duty to help workers decide whether to use RPE in the medium risk band. A further measure is the action plan, an instrument of strategic importance. Details about this instrument can be found in section 3.4.

The third element, the guide for setting exposure-risk relationships (ERRs), is essential for applying the concept to individual carcinogens. Only an ERR can transform the two substance-independent risk levels into substance-specific concentration levels. The guide ('Guide for the quantification of substance-specific exposure-risk relationships and risk concentrations after exposure to carcinogenic hazardous substances at the workplace') is a technical annex to TRGS 910 and can also be accessed at the website above.

3.2 The substance-specific elements and the initial results

Additional considerations have to be made when setting substance-specific concentration values. Two important ones have so far been identified. The first concerns detrimental non-carcinogenic health effects below the corresponding upper risk concentration value. In such cases where substances show such health effects, the upper concentration value is lowered to a protective value. The second concerns measuring the concentration values: for some substances, in particular certain carcinogenic metals, the calculated lower concentration values are lower than the limit of measurability under workplace conditions. In such a case the lower concentration value is increased to the current limit of measurability.

Of the 20 ERRs derived so far, values for the upper concentration were set above the former technical-based OELs for just three substances. OSH legislation sets a general mandatory obligation for continuous improvement of working conditions, so the former OEL cannot be exceeded. For two substances, acrylamide and methylene dianiline (MDA), the lower concentration value is above the former OEL. And for both substances, the TRGS 910 explicitly indicates that compliance with the lower concentration value is technically feasible. By contrast, the upper concentration values for 14 substances are below their former OELs. For some substances, in particular the carcinogenic metals (arsenic, cadmium, chromium VI, cobalt, nickel), the

difference is considerable: their upper concentration values range from 1 to 10 µg/m³. Compared to the former OELs, they are lower by factors of between 10 and 50. This implies that the former technical-based OELs for the carcinogenic metals correspond to additional cancer risks of between 4 and 20%.

It also means that it will be technically difficult to comply with the upper concentration value for certain tasks that use those metals. The Committee on Hazardous Substances has addressed this situation by setting some Technical Rules. Section 3.3 has further details.

In addition, health-based OELs have been set for five carcinogens through two separate means: either by modes of action that show the non-genotoxic effects underlying their carcinogenicity or with a threshold for a non-carcinogenic health effect (for concentrations with an extremely low cancer risk). An example from this second group is beryllium, for which a health-based OEL has been set for the alveolar fraction of 0.06 µg/m³.

3.3 The socio-economic dimension: Technical Rules

Like any regulation on occupational health and safety, regulations on occupational carcinogens cannot ignore the socio-economic dimension. The economic feasibility of regulatory measures is directly connected to the issue of job security.

The earlier approach made socio-economic considerations a key part of the derivation of technical-based OELs. Regulatory experts were aware of such considerations, but they were not clearly communicated. It meant that workers could easily get the wrong impression that these OELs were at safe levels.

The different aspects are strictly separated in the new concept: health and risk issues are communicated with concentration values, while socio-economic aspects are outlined as a separate instrument using Technical Rules.

At least 12 of such Technical Rules already exist or are being prepared for a number of carcinogens. They include crystalline silica, diesel engine emissions, carcinogenic metals, PAHs, nitrosamines, asbestos, ceramic fibres, wood dust, ethylene oxide, and formaldehyde. The Technical Rules guide employers on how to comply with their legal obligations for various tasks with these carcinogens, especially when the conditions create high exposure levels. One example is the long-established Technical Rule on demolition, renovation and maintenance work with exposure to asbestos. These rules include control measures like personal protective equipment (PPE). The Technical Rules also need to be adapted to technical progress on a regular basis: they are effectively temporary instruments, regularly updated by the Committee on Hazardous Substances.

3.4 The action plan

The action plan, which copies the Dutch approach, is an additional element in the documentation of risk assessment. It is drafted to take account of tasks with exposure in the medium and high-risk bands. Employers have to detail their plans for further exposure reduction in the action plan: what control measures they plan to implement; when they plan to implement them; and how much exposure reduction they are aiming at.

The strategic central role of this instrument should be clear: the action plan aims to make the company's exposure reduction efforts transparent, thus helping to ensure targeted enforcement by the labour inspectorate. At the same time, the plan also allows worker representatives to uphold their rights under German labour law.

