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Minimising chemical risk to workers' health and safety through substitution

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Minimising chemical risk to workers' health and safety through substitution

PART I

Practical Guidance

PART II

Study Report on identifying a viable risk management measure

European Commission

Directorate-General for Employment, Social Affairs and Inclusion

Unit Health, Safety & Hygiene at Work

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Authors:
Y. Gilbert, P. Pessala, J. Aho, R. Lehti, I. Vehviläinen, and M. Hjelt (Gaia Consulting Oy)

E. Priha, T. Santonen, M. Koponen, B. Bäck, E.-R. Hyytinen and A. Kangas (Finnish Institute for Occupational Health)

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Foreword

The implementation of effective chemical substitution policies and management practices at the workplace can deliver significant benefits in terms of protecting the health and safety of workers. To make this happen in practice requires a raised awareness and involvement of all stakeholders to develop an understanding of how successful substitution could look like in practice.

The effective practical implementation of the substitution principle can bring substantial benefits to EU employers and workers not only in terms of health and safety impact via improved risk management at the level of individual companies, or at sectoral level, but also in terms of wider socio-economic considerations.

Whilst it may be possible to agree that chemical substitution is important for improving working conditions, there is no clear objective information on how effectively it is used in practice. Substitution is associated with a number of issues that are not always easy to evaluate in order to facilitate the decision making process. It requires judgment to take account of workers health and safety protection, process performance, the ease and cost of introducing substitutes, environmental considerations and other factors in making a substitution choice.

DG Employment, Social Affairs and Inclusion recognises the multi-attribute challenges that substitution presents to individual employers. Several approaches to substitution exist ranging from ad-hoc approaches to methods that are defined, structured and documented. Less sophisticated substitution approaches may be more suitable for smaller companies compared to larger better resourced organisations that have a high level of technical expertise.

DG Employment, Social Affairs and Inclusion funded this study to analyse and evaluate the practical implementation of the principle of substitution of hazardous chemicals at the workplace with a view to further enhance the protection of workers health and safety while taking into account the above-mentioned factors.

DG Employment, Social Affairs and Inclusion hopes that this study and the associated guidance document will contribute to the development of a decision making framework which will consider all the relevant aspects of implementing the principle of substitution at the workplace.

Content

PART I

Practical Guidance

1. Introduction

The objective for this guidance

The objective for preparing this guidance was to provide workplaces across the EU with a common approach to chemical substitution. The guidance has been prepared for use in EU workplaces with particular emphasis on the needs on SME's. **The main target audience is companies with limited or some knowledge or experience of chemical risk management.**

Innovation and product development aiming for safer products and processes are a vital part in the drive for safer chemical use in workplaces. This guidance does not in detail address the innovation or R&D processes required for more challenging substitutions, such as substitution of reagents in chemical reactions or of complex process industry use of chemicals.

- ✓ At the individual company level you can also further develop the process presented to meet your specific needs or circumstances.
- ✓ Industry associations or national authorities can also adapt the model to better reflect specific needs of employment sectors or national approaches in Member States.

The developed approach presents a systematic yet flexible, risk based process for identifying chemicals that could or should be substituted and evaluating alternatives against risk, technical requirements and practical and cost considerations.

Substitution of very hazardous chemicals is part of the regulatory framework in the EU, through the Chemical Agents Directive, the Carcinogens and Mutagens Directive as well as within environmental legislation and the REACH Directive. Substitution may also be an element in each company's day-to-day product stewardship, product development and innovation activities. Both processes may lead to substitution but are quite distinct in nature. This guidance approaches substitution as an element of risk management, as part of the company's day-to-day business. **The main focus is on occupational health and safety**, but the importance of including environmental aspects is also highlighted.

This guidance does not attempt to produce new science or reveal major new ways of thinking about substitution – it aims to translate scientific considerations of hazard, risk and risk reduction through substitution into something more easily accessible for the target audience. The vast majority of companies within the EU do not have the expert knowledge or resources to undertake state of the art evaluations. It is acknowledged that this guidance simplifies scientific knowledge. Wherever there are simplifications, we hope the scientific community and experts in occupational hygiene, safety and chemical risk will accept this simplification as a necessity in the effort to reach a larger potential audience and make substitution a more widely used risk reduction measure.

"....Seeking perfection [in methodology] will only ensure that the prevention of work-related disorders will not be achieved for the majority of the world's work force..."

David M. Zalk; Deborah Imel Nelson: History and Evolution of Control Banding: A Review. Journal of occupational hygiene, 2008

Substitution as a risk management measure

Substitution – what is it?

Substitution is one way of eliminating or reducing the risks from chemicals to health and safety at the workplace. *All hazards to the safety and health of workers should be identified and risks arising from them eliminated or controlled in order to prevent occupational accidents and work-related diseases*.[1] Substitution is a way of reducing identified chemical risk at source by

- ✓ replacing a chemical used with a less hazardous one,
- ✓ using a safer physical form of a chemical, such as larger particle sizes or pellets,
- ✓ changing a process or technology using safer alternatives.

Substitution can be used to reduce risk at any workplace where chemicals or hazardous materials are handled, stored, or used. Substitution can be done to improve **occupational health** and reduce both acute and long term exposure risks, sometimes to improve **safety** by removing or reducing for example fire or explosion risks, and sometimes to reduce risk to the **environment**. Whatever the reason for substituting, you need to make sure the change does not lead to unexpected surprises, such as increasing safety risk whilst reducing acute occupational health risk.

Substitution – why consider it?

Substitution is a way of making the workplace healthier and safer. There are many reasons for substitution, but there are also aspects that can make it more difficult or less tempting to substitute.

Some of the strongest drivers come from society and include legislation, supply chain demand, industry standards, raw material availability as well as public opinion. Some of these can also act as barriers: Legislation may lack specific requirements, there may not be enough knowledge available of viable alternatives and some industry standards can be quite inflexible towards change. Within the company, technical, financial and management practices can act both as motivators and barriers. This guidance is intended to help you overcome such barriers through practical examples and a systematic approach.

Reducing risk at source is in accordance with good risk management principles and a safer alternative than using control measures such as personal protective equipment (PPE), alarms or technical solutions such as increased ventilation. Changing the way of working can be difficult and indeed substitution is often seen as something for experts only. However, there is no reason why many chemicals used in the workplace today could not be changed for safer alternatives in a relatively easy and straightforward manner. This guidance will help you work through the necessary things to consider when looking at reducing risk to workers health and safety through substitution.

[1] EU-OSHA (2010)

Substitution – could it be a way for us to reduce chemical risk?

To check if substitution could be an option for you, you can start by answering the questions in the table I-1. It is also good idea to repeat this type of check periodically. If you answer yes to one or more of the questions, substitution could be a good way of making your workplace healthier and safer!

Table I-1: Check-list for considering substitution

Question	Yes / No	Note
1. Are we using chemicals?		Using less hazardous chemicals or stopping the use altogether (eliminating) can **increase safety and reduce cost**. You can also apply the same type of thinking to any other hazardous materials or processes. **Make sure that you do not have many chemicals for one job – reducing the number of chemicals will also help you reduce risk.**
2. Could we/should we reduce the risk to workers health and safety from our chemical use?		By law, you must know and control risks from chemicals you use[2] . **Changing to less hazardous chemicals or reducing the number of chemicals could simplify the paperwork done for permits/ authorities.**
3. Do we have a legal obligation to substitute?		If you use chemicals classified as Cat 1/2 carcinogenic or mutagenic you must replace them so far as is technically possible[3]. **If it is not possible, you have to discuss the implications with the authorities.**
4. Are hazardous fumes or dust created at our workplace?		Even if the materials or chemicals themselves may not be hazardous, you may be using them in such a way that there is a risk to workers. **Changing the source of fumes or dust, the processes or working practices can increase safety and reduce cost.**
5. Do we use chemicals often and /or in large amounts?		If you use chemicals in large amounts and/or repeatedly, this increases the chance of harm to you, your workers and/or the environment. **Finding alternatives or different ways of working can help you reduce the amount of chemical you use or how often you have to use the chemical.**
6. Do we use control measures to reduce chemical risks?		You may be using technology, automation, procedures or personal protective equipment to control risks. Control measures are specified by the supplier for each chemical – look at the safety data sheet to check you are using these. Changing to less hazardous chemicals or changing the way you work can reduce the need for control measures, **protect workers health and safety** and enhance wellbeing. **You might also be able to reduce the cost of controlling chemical risk**.
7. Do we want our image and competitive edge to be better?		Increasingly, companies are looking for safe and sustainable solutions. Changing to safer chemicals or working practices could help you meet your customer's criteria and give you **competitive advantage. Innovative safer solutions may give you a powerful sales argument.**

[2] For legislative requirements, check your national legislation. See also Chemical Agents Directive 98/24/EC

[3] Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

Not everything can be changed

Reducing chemical risk can be a simple and straightforward process. Even small changes can reduce health risks and increase safety. Not all chemicals or process can however be changed. Changing the way you work may also lead to unexpected consequences, so it is important to assess and manage the change carefully. This guidance will take you through the required steps to find out if you could substitute a chemical or a particular work process **without increasing other risks**.

Change for safety - an overview of the guidance

A well carried out substitution process is based on a good change management process. The widely used Plan-Do-Check-Act model for change management is therefore a good framework for approaching substitution systematically. The same process can also be used to find the best alternative when you need to find a suitable chemical for a new process or task. The approach to the substitution process based on the Plan-Do-Check-Act model is shown in Figure I-1.

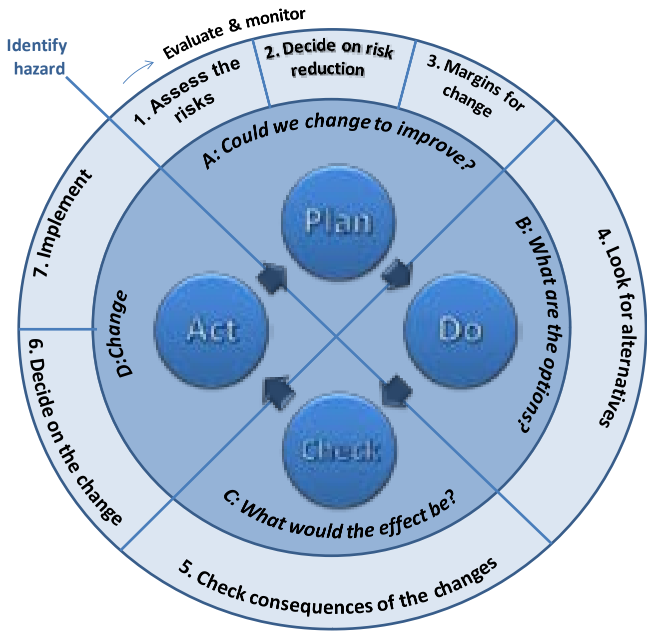

Figure I-1: Change for safety using the Plan-Do-Check-Act model

The time you will have to spend on this process depends on the chemical, the work you use it for and how easily available other alternatives are. Therefore two alternative models with different amount of details and complexity have been put together:

1. **A shorter process in four steps**, shown as the inner darker blue segments A-D in Figure I-1. This is a reasonably easy to use process, suitable for smaller businesses and workplaces where few chemicals are used or where chemical use is more generic. It can also be used as a first round of a more in-depth assessment to pinpoint chemical risks that could potentially be significantly reduced through substitution. You can find the 4-step version in Part II of this Guidance. Use this approach if:
   - ✓ You have little experience of chemical risk assessment and management
   - ✓ You want a fast overview of the potential for substitution

- ✓ The process or task where the chemical is used is generic, i.e. there are many ways of doing the task or process, such as cleaning, lubricating or painting

2. **A more detailed seven step process,** shown as the outer, lighter blue segments 1-7 in Figure I-1. Here, each step goes into more details and require more knowledge as well as more data. It will also take more time, but the evaluation will be more thorough. It is suitable for workplaces where more hazardous chemicals or larger quantities are used or for example where the chemicals are used within a process. You can find the 7 step process in Part III of the Guidance. Use this approach if:

   - ✓ You have at least some experience of chemical risk assessment and management
   - ✓ You want a detailed assessment of the potential for substitution
   - ✓ The process or task where the chemical is used is more complex or very specific

Mix & match: You can also use the shorter 4-step process, but go to the more detailed evaluation in the 7 step process when you reach a point where you need more information to make a decision.

The two main parts of the guidance address the same things in different amounts of detail. Therefore some tools, references to further reading or tools available on the web as well as case examples of each step have been put in separate Appendices. The case studies were chosen to illustrate the approach – there is a wealth of data on successful substitution cases contained in Appendix 2. There are also blank worksheets in Excel workbooks that you can use to record your assessment results in a structured manner and these are useful aids in discussions with authorities and within the supply chain.

Within the 7 step process, flow charts to illustrate the different tasks have been used for each step. This flow chart is also given in its entirety in Appendix 7 in a larger format for an easy overview. If you print Appendix 7, remember to set your print settings to A3 size paper. The content of the seven appendices and how and when these can be used during the different Parts of the four and seven step processes is shown in Figure I- 2.

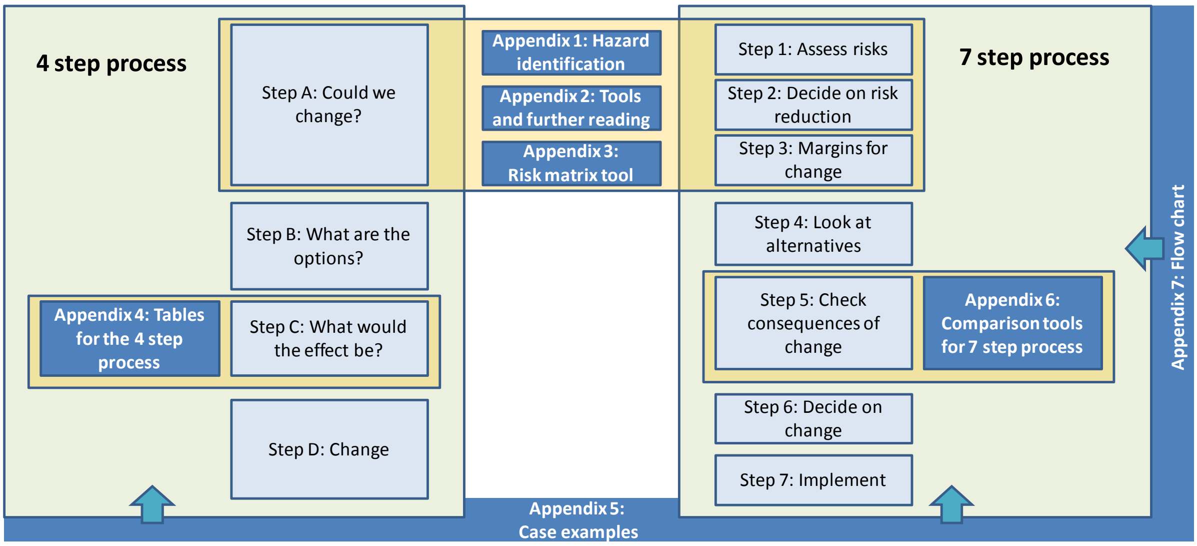

Figure I-2: Structure of Guidance and Appendices

Some definitions and concepts used in the guidance

Change management All changes carry a potential to initiate a conflict and there is the potential for practical conflict particularly if workers do not “see the point” of the change. You may also have to deal with conflicting requirements from customers or different areas of legislation. Making sure you check all requirements and listen to different viewpoints during the evaluation process will reduce the potential for conflict. The **conflict potential** should be taken into account early on in the substitution process.

Chemical is the name for anything made of material and includes liquids, solids and gases. In this guidance the term chemical covers substances and preparations/mixtures as defined by the REACH and CLP regulations. Mixtures are for example chemicals that are used to clean floors, coat metals, lubricate machinery and dye materials. Chemicals are also materia naturally occurring or given off as by-products of a process.

Hazard is an inherent property of a chemical describing the potential to cause harm. There are also other types of occupational health hazards that can be similar to chemical hazards, such as inhalation hazard from dust. This guidance does not specifically address these other types of hazards, but could be applied also to these.

- **Hazardous chemicals** have the potential to harm people or the environment[4]. In the workplace, for example flour, silica or wood, that although not classed as chemicals but which generate dust when used can also be regarded as **hazardous materials**. Substitution can equally well be applied to these.

Exposure potential is a way of summarising the possibility of the chemical affecting either the person using the chemical or persons at or near the place of use**.**

Management decision point is a term used in this document to describe stages where management decisions are needed. Assessing whether you should make a substitution or not can require large changes in a process or for example changing suppliers or making investments. These may be issues that require management to decide on whether to proceed or not. When presenting a substitution case to management, make sure you present relevant issues at each stage. If you are the manager, these points help you decide what information you need to make informed decisions.

Risk is the possibility that something with unwanted consequences will happen. For example, you take a risk of being run over when you cross the street. You reduce the risk of crossing a road by using a zebra crossing, but it would be even safer if you substituted crossing directly in the line of traffic by taking another route, such as a pedestrian bridge or subway.

- **Chemical risk** is the chance (likelihood) of harm to persons or the environment as a consequence of exposure to a chemical (or hazardous material). The level of risk is a way of describing the potential for the chemical to lead to harmful effects when made, used, handled, stored, disposed of or transported in a particular way.

[4] What the term hazard means from a legal point of view is defined in legislation such as REACH or the CLP. However, form a practical point of view, hazard is more easily understood when referred to as potential to cause harm

- **Chemical risk assessments** are systematic ways of combining the hazard of a chemical with the potential for exposure (likelihood) to the chemical and as a result give an indication of the level of risk. Chemical risk assessments are used to evaluate risk to health, safety or environment and sometimes to property or image. The risk can also be translated into costs. There are several tools on the internet available to help you do a chemical risk assessment. Environmental risk often is a key driver for change, but in this guidance, the main focus is on risks to workers health and safety.
- **Comparative risk assessments** are used to estimate consequences of certain alternatives. To make informed decisions, you need to compare the risk before and after any change or the risk between alternatives.
- **Comparing different types of risk** can be quite hard but it is important to try to cover all types of risk in your assessments. This means not only risks from the chemical such as safety risks, acute health risks, chronic health risks or risks to the environment, but also other types of risks from how you use the chemical. Taking into account risk from for example physical processes is important. If you do not cover all aspects, you can find yourself having, for example, reduced an acute chemical occupational health risk but, as a consequence of the change, also unintentionally increased the risk of repetitive strain. For example, if less data on an alternative is available, you need to take this into account when assessing the potential for overall risk.

Risk or safety policy refers to a specific company policy on safety or risk management. This is basically a document that states your safety targets, how you are going to manage risks, which risks are the most important ones to reduce and how you prioritise these. It should state acceptable risk levels and define what these are in practice. Make sure you check your legal obligations in relation to the acceptable risk level. Many companies do not have a formal risk or safety policy, but if you have one, it will make decisions on for example comparisons between different types of risk much easier. It should also detail which risks you need to remember to look at.

Substitution is one way of eliminating or reducing the risks to health and safety at the workplace arising from exposure to chemicals. *All hazards to the safety and health of workers should be identified and risks arising from them eliminated or controlled in order to prevent occupational accidents and work-related diseases*.[5] In this document, a broad risk based definition of substitution is therefore applied. Substitution here refers not only to reducing risk through replacing a chemical used with a less hazardous one, but also to reducing risk through replacing a physical form of a chemical (e.g. particle sizes, coating, etc), or a process or technology used with alternatives that leads to less risk.

Use is a word used in this guidance to refer to all the work tasks or processes in which the chemical "participates" at the workplace. This includes how the chemical is made, used, handled, stored, disposed or transported at your workplace.

[5] EU-OSHA (2010)

Workers involvement in substitution is vital. Consultations with workers and/or workers' representatives and their participation in workplace safety, is a legal requirement6. It is also common sense to make sure workers are included in discussions. People who are listened to and whose opinions are sought are much more likely to actively try to reduce risks and come up with better alternatives. The people doing the work are also a valuable source of information about practical consequences of changes.

[6] See article 11 of 98/24 or article 11 of 89/391/EC.

2. Change for health and safety in four steps

You have chosen to follow the FOUR STEP process. This is the simpler process, that does not require as much data or as detailed assessments as the 7 step process. If you want to a more thorough assessment, use the 7 step process in Section 3. instead.

STEP A: PLAN – Could we change the way we use chemicals to improve workplace health and safety?

It is a legal obligation to assess the chemical risks. To assess the risk, you need to know how you use the chemical and what the hazards of the chemical are. This step will help you assess the risk from the chemicals you use. You will also be taken through the steps necessary to decide what you can and cannot change in order to reduce chemical risks.

- *If you have already assessed the chemical risks and what you can change, you can go directly to the DO stage (2).*
- *If you know the hazards, but not the risks, go to phase IV on page 23.*

Working through the PLAN step will help you assess the chemical hazards and the potential for harm to workers from the way chemicals are used in the workplace. The risk is then estimated based on hazard and the way the chemical is used. The PLAN step also helps you decide what you can and cannot change. Once you have worked through this step, you will have a fair idea of whether substitution could help you reduce risk at the workplace. There are four phases in the PLAN step, each helping you find the answer to the following questions:

I. What are the chemical hazards?

II. How are the chemicals used?

III. How could this harm workers?

IV. What are the risks and are these too high?

V. What can be changed to reduce the risk?

The next sections will help you to work out the answers to these questions. There are many tools and sources of data listed in Appendix 2 that can be used to help you find the answers. To illustrate how each question could be approached in practice; there are cases studies and examples in Appendix 5.

I: WHAT ARE THE CHEMICAL HAZARDS?

The first thing to find out is what kinds of hazards are associated with the chemicals you use. A good source data on the hazard level is the **safety data sheet** (SDS) sections 2 and 15. There is also information on the label of the chemical container.

It is not always easy to interpret what the warnings, pictograms or different phrases /statements mean. This is particularly challenging at the time of writing this guidance, as the labelling, warning and hazard describing system is currently being changed. The new system is referred to as the CLP- system from the Classification, Labelling and Packaging of substances and mixtures EU Regulation 1272/2008. The old orange warning signs as well as the R-phrases will gradually be replaced by new pictograms and hazard statements and signal words by 2017. In the new system, chemicals are also given precautionary statements for storage, accidents, prevention and disposal. These will give you a fair idea of how you should manage any risks. All of the new hazard pictograms are shown in Figure II-1.

Figure II-1: The new hazard pictograms for chemical products[7]

Working out the level of hazard: There are many readily available tools on the web for working out the hazard. These are listed in Appendix 2.

If the chemical has so called **R-phrases** or the newer **Hazard statements**, these are given on the chemical container on the label and in the SDS. They describe what type and level of harm can be caused by the chemical. For example, a chemical labelled R36 "Irritating to eyes" and a chemical labelled R34 "causes burns" will both harm your eyes, but the one labelled R34 will be cause much more severe damage. In the new system, the Hazard Statement H335 "May cause respiratory irritation" indicates a less hazardous chemical than one that is labelled H331 "Toxic if inhaled".

You can find all the hazard statements, labels, warning signs and R-phrases in Appendix 1. To check the level of hazard these indicate, you can use the vertical axis on the risk matrix in Appendix 3, where each R-phrase and Hazard statement is categorised from 1 (low hazard) to 5 (very high hazard). This risk matrix covers both the old and the new systems of hazard labelling. Before you start to work out the hazard level, check whether there is a tool or approach that your national legislation obligates you to use. If in doubt, talk with your occupational health and safety authority.

Remember:

- ✓ Some hazards lead to a legal obligation to substitute with less hazardous alternatives whenever technically possible. Examples of this type are mutagenic and carcinogenic substances[8]. Make a note of these and always assess such chemicals for substitution.
- ✓ Exposure to more than one substance can lead to added or synergistic hazardous effects.
- ✓ An otherwise low hazard product can cause chemical reactions when it burns or reacts with other chemicals, and could form for example toxic or explosive gases. Chemical reactions can also occur between chemicals or a chemical and other materials, like between certain acids and aluminium tools, machine parts or containers. Make a note of such hazards at this stage and remember to include this type of assessment in your emergency action plans as well as in your risk assessments.

If you want to do a more detailed assessment, look at PART III- Substitution in 7 Steps.

[7] http://www.unece.org/trans/danger/publi/ghs/pictograms.html

[8] Directive 2004/37/EC

II: HOW ARE THE CHEMICALS USED?

To assess the risk, you must know how the chemical is used. Start by going through how the most hazardous chemicals you identified in Phase I are used. If you have already identified risks go to Phase V: WHAT CAN BE CHANGED TO REDUCE THE RISK on page 24.

Chemical use is in this guidance a term used to refer to all the work tasks or processes in which the chemical "participates" at the workplace. This includes how the chemical is made, used, handled, stored, disposed or transported. During all of these uses, there will be a possibility that the chemical could come into contact with skin or eyes, be ingested or inhaled. The possibility will be high in certain tasks such as manual mixing of chemicals and low in others, such as storing containers. It is important that you recognise and are aware of all the ways the chemical is used.

It can help to start by thinking "who, where, how, when and why you use chemicals". One way of doing this systematically is given in Table II-1. This type of tabulation will also be useful to show authorities or when discussing chemical risk prevention with workers. There are blank tables for you to use in Appendix 4. Remember to include all the ways you use the chemical – use different tables for different uses if you find this easier.

Table II-1: Describing chemical use (with fictional example)

DEFINE CHEMICAL USE	THINK about:	EXAMPLE: Paint stripping (fictional)
People	Who uses the chemical?	Painters
	Are there other people who could come in contact with the chemical?	Customers may be present when used
Process or task	What is done?	Paint stripping
	How is it done?	Apply chemical to surface, scrape paint and chemical away
	When is it done?	In renovation projects
Premise/ area	Where is the chemical used?	Customers premises, variable
Plant, equipment, tools	With what is the chemical used?	Brushes, scrapers, rags
Exposure type	How could the chemical cause harm to workers?	Breathing fumes Contact with skin, eyes
Exposure potential	How likely is it that the chemical could cause this harm?	Breathing fumes is likely, no mask used Contact with skin if spilled, gloves and overall are used Contact with eyes less likely, safety goggles are worn and the chemical is fairly thick so does not splash very readily
Environment	Waste	Tins containing liquid remnants of the paint and solvents used for washing the equipment are hazardous waste
	Discharges	Remnants into sewage when washing equipment with water
	Emissions	Fumes

Completing this type of table does not yet give you an indication of risk, but it will help you recognise all the aspects you need to pay attention to

III: HOW COULD THE CHEMICAL USE HARM WORKERS?