3.5 Role for worker representatives

Worker councils have wide-reaching control and co-determination rights in occupational health and safety under German labour law. Since details of the future exposure reduction are not prescribed in TRGS 910 (they remain at the discretion of the employer) the employer has to consult the workers' council, or Betriebsrat, on the plans, and has to reach agreement with the council.

The Betriebsrat has other powers involving control rights on risk assessment on tasks involving carcinogens performed by the employer. These rights include the control of:

— checks on the possibility of substitution and the use of a closed system;
— selection of control measures and its justification vis-à-vis substitution;
— determination of the degree and duration of workers' exposure;
— specification of the use of RPE;
— regular information and training of workers;
— regular offers of medical surveillance for workers;
— the existence of an up-to-date list of exposed workers carrying out tasks for which an action plan is obligatory.

The Betriebsrat can also negotiate an agreement with the employer on the concrete details of further exposure reduction.

4. Outlook

The risk-related concept was endorsed by the Committee on Hazardous Substances in late 2007 and then tested for a few years before a formal legal basis was established in the Hazardous Substances Ordinance in mid-2013. TRGS 910 was published in early 2014.

The next regulatory step is the integration of the concept as a whole into the Ordinance. The necessary adaptations are currently underway, as the Ordinance has to be adapted to the CLP system of classification and labelling by June 2015. A consensus has been reached at expert level on two important issues that will extend the current obligations on carcinogens prescribed by the Ordinance.

The first is the prescription for using carcinogens in a closed system if the upper concentration value cannot be complied within three years of publication of that value. Exemptions are possible if its use is detailed in a Technical Rule.

The second is a notification requirement for tasks involving carcinogens in both the high and medium risk bands, i.e. for exposure above the lower concentration value. Notifications to the factory inspectorate should contain the exposure information. Above the upper concentration value they should also forward their action plan, but below that value they have to forward the plan only on demand. This demand is likely to be met with major resistance by employer organisations complaining about the additional bureaucratic burden, in particular for SMEs.

ERRs or health-based OELs have been set for most relevant carcinogens. However, there are two controversial exceptions: crystalline silica and diesel engine emissions (DEE). The scientific discussions have mostly been completed for crystalline silica but a consensus has not yet been reached. By the end of 2015, it should be clear if a solution will be found. For DEE, the scientific committee in charge is awaiting the results of an assessment of some 2013 US epidemiological studies before it reaches any conclusions. That means no results are expected for DEE before 2016.

The controversy over those two substances is remarkable by comparison to the scientific discussions on other carcinogens. This is partly explained by the debate in international circles where limit values are heavily contested, especially in the US. Also, the German carmaking sector appears to be resisting environmental arguments against lowering limit values in the workplace as it could lead to additional pressure for stricter emission control to protect the general population.

A possible future controversy concerns the implementation of the final phase of the risk-related concept, agreed in principle as early as 2007: to reduce the lower risk limit by a factor of ten to its final value of 4:100 000 and thus adapt the substance-specific lower concentrations values. Talks are scheduled to begin on this after the adaptation of the Hazardous Substance Ordinance, which means in autumn 2015 or in spring 2016. There is currently a tentative agreement that lower concentration values should only be reduced to a level that is still measurable for the respective substance. If this pragmatic suggestion were accepted, it would imply that the current lower concentration values for carcinogenic metals could not be further reduced while there is no progress in measurement and analytics technology.

In conclusion, the new, risk-related concept has done much to stimulate debate on occupational carcinogens in Germany and put a fresh focus on exposure minimisation. It has moved certain carcinogens into the limelight, in particular carcinogenic metals, and has showed how their risks were massively underestimated in the past.

The concept is also an opportunity to set much higher levels of transparency on workplace exposure to occupational carcinogens and provides employee representatives with additional tools to prevent occupational cancer.

5. Transferring the approach across Europe

Could such a risk-related approach be implemented in other EU Member States or at EU level? The differences between Member State legal systems and cultures suggest it might be presumptuous to assume that a Dutch or German approach could be transferred to another system. Nonetheless, it is worth sketching the essentials of a risk-related approach for any national system.

The indispensable elements would include:

— transparency about the level of exposure at the workplace and the corresponding additional cancer risk, assuming a continuous, life-long exposure at that level;
— the introduction of a broad, substance-independent, upper risk limit above which no worker would be exposed without RPE;
— a clear regulatory separation between scientific and socio-economic considerations, which means abandoning any technical-based OELs;
— a mandatory action plan for the employer to detail his future measures on exposure reduction.

By contrast, the introduction of an overarching, lower risk limit as a target value seems of little relevance for the time being. It is already a major challenge to ensure carcinogens comply with their defined upper risk limit concentration values: the limited available resources should be focused on this urgent issue. The issue of a finite target value can wait until the high risks are sufficiently and successfully dealt with.

There are also concerns about whether these essentials can be agreed across all EU Member States. During recent discussions on binding OELs for carcinogens at EU level, the principle of a maximum additional cancer risk for the individual worker was found to conflict with the UK's cost-benefit analysis approach. But a consequence of the British approach is that the risk for individual workers can be much higher if small groups are affected and the significant investment in additional control measures is not vindicated by the comparatively small overall risk to the group.

This approach would be justified within the current framework of utilitarian ethics in the UK. However, two questions remain. First, how can such an

approach be reconciled with the basic rights enshrined in the EU Charter of Fundamental Rights, in particular human dignity and the right to the integrity of the person? The second concerns an implicit, yet rarely asked condition of cost-benefit analysis – the level of equality in society: who incurs the costs, and who reaps the benefits of a measure taken or not taken?

But given the rise in inequality over the past 30 years, for workers it seems politically wrong to found socio-economic considerations on cost-benefit analysis. The basic prerequisite of a minimum level of societal equality has completely evaporated.

Why should the scope of the Carcinogens and Mutagens Directive be extended to reprotoxic substances?

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1. Risks for reproduction: largely ignored by the EU legislation on safety and health at work

Toxic for reproduction (or reprotoxic) substances can adversely affect the ability of men and women to reproduce (threat to fertility) and alter child development during gestation and after birth (threat to development). This includes not only effects on libido, formation of sperm or eggs, fertilisation and implantation of the embryo, but also miscarriage, stillbirth, reduced birth weight, congenital defects and alterations in mental and physical development, up to and including pubertal development.

Some glycol ethers used as solvents or even certain phthalates used as plasticisers can, for example, reduce the quality or number of sperm. These effects can occur either in adulthood or following pre-natal exposure. They can be reversible or irreversible depending on the substance. Some of the other known reprotoxic substances that are frequently found in the workplace are lead and its compounds used in the manufacture of alloys, batteries, glass, etc. In France alone, over 115 000 workers were exposed to these substances in 2010 (Cavet and Léonard, 2013). Lead has effects not only on fertility but also on the neuronal development of children following exposure before or after birth. It is responsible for mental disabilities and losses of IQ. There is no threshold for the neurotoxic effects of lead and all exposures pose a risk. Warfarin used as a biocide and anticoagulant is teratogenic for humans. Following exposure during pregnancy, it causes cardiac defects, facial hypoplasia and mental retardation. In this case, the effects are not reversible.

Although difficult to put a figure on, many of these threats to reproductive health are due to occupational exposures[1], with victims being concentrated in certain sectors such as agriculture, care services, cleaning and maintenance, metallurgy and petrochemicals (Mengeot and Vogel, 2008) and hairdressing and cosmetology (Kim et al., 2016). These occupational exposures are entirely preventable, with effective prevention therefore being essential.

1. In addition to the chemical substances, there are other occupational risk factors for reproductive health: biological agents, ionising radiation, load carrying, prolonged and static work in a standing position, noise, stress, and irregular or night working. These will not be covered here.

The European legislation on the prevention of reproductive risks in the workplace is very patchy. There is no specific text and existing provisions are not only unsatisfactory but also scattered among various pieces of legislation. The 1992 Directive on the protection of pregnant workers and workers who have recently given birth or are breastfeeding (Directive 92/85/EEC) is, for example, inconsistent in terms of prevention. Measures to avoid exposure do not have to be taken until the worker informs her employer that she is pregnant, which occurs around the 10th week of pregnancy. However, exposure to a toxic for reproduction substance during the early weeks of gestation can result in miscarriage or a higher risk of congenital defects. The options of changing job or possibly taking leave from work, as recommended in the Directive, therefore come too late to prevent these risks.