Estimating the **exposure potential** is a way of summarising the possibility of the chemical affecting either the person using the chemical or persons at or near the place of use.

The chemical can be used in several ways. Each way of use can also have the potential to harm workers in several ways.

- ✓ To assess how the chemical use could lead to harm, think about the way you use the chemical.
- ✓ Estimate the exposure potential for all the different uses. Include both routine work and infrequent use such as maintenance or refurbishment or process start-up or shut down.
- ✓ Remember to also think about how the chemical could lead to harm for other people with access to the workplace (e.g. customers, visitors, service contractors, delivery personnel, as well as employees not using the chemical). The exposure potential for other people than workers may be higher due to for example lack of familiarity with the workplace or lack of protective equipment.

For each use, think about how this could lead to exposure to the chemical. Ask yourself "How are or could workers be exposed in each task, for how long and how often"? Is it possible for the chemical to splash on workers and come into contact with skin or eyes? Could you breathe in or swallow vapours, dust or small droplets of chemicals? The more likely it is that the chemical could come into contact with skin or be breathed as vapour, dust or aerosol, the higher the exposure potential.

There are a number of tools you can use on the web or recommended by your authorities for this step (See Appendix 2 Table AII-1 for some examples of tools). You can also use a simple categorisation for this, such as given in Table II-2. Before you use this, make sure you have a clear idea of what the different categories mean in your company. For example, if splashes during a specific task have happened several times before, the exposure potential is most likely very high. Take some time to decide on this, and provide examples that are easy to relate to in your own workplace. You can check with your authorities or industry organisation if there is a recommended tool for doing the exposure assessment.

Table II-2: An example of a categorisation of exposure potential

Very low	Low	Medium	High	Very high
Very unlikely that breathing chemical, fumes or dust would occur Very unlikely that contact with skin, eyes or mouth would occur	Unlikely that breathing chemical, fumes or dust would occur Unlikely that contact with skin, eyes or mouth would occur	Breathing of chemical, fumes or dust could occur Likely that contact with skin, eyes or mouth could occur	Likely that breathing of chemical, fumes or dust will occur Likely that contact with skin, eyes or mouth will occur	Very likely that breathing of chemical, fumes or dust will occur Very likely that contact with skin, eyes or mouth will occur

A more detailed categorisation where many different aspects of chemical use are taken into account is given in Appendix 3 (Risk Matrix) and in the Seven Step process. A case example of how to use the risk matrix to help you establish the exposure potential is provided in Appendix 5.

IV: WHAT ARE THE RISKS AND ARE THESE TOO HIGH?

In this step, you will estimate the risk level for any particular use. You have to combine the hazard of a chemical from phase I with the potential (likelihood) of exposure to the chemical (phase II).

Risk = likelihood of exposure X consequences of exposure (hazard level).

One of the easiest and most used tools to help you do this is the risk matrix. You simply read the hazard level on one axis and the exposure potential (or likelihood of harm) on the other axis and arrive at a certain cell in the matrix, usually given a risk category. An example of such a matrix is shown below. Note that the categories used by different companies or organisations can vary, but the basic principle remains the same.

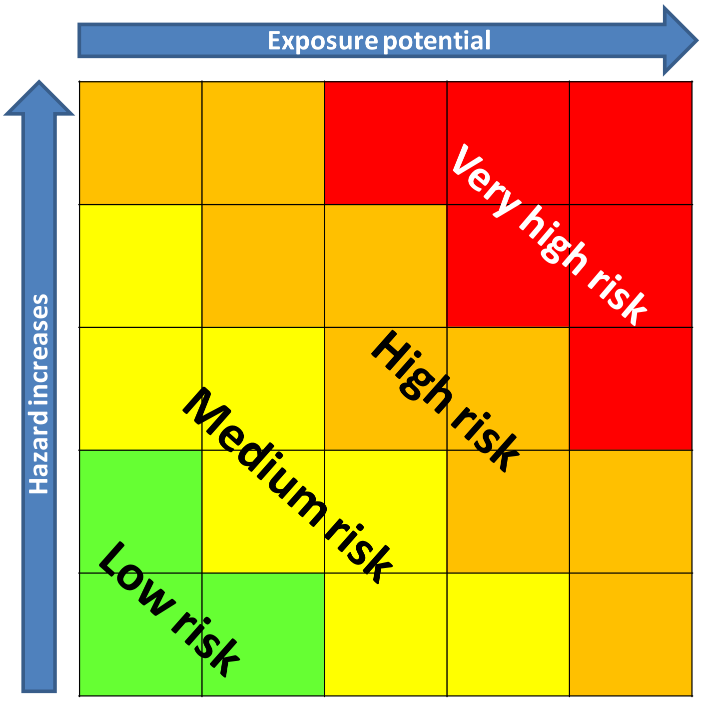

Figure II-2: An example of a risk matrix

Then ask yourself if you need to reduce the risk. If the risk is medium, high or very high -or the highest one in your workplace- you should look at ways of reducing the risk. Substitution is a good way of reducing risk at source, but you need to carefully assess if this is possible.

If you find this step difficult, note that there are a number of tools available free on the internet for assessing chemical risk and/or determining risk control measure needs. Some of these are listed with links to the tools in Appendix 2 Part 1. You can also use the risk matrix in Appendix 3. Examples of how to use the risk matrix can be found in Appendix 5. **Ask your occupational health and safety authorities, whether there is a tool they recommend you to use.**

V: WHAT CAN BE CHANGED TO REDUCE THE RISK?

Once you have a clear overview of the chemical risks, look in detail at those uses where the risk is highest. You can use the approach given in Table II-3, where further notes and examples are given. There are empty tables for your use in Appendix 4.

Table II-3: Check-list for setting margins for change

QUESTION	ANSWER	REASONS for answer; notes on whether more data is needed and what type of data. 
Could we do without the chemical or the work task?		Ask yourself - Why are we using the chemical? What are the benefits? Is it necessary to do this? Are there any other ways we could work? How much profit do you make from this? If the profit is marginal or the task is not vital for your business, you could consider it to be the best option to stop doing this task.
What can we change?		Look at the way you are using the chemical and identify what you can and cannot change. Make a list of the requirements for effectiveness and compatibility you have to meet. The more details on specific requirements you list, the easier it will be to compare performance of alternatives.
What type of limits does the materials used set for change?		Material requirements relate specifically to any materials the chemical will be in contact with. If you are painting metal roofs, you cannot use paint that is not intended for metal, nor can you use paints that cannot withstand outdoor conditions for a long time. The requirements are then simply "must work on metal and must withstand weather".
Are there any time re-straints?		Time restrains define the length of time the process or task can take to meet customer or market demands. If your processes are set up in such a manner that for example degreasing a surface has to be performed in a maximum of 30 minutes in order to allow the next stage to take place, any changes will have to allow this time limit to be met.
How does the chemical have to perform? Are there any specific re-quirements?		Note down the requirements for what the chemical should do. Remember to check whether your clients have any specific requirements. If you need to clean a fatty or oily surface, you will need to use cleaners that remove grease. The performance requirement is then "must remove grease".
The way we control the risk now – what can be changed?		Check if the existing control measures restrict the choice of alternatives. Note down any limitations of for example ventila-tion systems, filters or discharge controls as well as for example measuring devices calibration or renewal needs.
Are there any limits related to waste disposal?		Are there any specific limitations from waste disposal or envi-ronmental permits that must be considered? For example, if you have to meet certain permit criteria, you cannot perform worse in that area. However, you are always allowed to do better.

STEP B: DO - What are our alternatives?

Innovation in the chemical industry is continuously looking to develop safer products. There may be surprisingly many alternative chemicals or processes on the market that can be used to reduce risk.

Sometimes identifying alternatives can be relatively easy. For example, when you next go to the shop or wholesalers where you usually buy chemicals, stop and compare the technical performance of different brands and products and read any warnings on the label on the container. You can do the same if you order from a supplier by comparing different alternatives in their catalogue. A good indicator of relative hazard of an alternative can be the precautions the manufacturer recommends. In general, the more protection you need, the higher the hazard. Remember that when you look at alternatives that they will have to be able to meet your performance requirements you listed in Step A. Use the list you made on what you can and cannot change as your basic "shopping specification" (See Table II-4 on previous page).

If you cannot find an alternative as easily as in the example above, you can approach it through these steps.

1. **Make a list of alternatives.** Talk to your supplier and/or other suppliers, your workers and industry association to get ideas on innovative products or working methods that could reduce risk as well as information on alternatives. Your authorities are also a good source of ideas on safer ways of working – it is their job to help you be as safe as possible so you should feel free to ask. Look at different types of changes to decide what your alternatives could be.
2. **Check the alternatives against the requirements** and narrow down your options.
3. **Find the alternatives that best meet the requirements**. Remember to think about if the change could affect any other tasks or processes so that you do not end up increasing other risks.
4. **Test the alternative and see how well it performs.** Are you satisfied the end result will meet all requirements? Involve the people who do the actual work in the testing - their feedback on practical impacts will be valuable.
5. **Decide which alternatives meet the performance requirements**. If none of the alternatives does this, you may have to look for other alternatives or consider reducing the risk some other way.

The internet can also help you to identify alternative products and suppliers. For certain chemical uses such as solvents, there are internet based tools to help you identify what type of solvents will meet each requirement. There are a number of such sites listed in Appendix 2. For more details on how to identify alternatives, look at the 7 step process.

Check that you are not using many different chemicals for the same technical purpose - you may be able to reduce the number of chemicals or you may find you are already using a safer alternative at another location.

STEP C: CHECK - How would the change affect us?

Change can impact on workers or your business or the environment in sometimes unexpected ways. Make sure you are not changing one risk for another. Other risks could be, for example, ergonomic factors, noise, vibration and environmental risks or fumes and gases formed in the process. For example, if you are considering changing from using a chemical for cleaning surfaces to using pressure sprayed water, this eliminates the chemical risk, but it could damage the surface, cause strain injuries to workers and lead to higher noise levels. You then have to decide on which risk is the lesser.

- ✓ **Do a risk assessment for the alternative in the same way as you did in Step 1 for the chemical you consider changing.**
- ✓ Look at other risks that could emerge from changing equipment or working processes and m**ake sure that you are not exchanging one risk for another**, especially if you do not know what other type of risks the alternative could bring.

If you identify some negative effects, it does not mean you should not make the change if the overall situation increases health and safety levels. You do need to be aware of all the different impacts a change can lead to as well as any uncertainties. Make the decision based on overall risk, cost and practicality of using alternatives compared with the way you are working now.

A frequently discussed issue is whether there is enough known about the alternative to fully compare the risk – if in doubt; ask your industry association, suppliers or authorities for guidance.

A systematic approach to comparison of the alternatives will help you make good decisions on change. A simple table format with an example is given next and there are blank tables for your own use in Appendix 4. You can either answer the different questions with detailed descriptions, or simply use + and – or different colours to indicate the differences between the current practice and the alternative. For a more thorough comparison of the relative benefits and drawbacks, you can use the more detailed tables provided for the 7 step process (Appendix 6).

If the alternative appears to be better on paper, try working with it. Talk to the suppliers and arrange for a trial. Try it out first on a small-scale and ask workers and customers what they think. Check the performance is good and that you can do the job in the time required and that no unforeseen effects appear.

Table II-4: Comparison table for chemical and other risks with fictional example

COMPARE ALTERNATIVES – chemical risk	CURRENT	ALTERNATIVE
Will chemical risk be lower?		
Hazard: Are there differences in hazard level?	R34 Causes burns/ Skin Corr. 1B, H314	R38 Irritating to skin/ Skin Irrit. 2, H315
Exposure normal use: Is it possible to breathe in the chemical or get it on skin/eyes/mouth during normal use?	Yes	Yes
Exposure time: How often do we use this chemical?	Same	Same
Exposure long term: Are there any hazards from long term use?	No	No
Protection: Are there more control measures or PPE needed for either?	Yes, this one	
Environmental risk: Are there differences in risk to the environment?	R53 ***May cause*** long-term adverse effects in the aquatic environment/ Aquatic Chronic 4, H413	No environmental risk phrases
Accident likelihood: Is there a difference in how the chemical is used that could increase/decrease the chance of an accident?	no	no
Chemical risk: Which of the chemicals has a higher risk?	This one	
COMPARE ALTERNATIVES – benefits and drawbacks	**CURRENT**	**ALTERNATIVE**
What are the other benefits and drawbacks?		
Other risks: Are there other than chemical risks from this use (e.g. vibration, noise, strains etc.)?	Yes, ergonomics	Yes, noise higher; ergonomics less
Legislation: Are there any specific legal obligations for this chemical that impact on us and what is it?	No	No
Costs: What are the material costs?	1000 €	1050 €
Costs: What would the change to alternative cost? (potential changes in equipment, PPE, training needed, storage requirements etc. per annum)	–	100 €
Time: How long does it take to do the task/process done with the chemical? Is it time critical?	30 min	25 min
Supply: Is the supply secure, i.e. will we get this chemical when we need it?	Yes	Yes
Waste: Does the use of the chemical create waste that needs special treatment?	**Yes**	**No**
Environment: Are there differences in discharges to water or emissions to air?	**No**	**No**
Which is better? Current or alternative?		**This one**
CHANGE OR NOT?		**YES**

STEP D: ACT - When and how should we make the change?

The decision of change may need management approval. Make sure you know who can make this decision. If the decision is to change, you need to plan how and when to implement the change by:

- ✓ Making sure everyone is trained for the new working way.
- ✓ Making sure workers are supportive of the new way and listen to any doubts or concerns. Explaining why you made the change can help – most people appreciate a safer workplace.
- ✓ Double checking that no new unintended risks are brought in.
- ✓ Communicating openly with all participants during the change.

Involve the persons who do the task currently through participating in the trial. Discuss when and how to make the change. It is important that the people who will be working in the new way or with a new product are trained and feel comfortable with the new way to work. Remember, learning a new task will take some time and performance may be a bit slower than before for a while. Avoid making changes in particularly busy times.

Plan the change carefully. This will help you minimise any risks.

- ✓ Make a list of who needs to know about the change and what training is needed.
- ✓ Check if you have to make special arrangements for deliveries.
- ✓ Check if there are any particular risks during the change that you need to take into account.
- ✓ Inform management, workers and other persons involved about any potential new risks and safety measures.
- ✓ Talk to sales and marketing to see if the change will affect them. They may need new sales material or have to know if the delivery of products or services might be affected for a time.
- ✓ Make sure you do not run out of stock for the old process/task during the change period.
- ✓ Make sure that any old chemical stock is removed from storage areas.
- ✓ Check and update process descriptions, quality assurance procedures or other management systems before you make the change. Document the process, delayed options and reasons for change.
- ✓ Make sure that customers know and accept the chance.

The best way of making the change will depend on what you are changing. It could be as easy as stopping using the old product and starting using the new one. If you are changing something more complex, for example a production process, you could decide to run the new process in parallel with the old one for a time. Whether you make a change gradually or change over directly, make sure that you think of how to make sure it is safe also during the change process.

After you made the change, remember to check if the substitute meets your expectations. Monitor carefully to make sure any (unexpected) problems are not occurring. Keep yourself informed of any new alternatives – there may be new, safer innovations coming on the market in the future.

Substitution is a risk management measure

Substitution can be used to reduce risk at any workplace where chemicals or hazardous materials are handled, stored, or used. Substitution can be done to improve **occupational health** and reduce both acute and long term exposure risks, sometimes to improve **safety** by removing or reducing for example fire or explosion risks, and sometimes to reduce risk to the **environment**.

Whatever the reason, you need to make sure the change does not lead to unexpected surprises, such as increasing safety risk whilst reducing acute occupational health risk. Both direct and indirect consequences from substitution should therefore be carefully assessed.

The preferred target is **eliminating** chemical risk. Eliminating chemicals altogether can be difficult, but you may find another way of working, such as using joinery instead of glue. Remember to make sure you do not increase another type of risk instead. **Substitution** covers:

- **Changing the chemical used** to a less hazardous one. If you use it in exactly the same way, this will reduce the risk. If you change the process at the same time, make sure no new risks are introduced.
- **Changing the physical form of a chemical** to another, that is less likely to lead to exposure. One example is using pellets or slurries instead of powder to minimise dust and reduce inhalation risks.
- **Changing a process or task** to a safer one like using lower temperature process.

If you cannot reduce the risk at source, you can still control it through various other risk management options. These include:

- **Engineering controls** such as alarms, safety valves, double skinned tanks and others. Remember that these are often very good options for controlling the risk, but they will not remove the cause of the risk.
- **Administrative controls** such as workplace procedures and training are very important, but while reducing it, they do not completely protect from human error.
- **Personal Protective Equipment (PPE)** will only provide a barrier against exposure to a particular hazard and does not reduce the potential for harm of the hazard itself.

PPEs as safety measures should be only the last possibility. If you choose to control the risk purely through PPE, for example by requiring safety goggles to be worn, you cannot be sure that the workers will always were the PPE and in a correct way. This is the basic reason for looking for ways to remove the cause of risk rather than just provide barriers that reduce the chance of exposure. PPEs should also always be only in personal use and they should be clean, suitable for every chemical and changeable parts, such as filters, in valid condition. It also takes time to wear, clean and maintain the protective equipments. The overall costs of the PPEs might be significant compared to other safety measures.

3. Change for health and safety in seven steps

You have chosen to follow the SEVEN STEP process. The process is more detailed, if you want to use less details, use the 4 step process in Section 2. instead.

Getting started with the seven step process

This **part of the guidance contains the more detailed 7 step process.** Use this approach if:

- ✓ You have at least some experience of chemical risk assessment and management
- ✓ If you want a detailed assessment of the potential for substitution
- ✓ If the process or task where the chemical is used is more complex.

The 7 step process allows you to consider substitution thoroughly and systematically. Working through the process will help you achieve practical and effective change management.

Each of the seven steps includes data requirements, decisions and tasks to carry out. These have been presented in a flow chart format. The flow charts use standard symbols, as shown in Figure III-1

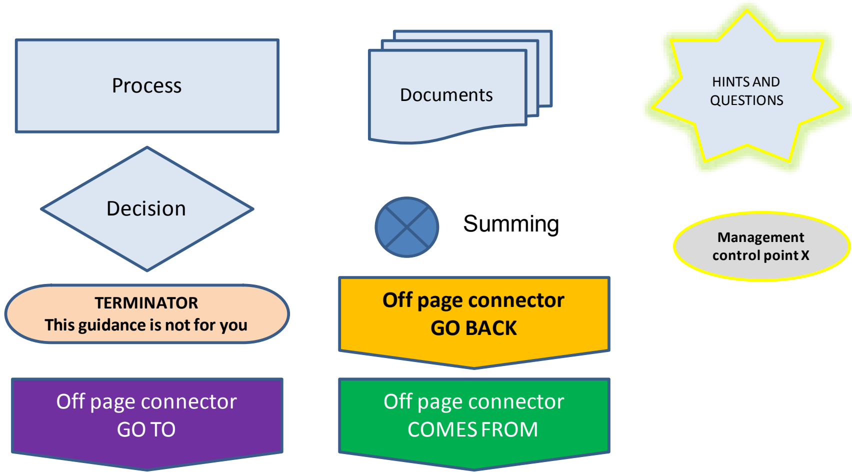

Figure III-1: Key to the symbols used in the flow charts

The most critical decisions are shown as **management control points.** Management always has the main responsibility for overall health and safety at the workplace, including meeting legal obligations. The level of management that make actual operative decisions depends on your company organisation. Some of the decision points are quite complex. It is a good idea to collate all the reasons for and against and make sure you feel comfortable that the data support the decisions that need to be taken.

Each of the seven steps can also be carried out individually without the need to go through the whole assessment process. For each step, there is information on:

- The outcome and benefits of carrying out that particular step
- Pointers to further information sources and examples of tools that can be used (Appendix 2)
- A case study or an example to illustrate the step in practice (Appendix 5).

A series of "*Frequently Asked Questions and Answers*" are also included for each step.

Where to start in the 7 step process?

If you have already done a lot of work to manage chemical risks, you can skip some of the early steps relating to risk assessments and legal obligations. Use the flow chart below to decide where to start. If you think you need to reduce the number of chemicals you are using, this process will also help you find those chemicals you should preferentially eliminate. There is no absolute order to go through the process and especially the first two steps can be carried out in the order that feels best.

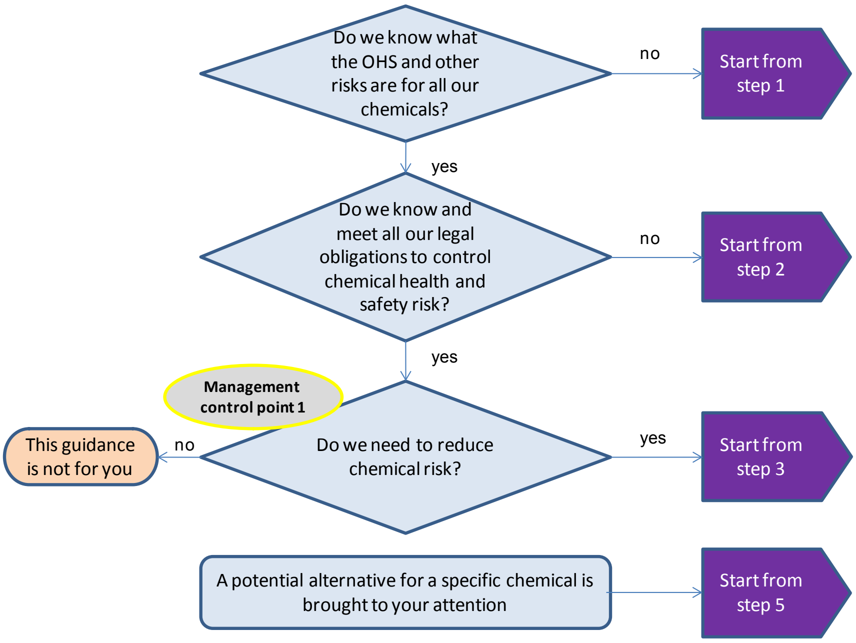

Figure III-2: Where to start? (OHS = occupational health and safety)

In some places in this guidance you may find references to a **company policy on health and safety or risk management.** Do not worry if you do not have one, but if you have, follow its principles. It helps you to decide which risks are acceptable and which ones need to be reduced. An example of a general high level statement that could be included in an occupational health, environment or corporate responsibility policy document, is:

> *"We will not use chemicals in a way that can harm workers, customers, the public or the environment"*

The base line for all companies is to comply with legal obligations. A more detailed safety or risk management policy should go one step further and contain a statement of your safety targets, how you are going to manage risks, which risks are considered most important ones to reduce and how you prioritise risk management measures. Ideally the policy or accompanying instructions should make reference to acceptable risk levels and define what these mean in practice. An example of a policy statement on chemical risk management that gives a clear mandate to use substitution as a risk management measure is:

> *"We will identify, assess and manage all chemical risks. We will eliminate the use of hazardous chemicals we can do without. Where chemicals are essential for us, we will as far as possible reduce chemical risks through finding safer chemicals or safer ways of working. If neither is possible or does not reduce the risk enough, we will implement control measures".*

STEP 1: ASSESS THE CURRENT LEVEL OF RISK

RESULT: A complete set of assessed risks for all tasks involving chemicals

BENEFITS

- ✓ *You will meet your legal obligations (EC Chemical Agents Directive 98/24/EC, CAD and the 2004/37/EC Carcinogens and Mutagens Directive).*
- ✓ *You will know if the way you use the chemical is a risk and what type and level of risk this is.*
- ✓ *You will have the basic data needed to design how to efficiently prevent accidents, incidents, exposure or long term effects.*

WHEN TO ASSESS THE RISKS

Chemical risk assessments should be always up to date for all your chemical uses. These results must be communicated to workers and subcontractors, who may be exposed to these risks and information should be available to authorities during inspections.

If you have not assessed your chemical risks, start on this straight away. Always update risk assessments when you make a change. Check at least annually that all chemical risk assessments are up to date and communicate the situation with the management. You may have to do chemical risk assessments for several purposes:

- Occupational health and safety impact – always as part of workplace risk assessments
- Environmental impact (e.g. for environmental permits)
- Major accident hazard potential (if you use or store large amounts of hazardous chemicals)
- Health and safety impacts to public or customers, for example for your product statements

You also need to assess other occupational health and safety risks. It is a good idea to integrate chemical risk assessments to be a part of your overall risk assessment procedures. If you are doing task or process based workplace health risk assessments, it can save you time and effort to include other aspects at the same time, such as environmental impacts or process safety aspects. If you assess safety and occupational health risks separately, make sure you link any findings with other risk assessments - you will need this to get the overall picture of risk. Finally, you need to make sure you can relate the chemical risk levels to other risk levels so that you can compare overall effects of any change.

HOW TO ASSESS CHEMICAL RISK

Parts of the risk assessment:

I: Identify the hazard (e.g. from SDS);

II: Establish how you use the chemical and what can go wrong;

III: Establish exposure potential; and

IV: Evaluate the risks from normal use and incidents to health and safety.