The 1998 Directive on the protection of workers from chemical risks (Directive 98/24/EC) is also unsatisfactory. It covers all chemical substances produced or used in the workplace without laying down any specific provisions on reprotoxic substances. It requires employers to eliminate or reduce risks to a minimum and provides for binding or indicative occupational exposure limits (OELs) to be set.

However, just one binding limit value has been set to date under this Directive, which is a biological limit value for lead and its ionic compounds. This OEL, determined in the early 1980s, has never been updated. In its 2002 Recommendation, the Scientific Committee on Occupational Exposure Limits (SCOEL) suggested lowering this value from 70 µg to 30 µg per 100 ml of blood, while recognising that this is not entirely protective of the offspring of working women (European Commission, 2002). A recent opinion of the European Chemicals Agency confirms that lead is toxic for child development and that a no-effect level does not exist for pre- or post-natal exposure. The Agency proposes classifying lead in the category of proven reproductive toxicants for humans (category 1A) with harmful effects on fertility, foetuses and babies fed with breastmilk (ECHA, 2013).

As regards indicative OELs under the Chemical Agents Directive, these currently cover only 121 substances, of which 8 are toxic for reproduction. These values are based on health. This means that the available scientific data has identified an exposure threshold below which exposure to the substance does not cause any harmful effect (see the article of T. Musu on OELs, p. 43). However, while it is generally accepted that such a threshold can be defined for most reprotoxic effects, this is not always the case, as shown by the example of lead. Moreover, this threshold is unknown for many reprotoxic substances.

This is one of the major failings of the Chemical Agents Directive with regard to preventing risks for reproductive health. If a reprotoxic substance has a threshold, but no OEL has been set, employers do not have any guidance on the exposure level not to be exceeded, and there is no minimisation obligation in the Directive ensuring that the exposure level is reduced, particularly below the threshold effect.

2. Benefits of the Carcinogens and Mutagens Directive

The nature, severity and potential irreversibility of the health effects resulting from exposure to reprotoxic substances are particularly worrying for exposed workers. Levels of protection at work should therefore be improved by applying the more stringent provisions of the Carcinogens and Mutagens Directive to substances that are toxic for reproduction.

This Directive, which was codified in 2004 (Directive 2004/37/EC), specifically covers all substances that are proven or suspected to be carcinogenic and mutagenic for humans (categories 1A and 1B). It requires employers to replace carcinogens and mutagens with safer alternatives where technically possible. If such precautions cannot be taken, employers must ensure that work is carried out in a closed system and they must reduce exposure to a minimum. The OELs adopted under this Directive are always binding and, even if the exposure level for workers is below the OEL, the obligation remains to reduce this level as far as possible. The Carcinogens and Mutagens Directive is therefore more demanding than the Chemical Agents Directive in terms of reducing exposure levels in the workplace.

The Carcinogens and Mutagens Directive has been under revision since 2004. Under consideration are the extension of its scope to reprotoxic substances and the adoption of binding OELs for new substances. This revision has unfortunately been held up by the European Commission for over 10 years (see article by L. Vogel on EU legislation, p. 7). However, there are good reasons to make these improvements in a revised directive.

Many reprotoxic substances are currently produced and marketed in the European Union. According to the health, socioeconomic and environmental impact study ordered by the European Commission as part of the revision procedures, there are 105 reprotoxic substances in categories 1A and 1B that fall outside the scope of the Carcinogens and Mutagens Directive (Milieu & RPA, 2012). These are substances with a harmonised classification as reprotoxic agents, but that are not also classified as carcinogens or mutagens under the CLP Regulation. These substances are therefore currently covered by the unsatisfactory provisions of the Chemical Agents Directive. However, in order to have a comprehensive view of the number of reprotoxic substances currently present on the European market and to which workers are potentially exposed, we should also take into account those substances that have been self-classified as R1A or R1B by undertakings under the CLP Regulation. A search of the Classification & Labelling Inventory available on the ECHA website shows that there are around 1 700 of these substances.

Including substances that are toxic for reproduction within the scope of the Carcinogens and Mutagens Directive would be consistent with the REACH Regulation. Under REACH, those chemicals identified as substances of very high concern include not only category 1A and 1B carcinogens (C) and mutagens (M), but also reprotoxic substances (R) in the same categories. This

alignment with REACH could be seen as a regulatory simplification. It would also improve the synergies between the two pieces of legislation.

Many substances that are toxic for reproduction have also been identified as endocrine disruptors (see the Risctox database on the ETUI website). As it is impossible to determine a no-effect exposure level for endocrine disruptors (Kortenkamp, 2001), the health-based OELs that may be determined for threshold reprotoxic substances would be useless for protecting workers from the adverse effects of endocrine disruptors. Including substances toxic for reproduction within the scope of Directive 2004/37/EC would automatically ensure that the more stringent provisions of the Carcinogens and Mutagens Directive were applied to numerous endocrine disruptors.

Five European countries (Germany, Austria, Finland, France and the Czech Republic) have already extended the scope of the Carcinogens Directive to substances toxic for reproduction when transposing it into their national law. The findings of the impact study ordered by the European Commission are that, in two of these countries (France and Germany – the only ones studied within the group of five), this extension has clearly led to benefits in terms of reducing the exposure of workers to reprotoxic substances (Milieu & RPA, 2012).

Finally, it is worth mentioning that the European Parliament, in its report adopted in December 2011, called on the Commission to extend the scope of Directive 2004/37/EC to include substances toxic for reproduction (European Parliament, 2011).

Contributions of the REACH and CLP Regulations to the prevention of CMR risks

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The vast majority of chemical substances present on the European market have been marketed without sufficient knowledge of their effects on human health or the environment (European Commission, 2001). Consumers and professional users are therefore faced with labelling that does not adequately inform them of the hazards of the substances and mixtures to which they are exposed. In the workplace, workers who handle hazardous substances and mixtures use safety data sheets that are ill-suited to risk prevention.

In order to overcome these problems, the European Union adopted the REACH Regulation (Registration, Evaluation, Authorisation and Restriction of Chemicals) at the end of 2006 and the CLP Regulation (Classification, Labelling and Packaging) in 2008. One of the main aims of these legislations is to ensure a high level of protection of human health and the environment from risks linked to exposure to chemical substances, including Carcinogenic, Mutagenic or Toxic for Reproduction (CMR) substances.

1. Nearly 8 000 CMR substances in circulation in Europe...

The total volume of chemical substances produced each year in the EU 28 is impressive. In 2013 this was estimated at 322 million tonnes, of which 9.5% (i.e. 30.7 million tonnes) was CMR substances (Eurostat, 2015). One of the benefits of the REACH and CLP Regulations managed by the Helsinki-based European Chemicals Agency (ECHA) is that they ensure more accurate information on the identity and number of these substances. According to data provided by suppliers, over 120 000 different hazardous substances are present on the European market, of which 7 687 are regarded as CMR (category 1A, 1B or 2). These figures are taken from the Classification & Labelling Inventory maintained by the ECHA as a result of the obligation under the CLP Regulation for suppliers to notify the Agency of the classification and labelling of all hazardous substances that they market in the EU, whatever the volume of production.

2. ...but only 1 500 CMR substances with a harmonised classification

The CLP Regulation also provides that all category 1A, 1B or 2 CMR substances and category 1 respiratory sensitisers shall normally have a harmonised classification and labelling. The aim is to force the various companies marketing these substances to provide the same information on their intrinsic hazards to all actors in the supply chain.

When the list of around 8 000 CMR substances notified to the ECHA is compared against the list of chemical substances with a harmonised classification (Annex VI to the CLP Regulation), it is clear that only around 1 500 substances (~20%) have a harmonised classification and labelling as CMR substances (Table 1). The rest are marketed with the classification and labelling determined by their suppliers based on the rules defined in the CLP Regulation. This self-classification system, which also applied under the previous legislation (Directive 67/548/EEC), is therefore used for ~80% of the CMR substances present on the European market. This has a major drawback: the classification and labelling of the same CMR substance may vary from one supplier to another depending on their interpretation of the classification rules. The raison d'être of the ECHA public inventory is therefore to highlight the different self-classifications of the same substance in order to encourage companies marketing those substances to agree on a single classification.