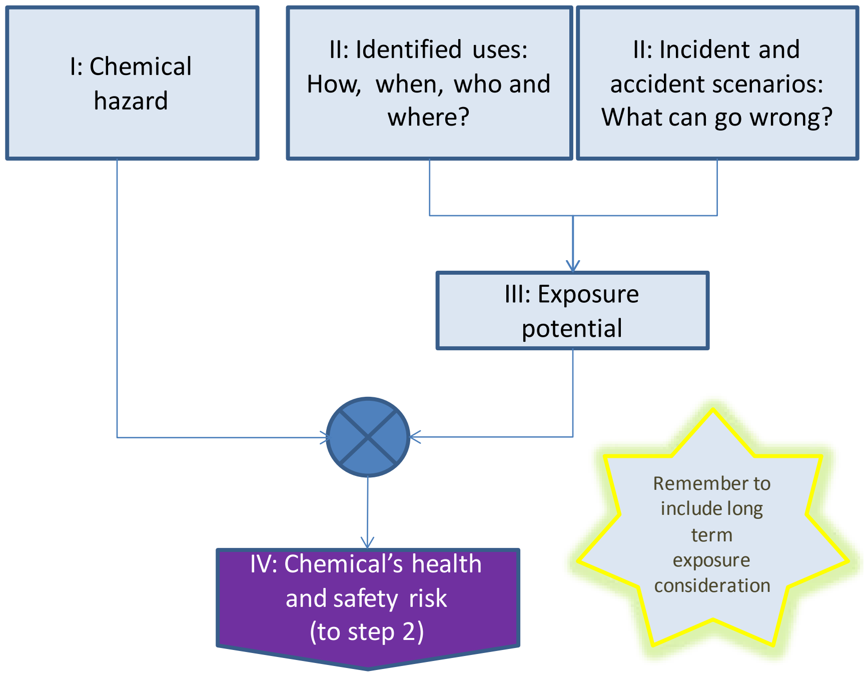

Figure III-3: Flow chart for Step 1

I: HAZARD ASSESSMENT

Before you start, make sure you have **an up to date list of all chemicals you use** and current Safety Data Sheets (SDS) for all classified substances. This is a legal obligation under the Chemical Agents Directive 98/24/EC (CAD) as well as the 2004/37/EC Carcinogens and Mutagens Directive.

Next, you should assess the hazard level of each chemical. Look at the SDS section 2 or 15. Later you will also be able to use the C&L inventory published by European Chemicals Agency ECHA for finding out classifications and labelling information[9]. Alternatively, if you have more experience, you can look at other EU sources on chemical data and exposure estimation[10].

Note that **even if the chemical is not classified as 'hazardous'**, it can still have effects on health and the obligation of making sure people's health and safety are protected still applies. You therefore still need to assess and control the risks, although this may be more complex as there is no longer a legal obligation under REACH to produce SDSs for non-classified substances[11].

A relatively straight forward way of assessing hazard levels is through **using a categorisation of hazard statements or R-phrases** to find the hazard level of a chemical. There is an example tool

[9] The C&L inventory (classification & labeling inventory) is to be published during 2011: http://echa.europa.eu/clp/c_l_inventory_en.asp

[10] For example REACH Guidance R.14 OCCUPATIONAL EXPOSURE ESTIMATION

[11] The SDS provides a mechanism for transmitting appropriate safety information on substances and mixtures which meet the criteria for classification, as dangerous, are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative, or are contained in the candidate list for eventual authorisation for any other reasons, and also under certain conditions some mixtures which do not meet the criteria for classification as dangerous (Article 31.3 of REACH).

where the categorisation has been done in Appendix 3 (Risk Matrix). You can use this, or there is a number of free web tools that can help you determine the hazard levels (see Appendix 2 Table A2-1).

- ✓ Remember to include all aspects of hazards[12].
- ✓ Remember to **assess whether there is sufficient data available** to make informed assessments.

  If, for example, you look at the SDS, there are no classifications and there are no or limited data on test results reported, this could indicate that the SDS does not provide you with all the data you need.

  If the chemical you are using is suspect of being more harmful than its R-phrases indicate, you can adjust the hazard level higher based on the precautionary principle. This might be the case if the chemical is suspect of being an endocrine disruptor or a mixture includes so small amounts of hazardous chemicals that it is not classified as hazardous.

  If in doubt, or there is for example conflicting classifications given by different manufacturers, apply the precautionary principle and use the worst possible classification. You can also ask for advice from authorities or independent experts.

Figure III-4: The new CLP pictograms for chemical products

For in-depth assessment of hazards, there is a wealth of different data on chemical, physical and toxicological/ecotoxicological properties available in data bases and in the literature. These types of data often require interpretation of, for example, toxicological test results. Where you have a choice of data, use data based on tests from high-quality information sources, such as data generated with OECD Test Guidelines in compliance with OECD GLP. You need to have some expert knowledge before embarking on this type of exercise. See Appendix 2 for databases on chemical properties.

EXAMPLE OF A MORE DETAILED ASSESEMENT: For a more detailed estimate of the inhalation hazard level, you can also look at the family of different limit values for occupational inhalation exposure: The occupational exposure limits (OELs), which include EU indicative occupational exposure limit values (IOELVs) and EU binding occupational exposure limit values (BOELVs), and any national limit values (LVs) or the manufacturer derived no effect levels (DNELs) under REACH. These may be given in the SDS or you may find them in government issued reports. The general principle is that the

[12] The different type of data you need for Human Health are: 1) Acute toxicity (skin / oral inhalation); Eye / Skin irritation and corrosivity; 2) Sensitization; 3) Mutagenicity / Carcinogenicity; 4) Repeated dose (skin / oral / inhalation); 5) Reproductive or Developmental toxicity (skin / oral / inhalation)). Also include consideration of physical-chemical safety hazards such as Flammability and Reactivity. The environmental aspects to consider include Acute toxicity, Chronic toxicity, Persistence, Bioaccumulation

lower the value, the more hazardous the chemical is through inhalation. If you want to use these values in accurate risk assessment, you need to measure actual breathing zone concentrations.

II: ESTABLISH HOW YOU USE THE CHEMICAL AND WHAT CAN GO WRONG

First, identify in what different ways you use the chemicals. The way you use - e.g. how you apply, handle, store, dispose or transport or use in any other way - the chemical will determine the exposure potential of the use and together with the hazard give the level of the risk.

It is good practice to write down how each task is or should be performed – you may indeed already have this data stored in your work procedures. If you have not done this already, there is an example provided in Appendix 4 of how to record uses. A good way of making sure you take into account all the different ways you are using the chemical is to make a flow diagram. Extend this to include all processes or tasks affected by the chemical use. This will be important when assessing any potential for affecting other processes if you end up considering a change.

- ✓ **Establish the planned uses:** The more complex each chemical use case is, the more you need to spend time on this step. Make a list, diagram or flow chart of how the chemical is used, how often and where and by whom.
- ✓ **Establish the "non-routine" uses**, i.e. periodic or occasional uses. These are, for example, process start-ups and shut-downs, field trips, refurbishment, use during extreme weather conditions, maintenance work, temporary arrangements or emergency situations. Use the same approach to describe these as you did for planned uses.
- ✓ **Establish what can go wrong.** Are there possibilities for spills, splashes, unintended discharges, leakages, reaction issues, fires or explosions? You can also use scenarios, such as: "Carrying an acid container manually, the worker slips on the stairs and the container is dropped and damaged. Acid splashes the workers face and hands and severe chemical burns result."

III: EXPOSURE POTENTIAL

There can be several types of uses for one chemical and therefore different types of exposure potential for any one chemical. When assessing the exposure potential, you need to look at each use and think about how it could lead to exposure to the chemical through skin, eyes, lungs or mouth.

Note that although it is possible to attempt to combine all the different use cases into one overall exposure potential, this can lead to inaccuracies or oversights. To enable more detailed assessments and accurate risk control requirement assessments, it will be beneficial to record the results for each type of use separately. This will, however, inevitably make it a more time consuming task.

Ask yourself "How are or could workers be exposed in each task, for how long and how often?" The more chance there is for example for contact with skin or breathing vapours, dust or aerosols, the higher the exposure potential will be.

There are a number of ways of assessing exposure potential, ranging from a simple qualitative categorisation of low, medium or high, to very complex models involving measuring workplace concentrations, calculating accident frequencies and various types of computer modelling. Using one of the axis on a risk matrix for assessing exposure potential is the most commonly used approach of categorisation. In the following different variables are classified on a scale of 1-5 and the overall assessment is taken as the worst case category. Two of the main issues to include are type of working process and physical format of chemical.

- **The type of working process:** Is the chemical used in a fully enclosed system, an open system with ventilation or open system without any ventilation? This gives an indication of relative exposure potential, e.g. how easily the chemical can be inhaled or splashed on skin.

Table III-1: Working and process conditions

Category	1	2	3	4	5
Working / process conditions	**Fully enclosed system** -> No possibility of direct skin contact -> No possibility of exposure by inhalation	**Closed system,** with small possibility of exposure during some work steps such as decanting or sampling -> Low possibility of direct skin contact -> Low possibility of inhalation	**Semi-enclosed system** or open system with automatic ventilation and control barriers -> Some possibility of direct skin contact -> Some possibility of inhalation	**Open system,** passive ventilation and protective barriers -> Medium possibility of direct skin contact -> Medium possibility of inhalation	**Open system,** no ventilation -> High possibility of direct skin contact -> High possibility of inhalation

- **In what physical form or state are you using the chemical:** You should only take this into account in the exposure assessment if you first change the form from what you bought it in, as that is already assessed in the hazard assessment. The physical form or state of the chemical can increase the exposure potential i.e. it may not be possible to breathe the solid, but this will be a distinct possibility if you first grind it into a fine, breathable powder or heat it so that vapour is produced. Some forms, such as a fibrous form of a substance which can increase the health hazard, should be taken into account in the hazard assessment. It is a good idea to check that it has been included.

Table III-2: Physical properties

Category	1	2	3	4	5
Physical properties affecting exposure	Vapour pressure of liquid is below 2 hPa	Vapour pressure of liquid is 2-10 hPa	Vapour pressure of liquid is 10-50 hPa	Vapour pressure of liquid is 50-250 hPa	Gases; Liquids with a vapour pressure over 250 hPa
	Non-dust-generation	Low dust generation	Some dust created	Increased dust generation	Very high dust generation, aerosols

To estimate the overall exposure potential category, you can use the precautionary principle and assign the worst case of the above. For example, if the vapour pressure is low, no dust is generated (category 1) but the system is fully open (category 5), the overall category would be 5.

Sometimes this type of approach gives too high an exposure potential, and you could choose to use the average value, which for the earlier example would be (1+6)/2=3. There are differences of opinion here, and often other variables are used to help or to fine tune the overall exposure potential assessment. Some such are:

- **The frequency and duration of the chemical use.** Do you use the chemical only a few times per year, monthly, weekly or daily? Is the duration only a few minutes or longer? More frequent and long lasting use will increase the relative exposure potential.

Table III-3: Frequency and duration

Category	1	2	3	4	5
Frequency or duration of use	Rarely, a few times a year Very short use, minutes	Occasional, monthly Short use, less than 1 hour	Frequent, once a day, several times a week Medium use, 1-2 hours at a time	Very frequent, several times a day Use for more than 2 hours at a time	Continuous process

- **The quantity of chemical used each time:** Are you using milligrams, grams or kilograms of the chemical? The more of a chemical you use, the more relative potential for exposure. This does not on its own indicate exposure level, but you can use it to modify the level up or down. For example, mixing 20 millilitres of a chemical into a bucket of water leads to less overall exposure potential than if mixing 2 litres of the same chemical into the same bucket of water.

Table III-4: Quantity

Category	1	2	3	4	5
Quantity used	Very small; grams or millilitres Examples are lock sprays, certain additives in laboratories	Small; less than 1 kg or litre	Medium; between 1-10 kg or 1-10 litres	Large; over 10 kg or over 10 litres	Very large; over 100 kg Often chemical use is measured in tonnes or cubic metres

- **How often accidents** could occur. In the example used for the accident exposure, think about how often the acid is carried manually and how often do you think this type of slipping could occur? The more often it could occur, the higher the accident potential will be.

Table III-5: Accident potential

Category	1	2	3	4	5
ACCIDENT potential	Very unlikely	Unlikely	Could happen, has occurred in industry	May happen	Very likely, has happened before at our work place

In addition you could consider items such as: how many people are using the chemical; where is it used (outside, inside, confined space); at what temperature and pressure the chemical is used and for example the level of expertise of the user. You can also assess the potential with and without control measures.

Use these results to adjust the value you got from the physical properties and type of system either up or down. Be consistent in your approach and always do it the same way.

You can use tools on the web or recommended by your authorities to carry out exposure assessment (See Appendix 2 Table AII-1 for some examples of tools). The **5 x 5 risk matrix in Appendix 3** with its horizontal axis is one example of a tool to assess the exposure potential. A case on how to use the risk matrix to help you establish the exposure potential is provided in Appendix 5.

In this step, you will estimate the risk level for any particular use. You have to combine the hazard of a chemical with the potential for exposure (likelihood) to the chemical.

Risk = likelihood of exposure X consequences of exposure (hazard level).

For substitution assessments, it is important to look at overall effects of both current and potential alternatives. Therefore you need to estimate the overall risk from using a chemical in a particular way for a particular purpose. Remember to include all possible cases for that particular use. For eample handling in storage area; pouring into mixer; mixing; emptying mix into containers; sealing containers; cleaning mixers and maintenance of mixers; disposing of empty containers and waste.

You should also think about risk from the exposure and accident potential that can result from the activities of all people with access to the workplace (e.g. customers, visitors, service contractors, delivery personnel, as well as employees). The risk caused by for example potential lack of familiarity with the workplace may also be higher for such outsiders than to your regular workers.

- ✓ If you have several types of use and accident scenarios for one chemical, you can start with those uses where you have identified that the exposure potential is highest. The overall occupational health risk is often more dependent on exposure during planned uses, so you can do the risk assessment first for normal use.
- ✓ Then look at the exposure potential from infrequent use cases and the accident potential. Are they higher? If so, you must take these into account as well when you assess overall risk.
- ✓ To get an estimate of overall risk from the chemical use**,** you can use several approaches. One often used relatively straight forward approach is to take the overall worst case (highest risk) and use this as your overall risk level. You can also assign weighting to the different uses depending on how frequent these are and then calculate the overall risk. This can be a good approach in expert hands, but must be done with a great deal of caution. If you err in your risk assessment, it is better to err on the safe side. You could also take the worst case from planned use as your base level, and then adjust the risk higher by one step if the non-routine use or accident scenarios have a higher risk level.

Note that for certain chemicals a single exposure to high levels may be the risk you should use as your base case. For example a single exposure to high levels of isocyanates may lead to asthma. If in doubt, talk to you country's occupational health authorities, they should be able to guide you.

- ✓ Then repeat this step for all chemicals and all tasks (remember, it is a legal obligation to have done chemical risk assessments). You may also find a surprising number of small changes you can make to reduce risk by looking in detail at all chemical uses.

To help you carry out the risk assessment, there are tools available (See Appendix 2, Table AII-1) or you can use a matrix. Your company may already have one specifically for chemical risk, or you can use the example given in Appendix 3. Examples of using this risk matrix are given in Appendix 5. You should also check if there is a tool that your national legislation obligates you to use for risk assessment. If you do not know, ask your local or national occupational health and safety authorities.

Frequently asked questions

Q: What data do I need for risk assessment?

A: You need to have the hazard data and relevant data about how you use the chemical. Relevant data about how you use the chemical are: How often, how much, how is it used (e.g. mixed, poured, painted, brushed, dipped etc.), by whom is it used, where it is used. You are highly encouraged to use any data from occupational hygiene measurements, if available. If you are unsure about how to pull all this together, use one of the web tools that will prompt you to define usage. For hazard related data, start by looking at the SDS. If there appears to be little data there, you can use other data sources such as databases available on the internet or ask your supplier for more data.

Q: What if I do not have the required data?

A: Your supplier has an obligation to provide you with the hazard data of the substance if it is classified. Even if it is not, your supplier should have fair knowledge of potential hazards, or you can look in the literature or databases. If you do not know how the chemical is used in your company, you need to find out!

Q: Why do I need to assess both normal use and unwanted incidents?

A: If you only assess the normal use, you are not aware of what can go wrong. If you only assess unwanted incidents, you are not aware of the potentials for long term exposure related issues such as chronic illnesses. Both are needed to give you a complete picture.

STEP 2: DECIDE ON RISK REDUCTION NEEDS

RESULT: A ranked list of the chemical risk levels and types, annotated with any specific legal requirements to reduce risk.

BENEFITS

- ✓ *You will be able to get a clear view of which risks are high and why these are high. This is essential in order to reduce the risks.*
- ✓ *Ordering these into a priority (from highest to lowest) allows you to target measures so that you get most for the time, money and effort spent. The ranked list is your starting point for effective risk management. Looking at overall chemical risk and all specific chemical risks you need to reduce in one go, you can also find measures that will reduce many risks at the same time, providing cost effective risk reduction.*

WHEN TO ASSESS THE NEED TO REDUCE RISKS

Immediately after or at the same time as you are doing the risk assessment. As soon as you have listed your chemical risks, decide if they are too high. Sort them in order from highest to lowest. *You can skip this step if you have already identifed the chemical uses that need controlling, for example in your assessments according to the CAD.*

HOW TO CHECK THE NEED TO REDUCE RISK

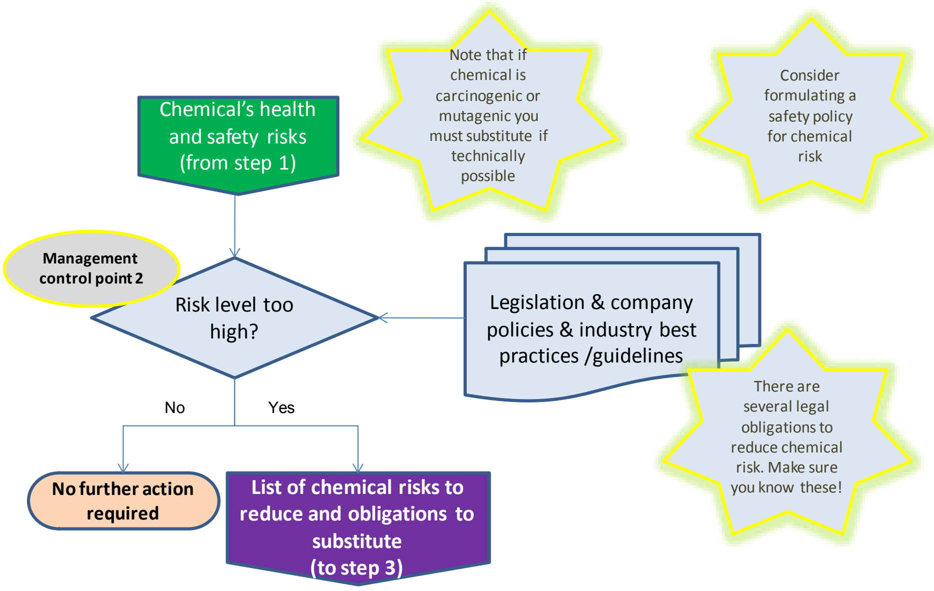

Figure III-5: Flow chart for Step 2

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[13] For example DIRECTIVE 2004/37/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC)

Define what type of risk level is too high. As a rule of thumb, all risks above low risk should be considered too high and efforts made to reduce them, although this raises the question of what is low. First check what your national legislation says – does it define for you what risk level is too high? If not, consider using these guidelines for **acceptable risk levels**:

- ✓ For normal use: risk level so low it does not cause harm to people or environment (very low hazard level and/or very low exposure)
- ✓ For incidents: risk is either very improbable or with insignificant potential to harm people or environment

Note that in most countries you need to decide for yourself what acceptable risks are. Not all EU member states define this for you. You may also want to take a more rigorous definition to for example acceptable chronic risks than is required. Management has to be responsible of this decision. If you find this difficult, discuss it with your national authorities, they should be able to help you.

Check and list your legal obligations to reduce risk. There are types of chemicals, risks and user groups that require specific measures, for example, carcinogens Cat 1 and 2 have to be substituted if technically possible. If it is not possible, you have to be ready to explain this to authorities and take exceptional safety measures. Take into account specific legal requirements relating to protecting workers against risk, and remember to specifically take into account risks to young workers and pregnant and breastfeeding workers[14]. Some chemicals could be potentially hazardous to all people in fertile age.

Rank the chemical risks you assessed. You can rank the risks from highest risk to lowest risk for different types of risk (acute health, chronic health, safety, environment, property etc.) or you can attempt to find the highest overall risks. Different types of risks cannot strictly speaking be directly compared, but you can use tools to help you define if each type of risk is acceptable or not.

Ranking the chemicals is a vital step; it allows you to find out where it is most beneficial to start the mitigation process. If you end up with for example 5 chemical uses in the medium category based on different reasons, it can be hard to prioritise between different types of risk and which one to reduce first; in theory they should all be reduced. Your risk or safety policy should help you here.

One way to decide on which risk must be reduced first is to look at both the risk level and your ability to reduce it easily. Then start with the ones that are easy and cost efficient to control. One tool for this is shown to the right and an example on how to use it can be found in Appendix 5.

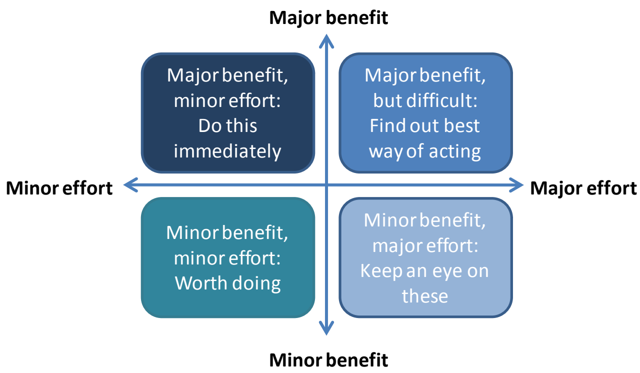


Figure III-6: Prioritising tool

[14] COUNCIL DIRECTIVE 94/33/EC of 22 June 1994 on the protection of young people at work. COUNCIL DIRECTIVE 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)

Frequently asked questions

Q: How do I decide what risk is acceptable?

A: Start by looking at your legal obligations. These will give you the minimum level. Then think about what will happen to workers if certain risks are realised. Are you prepared to face that occurrence or do you have to reduce it? This will effectively set your risk acceptance policy. Think in terms of realistic consequences and concrete examples to make it easier to decide on an abstract issue: Is it acceptable that an employee would be off work for at least two weeks or should this be reduced? If using a cleaning agent for 20 years would cause that person such health problems that he/she would have to take disability pension, would we need to reduce the risk?

Q: How do I rank chronic versus acute health risks or environmental versus health risks?

A: Ranking different types of risks is notoriously difficult and requires ethical decisions, which should be taken by the management. The easiest, and recommended, option is to treat all types of risks as equally important and make efforts to reduce all these to acceptable levels. Using a risk matrix that takes into account the different types of risks can help you do this. However, if you have identified that reducing inhalation health risks is a main target you can prioritise these risks for reduction. It does not mean that you should ignore other risks, simply that you will address the inhalation health risks first. You can also reflect your priorities by setting different thresholds for what constitutes an unacceptable risk. It is best if your safety or risk management policy guides you in how to do this type of priorisation of chemicals with different risk patterns (e.g. high risk for workers and low for the environment vs. low risk for workers and high for the environment). In practice, you will not have to choose which risk is most important; simply decide on which risks to reduce first.

Q: How long will this task take?

A: If you have done your risk assessment properly and have a clear policy on which risks to prioritise, this task is just about sorting the risks. If you have not assessed the risks, you cannot prioritise. The time to sort the risks depends on the tools you used earlier, how many risks you are looking at and how easy these are to use to sort risks by risk levels. Excel is one tool for this type of work which makes sorting into numeric order easy. If you have not decided on how to rank risks, or if your risk assessments are purely qualitative, or in different formats on different papers, this task can take considerable time. First decide on how to prioritise, then sort by these principles and double check to see if it makes sense. Beware: this is a step that can take eons of time if you look for absolute truths and water tight rules. You have to make some assumption, but remember to document them.

Q: If I do not have a risk management policy, how do I go about making one?

A: Think about how you want to manage risks. State these in simple terms, for example "our vision is to have no lost time incidents and we will ensure our workplace is safe". Then think about your risk acceptance levels (for example, "any risks where skin contact risk is higher than low must be reduced"). You can also make priority statements, such as "To us, the health and safety of our workers is our number one target in chemical risk management. We will make sure no chronic illnesses or occupational diseases are caused by the chemical we use. We will control sources that may lead to acute health problems." This would give you a clear answer to prioritise health issues. Ethical choices such as choosing which types of risks to reduce first will always be difficult to make and there are no absolute rules. Finally set some specific performance and improvement targets, such as "We will reduce our chemical risks by 10% within 2 years".

STEP 3: MARGINS FOR CHANGE

RESULT: A clear overview of all the different types of requirements and what you can change and what you cannot change. An understanding of the tolerance of change – i.e. how much can you change. A summary of all aspects you need to consider when looking to reducing risk.

BENEFITS

- ✓ *A clear understanding of requirements and the flexibility of technical systems gives you vital information for overall risk management approaches.*
- ✓ *Gives you a good understanding of what you can and cannot change.*
- ✓ *Makes the consideration of chemical risk management measures much more targeted and saves time, money and effort through narrowing down your options at an early stage.*
- ✓ *A systematic check of technical restrictions may also give you ideas or information on how you could improve your processes.*

WHEN TO ASSESS THE MARGINS FOR CHANGE

Check the requirements, ability and flexibility of systems, processes or tasks to accommodate change before you start looking at mitigation measures. These may limit your choice of mitigation measures.

HOW TO ASSESS MARGINS FOR CHANGE

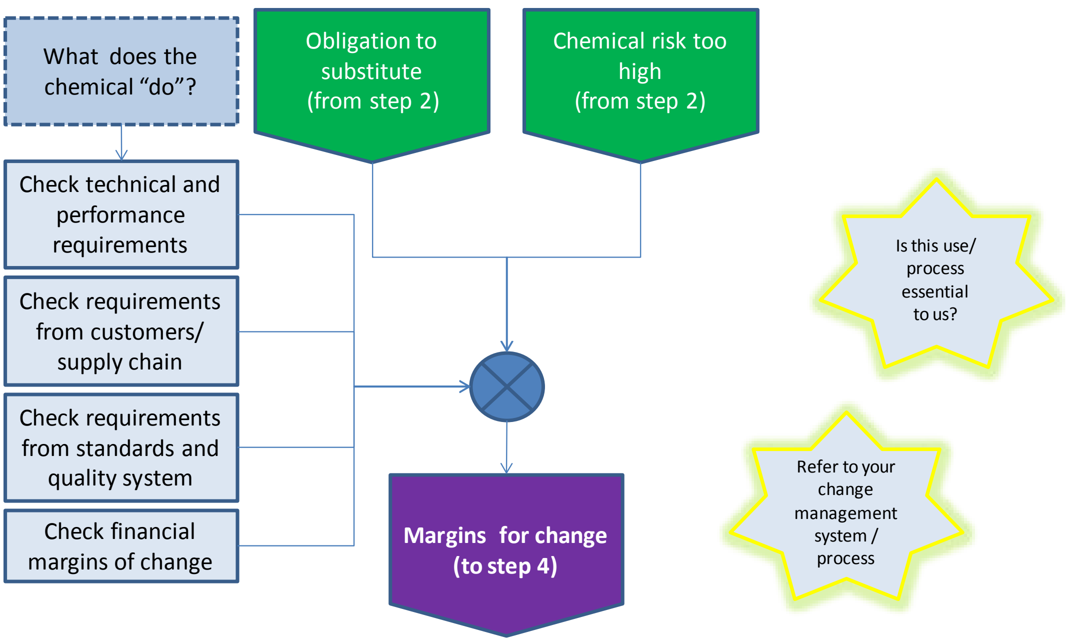


Figure III-7: Flow chart for Step 3

For each of the chemical risks you identified in the previous step (2) as being too high, you need to find out what you can change. Start by looking at chemical uses with the highest risk and continue down the list until you reach chemical uses with an acceptable risk level. For each chemical use identified, map any technical, standard or supply chain requirements. Remember also to look at any processes or tasks affected by the chemical use. Try to consider the whole supply chain. You can do this as a list or table.

Technical and performance requirements: Think about what task the chemical does, i.e. what do you do with the chemical, who does it and why. Consider at least the following:

- ✓ Could we do without the chemical or the work task? Why are we using the chemical? What are the benefits? How reliant is the task or process on using this particular chemical? Why? Is it necessary to do this? Are there any other ways we could work? Consider how much profit you make from the particular product or service that the chemical is used in. If the risk is high, the profit is marginal or the task is not vital for your business, it may be the best option to stop doing this task.
- ✓ Which are the key performance criteria? What are the parameters that have to be met? For example think of the material compatibility requirements and time restraints.
- ✓ Are there specifications listed in official permits from authorities, for example related to maintaining the hygiene in certain industries?
- ✓ How reliant is the success of the overall process /operation or product on this particular step?
- ✓ How difficult would it be to change any or all parts of the process or task identified as a source of risk? Do not leave this step at "*we have to use this because there is no other way*" level but think openly and critically about your own processes.
- ✓ Are there other possible technical boundaries (e.g. any technical standards that have to be met in the use/production of the chemical)?

Mapping technical boundaries can be highly complex when the chemical is used as an integral part of a production process. On the other hand, in such a business you will probably already have a clear picture of your processes and their interdependency. In a more generic task, the mapping of the technical boundaries can be as simple as determining that "The maximum temperature that can be used is 40°C".

Check supply chain requirements: Ask if your customers have any specific requirements to use or not to use a particular chemical. This is especially important if you are a subcontractor. Supply chain requirement may be linked to for example end of life disposal options. Think about the whole life cycle of the product or process the chemical is used in. This means you have to take into account any waste and final product requirements that your customers may have. Are there strict specifications from the customers? Does change initiate their change management? Make these inquiries via official routes together with sales persons responsible for that customer.

Look for quality control and specific quality standards that have to be/are recommended to be followed (product and process). This can be particularly relevant for laboratory test chemicals and in highly regulated industries such as aerospace, pharmaceuticals and others.

Check financial margins of change. Pragmatically, it is most likely there is a limit to the cost of change that can be afforded. Note that substituting a carcinogen or mutagen should always be done "so far as is technically possible"[15]. You should establish the financial manoeuvrability you have, as this will both help you find alternatives that fall within this margin. The financial margins of change

[15] Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work; article 4. Point 1.

should always be related to the total cost of using the chemical, never to just the price of buying the chemical. This is particularly vital in substitution comparisons, as you may change parts of a process or task to one with a different cost structure.

In the next table, examples of how you can go about listing requirements are given. The starting point, i.e. the level of risk, has been included here as a reminder of why you are looking at these requirements. You can modify this approach to take into account the aspects relevant for you – these may also come from end users (consumers).

Table III-1: An example of listing margins for change (with fictional examples)

Chemical	Task	Overall risk	Technical require-ments	Supply chain requirements	Specific stan-dards
Potassium dichro-mate	Used for glass-ware cleaning	Very high risk	Fast and thorough purification is needed	Check purity requirements with the customer	No specific standards
Trichloro-ethylene	Used for sample analysis	High risk	Solubilization of the sample, equipment compatibility	Required from the customer	Standard solubility test for asphalt bitumen
Phenyl hydrazine	Used for a synthesis of a pharmaceuticals	Very high risk	Cannot be replaced without changing the entire synthetic route	No supply chain requirements	No specific standards but have to meet quality standard criteria
Brake parts cleaner	Used for de-greasing	High risk	Needs to remove grease effectively	No supply chain requirements	No specific standards

Frequently asked questions

Q: How do I know which requirements to consider?

A: Talk with your workers and with the people responsible for the particular process. For example, if you are looking at a cleaning chemical, talk with the person using the chemical. What does it have to do? What needs to be taken into account? If you are using a chemical in a more complex process, make sure you consider the technical and engineering design restraints. A process where the chemical is used in a reaction will require you to involve your chemists or product development department. In general, the more specific the chemical has to be, the less you can change.

Q: How important is this step for me?

A: It is vital to know what you can change and what not. Remember to consider the whole process otherwise you may end up with unwanted things happening further down the chain.

Q: Are all requirements equally important?

A: This is dependent on your case. If you find it hard to decide which requirements to include, you can approach each one through asking the question of what will happen if this requirement is not met. For example, if you are degreasing metal, ask yourself what will happen if the metal is not fully clean? How long can it take to dry? Is there any particular dirt that must be removed?

Q: How can I ensure that my list of requirements is kept up to date?

A: Knowing your performance criteria makes it easier to manage any changes – whatever they may be. Make the list of requirements a working document for your critical tasks or operations. Update it whenever any changes are made as part of your change management program.

Q: I sell this chemical. Why should I stop a product line that brings me profit?

A: If you sell the product, you can still approach substitution by thinking of alternative ways you can meet your customers' needs by focusing on supplying the customer benefit, and see if you can meet these in a safer way. This could bring you competitive advantage. If the chemical production is essential to you, you can still try to make the process or work practices safer. Innovation and product development can be targeted towards safer solutions, or you can develop new business models that may reduce the risk to the customer.

Q: I do not have any technical processes – why do I need to do this step?

A: Even if you have no technical processes, you are still using the chemical for some reason. Going through the list of requirements will help you define the reason for using the chemical and make it easier for you to see what could be changed. For example, if you use a paint stripper, the process is paint stripping, the technical requirement is to remove all the paint, and you may have a time limit for how long this can take so that it still is commercially viable.

STEP 4: LOOK FOR ALTERNATIVES

RESULT: A clear overview of what your different options are

BENEFITS

- ✓ *Gives you information on available options and on their various properties. Innovation moves fast and safety is often a product development target. Less hazardous products or products that can be used in a way that leads to less risk are becoming more reliable and cost efficient.*
- ✓ *Knowing what your options are opens up the potential for finding more efficient, safer or otherwise better solutions. By looking at the feasibility of using less hazardous chemicals or alternative processes, you can also get good ideas for other potential changes that could benefit your business.*
- ✓ *If you include looking at what your competitors do, you could also find market potentials where change could give you new competitive advantages.*

WHEN TO LOOK FOR ALTERNATIVES

Identifying and keeping up to date with what alternatives you have should be - and probably is - done as a part of maintaining your business plans. As a minimum, you should always check for alternatives when you think of changing something.

HOW TO FIND ALTERNATIVES

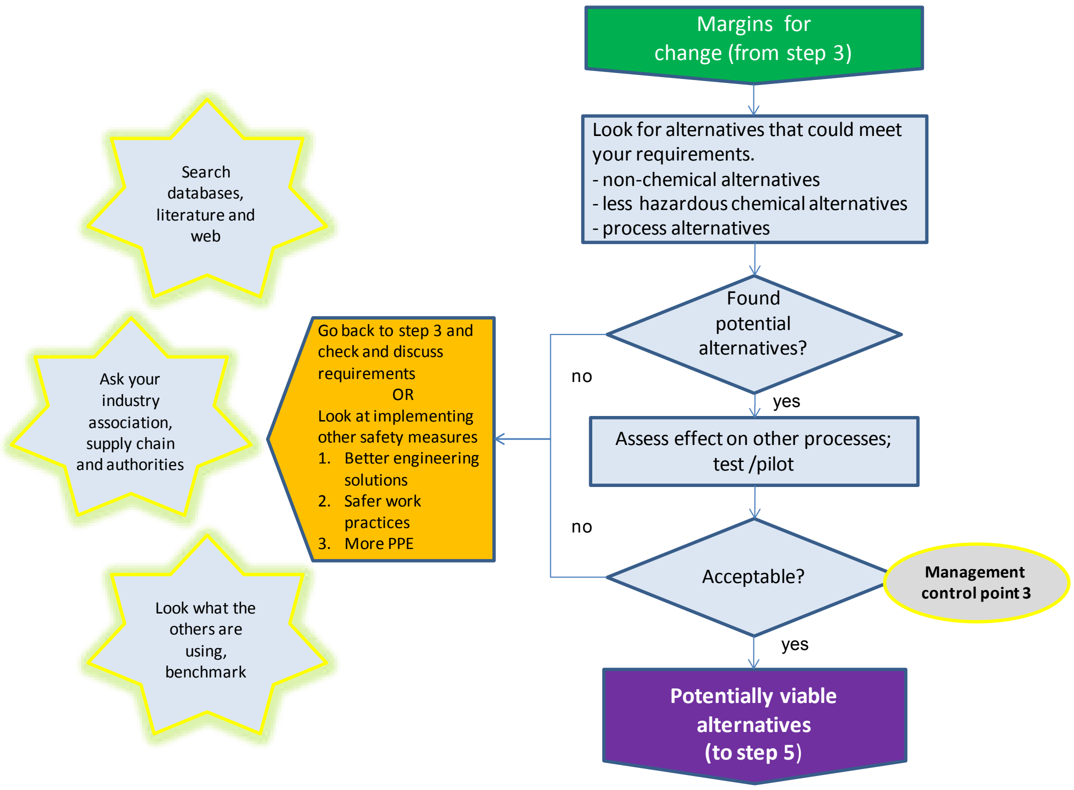


Figure III-8: Flow chart for Step 4

Before you start on this step, it is a good idea to clarify who decides and based on what alternatives can be considered viable. You can approach this through making the outline of an approval process case. You may indeed already have a standard procedure for this. If not, do it before you start the assessment. It will help you define what is important for your company and it will also help you formulate decision criteria. An added bonus is that you will assemble the data in the required format from the start, knowing what will be important.

Make a list of alternatives. Talk to your supplier and/or other suppliers to get ideas and information. Look through the literature and different databases for chemicals that are used in the same or similar way. Your authorities are also a good source of ideas on safer ways of working – it is their job to help you be as safe as possible so you should feel free to ask. Look at different types of changes to decide what your alternatives could be. Alternatives you may consider include

- ✓ replacing the chemical with a less hazardous one
- ✓ reducing the risk related to chemical physical form (e.g. moving from powder to pellets generally reduces airborne particles and therefore reduces inhalation risk)
- ✓ replacing the process or task with a safer one (e.g. from a process where 150 degrees C temperature is required to a process that takes longer but works in ambient temperature).

Check the alternatives against legal obligations, technical, quality and standard requirements and narrow down your options. Think broadly, as you may find unexpected potentials also from economic point of view.

Find the alternatives that best meet the requirements. Remember to think of the potential of a change to affect any other processes or tasks, so that you do not end up increasing other risks. Look at your process diagram or description of how the chemical use is linked to other processes or tasks from the earlier steps. Check if there are any practical implications that relate to the alternative. Include an evaluation of whether reducing risk in this part of the process could potentially increase /decrease risk in the other processes. Also include a consideration of whether you have **sufficient data available** on the alternative to make informed assessments.

Testing and piloting can be essential to understand how the alternatives would perform in your process or task. This might be as simple and quick as testing of alternative cleaning chemicals for floors or as complicated and time consuming as R&D work to design new synthetic routes. Tailor the testing to your circumstances. Involve the people who do the actual work in the testing - their feedback on practical impacts will be valuable. Think also about the possible risks of not finding out all during the test situation and document all the results. Remember to include the consideration of potential effects on other processes or tasks in the testing.

Decide which alternatives meet all essential performance requirements based on both the assessment on paper and the testing. If none of the alternatives does this, check your list of requirements to see if there are some requirements where more flexibility is possible. Then check if there are any other alternatives that you have not yet thought of. Remember also to think of changing the process or the way you work, not just about changing the chemical.

Frequently asked questions

Q: This seems very complex. Is there any easier way of doing this?

A: The task of finding alternatives does not have to be complex, but before you start you do need to check that you have identified all necessary requirements. If you do it at this stage, you eliminate all alternatives that could lead to technical issues or not be acceptable to your customers before taking the evaluation any further. For some chemicals, it may be as easy as going to the hardware store and looking at the products available to see if the alternative meets your technical performance requirements. In other cases, this may indeed require close cooperation with suppliers and/or researchers.

Q: If my supplier does not know of any alternatives, what do I do?

A: Your suppliers are a vital source of information, and many will actively work with you to find alternatives. If your supplier does not know of any alternatives, consider talking to other suppliers. Your industry association and authorities can also be a good source of information. There are also databases available on potential alternatives that you can use for ideas. Some are given in Appendix 2, Table AII-2.

Q: What kind of testing do I need to do?

A: Testing the alternative chemical can mean testing in the laboratory. Here it also means that you try it out in practice. It is a good idea to involve workers in the test, as they will give you feedback on practical issues. Note the performance of the alternative and relate this to your requirements. If you have to lubricate machinery to be functional in -30 degrees C and the alternative stops working at -20 degrees C, this will not be a viable alternative. Remember to check how vital the requirement is before you discard the alternative as unsuitable. For example, if you only sell lubrication products for machinery in the UK, you may decide that -30 degrees is not going to happen and performance at -20 is good enough. If you sell to, for example, Scandinavia or Russia, performance at lower temperatures can however be a critical requirement.

Q: What about the cost and risk of the alternatives?

A: The cost and risk of alternatives will be assessed in the next step. To save you going through this work with chemicals that may not give you the performance you require, the technical performance is evaluated first. However, you could also assess the risks and costs before the technical requirements; there is no rule that requires a particular order to be followed.

Q: Who decides what is acceptable?

A: You need to define this before you start the process. Talk with management or your HSE personnel. If you are responsible for HSE, it can mean you have to define acceptability from an HSE performance point of view, whereas technical management defines technical performance requirements. Listen also to your sales people – they will know what is acceptable to the customers.

STEP 5: CHECK THE CONSEQUENCES OF A CHANGE

RESULT: An analyzed set of alternatives that will enable informed decisions

BENEFITS

1. *Comparing risks, costs and benefits of different alternatives against each other and the original solution in a systematic and transparent manner enables informed decision making.*
2. *The comparison will give the details needed to make a "case for change" to management.*
3. *Unexpected benefits can be identified to support further development.*
4. *Comparing risks, costs and benefits of alternatives both long term and short term will help you find the best long term solutions.*
5. *This exercise can give you good ideas for other risk reduction measures and/or operational savings.*

WHEN TO CHECK

Whenever you change chemicals, the process or a task you should evaluate what the consequences are. Note down any uncertainties at the beginning, such as if less is known about the toxicology of the alternatives. Risks from chemical use form one part of the overall workplace risks. Keep in mind the need to check that increases in other types of risks do not occur as a consequence of chemical risk reduction. For example if you stop using chemicals and start using pressure cleaning, you can have a different set of risks. Make sure you do the comparative evaluation before you make a change. Note that you should also follow up the process and re-evaluate the risks and effects after a change.

HOW TO CHECK

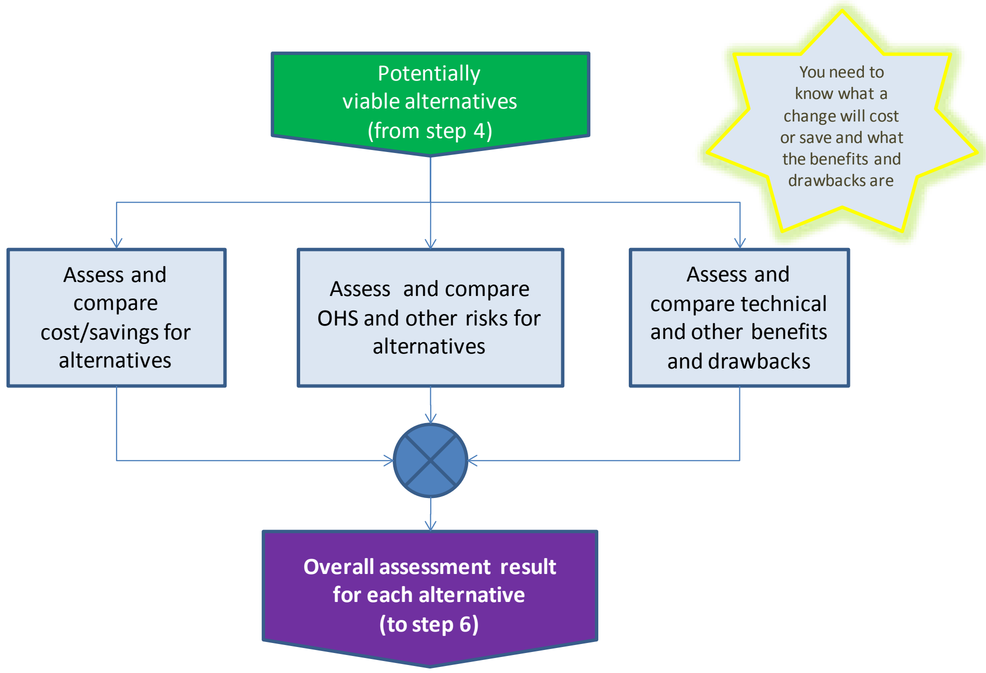


Figure III-9: Flow chart for Step 5

Calculate the costs for the old and the new method. Do the comparison for each of the identified alternatives. You need to take into account costs related to the task, buying the chemical and any control measures needed. If environmental emissions or for example waste management actions change, are there any changes of cost related to these? Take into account training costs, savings from giving up the safety measures like PPEs and any investments. A tool in table format to help you identify costs to take into account is given in Appendix 6. The use of this table has been illustrated in a case study in Appendix 5. This tool can also be used to compare alternatives through recording only approximations of details, through for example colour coding or using ++ and - - approaches. An example of using the comparison tool through colour coding is given in Appendix 5 case studies.

Information: Find out if there is sufficient information available about the alternative's hazards and technical performance so that you can evaluate risks and performance properly. Check that you know enough about the alternative's hazards. Has it been tested to an equivalent extent to the chemical you are looking to substitute? If not, would the tests potentially reveal more hazards? This may require expert assessment, or talking with suppliers or users of the alternative. Remember to take into account both acute and chronic health as well as safety and environmental hazards. See also the guidance on ensuring sufficient information is available for hazard assessment as given in Step 1-I (Hazard Assessment).

Assess the risks for the alternatives in the same way that you have assessed the risks for the current task. Remember to include at least chronic and acute health risks, safety risks and environmental risk. For example fumes and gases formed in the process could be one type of risk. Note down any uncertainties in relation to hazard levels. Other risks that you should include in the assessment are technical performance risks and supply chain risks. Follow the procedure in Step 1. Are there any differences in how you would use the alternative that could create new risks (e.g. higher temperature, more noise, different procedures etc.)? Record the risks using for example the table given in Appendix 6.

Assess other benefits and drawbacks. Go through all relevant aspects such as waste, discharges, emissions, image enhancement, technology modernization, environmental footprints, potential market benefits, consent condition changes etc. for the alternatives. Make sure you list these other than risk and cost aspects also for the current way of working. You can use the table in Appendix 6 to assemble all these aspects.

Compare the risks, cost and benefits of the alternatives with each other and with the substance or process you are using at the moment. Remember to also consider indirect, cumulative and long-term effects during the entire life-cycle.

If you notice any uncertainties, lack of data or unreliable data you might need to go back to step 4 for more information.

Frequently asked questions

Q: How do I make sure I include all relevant parameters so that no unexpected consequences appear later?

A: The more thorough you have been in describing the task and identifying how task performance may affect other operations, the easier this step will be. Try to think openly about effects. Include all aspects that you think may be relevant. Remember to think about how secure the supply of the alternative is, and you may want to include an assessment of price stability predictions as well as on the reliability and knowledge support you can get from the supplier.

Q: How should I compare the overall effect – i.e. how do I rank performance in different categories (such as cost versus health or waste versus potential liability)

A: This is notoriously difficult. You can attempt to translate all categories into monetary terms, deciding on how to do this together with your management. There are drawbacks with this, such as putting a value on intangible aspects. You can also assess the costs of unwanted results, such as costs of absences, cost of accidents, unwanted publicity and cost of liabilities. If you do decide to use this approach, make sure you are absolutely clear on how the assessment is going to be done before you start. Another way to do this is to assign weighting to the different categories, for example, you may decide risk to health and safety is three times as important as cost. You can also rank the alternatives within each category from best to worst. You would then choose the alternative where there overall ranking from all categories is best. Whichever way you decide to do the comparison, make sure you define the criteria before you start.

Q: How do I assess advantages and disadvantages of alternatives if there are a lot of uncertainties?

A: There is no clear answer to this question. You may have to make an educated guess in some cases and final decisions should be made together with the management. You may also decide that the uncertainties are such that in themselves they lead to a risk that you are not willing to take. Uncertainties that relate to the level of information available on the alternative's hazard level are particularly important. If there is not enough hazard data available, this could lead to changing a known risk for an unknown. Uncertainties are a definite drawback. Recording these for each assessment will help you decide on the overall reliability of your assessment. It will also make it easier to come back and check the assessment at a later stage if more information emerges or if you decide not to implement any changes right now.

Q: Why should I include consideration of image and indirect effects?

A: Increasingly customers are taking into account sustainability and corporate responsibility matters when deciding on purchase criteria. Image can potentially provide you with competitive edge in the market. If you sell products or services that are not so differentiated from others, the ability to show that you have reduced risks can be a selling argument. It can also help boost your company's predicted value, giving shareholders higher returns. You may proudly communicate your good achievements with chemical substitution to public and shareholders.

STEP 6: DECIDE ON CHANGE

RESULT: Decision on what to do

BENEFITS

- ✓ *Good decisions benefit your company and your workforce, whereas bad or hasty decisions that are based on too little information can increase the risk and lead to unexpected negative consequences.*
- ✓ *It is easier to make a change if you decide before the evaluation on what basis you will make the decision.*

WHEN TO DECIDE

Decisions that have far reaching potentials for influencing workers health and safety should not be rushed but neither delayed. Make sure you first set your decision making criteria clearly and follow these. Otherwise you may be biased without intention. Allow enough time between decision and implementation to ensure the approach can be tested and necessary training etc. done well in advance. The best decision may be to not make a change – the system may already be optimised and any identified risk reduction requirements may need to be addressed through focusing for example on risk control through procedures and training.

HOW TO DECIDE

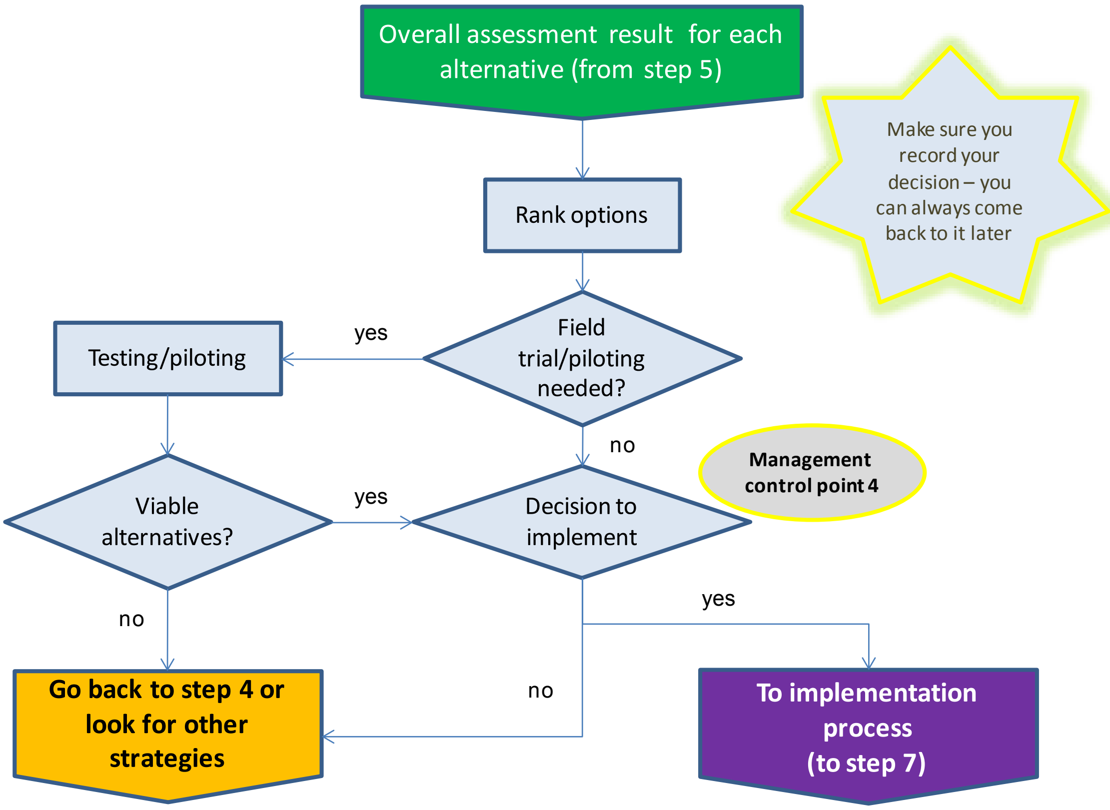


Figure III-10: Flow chart for Step 6

Rank your alternatives based on the results from the previous steps. Use criteria from the company policy or make a decision in regards to for example how much costs can increase if health and safety improves only little. Include your workers in the discussion, present the alternatives to them and openly discuss any drawbacks and benefits of the options. Make sure you listen to their views on whether the implementation is feasible in practice or not.