Table 1 **Comparison between the number of CMR substances in the ECHA's Classification and Labelling Inventory and in the list of substances with a harmonised classification (Annex VI to the CLP Regulation) (May 2015)**

Type of CMR substance (category 1A/1B/2)	ECHA Classification and Labelling Inventory	Annex VI to the CLP Regulation	Self-classifications proposed by manufacturers
Carcinogenic	4 213	1 213	3 000
Mutagenic	2 261	620	1 641
Reprotoxic	4 149	359	3 790
Total	**7 687**	**1 480**	**6 207**

Note: category 1A: known for humans; category 1B: presumed for humans; category 2: suspected for humans.

The harmonised classification of CMR substances is important, not only because it allows all European workers and consumers to be informed through the same labelling, but also because it automatically brings these substances within the scope of around 20 other pieces of European legislation controlling their use. For example, these include regulations on pesticides, biocides and cosmetics, as well as various directives on worker protection. Accordingly, although formaldehyde has been classified as carcinogenic for humans since 2004 by the International Agency for Research on Cancer (IARC), it has been covered by the Carcinogens and Mutagens Directive only since May 2015, when it was included in Annex VI to the CLP Regulation under the harmonised

classification of a category 1B carcinogen. This now forces employers to eliminate or replace this industrial compound in the workplace with a less hazardous substance or process. This tightening of the regulations should result in reduced exposure for millions of workers in Europe due to changes to production facilities.

A recent ECHA report on CMR substances confirms that nearly 6 000 CMR substances are being marketed in Europe without a harmonised classification (ECHA, 2015a). Unfortunately it is clear that this harmonisation work, undertaken by an ECHA scientific committee following the adoption of the CLP Regulation, is quite slow. The harmonised classifications of almost all the 1 500 CMR substances in the current Annex VI were adopted under the previous European legislation (1967 Directive on the classification of dangerous substances). According to another report of the Agency, between 2009 and 2014 only 25 new CMR substances were added to Annex VI to the CLP Regulation, and only 8 former CMR substances on this list saw their harmonised classification updated (ECHA, 2015b).

3. What about the missing data on CMRs in circulation in the EU?

Companies are also required, this time by the REACH Regulation, to provide the ECHA with a registration dossier for each chemical substance manufactured in or imported into the EU above 1 tonne per year. Around 30 000 substances are estimated to be registered out of the 120 000 substances currently listed. This system, based on the 'no data, no market' principle, was designed to force registrants to collect and supply ECHA with the missing data on the substances that they market. Throughout the supply chain, companies are also required to provide the information needed for safe use of their substances by means of safety data sheets.

Out of the roughly 8 000 CMR substances present on the European market, at least 1 169 (~15%) have been registered with the Helsinki Agency (ECHA, 2015a). This relatively modest fraction is explained by the registration rules laid down by the REACH Regulation. In essence, if less than one tonne of the substance is produced per year and per manufacturer, there is no registration obligation. The same applies for all substances that fall within the scope of other specific European legislation (pesticides, biocides, cosmetics, medicinal products) or that are used for research and development purposes. This means that the number of CMR substances marketed in Europe for which REACH ensures that some of the missing data is collected (physical properties, (eco)toxicological information, uses, identity of manufacturers, volumes) is limited. However, this still covers a large part of the 30.7 million tonnes of CMR substances that annually circulate on the European market.

The data set required under REACH registration has also some limitations in identifying new CMRs. For example, serious doubts have been raised over the

likelihood that potential effects on hormonally mediated carcinogenesis will be detected for registered substances on the basis of current requirements (Kortenkamp, 2011).

4. The REACH system of authorisation

In addition to the registration system provided for by REACH, companies must obtain authorisation for each of the uses made of CMR substances and other substances of very high concern[1] that are included in Annex XIV to REACH (authorisation list).

These substances cannot be placed on the market or used after a given date, unless an authorisation is granted for their specific use, or the use is exempted from authorisation. This system was designed to encourage manufacturers to progressively replace substances of very high concern with safer alternatives. The authorisation procedures are in fact long and costly and companies have a vested interest in avoiding them if the use of these substances is not essential to their industrial activities.