You may have to conduct **a field testing programme** at this stage also to make sure the preferred alternative meets performance expectations. Make sure you look at any other potential risks that may be identified during the testing.

Deciding whether substitution should be implemented or not. Take into account all the benefits and drawbacks. Even if the results look good on paper and test results are positive, you may decide you cannot implement the change right away. If for example the implementation requires an investment you may not be able to allocate the money to this right now. You can still make a decision to do the change but to postpone the implementation. You could also decide that the benefits are negligible in relation to the effort required and therefore you will not proceed to implement the change. Depending on the implications of the decision, i.e. on cost, processes or health and safety levels, the decision may be taken at different levels in the company. Make sure you have established who can make the decision and based on what.

How to take your case to management: If you present a case for substitution or added risk management measures to management for a decision, make sure you know what the decision criteria for implementation are. Discuss these beforehand. Make sure you know your facts and can give an overview of consequences of both action and non-action in both risk reduction and monetary terms. Remember to include long term effects, investment and training needs as well as an overview of all processes, tasks or products the change will impact on.

Once **a decision to change** has been made, this should be:

- ✓ Communicated to all relevant parties, particularly to those who will work with the changed process, task or chemical.
- ✓ Documented, e.g. including the decision making process and the justifications behind it.

If you cannot find a viable alternative and your risk is still too high, go back to stage 4 and search for new alternatives. You can also look at other ways of increasing safety, such as replacing the technology with a safer one (e.g. automation and going from open mixing tanks to closed mixing systems or finding safer work practices or make current work practices safer (e.g. going from moving the chemical by hand to rolling it on a bunded table from place to place or wetting a chemical before use to avoid dust related risks).

Frequently asked questions

Q: How do I get support/convince the management that a change is needed?

A: You need to present the case in an objective manner and take into account all relevant impacts. The tables provided in Appendix 6 for comparing the different aspects can help you summarise impacts and consequences in a way that is useful when presenting the case to management. You may want to summarise the data from the tables into short bullet points or use graphs. Make sure you include aspects such as investment needs, costs for use, change in health and safety levels, what the change would require in terms of internal resources (e.g. training) and how the change would benefit your business as a whole. Include assessment of productivity, workers well-being, and potential savings in giving up the unnecessary old and heavy safety measures as well as customer and supply chain aspects. At the same time, you need to make sure you present an overview, not a mass of details. Focus on what is important to your organisation. For example, if customer requirements are the driving force for the change, you can present the case for meeting these market needs.

Q: How do I overcome resistance to chance in the organisation?

A: Despite planning and implementing change carefully, it is very probable, that you will still meet resistance, as it is a common reaction in many people to any changes. One way to try to overcome this resistance to change is to explain to all why the change is made, what the benefits will be and when the change will be implemented. Listen to and take into account the viewpoints relating to practical aspects. Make sure you pay attention to what the people performing the task think. It is important to ensure their opinions are included in the decision. Make sure management supports the change and communicate the importance of continuous improvement of the working environment.

STEP 7: IMPLEMENT, MONITOR AND EVALUATE

Outcome: Implementation of change and continuous improvement

BENEFITS

- ✓ *Careful planning of implementation will reduce any unforeseen impacts.*
- ✓ *The change can be implemented at the best possible time.*
- ✓ *The implementation itself will then lead to reduced risk from chemicals used in the workplace, protection of workers health and safety and/or potentially better environmental performance and/or safer and healthier products.*
- ✓ *Monitoring and evaluation enables you to identify success and failures of the change.*
- ✓ *Audits help to recognise long-term impacts/problems and ensure continuous improvement.*

WHEN TO IMPLEMENT

Once you have decided to make a change, start planning the implementation. If it is a complex process you are changing, it is likely that there will be a period of time before the process is back to full efficiency and quality. Decide when to implement and avoid making changes in particularly busy times, i.e. avoid high season. Changes should preferably be done during less busy periods, although you should ensure there are enough workers present to provide practical feedback. Try to decide when to start the implementation right at the beginning of the planning. This will give you a clear schedule and a target to meet.

HOW TO IMPLEMENT

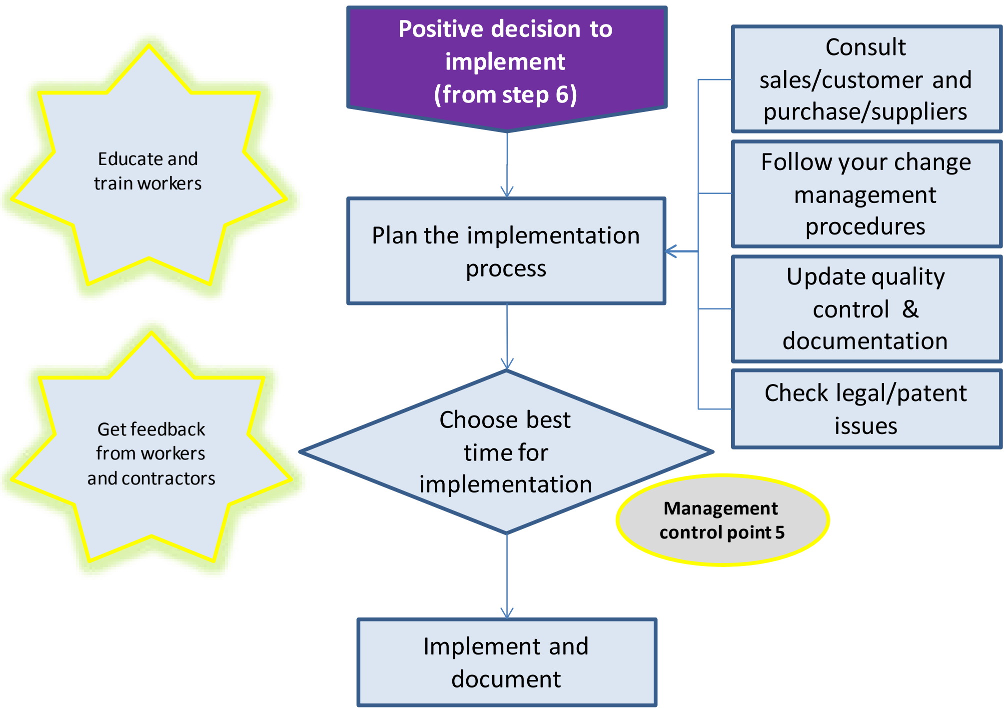


Figure III-11: Flow chart for Step 7

Plan the implementation process step-by-step. Risks can be minimized by careful planning. Decide what to do first, who needs to be involved and what training you need to provide. Check delivery time restrictions and make sure you include a thorough consideration of any risks that could occur during the implementation phase itself. Talk to sales and marketing to see if the change will affect them, for example through a new or modified product or potential time periods when delivery of products or services may have to be reduced. Check that you will not run out of stock for the old or new process/task during the change period. Make sure you check your quality and other management systems and update these as necessary before you make the change.

Document what you are going to do and make this available to staff. Cross check that you have taken all issues into account.

Provide training and actively communicate with workers. It is important that information about the changes and training are given both before and during the implementation phase.

- ✓ Regular communication with personnel helps you identify practical issues with the implementation phase and contributes to problem-solving.
- ✓ You might face resistance towards change. To minimise resistance, make sure you present the benefits of the change and include workers and management in open discussion.

Decide on the best time schedule for implementation in order to cause minimum disruption of business activities.

- ✓ Discuss the timing with management, sales and purchase personnel as well as line management.
- ✓ Communicate in the supply chain: Make sure that the needed new chemicals are available, and that customers are informed about possible delays and changes in products or services.

The actual implementation method will depend on you processes. You may run the new process in parallel to the old one, make phased changes, or change over directly. Make sure that the chemical that is substituted is removed from storages etc. Make sure the implementation of any documentation changes etc. is done concurrently.

WHY MONITOR AND EVALUATE

The aim of the monitoring and evaluation process is to facilitate continuous improvement. An important part of this is to react to any incidents, near misses or unforeseen changes and try to find the reasons for this and then define how such occurrences can be avoided in the future. Another equally important part is to find ways of performing even better through analysing performance.

HOW TO MONITOR AND EVALUATE

Monitoring and evaluating the consequences of the change basically means that you compare the actual impacts on performance and efficiency of the tasks or processes as well as on sales, services and, importantly, on impacts on health, safety and environment. You can do this through looking at the data you used to make the decision to change and recording any differences from predictions. Monitoring also means periodic assessments of risk, discussions with workers on how the practical side of the change has impacted on them and evaluations of any changes in productivity or sales. If you do not have a process already for monitoring and evaluating, you can use the Plan-Do-Check-Act model presented here as a template for designing one. Monitoring and evaluation is also often part of quality systems, OHSAS management systems or other internal management approaches. An overview of the steps to take is given next. Make sure the process you follow meet your internal requirements before you start.

- ✓ Check whether the new product, task or process meets your expectations.
  - Are there any (unexpected) problems?
  - Is it possible to reduce the risks even further?
  - If desired results are not obtained in practice or the risk is no less, you need to go back to the drawing board.
- ✓ Keep up with new requirements and alternatives, just because you made one change, it does not mean you could not do another one.
- ✓ Conduct periodic audits of both individual tasks and overall performance to identify areas for further improvement.
- ✓ Include feedback from customers and suppliers on effects in the entire supply chain.

Frequently asked questions

Q: What if there is never a good time to start implementation? (As it is, the process is running at a full 100% load, 24 hours a day to satisfy customer needs)

A: There may not be a clearly best time to disrupt the process. If you have to perform maintenance that requires process run-down; this can be your best time to implement changes. Consider running parallel processes if there really is no natural time window for change. If the task is not process related, the timing will be more dependent on ensuring sufficient training is provided. Calculate the costs of the additional shut-down as a part of your substitution costs.

Q: How do I know what type of training and at what level should be offered?

A: There is no straight forward answer to this. The training requirement will depend on the complexity of the task, the level of change and also on the current training standard of workers. The perhaps unhelpful answer is that the training is sufficient once workers show they are fully aware of new duties and risks. But many short repetitive periods are usually more effective than long ones. Use the normal internal communication methods as support, like internal newsletters and intranets. Use pictures from the actual work to help illustrate the change. Relate the training to what has to be done in practice rather than theoretical aspects.

Q: How do I convince workers that the new way is a better way and not just decided on a whim?

A: Talk openly about why you are making the change. Explain the process that has been behind the decision and what the benefits from the change are. Benefits such as reduced occupational health risk is something workers have nothing against, when thoroughly explained. Workers' early participation into the process of substitution and risk reduction in general is beneficial.

Substitution is a risk management measure

Substitution can be used to reduce risk at any workplace where chemicals or hazardous materials are handled, stored, or used. Substitution can be done to improve **occupational health** and reduce both acute and long term exposure risks, sometimes to improve **safety** by removing or reducing for example fire or explosion risks, and sometimes to reduce risk to the **environment**.

Whatever the reason, you need to make sure the change does not lead to unexpected surprises, such as increasing safety risk whilst reducing acute occupational health risk. Both direct and indirect consequences from substitution should therefore be carefully assessed.

The preferred target is **eliminating** chemical risk. Eliminating chemicals altogether can be difficult, but you may find another way of working, such as using joinery instead of glue. Remember to make sure you do not increase another type of risk instead. **Substitution** covers:

- **Changing the chemical used** to a less hazardous one. If you use it in exactly the same way, this will reduce the risk. If you change the process at the same time, make sure no new risks are introduced.
- **Changing the physical form of a chemical** to another, that is less likely to lead to exposure. One example is using pellets or slurries instead of powder to minimise dust and reduce inhalation risks.
- **Changing a process or task** to a safer one like using lower temperature process.

If you cannot reduce the risk at source, you can still control it through various other risk management options. These include:

- **Engineering controls** such as alarms, safety valves, double skinned tanks and others. Remember that these are often very good options for controlling the risk, but they will not remove the cause of the risk.
- **Administrative controls** such as workplace procedures and training are very important, but while reducing it, they do not completely protect from human error.
- **Personal Protective Equipment (PPE)** will only provide a barrier against exposure to a particular hazard and does not reduce the potential for harm of the hazard itself.

PPEs as safety measures should be only the last possibility. If you choose to control the risk purely through PPE, for example by requiring safety goggles to be worn, you cannot be sure that the workers will always were the PPE and in a correct way. This is the basic reason for looking for ways to remove the cause of risk rather than just provide barriers that reduce the chance of exposure. PPEs should also always be only in personal use and they should be clean, suitable for every chemical and changeable parts, such as filters, in valid condition. It also takes time to wear, clean and maintain the protective equipments. The overall costs of the PPEs might be significant compared to other safety measures.

Appendix 1 Hazards signs and CLP pictograms

Dangerous substances directive: Risk phrases

R1	Explosive when dry
R2	Risk of explosion by shock, friction, fire or other sources of ignition
R3	Extreme risk of explosion by shock, friction, fire or other sources of ignition
R4	Forms very sensitive explosive metallic compounds
R5	Heating may cause an explosion
R6	Explosive with or without contact with air
R7	May cause fire
R8	Contact with combustible material may cause fire
R9	Explosive when mixed with combustible material
R10	Flammable
R11	Highly flammable
R12	Extremely flammable
R14	Reacts violently with water
R15	Contact with water liberates extremely flammable gases
R14/15	Reacts violently with water, liberating extremely flammable gases
R16	Explosive when mixed with oxidizing substances
R17	Spontaneously flammable in air
R18	In use, may form flammable/ explosive vapour-air mixture
R19	May form explosive peroxides
R20	Harmful by inhalation
R21	Harmful in contact with skin
R22	Harmful if swallowed
R20/21	Harmful by inhalation and in contact with skin
R20/21/22	Harmful by inhalation, in contact with skin and if swallowed
R20/22	Harmful by inhalation and if swallowed
R21/22	Harmful in contact with skin and if swallowed
R23	Toxic by inhalation
R24	Toxic in contact with skin
R25	Toxic if swallowed
R23/24	Toxic by inhalation and in contact with skin
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed
R23/25	Toxic by inhalation and if swallowed
R24/25	Toxic in contact with skin and if swallowed

R26	Very toxic by inhalation
R27	Very toxic in contact with skin
R28	Very toxic if swallowed
R26/27	Very toxic by inhalation and in contact with skin
R26/27/28	Very toxic by inhalation, in contact with skin and if swallowed
R26/28	Very toxic by inhalation and if swallowed
R27/28	Very toxic in contact with skin and if swallowed
R29	Contact with water liberates toxic gas
R15/29	Contact with water liberates toxic, extremely flammable gases
R30	Can become highly flammable in use
R31	Contact with acids liberates toxic gas
R32	Contact with acids liberates very toxic gas
R33	Danger of cumulative effects
R34	Causes burns
R35	Causes severe burns
R36	Irritating to eyes
R37	Irritating to respiratory system
R38	Irritating to skin
R36/37	Irritating to eyes and respiratory system
R36/37/38	Irritating to eyes, skin and respiratory system
R36/38	Irritating to eyes and skin
R37/38	Irritating to respiratory system and skin
R39	Danger of very serious irreversible effects
R39/23	Toxic: danger of very serious irreversible effects through inhalation
R39/23/24	Toxic: danger of very serious irreversible effects through inhalation and in contact with skin
R39/23/24/25	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed
R39/23/25	Toxic: danger of very serious irreversible effects through inhalation and if swallowed
R39/24	Toxic: danger of very serious irreversible effects in contact with skin
R39/24/25	Toxic: danger of very serious irreversible effects in contact with skin and if swallowed
R39/25	Toxic: danger of very serious irreversible effects if swallowed
R39/26	Very toxic: danger of very serious irreversible effects through inhalation
R39/26/27	Very toxic: danger of very serious irreversible effects through inhalation and in contact with skin
R39/26/27/28	Very toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed

R39/26/28	Very toxic: danger of very serious irreversible effects through inhalation and if swallowed
R39/27	Very toxic: danger of very serious irreversible effects in contact with skin
R39/27/28	Very toxic: danger of very serious irreversible effects in contact with skin and if swallowed
R39/28	Very toxic: danger of very serious irreversible effects if swallowed
R40	Limited evidence of a carcinogenic effect
R41	Risk of serious damage to eyes
R42	May cause sensitization by inhalation
R43	May cause sensitization by skin contact
R42/43	May cause sensitization by inhalation and skin contact
R44	Risk of explosion if heated under confinement
R45	May cause cancer
R46	May cause heritable genetic damage
R48	Danger of serious damage to health by prolonged exposure
R48/20	Harmful: danger of serious damage to health by prolonged exposure through inhalation
R48/20/21	Harmful: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin
R48/20/21/22	Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed
R48/20/22	Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed
R48/21	Harmful: danger of serious damage to health by prolonged exposure in contact with skin
R48/21/22	Harmful: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed
R48/22	Harmful: danger of serious damage to health by prolonged exposure if swallowed
R48/23	Toxic: danger of serious damage to health by prolonged exposure through inhalation
R48/23/24	Toxic: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin
R48/23/24/25	Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed
R48/23/25	Toxic: danger of serious damage to health by prolonged exposure through inhalation and if swallowed
R48/24	Toxic: danger of serious damage to health by prolonged exposure in contact with skin
R48/24/25	Toxic: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed
R48/25	Toxic: danger of serious damage to health by prolonged exposure if swallowed
R49	May cause cancer by inhalation

R50	Very toxic to aquatic organisms
R51	Toxic to aquatic organisms
R52	Harmful to aquatic organisms
R53	May cause long-term adverse effects in the aquatic environment
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R52/53	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R54	Toxic to flora
R55	Toxic to fauna
R56	Toxic to soil organisms
R57	Toxic to bees
R58	May cause long-term adverse effects in the environment
R59	Dangerous for the ozone layer
R60	May impair fertility
R61	May cause harm to the unborn child
R62	Possible risk of impaired fertility
R63	Possible risk of harm to the unborn child
R64	May cause harm to breastfed babies
R65	May cause lung damage if swallowed
R66	Repeated exposure may cause skin dryness or cracking
R67	Vapours may cause drowsiness and dizziness
R68	Possible risks of irreversible effects
R68/20	Harmful: possible risk of irreversible effects through inhalation
R68/20/21	Harmful: possible risk of irreversible effects through inhalation and in contact with skin
R68/20/21/22	Harmful: possible risk of irreversible effects through inhalation, in contact with skin and if swallowed
R68/20/22	Harmful: possible risk of irreversible effects through inhalation and if swallowed
R68/21	Harmful: possible risk of irreversible effects in contact with skin
R68/21/22	Harmful: possible risk of irreversible effects in contact with skin and if swallowed
R68/22	Harmful: possible risk of irreversible effects if swallowed

Dangerous substances directive: Hazard Symbols

 E	**Explosive**	 T	**Toxic**
 C	**Corrosive**	 T+	**Very toxic**
 F	**Highly flammable**	 Xi	**Irritant**
 F+	**Extremely flammable**	 Xn	**Harmful**
 N	**Dangerous for the environment**		
 O	**Oxidizing**		

CLP: Hazard statements

H200	Unstable explosive
H201	Explosive; mass explosive hazard
H202	Explosive; severe projection hazard
H203	Explosive; fire, blast or projection hazard
H204	Fire or projection hazard
H205	May mass explode in fire
H220	Extremely flammable gas
H221	Flammable gas
H222	Extremely flammable aerosol
H223	Flammable aerosol
H224	Extremely flammable liquid and vapour
H225	Highly flammable liquid and vapour
H226	Flammable liquid and vapour
H227	Combustible liquid
H228	Flammable solid
H240	Heating may cause an explosion
H241	Heating may cause a fire or explosion
H242	Heating may cause a fire
H250	Catches fire spontaneously if exposed to air
H251	Self-heating; may catch fire
H252	Self-heating; in large quantities; may catch fire
H260	In contact with water releases flammable gases which may ignite spontaneously
H261	In contact with water releases flammable gas
H270	May cause or intensify fire; oxidizer
H271	May cause fire or explosion; strong oxidizer
H272	May intensify fire; oxidizer
H280	Contains gas under pressure; may explode if heated
H281	Contains refrigerated gas; may cause cryogenic burns or injury
H290	May be corrosive to metals
H300	Fatal if swallowed
H301	Toxic if swallowed
H302	Harmful if swallowed
H304	May be fatal if swallowed and enters airways
H310	Fatal in contact with skin
H311	Toxic in contact with skin

H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H319	Causes serious eye irritation
H330	Fatal if inhaled
H331	Toxic if inhaled
H332	Harmful if inhaled
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
H340	May cause genetic defects (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)
H341	Suspected of causing genetic defects (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)
H350	May cause cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)
H350i	May cause cancer by inhalation
H351	Suspected of causing cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)
H360	May damage fertility or the unborn child (state specific effect if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)
H360D	May damage the unborn child
H360Df	May damage the unborn child. Suspected of damaging fertility
H360F	May damage fertility
H360FD	May damage fertility. May damage the unborn child
H360Fd	May damage fertility. Suspected of damaging the unborn child
H361	Suspected of damaging fertility or the unborn child (state specific effect if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)
H361d	Suspected of damaging the unborn child
H361f	Suspected of damaging fertility
H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child
H362	May cause harm to breast-fed children
H370	Causes damage to organs (or state all organs affected, if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)

H371	May cause damage to organs (or state all organs affected, if known)(state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)
H372	Causes damage to organs (state all organs affected, if known) through prolonged or repeated exposure (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)
H373	May cause damage to organs (state all organs affected, if known) through prolonged or repeated exposure (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H411	Toxic to aquatic life with long lasting effects
H412	Harmful to aquatic life with long lasting effects
H413	May cause long lasting harmful effects to aquatic life
EUH001	Explosive when dry
EUH006	Explosive with or without contact with air
EUH014	Reacts violently with water
EUH018	In use, may form flammable/explosive vapour-air mixture
EUH019	May form explosive peroxides
EUH029	Contact with water liberates toxic gas
EUH031	Contact with acids liberates toxic gas
EUH032	Contact with acids liberates very toxic gas
EUH044	Risk of explosion if heated under confinement
EUH059	Hazardous to the Ozone Layer
EUH066	Repeated exposure may cause skin dryness or cracking
EUH070	Toxic by eye contact
EUH071	Corrosive to respiratory tract
EUH201	Contains lead. Should not be used on surfaces liable to be chewed or sucked by children
EUH201A	Warning! Contains lead (In the case of packages the contents of which are less than 125 ml)
EUH202	Cyanoacrylate. Danger. Bonds skin and eyes in seconds. Keep out of the reach of children
EUH203	Contains chromium (VI). May produce an allergic reaction
EUH204	Contains isocyanates. May produce an allergic reaction
EUH205	Contains epoxy constituents. May produce an allergic reaction
EUH206	Warning! Do not use together with other products. May release dangerous gases (chlorine)
EUH207	Warning! Contains cadmium. Dangerous fumes are formed during use. See information supplied by the manufacturer. Comply with the safety instructions
EUH208	Contains <name of sensitising substance>. May produce an allergic reaction

EUH209 Can become highly flammable in use

EUH209A Can become flammable in use

EUH210 Safety data sheet available on request

EUH401 To avoid risks to human health and the environment, comply with the instructions for use

CLP: Hazard Pictograms

	Met. Corr. 1 Skin Corr. 1A Skin Corr. 1B Skin Corr. 1C Eye Dam. 1
	Aquatic Acute 1 Aquatic Chronic 1 Aquatic Chronic 2
	Press. Gas (Compressed gas) Press. Gas (Liquefied gas) Press. Gas (Refrigerated liquefied gas) Press. Gas (Dissolved gas)
	Acute Tox. 4 Skin Irrit. 2 Eye Irrit. Skin Sens. 1 STOT SE 3
	Unst. Expl Expl. 1.1 Expl. 1.2 Expl. 1.3 Expl. 1.4 Self-react. A Self-react. B Org. Perox. A Org. Perox. B

	Flam. Gas 1 Flam. Aerosol 1 Flam. Aerosol 2 Flam. Liq. 1 Flam. Liq. 2 Flam. Liq. 3 Flam. Sol. 1 Flam. Sol. 2	Self-react. B Self-react. CD Self-react. EF Pyr. Liq. 1 Pyr. Sol. 1 Self-heat. 1 Self-heat. 2	Water-react. 1 Water-react. 2 Water-react. 3 Org. Perox. B Org. Perox. CD Org. Perox. EF
	Ox. Gas 1 Ox. Liq. 1 Ox. Liq. 2 Ox. Liq. 3 Ox. Sol. 1 Ox. Sol. 2 Ox. Sol. 3		
	Resp. Sens. 1 Muta. 1A Muta. 1B Muta. 2 Carc. 1A	Carc. 1B Carc. 2 Repr. 1A Repr. 1B Repr. 2 STOT SE 1	STOT SE 2 STOT RE 1 STOT RE 2 Asp. Tox. 1
	Acute Tox. 1 Acute Tox. 2 Acute Tox. 3		

Appendix 2 Tools and further reading

The following tables contain an overview of tools, databases and further reading that can prove useful when working through the substitution process. A direct link to the source is provided. As with all web based links, these may be changed by the service provider at some time in the future.

Table A2-1: *Tools, databases and further reading for the PLAN steps (Step A in the 4-step process and steps 1, 2 and 3 in the 7-step process)*

When to use it	What can it be used for	Languages (country)	Service provider and where to find it
Step A/ Step 1	Acute Exposure Guideline Levels (AEGL) Program. Use this to check acute exposure guideline level values for chemicals that could potentially cause dangerous inhalation exposures to persons	English (USA)	U.S. Environmental Protection Agency www.epa.gov/oppt/aegl/index.htm
Step A/ Step 1	The Advanced REACH Tool (ART) incorporates a mechanistic model of inhalation exposure and a statistical facility to update the estimates with the user's own data	English (Europe)	ART consortium http://www.advancedreachtool.com/
Step A, B/ Step 1, 4	BASTA is a database of the Swedish construction industry to accelerate the phasing out of hazardous construction products	English Swedish (Sweden)	BASTAonline, provided through the IVL Swedish environmental Institute and Swedish construction sector federation www.bastaonline.se/
Step A, C/ Step 1, 5	The Column model is a tool for identifying the risks of different chemicals	English German (Germany)	BAuA - German Federal Institute for Occupational Safety and Health http://www.dguv.de/ifa/en/pra/ghs_spaltenmodell/index.jsp
Step A/ Step 1	COSHH Essentials a web tool for chemical risk management	English (UK)	Health and Safety Executive UK together with TUC and CBI www.coshh-essentials.org.uk
Step A/ Step 1	Database of Environmental Information for products and services	English (USA)	U.S. Environmental Protection Agency http://yosemite1.epa.gov/oppt/eppstand2.nsf

When to use it	What can it be used for	Languages (country)	Service provider and where to find it
Step A/ Step 1	ECETOC Targeted Risk Assessment Tool	English	ECETOC[16] www.ecetoc.org/tra
Step A/ Step 1	EMKG (Einfaches Maßnahmenkonzept Gefahrstoffe) supports the performance of hazard assessment	German English (Germany)	BAuA - German Federal Institute for Occupational Safety and Health www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/EMKG/EMKG.html
Step A/ Step 1	EMKG-EXPO-TOOL is a tool for inhalation exposure estimate at the workplace	English (Germany)	BAuA - German Federal Institute for Occupational Safety and Health http://www.reach-clp-helpdesk.de/en/Homepage.html
Step A/ Step 1	ESIS is a chemical information database	English (Europe)	JRC - Joint research centre http://esis.jrc.ec.europa.eu/
Step A/ Step 2	ETUC list of substances of Very High Concern (SVHC), which from a union perspective should have priority for inclusion in the candidate list and potentially in the authorisation list	English (Europe)	European trade union confederation, ETUC www.etuc.org/IMG/pdf/TUListREACH.pdf
Step A, B, C, D/ Step 1, 2, 3, 4, 5, 6	German technical rules for hazardous substances (TRGS) – overall approach on risk assessment and substitution	English German (Germany)	BAuA - German Federal Institute for Occupational Safety and Health www.baua.de/cln_135/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/TRGS.html

[16] ECETOC is a scientific, non-profit making, non-commercial trade association with a mission to act as an independent, credible, peer-reviewed technical resource to all concerned with the identification of research needs and provision of scientific rationale for the assessment of health effects and environmental impact

When to use it	What can it be used for	Languages (country)	Service provider and where to find it
Step A/ Step 1	GESTIS-database on hazardous substances	English (Germany)	IFA - Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (Institute for Occupational Safety and Health of the German Social Accident Insurance) www.dguv.de/ifa/en/gestis/stoffdb/index.jsp#
Step A/ Step 1	GISBAU contains information about hazardous chemicals and their safe use in construction industry	German English (Germany)	Berufsgenossenschaft der Bauwirtschaft (Industrial Accident Injuries Insurance and Labour Accident Prevention Corporation under Public Law for the Construction Industry) www.gisbau.de
Step A/ Step 2	Guidance on Chemical Risk Assessment contains detailed reviews of deciding on risk levels	English (International)	ICCA - International Council of Chemical Associations http://www.icca-chem.org/ICCADocs/ICCA---Global-Product-Strategy.pdf
Step A, B/ Step 1, 4	IMDS (International Material Data System) is the automotive industry material data system which archives all materials used for car manufacture	English (International)	Hewlett-Packard Development Company www.mdsystem.com/index.jsp
Step A/ Step 1	INCHEM - Chemical Safety Information from Intergovernmental Organizations	English (International)	CCOHS - Canadian Centre for Occupational Health and Safety www.inchem.org

When to use it	What can it be used for	Languages (country)	Service provider and where to find it
Step A/ Step 1	Kemi-Arvi is a program for chemical risk assessment that helps in assessing workers exposure hazard and compiling chemical lists	Finnish (Finland)	Tksoft Oy, VTT Technical Research Centre of Finland, Tampere University of Technology http://kemi-arvi.tksoft.com/
Step A/ Step 2	Kemiguiden provides guidance in which demands and obligations to manage chemicals and chemical risk is applicable to a workplace. It will also give hints on what will need to be done and how to work	Swedish (Sweden)	Prevent www.kemiguiden.se/
Step A/ Step 1	MAL Code is a two-part numerical code system that describes product's effects on health by representing the minimum safety precautions needed in certain work. In Denmark MAL codes are mandatory on packaging for certain products (e.g paints and coatings).	Danish English (Denmark)	The Danish Working Environment Authority www.at.dk
Step A, B/ Step 1, 4	NEPSI Good Practice Guide (Chapter 4) provides a simple risk assessment procedure to assess the risk related to workers' exposure to respirable crystalline silica dust and related safer work practices	23 languages (Europe)	European Network for Silica www.nepsi.eu
Step A/ Step 1	OEKOpro is a chemical database with substance specific information in technological processes and usages	German English (Germany)	Institute for Environmental Research (INFU) University of Dortmund www.oekopro.de/

Note that the results that the tools give are solely the responsibility of the providers of the tools. Some of the tools have originally not been developed for substitution purposes, but may still be very helpful also in this area. YOU SHOULD ALWAYS EVALUATE ANY ALTERATIVE PROPERLY BEFORE CHANGE

When to use it	What can it be used for	Languages (country)	Service provider and where to find it
Step A/ Step 1	BS OHSAS 18004: 2008 - Guide to achieving effective occupational health and safety performance	English (UK)	BSI Group http://shop.bsigroup.com/en/
Step A/ Step 1	OSHA has a good database with several tools to help you carry out a good risk assessment	English (Europe)	European Agency for Safety and Health at Work http://osha.europa.eu/en/practical-solutions/risk-assessment-tools
Step A/ Step 1	PRIO is a web-based tool that can be used in setting chemical risk reduction priorities	English (Sweden)	Kemi - Swedish Chemicals Agency http://www.kemi.se/en/Search/?q=prio+database
Step A/ Step 1	REACH Guidance on information requirements and chemical safety assessment (R 14 Occupational exposure estimation)	English (Europe)	ECHA - European Chemicals Agency guidan-ce.echa.europa.eu/docs/guidance_docu-ment/information_requirements_en.htm#r14
Step A/ Step 1	Riskofderm is a toolkit for risk assessment and risk management of dermal exposure	English	Eurofins, and others http://www.eurofins.com/product-testing-services/services/research-development/projects-on-skin-exposure-and-protection.riskofderm-skin-exposure-and-risk-assessment.aspx
Step A/ Step 1	RISCTOX is a database on hazard-ous properties of 100.000 sub-stances	Spanish (Spain)	ISTAS www.istas.net/risctox/
Step A/ Step 2	SIN-list contains chemicals identi-fied as Substances of Very High Concern based on the criteria established by the EU chemical regulation, REACH	English (Interna-tional)	ChemSec - The International Chemi-cal Secretariat www.chemsec.org/list

When to use it	What can it be used for	Languages (country)	Service provider and where to find it
Step A/ Step 1	Stoffenmanager is a validated web-based occupational risk and exposure assessment IT-tool	Dutch English (Nether-lands)	Arbo Unie, TNO, Beco www.stoffenmanager.nl
Step A/ Step 1	TOXNET - Toxicology Data Network provides chemical information	English (USA)	U.S. National Library of Medicine www.toxnet.nlm.nih.gov
Step A/ Step 1	ToxSeek meta-search engine for environmental health and toxicology (covers e.g. Toxline and HSDB)	English (USA)	U.S. National Library of Medicine http://sis.nlm.nih.gov/enviro.html

Table A2-2: *Tools, databases and further reading for the DO step (Step B in the 4-step process and steps 4 in the 7-step process)*

Type of tool	What can it be used for	Languages (country)	Provider and where to find it
Step B/ Step 4	ANSES – an internet site, which aims to inform about the actions taken, courses and advanced research in the field of substitution. By offering several levels of information, it should allow different actors to help them find alternatives to the use of CMR	French (France)	ANSES - French Agency for Food, Environment and Occupational Health Safety www.afsset.fr/index.php?pageid=1173&parentid=424
Step B/ Step 4	ALTERNATIVAS is a database on alternatives for substitution prepared by ISTAS	Spanish (Spain)	ISTAS www.istas.net/risctox/index.asp?idpagina=576
Step A, B/ Step 1, 4	BASTA is a database of the Swedish construction industry to accelerate the phasing out of hazardous construction products	English Swedish (Sweden)	BASTAonline AB www.bastaonline.se/
Step B/ Step 4	Catsub is a database that contains case examples of substitution of hazardous chemicals in different industries	Danish German English French (Denmark)	JobLiv Danmark As, bst Sjaelland www.catsub.dk
Step B/ Step 4	CleanerSolutions gives alternatives to hazardous solvents used in surface cleaning	English (USA)	TURI - Toxics Use Reduction Institute http://www.turi.org/
Step B, C/ Step 4, 5	CLEANTOOL is a tool with accompanying database for parts cleaning, metal surface cleaning, component cleaning and degreasing	German English French Spanish (Europe)	INRS, ISTAS, Kooperationsstelle Hamburg http://www.cleantool.org/?lang=en

Step B/ Step 4	CMR substitution is a website that contains methodologies and datasheets for chemicals classed as carcinogens, mutagens or reprotoxins. You can find alternatives for CMR chemicals as well as substitution success stories	French (France)	ANSES - French Agency for Food, Environment and Occupational Health Safety www.substitution-cmr.fr
Step B/ Step 4	Design for the Environment, an EPA partnership program, helps industries choose safer chemicals for applications such as fire safety in circuit boards and furniture	English (USA)	U.S. Environmental Protection Agency http://www.epa.gov/dfe/
Step B/ Step 4	Ecology Center and Clean Production Action report on the use of sustainable plastics in the auto sector	English (USA)	Ecology center http://www.ecocenter.org/publications/
Step B/ Step 4	ESIG – European Solvents Industry Group's comprehensive safety material on solvents in up to 17 European languages to create awareness amongst downstream users and to promote health and safety at work	17 languages (International)	ESIG – European Solvents Industry Group's www.esig.org
Step A, B, C, D/ Step 1, 2, 3, 4, 5, 6	German technical rules for hazardous substances (TRGS) – overall approach on risk assessment and substitution	English German (Germany)	BAuA - German Federal Institute for Occupational Safety and Health www.baua.de/cln_135/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/TRGS.html
Step B/ Step 4	"Green" alternatives Wizard is a databank that gives general information about possible substitutes for certain substances e.g. laboratory solvents	English (USA)	MIT - Massachusetts Institute of Technology http://ehs.mit.edu/greenchem/
Step B/ Step 4	Forum Standing Committee Working Group 'Substitution and Alternatives' Case studies, Examples and Tools	English Spanish (International)	IFCS - Intergovernmental Forum on Chemical Safety www.who.int/ifcs/documents/standingcommittee/substitution/en/index.html

Step A, B/ Step 1 and 4	IMDS (International Material Data System) is the automotive industry material data system which archives all materials used for car manufacture	English (International)	Automobile industry www.mdsystem.com/index.jsp
Step A, B/ Step 1, 4	NEPSI Good Practice Guide (Chapter 4) provides a simple risk assessment procedure to assess the risk related to workers' exposure to respirable crystalline silica dust and related safer work practices	23 languages (Europe)	European Network for Silica www.nepsi.eu
Step B/ Step 4	SUBSPORT is an internet portal that constitutes a state-of-the-art resource on safer alternatives (substances and technologies) to the use of hazardous chemicals and tools and guidance for substance evaluation and substitution management. A first version is expected for 2012 in four languages.	English German (Europe)	Kooperationsstelle Hamburg www.subsport.eu/index.php/de
Step B/ Step 4	Sustainable Design Guide by Chemistry Innovation is a detailed overview of how to apply eco-design principles in the chemistry-using industries in innovating new products, processes and services	English (UK)	Technology Strategy Board https://connect.innovateuk.org/web/sustainability-theme1/sustainable-design

Table A2-3: *Tools, databases and further reading for the CHECK step (Step C in the 4-step process and step 5 in the 7-step process)*

Type of tool	What can it be used for	Languages (country)	Provider and where to find it
Step C/ Step 5	AWARE (Adequate Warning and Air Requirement) is a two digit-code for solvent-based products. The AWARE can be used for comparing products regarding their potential and health-related hazards	English (Nether-lands)	IVAM http://213.206.93.221/aware/
Step B, C/ Step 4, 5	CLEANTOOL is a tool with accompanying database for parts cleaning, metal surface cleaning, component cleaning and degreasing	German English French Spanish (Europe)	INRS, ISTAS, Kooperationsstelle Hamburg www.cleantool.org/en/reinigungssuche.php
Step A, C/ Step 1 and 5	Column model is a tool for identifying the differences in the risks of different chemicals	English German (Germany)	BAuA - German Federal Institute for Occupational Safety and Health http://www.dguv.de/ifa/en/pra/ghs_spaltenmodell/index.jsp
Step C/ Step 5	Evalúa y compara lo que usas - a tool to assess and compare alternatives	Spanish (Spain)	ISTAS www.istas.net/risctox/evalua/dn_auto_portada.asp
Step A, B, C, D/ Step 1, 2, 3, 4, 5, 6	German technical rules for hazardous substances (TRGS) – overall approach on risk assessment and substitution	English German (Germany)	BAuA - German Federal Institute for Occupational Safety and Health www.baua.de/cln_135/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/TRGS.html

Step C/ Step 5	Pollution Prevention Options Assessment System (P2OASys) is a tool for checking whether the potential alternatives may have unforeseen negative environmental, worker or public health impacts. The tool allows the comparison of the total environmental and occupational impacts of process changes and not just those of chemical changes	English (USA)	TURI - Toxics Use Reduction Institute http://www.turi.org/Our_Work/Research/Alternatives_Assessment/Chemical_Hazard_Comparison_Tools/P2OASys_Tool_to_Compare_Materials

Table A2-4: *Tools, databases and further reading for the ACT step (Step D in the 4-step process and steps 6 and 7 in the 7-step process)*

Type of tool	What can it be used for	Languages (country)	Provider and where to find it
Step A, B, C, D/ Step 1, 2, 3, 4, 5, 6	German technical rules for hazardous substances (TRGS) – overall approach on risk assessment and substitution	English German (Germany)	BAuA - German Federal Institute for Occupational Safety and Health www.baua.de/cln_135/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/TRGS.html
Step D/ Step 7	ISO 9001:2008	English (International)	ISO - International standardisation organisation www.iso.org/iso/iso_9001_2008
Step D/ Step 6	"Our South West" site with Managing Change Guide	English (UK)	Our Southwest www.oursouthwest.com/SusBus/mggchange.html

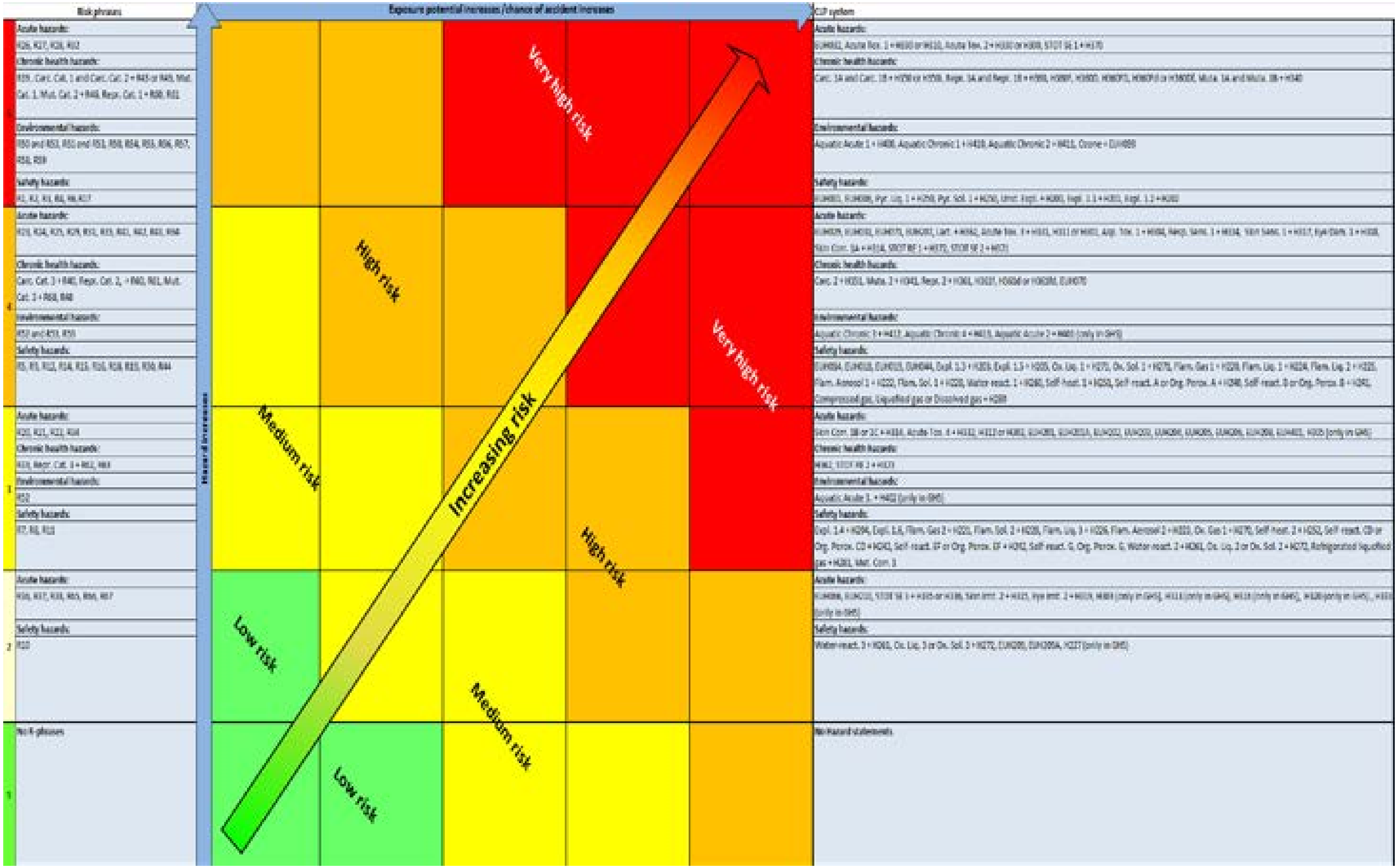
Appendix 3 Risk matrix

Category	1	2	3	4	5
Quantity used	Very small; grams or millilitres Examples are lock sprays, certain additives in laboratories	Small; less than 1 kg or litre	Medium; between 1-10 kg or 1-10 litres	Large; over 10 kg or over 10 litres	Very large; over 100 kg Often chemical use is measured in tonnes or cubic metres
Physical properties affecting exposure	Vapour pressure of liquid is below 1 kPa	Vapour pressure of liquid is 1-10 kPa	Vapour pressure of liquid is 10-50 kPa	Vapour pressure of liquid is 50-250 kPa	Gases; liquids with a vapour pressure over 250 kPa
	Non-dust-generation	Low dust generation	Some dust created	Increased dust generation	Very high dust generation, aerosols
Working / process conditions	**Fully enclosed system** -> No possibility of direct skin contact -> No possibility of exposure by inhalation	**Closed system**, with small possibility of exposure during some work steps such as decanting or sampling -> Low possibility of direct skin contact -> Low possibility of inhalation	**Semi-enclosed system** or open system with automatic ventilation and control barriers -> Some possibility of direct skin contact -> Some possibility of inhalation	**Open system**, passive ventilation and protective barriers -> Medium possibility of direct skin contact -> Medium possibility of inhalation	**Open system**, no ventilation -> High possibility of direct skin contact -> High possibility of inhalation
Frequency or duration of use	Rarely, a few times a year Very short use, minutes	Occasional, monthly Short use, less than 1 hour	Frequent, once a day, several times a week Medium use, 1-2 hours at a time	Very frequent, several times a day Use for more than 2 hours at a time	Continuous process
ACCIDENT potential	Very unlikely	Unlikely	Could happen, has occurred in industry	May happen	Very likely, has happened before at our work place

[Disclaimer and important note to users!]

This general risk matrix has been prepared for helping companies in risk assessment. However, it should be noted that the risk matrix does not represent an absolute truth, nor is it the only way of ranking different hazards and potentials for exposure. Within each company, relative risk may be considered differently. You can use this model to construct your own definition of a risk matrix. If you do this, you should think carefully about at least the following: How do we rank different types of hazards in relation to each other? Are, for example, environmental hazards as important in overall risk as chronic health hazards? You can also use different risk matrices for different types or risk, such as inhalation, skin and eyes, ingestion, chronic health effects, safety effects and effects on environment.

MAKE SURE YOU CHECK WHETHER THERE ARE LEGAL REQUIREMENTS OR DEFINITIONS OF RISK LEVELS IN YOUR COUNTRY!


Risk phrases
Exposure potential increases / chance of accident increases
CLP system
Hazard increases
Very high risk
Very high risk
High risk
High risk
Medium risk
Medium risk
Low risk
Low risk
Increasing risk
Acute hazards:
Chronic health hazards:
Environmental hazards:
Safety hazards:
No R-phrases
No Hazard statements

Appendix 4 Tables for the 4 step substitution process

Blank Table I-1: Check-list for considering substitution

Question	Yes / no + comments
1. Are we using chemicals?	
2. Do we know what risks our chemical use creates?	
3. Do we have a legal obligation to substitute?	
4. Are there hazardous fumes or dust created at our workplace?	
5. Do we use chemicals often and /or in large amounts?	
6. Do we use control measures to reduce chemical risks?	
7. Do we want our image and competitive edge to be better?	

Blank Table II-1: Chemical use and potential impacts – PLAN

How is the chemical used?	Questions to help you	Answers
People	Who uses the chemical?	
	Are there other people who could come in contact with the chemical?	
Process or task	What is done?	
	How is it done?	
	When is it done?	
Premise/ area	Where is the chemical used?	
Plant, equipment, tools	With what is the chemical used?	
Exposure type	How could the chemical cause harm to workers?	
Exposure potential	How likely is it that the chemical could cause this harm?	
Environment	Waste	
	Discharges	
	Emissions	

Blank Table II-3: Check-list for setting margins for change – PLAN

QUESTION	ANSWER	REASONS for answer; notes on whether more data is needed and what type of data.
Do we need to reduce the risk?		
Could we do without the chemical or the work task?		
What can we change?		
What type of limits do the materials used set for change?		
Are there any time re-straints		
How does the chemical have to perform? Are there any specific re-quirements		
The way we control the risk now – will it have to be changed?		
Waste disposal		

Table II-4: Comparison table for chemical and other risks – CHECK

COMPARE ALTERNATIVES	CURRENT	ALTERNATIVE
Will chemical risk be lower?		
Hazard: Are there differences in hazard level?		
Exposure normal use: Is it possible to breathe in the chemical or get it on skin/eyes/mouth during normal use?		
Exposure time: How often do we use this chemical?		
Exposure long term: Are there any hazards from long term use?		
Protection: Are there more control measures or PPE needed for either?		
Environmental risk: Are there differences in risk to the environment?		
Accident likelihood: Is there a difference in how the chemical is used that could in-crease/decrease the chance of an accident?		
Chemical risk: Which of the chemicals has a higher risk?		

COMPARE ALTERNATIVES	CURRENT	ALTERNATIVE
What are the other benefits and drawbacks?		
Other risks: Are there other than chemical risks from this use (e.g. vibration, noise, strains etc.)?		
Legislation: Are there any specific legal obligations for this chemical that impact on us, and what is it?		
Costs: What are the material costs?		
Costs: What would the change to alternative cost? (potential changes in equip-ment, PPE, training needed, storage requirements etc. per annum)		
Time: How long does it take to do the task/process done with the chemical? Is it time critical?		
Supply: Is the supply secure, i.e. will we get this chemical when we need it?		
Waste: Does the use of the chemical create waste that needs special treatment?		
Environment: Are there differences in discharges to water or emissions to air?		
Which is better? Current or alternative?		
CHANGE OR NOT?		

Appendix 5 Case studies

Content

STEP 1- Using a risk matrix to determine hazard, exposure and risk levels

This is an example on using a risk matrix for risk assessment.

A risk matrix is a tool for combining exposure potential and consequence assessment to arrive at a risk level for a particular chemical use. This example guides you through risk assessment in four steps using one type of a risk matrix – a risk matrix that is provided for you in Appendix 3.

1. The first thing to do is to determine the **hazard level**. Look at the Safety Data Sheet **Section 2 or 15** for the chemical and note down the R-phrases or Hazard statements. Then look at the risk matrix in Appendix 3. Find the hazard category that corresponds to the R-phrases or Hazard statements on the vertical axis in the risk matrix. Use the highest category to place the chemical on the vertical axis. The higher up the Hazard statements or R-phrases place the chemical on the vertical axis, the more hazardous the chemical is (see Figure AV-1).