To obtain authorisation, the applicant must demonstrate, through an application dossier, that the risk from the use of the substance is 'adequately controlled'. If not, authorisation may still be granted if it is proven that the socio-economic benefits of using the substance outweigh the risks and if there are no suitable alternative substances or technologies. Authorisations are granted by the European Commission based on an opinion prepared by the ECHA. They are issued for a set period and on a case-by-case basis. The authorisation procedure could in theory be applied to all CMRs (1A and 1B) registered under REACH, whatever their volume of production. However, in practice, a system of selection is provided for by the Regulation because the Helsinki Agency can deal with only around 20 applications for authorisation per year. Substances are initially included in a candidate list, before being transferred, where applicable, to the list of substances subject to authorisation (Annex XIV). Nine years after the REACH Regulation entered into force, the candidate list contains only 161 substances (including 145 CMRs) and Annex XIV itself contains only 31 substances (including 29 CMRs). The substances included in Annex XIV are selected from among those on the candidate list, in particular by prioritising those produced in large volumes. This means that numerous CMR substances produced in low or average volumes (< 1 000 t/year) will continue to be used pending their possible inclusion in the REACH authorisation system. At the rate that substances are being included in the candidate list and then transferred to the authorisation list, it will be a very long time before all CMR substances (1A or 1B) registered under REACH are assessed. Following criticism of the slowness of the system,

1. Substances of very high concern under the REACH Regulation are substances that are carcinogenic, mutagenic and toxic for reproduction (categories 1A and 1B), PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) as well as substances giving rise to an equivalent level of concern (endocrine disruptors or sensitisers).

in 2013 the European Commission, in collaboration with the Member States and the ECHA, adopted a Roadmap on Substances of Very High Concern (Council of the EU, 2013). It undertook to ensure that all relevant and currently known substances of very high concern are included in the REACH candidate list by the end of 2020. Environmental NGOs and trade unions have drawn up their own lists of substances that they consider should be included in the REACH candidate list. In total, the SIN list of the NGOs (Chemsec, 2014) and the list of the European Trade Union Confederation (Musu, 2011) identity nearly 900 substances of very high concern. With only 161 substances on the candidate list just five years before the deadline set by the Commission, it is highly likely that the civil society organisations will be sorely disappointed by the results of the roadmap.

5. Initial assessment of the authorisation system

Twenty-eight applications for authorisation for a total of 8 substances of very high concern have been received to date by the ECHA from 44 applicants (see Table 2). The Helsinki Agency and its scientific committees must prepare an opinion on each application to help the Commission decide whether or not to grant the authorisation requested. Out of the 63 opinions already adopted, the ECHA has not yet given a negative opinion to the Commission. In all cases the Agency has recommended granting the authorisation for uses requested by the applicants, and the Commission has already formally granted two of these authorisations. It is likely that the Commission will systematically follow the ECHA's opinion.

Table 2 **Overview of applications for authorisation received and processed by the ECHA (February 2015)**

Substances	Type of substance of very high concern	Number of applications for authorisation received (Number of applicants)	Number of uses	ECHA opinions	Commission decisions
				Per use and applicant	
DEHP	Phthalate, toxic for reproduction	**5** (7)	10	11 favourable	1 favourable
DBP	Phthalate, toxic for reproduction	**2** (2)	4	4 favourable	1 favourable
DEHP + DBP	Phthalate, toxic for reproduction	**1** (1)	3	3 favourable	-
Lead chromate (yellow and red)	Pigment, toxic for reproduction and carcinogenic	**1** (1)	12	12 favourable	-
HBCDD	Flame retardant, PBT	**1** (13)	2	26 favourable	-
Arsenic trioxide	Additive, carcinogenic	**4** (4)	5	5 favourable	-
Trichloroethylene	Solvent, carcinogenic	**13** (15)	19	2 favourable	-
Lead chromate	Pigment, toxic for reproduction and carcinogenic	**1** (1)	1	-	-
Total		**28** (44)	**56**	**63 favourable**	**2 favourable**

Note: an application for authorisation may be submitted by one or more companies. The application may cover one or more uses. Authorisations are granted (or refused) for a specific use and to each applicant.
Source: http://echa.europa.eu/view-article/-/journal_content/title/conference-on-lessons-learned-on-applications-for-authorisation