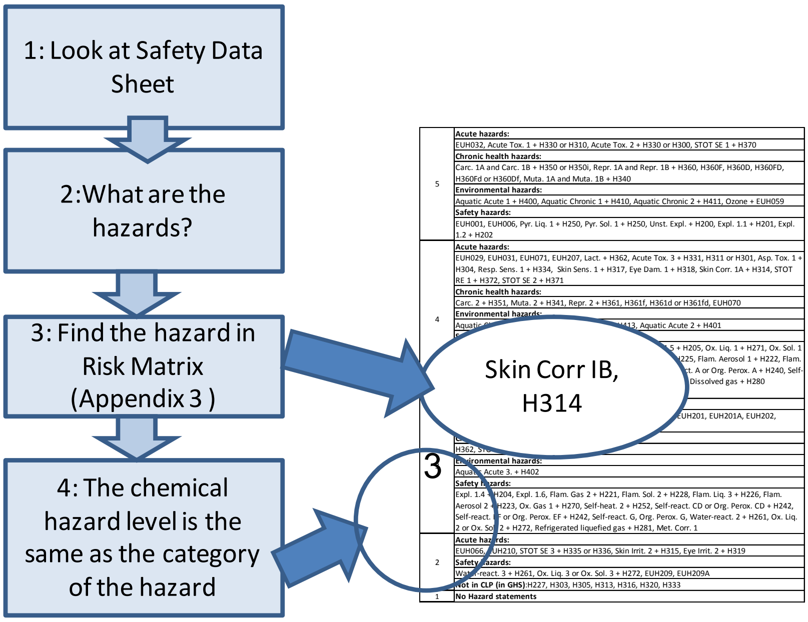


Figure AV – 1: Determining hazard level

2. Then think about what type of task or process you are using the chemical in. This is used to determine the **exposure potential** from use and accidents (horizontal axis). The exposure potential is determined by where, how often and in what way the chemical is used. For example, if you are using large amounts of a chemical or do the same task continuously, the possibility of exposure from the same use is higher than if you would be using just a few milligrams or doing the task only once a month. Other things affecting exposure are the frequency and duration of use, working and process conditions and physical properties of the chemical. For example, if the use of the chemical creates a mist or aerosol, these are more easily breathed in than when working with a solid, non-dust creating material. The different factors affecting the exposure potential are given as the use conditions at the top of the risk matrix (Appendix 3). Use these to find the exposure potential that describes the way you use the chemical on the vertical axis (see Figure AV-2).

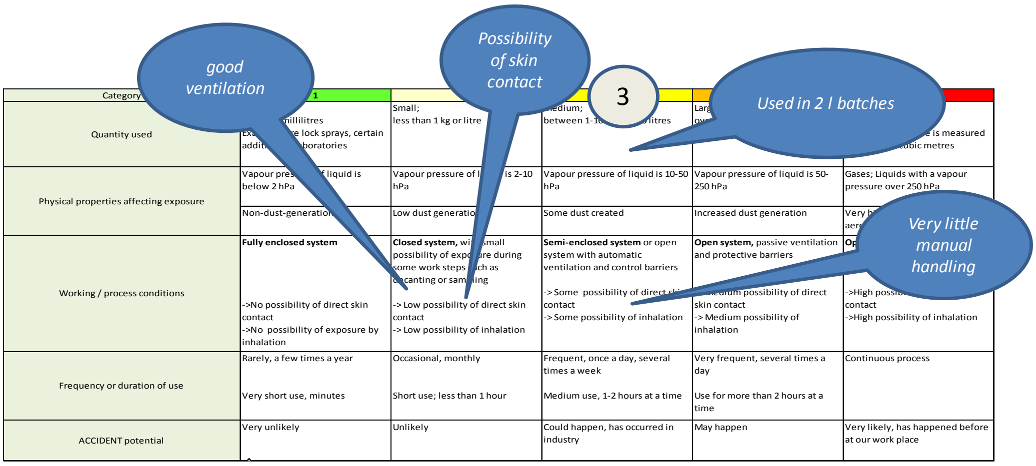


Figure AV- 2: Determining exposure potential

3. Now repeat the same for irregular uses, such as cleaning or maintenance. Also assess the likelihood of accidents. Then mark all the evaluated exposure categories in the risk matrix. (There are empty tables for your use in Appendix 4). An example is given below.

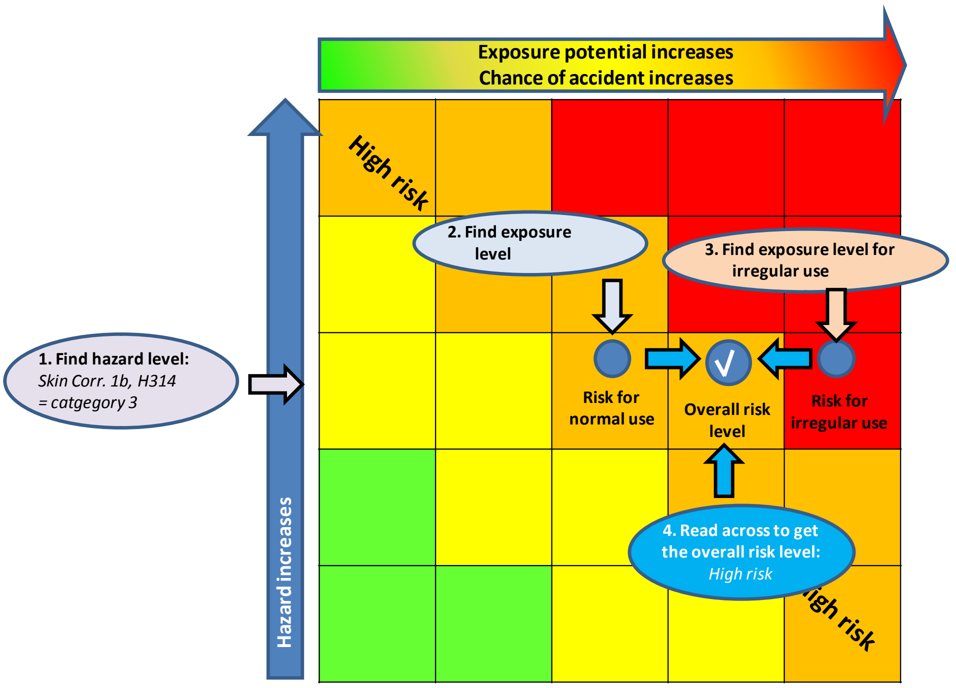


Figure AV-3: Assessing overall risk level

4. Choose the risk based on the exposure level for normal use as your baseline. If either the exposure potential from irregular use or the accident potential is higher (more to the right) than that for normal use, you can adjust the overall risk level to the right. Never move the exposure potential level to the left (e.g. to lower) of what the normal use exposure level is. In the above example (Figure AV-3), the exposure potential for normal use is level 3, whereas that for irregular use is level 5. The overall risk level has been determined as a 4. If you find this difficult, you can always simply use the highest risk level – or you can also do completely separate risk assessments for normal use, infrequent use cases and accidents, but remember to take all of these into account when assessing overall risk from a chemical for substitution considerations.

STEP 2 - Ranking chemicals using the risk matrix

This example will give you some suggestions on how to prioritise risk reduction measures.

Categorise risk

The risk matrix is a tool that can be used for ranking chemical risk and identifying which risk should be reduced as a priority. Based on the relative hazard and exposure potential, you should find a risk level category for all your chemicals. In the example matrix there are 4 categories (very high, high, medium or low). Other tools or matrices may give you for example 3, 5 or more risk categories.

The chemical risks that fall within the red category in the risk matrix (very high risk) are clearly the ones you need to address first, whereas the green (low risk) should be addressed once all others are controlled. The yellow and orange categories (medium risk and high risk) are the more difficult ones to prioritise. In this example all the assessed uses of chemicals A-E are of high risk.

Chemical D or C? In the example, chemical C has higher hazard than chemical D, but the exposure potential is of the same level. It is therefore relatively easy to decide that chemical C should be looked at first.

Chemical B or D? Deciding between chemical B and chemical D is not as easy, particularly if the hazards are different (e.g. chemical B hazard categorisation based on chronic health and chemical D on acute health and safety). Here you may need additional tools, such as given in step III. For now, you can record both are of high risk.

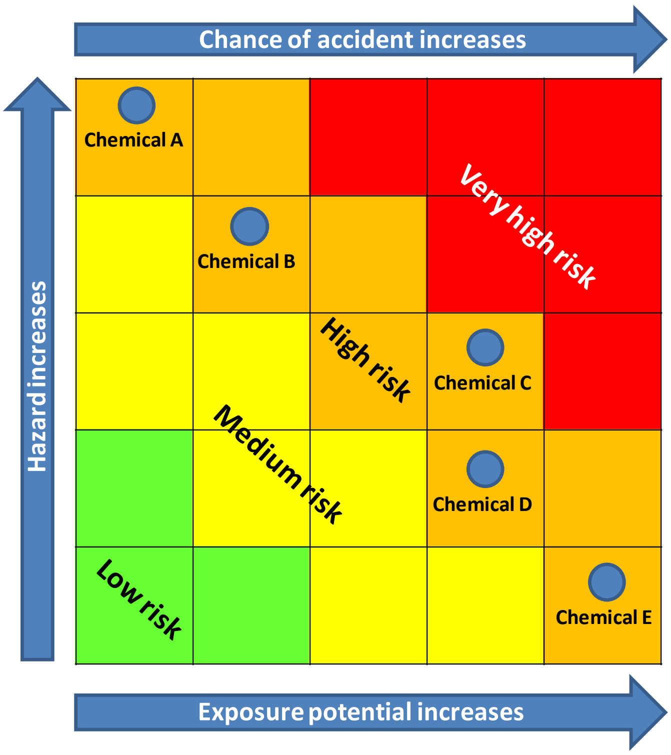


Figure AV-4: Categorisation of risk

Tabulating results from the risk matrix.

Tabulating risk assessment results is a way of documenting your assessment, making it easier to return to later or show authorities that you have assessed the risks. Below is an example of some chemical risk assessment results listed in a table. These are based on use of the risk matrix. Using tables such as this will also help you prioritise actions later on.

Table AV-1.Tabulating chemical risk assessment results

Chemical	Hazards	Task	Exposure potential	Accident potential	Overall risk
Tri-chloro-ethylene	Carc. Cat. 2; R45, Muta. Cat. 2; R68, R67, Xi; R36/38, R52/53 ➔ **5**	Used for sample analysis. Using a pipette ca. 1 mL per use is transferred from flask to another	Used frequently but small amounts -> medium exposure potential (**3**) Used in an open system, but within fume cupboard -> lowers exposure potential ➔ **2**	Low safety risk, only small amounts are used. Accidental spills may release the chemical into the laboratory -> potential for acute exposure to fumes, but amounts are small ➔ **2**	Orange, high risk *-> Evaluate substitution*
Brake parts cleaner	F; R11, R33 ➔**3**	Used for degreasing daily	The product is sprayed in very small amounts (aerosol) and used in well ventilated area -> possibility of exposure by inhalation ➔**2**	Low safety risk, small container, but flammable -> low incident potential ➔ **2**	Yellow, medium risk *-> Risk should be decreased if possible*
Isopropyl alcohol	F; R11 Xi; R36, R67 ➔**3**	Used as a solvent for organic synthesis (batch of 5 litres)	Open vessel reaction -> high exposure potential, but done only infrequently ➔ **4**	Highly flammable liquid, large amounts used in an exothermic reaction -> high incident potential ➔**5**	Red, very high risk *-> Priority for substitution*

Prioritise actions

One way to decide on which risk must be reduced first is to look at both the risk level and your ability to reduce it easily (see Figures AV-5 and AV-6). Actions that need only minor effort but give major benefits in risk reduction should be taken care of first. For example, if the risk level of chemical E can be reduced from high to low by using a control measure which is already available, the actions to change working procedures should be made immediately. Also changes that are easily done, even if the risk reduction is small, are worth doing. Change from powder to readily available granular form (for chemical B) is an example of such actions.

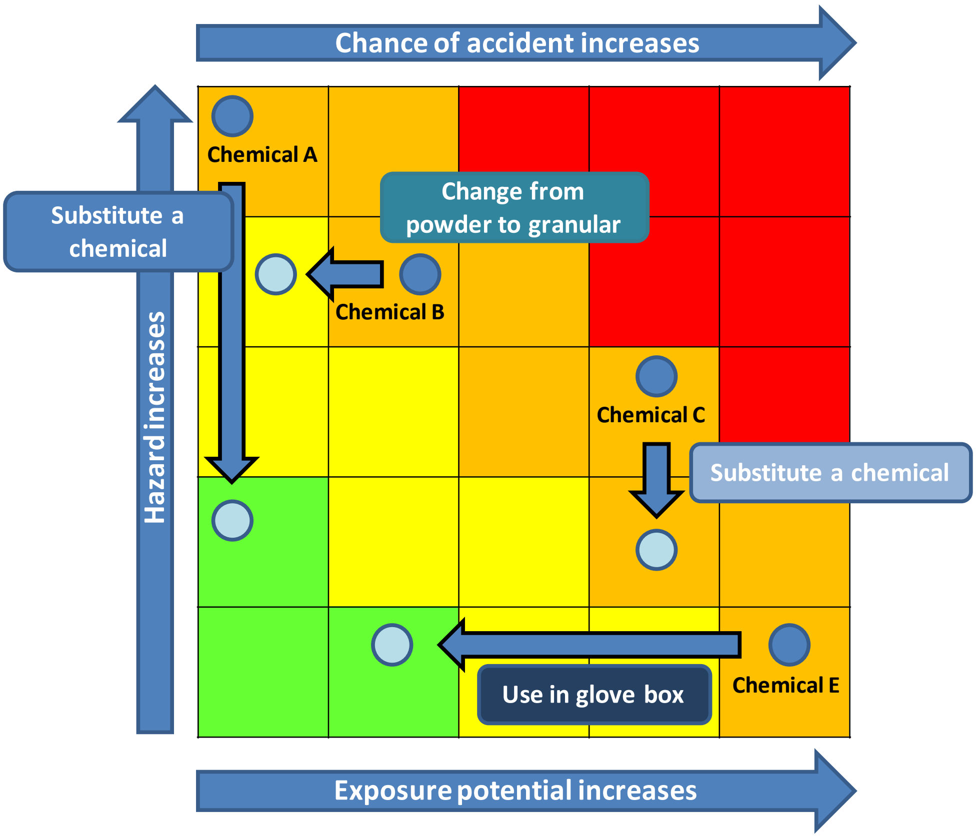


Figure AV-5: Actions for risk reduction

Actions that need more effort and resources are of course more challenging, and they might also be difficult to justify to management. For example, if by substituting chemical A with another less hazardous chemical the risk level can be significantly reduced, but major process changes are required, you might need more thorough analysis to find the best way to go forward. Substitutions that need major effort such as a process change and give only small benefits (e.g. chemical C) should be kept an eye on for possible actions in the future.

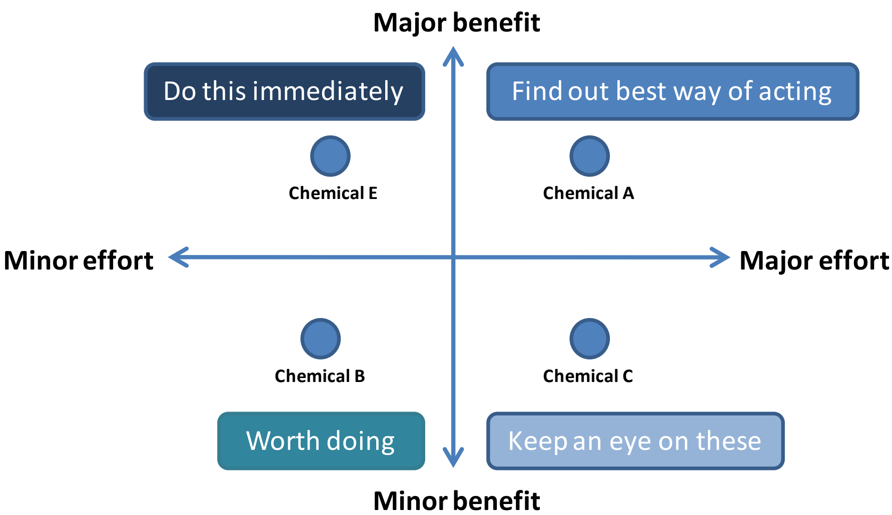


Figure AV-6: Prioritising actions

Whilst prioritising which risks to reduce first makes common sense, you should always remember that all risks should be reduced to low in order to ensure workers health and safety in all situations.

STEP 3 - Criteria for alternative cleaning chemicals in hospitality industry

This case example highlights how to identify the margins for change.

Many different types of ***cleaning products*** are used in the hospitality ***industry.*** Consumer demand and awareness of the hazards of many chemical ingredients are motivating companies to manufacture less hazardous cleaning products. Cleaning services providers are paying more attention to the chemicals they are using to avoid risks to ***workers*** as well as to health and ***environment*** in general.

There are nevertheless several performance related requirements or criteria for the cleaning products, which in some cases can act as barriers for substitution. Some key criteria are listed in Table AV-2 below. When looking at substitution possibilities, these criteria need to be met.

Table AV-2: An example of listing criteria for alternatives

CRITERIA	SPECIFIC CONSIDERATIONS	POSSIBLE SOLUTIONS
Match chemical to the task	The surface or item being cleaned might have special requirements that must be taken into account. The required concentration (mild or strong) of the chemical must be assessed.	**Sensitive surfaces**: Microfiber clothes can be used in many cleaning applications. They are especially suitable for cleaning sensitive surfaces **Light applications:** Using a strong chemical for light applications can be wasteful as well as harmful for the surfaces. But also using a mild chemical might call for mechanical action not suitable for the surface cleaned. By working in cooperation with manufacturers, safer cleaning products suitable for your use could be developed.
Effectiveness	The chemicals used have to meet the exact cleaning standards, which may be very high. These need to be noted down for each task and each area.	Most often, any issues with meeting standards are associated with the cleaning practices rather than the products used. Using the right proportions of cleaning agents with right tools require training, and automatic dispensers and similar tools can help. In some areas the use of chlorine can be substituted with dilute basic chemicals. By using the milder products regularly and as effectively as possible, the need to use stronger products can be diminished or in some instances eliminated altogether.
Convince supply chain	The customer might require the use of strong cleaning products with a view it will maintain higher quality standards. The smell of some strong cleaning products is associated with cleanliness. This can make it difficult to use milder products.	Discussions with customers about alternatives. The benefits and drawbacks of less hazardous products may need explaining. Work together with the customer to find solutions that meet customer requirements at the same time as being less hazardous to health and safer to use.
Time and costs	Safer or environmentally friendlier products are perceived as being more expensive. The time needed for the work could also increase because more time might be needed for the agent to be effective. Both potential cost increases must be taken into account.	Higher direct costs can yield cost savings in the future. Time related costs can be reduced if extra work steps such as rinsing can be eliminated. It is important to do a full cost-benefit analysis of the alternatives and not just look at the cost of the products.

STEP 3 - Example of a substitution approach taken by a cleaning provider

One of the largest cleaning services providers in the world is actively working to enhance health and safety aspects of their services, and to find ways to deliver sustainable services and cleaning solutions that reduce the environmental impact. In order to ensure a sustainable business model, the objective is to balance the well-being of:

- People (workers and customers and public when associated with the activities in any form)
- Environment
- Economic Value (generating the maximum for the total of all parties involved)

Supply chain requirements: The customers' main interest is to have a cleaning services provider that delivers the required quality at the right price. There is also an increasing demand for sustainable cleaning solutions from customers who place a high priority on health and environmental issues.

- ✓ By documenting work performance and stipulating ***key performance indicators,*** the quality standards agreed in the contracts can be secured.
- ✓ Proactive and continuous work towards sustainable services provides means to meet the present and future needs and requirements of customers.

Costs: The traditional purchasing criteria from just performance and cost, has been changed into focusing on overall added value.

- ✓ This has changed the purchasing equation from the lowest initial cost to one that also looks at product usage, training requirements, employee's health and safety, and environmental impacts.

Benefits: By working in close co-operation with leading suppliers and using the latest processes:

- ✓ The use of chemical detergents has been reduced by 75%.
- ✓ Water consumption and disposal has reduced by up to 70% with technologies like the use of e.g. microfibers.
- ✓ The workplace environment has become healthier, safer and more pleasant to work in.

STEP 4 - Finding alternatives for a solvent: Team work with the supplier

This case highlights the importance of communication within the supply chain.

Glass reinforced plastics are used for a variety of structures including the bodies of boats and yachts. The process involves the impregnation and roll-out of resins onto glass fibre. Traditionally, the rollers have been cleaned by dipping into containers filled with acetone. Acetone is a volatile flammable solvent which evaporates readily. The accumulation of vapours has in some cases resulted in explosions within boatyards, which in the most severe cases has resulted in worker deaths.

The challenge: To find a substitute that removes the build-up of resin from the rollers, allowing operators to immediately continue with the working process. The target was to design an alternative process which would allow for less hazardous materials to be used. Several other materials trialled did either not remove the resin adequately to allow a swift continuation of the operational process, or resulted in a large amount of rollers being unusable.

The solution: The challenge was solved through a multi-stage process involving custom designed equipment that utilised a non-volatile ester as a cleaner fluid, an aqueous micro-emulsion to remove final residues and finally a compressed air drying unit that removed all traces of fluid leaving dry rollers ready to be reused.

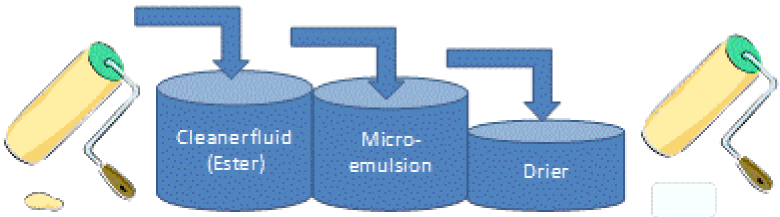


Figure AV-7: The solution – a multi-stage process

Timeframe: The new kit was designed, built, trialled, refined, further tested, and was in commercial operation within 2 years.

Practical challenges: Creating a process that would allow for the rollers to be cleaned and to ready for immediate reuse within a similar timeframe and with similar ease to the acetone route.

Decision: The decision to substitute acetone was based on a wish to reduce an identified high risk. The new process had to meet targets of practicality and cost. The final solution was arrived at after numerous modifications based on workers' feedback on the practicality of the process.

Cost: Cost was not the overriding factor, although it could not be prohibitive to the business.

Risk reduction: Removed explosion risk and inhalation exposures.

Added benefits: The rollers lasted longer in comparison to other substitution methods trialled, thereby saving money on material purchases. Less solid waste was generated to take to landfill, and the waste created by the esters and resins could be used by cement kilns for energy recovery.

Lessons learned: Involving workers at the beginning of the process and explaining why the substitution would be necessary ensures less resistance to change and brings the added benefit of ensuring practical considerations are taken into account early on.

STEP 5 - Comparisons can be challenging: Case paint stripping

This case example highlights the difficulties of comparing alternatives properties and benefits when different sources present different viewpoints and technical performance is pitted against risk. Whilst using the example of paint stripping, similar arguments can be found in many industries. If in doubt, ask your health and safety authority for advice!

Chemical: Dichloromethane (DCM) is a rapidly evaporating solvent that is used as a paint stripper. It is a chemical that many view as highly effective and it has indeed been in widespread use for long by the public, painters and decorators and industry.

Hazards: When used as a paint removal, the typical composition is 70-90% DCM and some 10% methanol. DCM has the following labels: Xn (harmful), R40 (possible risk of irreversible effects) and Carc. Cat 3 (possible carcinogen). The CLP classification for DCM is Carc. 2 H352. Methanol is classified as flammable and toxic[17]. Previous uses of DCM include use as a general anaesthetic in the early 20th century and DCM has indeed a narcotic effect, through depression of the central nervous system leading to loss of consciousness. It also has cardio-toxicological effects at high exposure, with a direct risk of death as a result of misuse. Other effects include irritation of the eyes and respiratory tract, lung oedema and acute effects on the heart, liver and kidneys. It also leads to light-headedness and headache.[18]

Alternatives: Various alternatives to DCM-based paint strippers are available on the market: physical/mechanical stripping, pyrolitic/thermal stripping, and chemical stripping involving other chemicals than DCM.

Figure AV-8: Alternative chemicals allowing safe working without PPE? Picture courtesy of Sheidel

Risk: The European Association for Safer Coatings Removal claims that since 1976, 52 fatalities worldwide are attributable to the use of DCMs[19]. Between 1989 and 2007, 18 fatalities (9 for Industrial use, 8 for professional use, 1 for consumer use) and 56 non-fatal injuries were registered in the

[17] DSD classification: F; R11, T; R23/24/25, R39/23/24/25 OR CLP classification: Flam. Liq. 2 H225, Acute Tox. 3 H331, H311, H301, STOT SE 1 H370

[18] http://www.europarl.europa.eu/sides/getDoc.do?language=EN&reference=A6-0341/2008

[19] http://www.eascr.org/dcmincidents.html

EU[20]. The EU Decision No 455/2009/EC bans the marketing and use of DCM paint strippers. The decision is based on results of several studies which have been evaluated by the Commission's Scientific Committee on Toxicity, Ecotoxicity and the Environment, which has confirmed that exposure to DCM released from paint strippers is of concern for human health. However, the decisions also allows for member state derogations for systems that can be shown to be safe for professional application.

There are risks associated with these alternatives too, for example, according to the members of the UK and Ireland Paint Stripper Formulators Group and the European Chlorinated Solvents Association (ECSA), there are approximately 200 serious accidents per year in the UK alone with pyrolitic/thermal methods of paint removal. Some chemical alternatives may be flammable.