However, in the view of certain observers, several dossiers do not meet the conditions for authorisation to be granted. This is the case, for example, with the application for authorisation of DEHP, a substance in the phthalate family used as a plasticiser in recycled PVC articles. According to the environmental NGOs, safer alternatives are available on the market and the ECHA should logically have given a negative opinion. The ECHA recognises in its opinions that certain alternatives exist, but as these are more expensive to use than DEHP, the Agency regards them as economically unfeasible for applicants. This practice of the ECHA is debatable because the REACH legislation does not define what constitutes an economically feasible alternative.

6. Pro-industrial attitude of the ECHA

It would appear that the ECHA's strategy is to systematically give a favourable opinion to show that the system works and so that future applicants are not deterred from applying for authorisation. The Helsinki Agency also, on its own initiative, organises information sessions prior to the submission of dossiers in order to better prepare those companies using Annex XIV substances. When poor quality dossiers are submitted, an analysis of the opinions adopted to date shows that the ECHA prefers to grant the authorisation for a short period rather than give a negative opinion. This pro-industrial attitude of the ECHA is not new. The aims of REACH also include efficient functioning of the internal market and enhanced European competitiveness. The Helsinki Agency has already shown that it is ready to protect the interests of companies, such as, for example, when it had to decide on the balance between protecting commercial data in its possession and transparency vis-à-vis the public (Schaible C. and Buonsante V., 2012). In assessing applications for authorisation, two factors have certainly influenced its policy. First, the economic crisis. The ECHA takes the view that, if companies apply for an authorisation that can cost them over EUR 200 000, this is because they really need this authorisation and they should not be penalised by a refusal, particularly against the background of an economic slump. Secondly, there is the Commission's REFIT deregulation programme. All European legislation is being screened to check whether it is truly fit for purpose. As far as the Agency is concerned, it is therefore essential to show that the REACH authorisation system works and is not an obstacle to the efficient functioning of the internal market.

Although we may wonder whether an authorisation system under which no application is ever refused is efficiently functioning, it is worth noting that the aim of encouraging substitution seems to be bearing fruit. For example, no application for authorisation was received by the ECHA before the cut-off date for certain substances of very high concern included in Annex XIV (this was the case, for example, with the fragrance Musk Xylene and the processing agent 4,4'-methylenedianiline). All uses of these substances are therefore automatically prohibited in Europe and only their replacements may be used. Small and medium-sized enterprises in the craft glass production sector have also chosen to find alternatives to the use of arsenic trioxide, rather than trying to obtain authorisation to continue using this carcinogenic substance (Alhaique,

2013). It is also generally noted that, when substances are included in the candidate list, many companies stop using them in anticipation of their potential transfer to Annex XIV and the possible break in supply if authorisations were to be refused.

7. Conclusions

The REACH and CLP Regulations have undoubtedly improved European legislation on the use and marketing of chemical substances, including CMR substances. The obligation to register all CMR substances (category 1A and 1B) produced above 1 tonne per year has led to new knowledge being acquired and the quality of labelling and of many safety data sheets being improved for professional users. The obligation to notify classifications and labelling has enabled an inventory to be made of all CMR substances present on the European market (whatever their volume of production). As this inventory is public, it ultimately ensures greater transparency with regard to the CMR substances around us. It is also useful for the authorities in selecting priority CMR substances for harmonised classification.

Although these two regulations now ensure a better understanding of the hazards and risks of numerous CMR substances synthesised by humans, it should be noted that very many European workers are exposed to carcinogens not covered by these regulations. These are CMR substances that result from industrial processes and that are not intended to be marketed, such as diesel emissions, crystalline silica, wood dust, etc. The reduction of occupational cancers, which we should remember are the primary cause of occupational mortality, cannot therefore rest entirely on these two pieces of legislation and their correct application.

However, the fact remains that the authorisation system provided for under REACH genuinely encourages the replacement of carcinogens and therefore prevents occupational cancers. It is regrettable that it is not being fully used by the ECHA, the Commission and the Member States, not only to reduce the huge direct and indirect costs of using substances of very high concern, but also to encourage innovation and the green economy.

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