How to choose: This case is one that illustrates how confusing it sometimes can be to decide on what type of method or chemical to use.

- **The case against change:** The members of the UK and Ireland Paint Stripper Formulators Group and the European Chlorinated Solvents Association (ECSA) claim that "*as alternative chemical paint strippers to DCM are demonstrably less effective, it is to be expected that the use of blow torches and heat guns for paint removal will increase with corresponding future increase in serious accidents*"[21].
- **The case for change:** Manufacturers of certain alternative paint strippers based on aqueous alcohol solvents with active oxygene on the other hand claim the working method for alternatives is different, as the reaction time is longer, but the paint is removed in several layers at a time, giving just as good if not better results. An alternative was successfully tested by one of Germany's largest decorator companies that employ approximately 1500 decorators. The alternative has since been used in several high profile jobs across the globe and a main benefit of the change was the reduction of necessary personal protective equipment. The change was considered particularly beneficial as painters and decorators can be hard to persuade to wear protective equipment. The Trade Association of the Construction Industry in Germany (GISBAU) also recommend the use of dichloromethane-free paint strippers. [22]

Technical performance of one method over the other is not something this guidance can comment on, but there are clearly severe health concerns associated with DCM based paint strippers.

- ✓ Make sure you do a thorough risk assessment. If you are unsure about how to do it, consider using expert advice from an independent body (e.g. Research institute or consultant).
- ✓ Check what your country's legislation says and make sure you take this into account.
- ✓ Assess your ability to ensure safety during working conditions at your workplace. Always err on the side of caution.

For example, if you are considering using DCMs, if you cannot guarantee safety through ensuring ventilation is sufficient – which can be almost impossible at for example customer premises – and your workers are reluctant to use full air respirators, you could place yourself, your workers or your customers at high risk if you continue to use DCM in non-industrial settings.

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[20] http://www.europarl.europa.eu/sides/getDoc.do?language=EN&reference=A6-0341/2008

[21] http://www.eurochlor.org/

[22] http://www.gisbau.de/service/brosch/dichlo_e.pdf

STEP 5 - Comparing possible substitutes using the risk matrix

This example illustrates two real cases of using the risk matrix for assessing possible substitutes and high-lights the relative ease with which substitution of some carcinogens can be done once the need to do so has been recognised..

In a large Finnish company with offices for several hundred people, the chemicals used include fuels, maintenance and cleaning chemicals. A systematic look at the risks associated with chemical use took approximately 4 days. Most of this time was spent on assessing the hazard of all the chemicals used (approximately 100 chemicals). Most of the chemicals had relatively low hazard levels and were used in a way that caused little or some exposure potential. This made the identification of which risks to look at first relatively easy.

One of the products used within the offices was identified as high hazard (Category 5). The product contains 70% of a category 2 carcinogen, trichloroethylene[23], which is named on the list of substances of very high concern (SVHC). The product was used in maintenance of electronic equipment to remove solder resin residues. The exposure potential was low because the chemical was used within a ventilated paint booth and only small amounts were used per time. However, as the chemical was on the SVHC list and is a carcinogen, it was identified as a target for substitution. Cost was not considered relevant as the material was used in such small amounts annually. Alternatives were identified by calling the main suppliers. Testing of an alternative, containing ethanol, 2-propanol and small amounts of methanol was undertaken to ensure it worked as efficiently. The hazard level for this possible substitute is significantly lower[24], and the way it is used the same, giving a clear reduction in risk as shown in the below risk matrix.

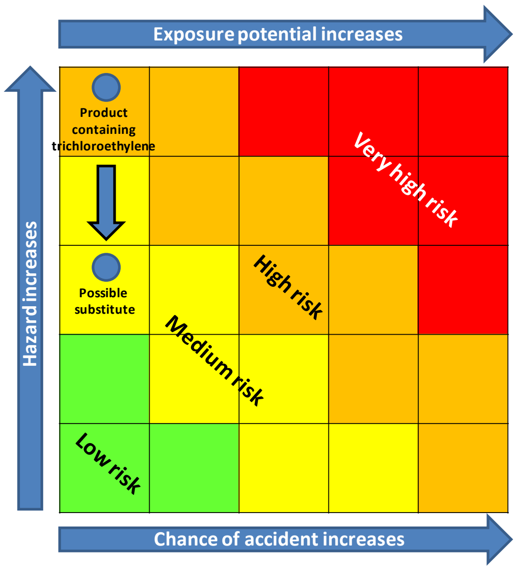


Figure AV-9: Comparing alternatives for maintenance using a risk matrix

[23] DSD classification: Carc. Cat. 2; R45, Mut. Cat. 3; R68, R67, Xi; R36/38, R52-53 OR CLP classification: Carc. 1B H350, Muta. 2 DSD classification: F; R11, Xn; R20/21/22, R36, R68/20/21/22 OR CLP classification: H341, Eye Irrit. 2 H319, Skin Irrit. 2 H315, STOT SE 3 H336, Aquatic Chronic 3 H412

[24] CLP classification for the substituent: Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336.

In a food product manufacturer company **potassium dichromate**, a chemical with carcinogenic and reprotoxic properties[25], and recently added to the SVHC list, was used to prepare a chromic acid glassware cleaning solution in the laboratory. Although the chemical was used within a fume cupboard, the ventilation was not on continuously and the container was not stoppered.

Once the hazards and risks were identified, the use of potassium dichromate was stopped immediately, and alternatives were first sought from other laboratory units inside the company. A possible substitute, with the hazards C; R34[26] was identified and tested. Also, the use of sonication, a non-chemical method will in the future be considered as one possible.

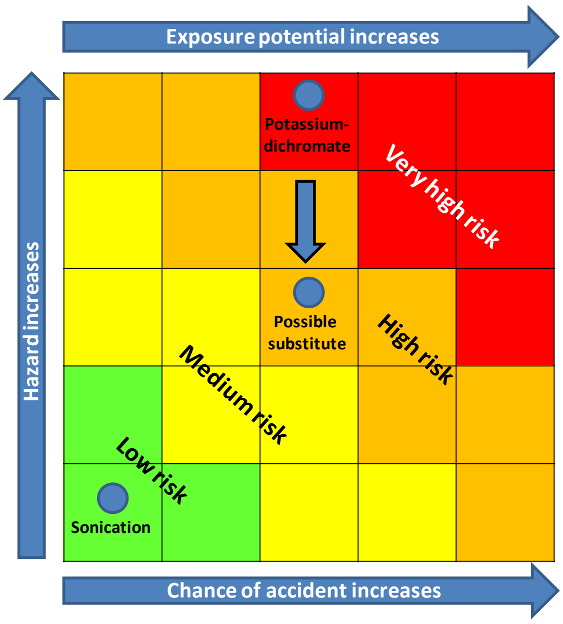


Figure AV-10: Comparing alternatives for cleaning laboratory glassware using a risk matrix

Both of these examples highlight the fact that it is not always the substitution itself that is difficult, but the recognition of the fact that a certain chemical is hazardous and may cause a significant risk to health.

[25] DSD classification: Carc. Cat. 2; R45, Mut. Cat. R46; Repr. Cat. 2; R60-61 OR CLP classification: Ox. Sol. 2 H272, Carc. 1B H350, Muta. 1B H340, Repr. 1B H360-FD, Acute Tox. 2 H330, Acute Tox. 3 H301, STOT RE 1 H372, Acute Tox. 4 H312, Skin Corr. 1B H314, Resp. Sens. 1 H334, Skin Sens. 1 H317, Aquatic Acute 1 H400, Aquatic Chronic 1 H410

[26] The substitute contains sodium hydroxide (max 5%) and different sodium salts. CLP classification for the substitute: Skin Corr. 1A H314

STEP 5 – Comparing chemicals at point of purchase through chemical risk assessment

This is an example of assessing and comparing chemicals using a tailored tool that ensures risk policy is taken into account in purchasing decisions. Detailed assessments of high risks before use are still conducted on a project basis.

Working at a safe level in process industry requires health, safety and environmental aspects to be integrated into all management actions. An EU based energy company recognized a need for a method that would streamline the existing chemical risk assessment procedure. Extending the chemical HSE risk management responsibility to the whole organization, including operational staff and purchasers was considered important. Screening and comparing chemical risks rather than just hazards prior to procurement was seen essential to encourage substitution and use of safer materials.

The challenge: A method for achieving consistent and comparable answers without a need for HSE expertise was needed. Any tool had to be sufficiently simple and not require prior knowledge of chemical HSE risks. The method should take into account all the regulatory demands, support chemical substitution, and, importantly, clearly link chemical risk management actions to corporate policy.

The solution: A methodology and a simple IT-tool for chemical risk assessment and management were developed. In order to make the tool easy to use, data input need from the users was minimized. The user only enters the chemical data from the manufacturer´s SDS and selects variables that describe the use case. The tool then generates a risk profile and displays the result.

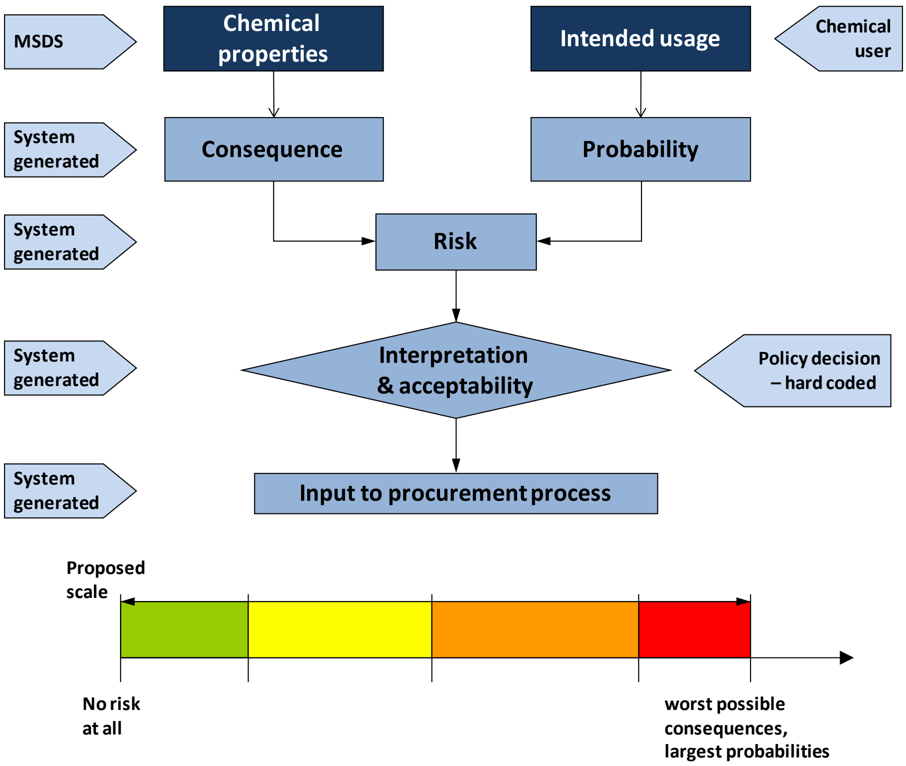


Figure AV-11:Tailoring a tool for comparing risks

The risk profile is the result of risk classification, which is based on HSE targets for overall risk reduction. Management actions were then linked to risk levels to allow definition and setting of targets for overall risk reduction. The risk profile encourages the user to compare different options and select chemicals with low HSE risk, and presents the risks in a compact and understandable format. The tool also allows easy comparison of how different use patterns affect the risks.

The benefits: The developed risk assessment format is based on the company HSE policy and strategic corporate goals. It integrates chemical HSE risk assessment into the overall consideration of chemical suitability, supporting integrated decision making process. By integrating the assessment into the company's IT-system, operational staff has easy access to assess the risks of their own jobs. The results are comparable and presented in a simple and understandable form, encouraging and giving new opportunities to influence and improve workers health. The tool is helpful for prioritizing chemicals for substitution.

Note: If you do not want to build or buy a system, you can use the free web-based tools such as COSHH Essentials to assess each chemical and get an idea of the required risk reduction measures. The benefits of an integrated approach are that you store all the assessments in the same format and can return to these any time. You can also use indicators to give you a clear overview at all times.

STEP 5 - Making complex comparisons easier

This case is an example of using a specific tool with predetermined assessment criteria to help making comparisons between different chemical properties and risks.

When deciding on chemical use, cost consideration often stops at the prize of the chemical. However, chemical choice can have a large impact on both direct operational and HSE related costs. A hazardous chemical has the potential for creating HSE impacts during its entire life cycle, and in order to select the most cost-effective chemical, the effects of chemical hazard should be included in the overall cost assessment.

In a large chemical user company, the objective was to develop a new method and accompanying tool for assessing overall costs of chemical use, enabling managers and engineers to rank options and minimize cost and risk through choosing the most cost efficient chemical with the lowest HSE risk that fully meets technical requirements. The technical requirements had to be met, as otherwise the risk of process failure would have far outweighed any chemical risks in terms of both HSE effects and costs.

The challenge: To develop a comparative tool that allows the influence of the chemical hazard profile on the overall cost to be routinely included in the planning process. The way alternative chemicals are used were the same, so hazards were combined with standard use cases and accident scenarios. The main challenge was how to compare different types of chemical impacts (e.g. health vs. environment) and relate these directly to costs in a consistent and transparent manner. Including all cost consequences required a life-cycle analysis approach. The main hurdle was to construct a systematic and logical approach for capturing all relevant cost elements. In particular, the inclusion of consideration of chemical risk was vital to the outcome but involved both ethical value discussions and complex calcuations.

The solution: In order to develop a robust and scientifically acceptable framework for data collation and calculations, cross-disciplinary cooperation between experts from HSE, risk management, economic modelling, ecotoxicology and statistics as well as operational experts was required. EMA (Environmental Management Accounting) principles of accurate accounting of effects were used as the starting point, and combined with Operational Expenditure (OPEX) analysis to ensure all relevant cost points were accounted for.

The benefits: The approach was embedded in a tool that enables operational engineers to include chemical HSE impacts, HSE risk and cost considerations into project planning stages *on par* with other technical and financial variables. The approach allows a systematic comparison of costs and risks, and directly supports decision making.

NOTE: It took several months to construct the framework and the detailed yet automated tool for comparative assessments. This kind of investment in time is justified when the projects are long, chemical use is extensive and there are clear risks associated with the chemical uses. For smaller businesses or where chemical use is less varied, a less detailed approach will be sufficient, but the basic approach of deciding beforehand on what grounds you will compare alternatives would still be the same.

You can approach this through the comparison tables provided in this Guidance. Use Appendix 4 for a less detailed evaluation and Appendix 6 for a more in depth evaluation. Next a case study on the use of Appendix 6 tools is given.

STEP 5 - Using the comparison tool in Appendix 6

The comparison tool in Appendix 6 can be used to compare your original chemical solution with different alternatives or to help you choose between alternatives for a new process. The tool takes into account chemical hazard level, HSE risks related to chemical use, other risks such as supplier reliability and stability of material prices, costs (material, equipment, safety, time, waste, risks) and also other aspects such as image and administrative requirements.

It is important to note that exact price and cost details are not necessarily needed. The comparison can also be made by using approximates or relative details. An example of using the comparison tool with relative benefit levels is presented here in Table AV-3 below. In this example different approaches to dealing with unwanted organisms (biocide chemicals) are compared using a colour scale to indicate relative benefits (scale from green (best) through yellow and orange to red (worst)). This allows a very fast relative comparison that can then be looked at in detail if and when required.

Table AV-3: Fast comparison of alternatives using relative benefit levels

ASSESSMENT	Formaldehyde	Glutaraldehyde	Calcium nitrate
Technical feasibility	Excellent	Excellent	Excellent
Workers wellbeing			
Technical safety level	Excellent	Excellent	Excellent; but is not suitable for all applications; depends on the waste treatment process (nitrate may react in certain processes)
Performance	Excellent	Excellent	Excellent
Image			
Environmental permits			
Other considerations			
Risk assessment			
Cost comparison			
Overall assessment			BEST ONE

STEP 6 - Deciding on the best chemical for a demanding process

This case highlights how decisions are based on several different properties of a chemical in a complex technical operation.

Decisions on which chemicals to use in a complex technical project in a multinational company involved in highly complex well construction operations are based on evaluations done within the operations design project, which can be up to 4-5 years long. Evaluations aim to identify the technically most robust solution, the solution with the best HSE profile and the least expensive and most expensive solution. The final decision is based on an overall assessment.

Technical performance considerations include material compatibility, productivity, technical safety and technical performance. Technical specialist groups identify the technical requirements and potential alternatives that meet these requirements. The work involves testing and evaluating experimental data. If the chemicals are not compatible with the process, a control issue may occur, which at its worse can lead to explosions and/or large leakages of hydrocarbons through riser problems. In the early 2000, the company encountered such a situation which would not have occurred with a denser material. This was a prime driver for initiating a thorough evaluation of alternatives.

HSE considerations: Environmental regulations for the North Sea offshore operations classify traditionally used heavy halide brines as leading to high environmental risk. The company has long had a company policy to not use chemicals that are classified as very hazardous to the environment. The alternative formate brines are less environmentally hazardous and, in the case of accidental release, will not lead to large environmental problems. The handling requirements differ, as the formate fluid is an irritant whereas the dense halide brines are highly corrosive and can cause chemical burns. This means less PPE is required for formates and the use is much safer.

Cost considerations: Based on the overall picture, the technical specialists gave a recommendation to the operational unit. The operational units then quantified the risks in relation to costs involved and made a final decision on which chemical to use. In the company, cost evaluations are done based on worst case scenarios. The identified alternative formate is a very expensive material. The significantly higher costs therefore required a very strong technical and HSE case for using the formates. Cost considerations have also later lead to experimental work on using the formate in mixtures with other fluids to bring the cost down and enhance technical performance.

Benefits, costs and challenges: Cesium formate is the least hazardous alternative, and the technical safety profile is also good. As a fluid alternative, it may be several times more expensive than alternative fluids, but actual operational costs are lesser. Challenges are related to long-term material compatibility and potential corrosion, which however only become issues if the completion fluid is left in the well for extended periods of time. Overall, the decision was taken that the benefits outweighed the cost and the change was implemented.

STEP 7 - Implementation of a new solvent in fine chemical factory

This case study highlights how decisions on change are made within quality management system.

The case represents the substitution of methylene hydrochloride by ethanol. The hydrochloride was used as a solvent in a certain chemical synthesis. Although in this particular case substitution was undertaken due to the solvent being banned by environmental authorities, the approach is equally well suited for substitution based on health grounds. The case study company was a middle-sized chemical plant selling fine chemicals for pharmaceutical production. Pharmaceuticals are not subject to chemical legislation, but their ingredients are, as was the chemical produced in this case. The chemical plant had to fulfil both ISO 9001 and Good Manufacturing Practice (GMP) requirements.

Substitution and quality system: Change of a chemical is a good “fitness” test for quality management. Functioning systems make the implementation step easy, because the change management procedure contains all aspects of the implementation process: planning, documentation, training and communication.

From the quality point of view, implementation was just one step in change management. In the first phase all necessary information was gathered from different organizations: production planning, production, safety advisors, analytical department etc. This produced user requirements of the new process. Implementation was only started after the process was officially accepted and documented by the quality managers and responsible managers.

Qualification and analytical quality: User requirements define the process in which quality is ensured. In the process qualification step, the entire new process was assessed and documented to ensure all user requirements are met. The technical part (process validation) included measurements and covered the most important risks. Here process validation made sure that the new process worked equally well as the previous one.

In quality management of a chemical process, analytical testing is a very important part. Change of the solvent required development work on updating the analytical testing procedure. All measures were documented in both laboratory and pilot scale testing and the new procedures were implemented simultaneously with the new process.

Customer requirements: When a pharmaceutical manufacturer faces a change in raw materials, the manufacturer launches its own change management, which might require much work, including new registrations. Therefore discussions with the customers were started long before the actual implementation of the solvent change. These two change management processes were run simultaneously with open communication, and agreements were made with authorities about running the old process long enough to obtain good storages of raw materials.

Parallel process: The actual substitution process was quite long due to slow changes at the customers’ end. All the customers did not manage to complete their own change management in time. Therefore exception permits had to be obtained from the authorities and small amounts of the product were still made with old process. This parallel process required significant work from quality management. Both raw materials and ready products had to be stored and handled separately. Numbering and documentation of the production batches was an essential part of the quality management and helped to ease the company through this transition state.

Appendix 6 Comparison tools for the 7 step process

1. Risk assessment

CHEMICAL HAZARD ASSESSMENT	Current (insert name)	Alternative 1 (insert name)	Alternative 2 (insert name)	NOTES
Acute health - inhalation				
Acute health ingestion				
Acute health - skin				
Acute health - eyes				
Chronic health				
Environment - air				
Environment - water				
Environment - soil				
Safety				
Hazard profile	Record here summary of current case/alternative			Record on these lines if increases or decreases for alternatives (OVERALL)

HSE RISKS	Current (insert name)	Alternative 1 (insert name)	Alternative 2 (insert name)	NOTES
Acute health - inhalation				[text description + note on which is best alternative from this perspective]
Acute health - ingestion				[text description + note on which is best alternative from this perspective]
Acute health - skin				[text description + note on which is best alternative from this perspective]
Acute health - eyes				[text description + note on which is best alternative from this perspective]
Chronic health				[text description + note on which is best alternative from this perspective]
Environment - air				[text description + note on which is best alternative from this perspective]
Environment - water				[text description + note on which is best alternative from this perspective]
Environment - soil				[text description + note on which is best alternative from this perspective]
Safety				[text description + note on which is best alternative from this perspective]
Other HSE risks: noise				[text description + note on which is best alternative from this perspective]
Ergonomics				[text description + note on which is best alternative from this perspective]
Others				[text description + note on which is best alternative from this perspective]
RISK of process /task	**Record here summary of current case/alternative**			**Record here if increases or decreases for alternatives (OVERALL)**

OTHER RISKS	Current (insert name)	Alternative 1 (insert name)	Alternative 2 (insert name)	NOTES
Stability of material price (prediction)				[text description + note on which is best alternative from this perspective]
Risk of discontinuation of material?				[text description + note on which is best alternative from this perspective]
Supplier reliability				[text description + note on which is best alternative from this perspective]
Other contingency risks				[text description + note on which is best alternative from this perspective]
Technical risks				
Financial / image risks?				[text description + note on which is best alternative from this perspective]
OTHER RISKS				**Record here if increases or decreases for alternatives (OVERALL)**
RISK LEVEL TOTAL				**Record here if increases or decreases for alternatives (OVERALL)**
OVERALL ASSESSMENT	**Record here summary of base casealternative**			**Which one is best?**

2. Cost Comparison

Cost €/period: TIME PERIOD : day /week / month /year		Current (insert name)	Alternative 1 (insert name)	Alternative 2 (insert name)	NOTES
Material costs	Cost of chemical per unit bought (ton)				Make a note of the units used here
	Amount of chemical used (number of units bought)				Estimated how?
	Cost of chemical in time period				Calculated
	Cost of any additives needed (total in time period)				Include all of the additives
	Other direct material costs				Think widely if other materials are needed also
	Cost of transport of materials in the time period considered				If you pay for the transport, otherwise you should leave this empty
	Storage costs of materials in the time period considered				Are there specific costs related to storage?
	TOTAL MATERIAL COSTS	0	0	0	
Equipment costs	Equipment investment				
	Maintenance costs in time period				Remember to include all maintenance, including allocating a proportion of less frequently occuring maintenance cost
	Cost of energy use in time period				Cost of energy = number of units of energy, e.g. kWh used times cost per kWh
	Other equipment costs				
	TOTAL EQUIPMENT COSTS	0	0	0	

Safety costs	Ventilation (investment + running cost)				
	Automation (investment + running cost)				
	Alarms (investment + running cost)				
	Fire /explosion protective measures				
	PPE (investment + running cost)				
	Change in cost related to permits and/ or inspections or other audits /checks				
	Other safety control measures (investment + running cost)				
	TOTAL SAFETY CONTROL COSTS	**0**	**0**	**0**	
Time related costs	Work time per produced unit/specific use (hours)				Record here how long each use takes OR how long making each unit of final product takes with the chemical. Record in hours, so 10 minutes = 1/6
	Cost of 1 hour work				Remember to include all direct and indirect labour costs
	Cost of work time per unit/ specific use case				CALCULATED: This will give you the cost of labour for producing 1 unit/ one use case
	Number of units produced or specific use cases in the time period				
	TOTAL TIME RELATED COSTS	**0**	**0**	**0**	**Calculated**

Waste costs	Recycling costs (per kg/tonne chemical bought)				Recycling may be related to for example tins or cans or cleaning containers before sending back. make sure you use the same units!
	Total recycling costs				Calculated
	Waste created (kg or tonne)				
	Waste handling costs (per kg or per tonne)				
	Waste handling costs total				Calculated
	Emission related costs in time period				
	Discharges created (amount, e.g. in cubic m)				Especially important if waste water has to be treated separately. Make sure you use the same units!
	Discharge related cost, e.g. waste water costs per unit, (e.g. cubic m or similar)				
	Total waste water/discharge costs				calculated
	TOTAL WASTE, EMISSION & DISCHARGE COSTS	**0**	**0**	**0**	**calculated**

Cost of risk	Insurance premium change				
	Estimate of direct cost of incident, where costs include: Days lost, liabilities, fines, remediation, relief workers, clean up costs, time lost on incident management. You can also include intangible effects such as image, goodwill, etc.				
	Likelihood of incident per year (as times per year estimated to occur)				For example, if you think this could occur once every ten years, the likelihood per year is 1/10, or 0.1
	Cost at risk				Calculated: Cost of incident x likelihood
	Occupational diseases that may be caused by use of chemical				Write down which ones
	Estimate of potential to lead to lost working days due to occupational illnesses or diseases or other ill effects caused by chemical use per year (number of days)				You can approach this through differences also, i.e. alternative with lowest potential = 0, the others are then estimated as more than the lowest potential. This may be difficult to estimate, you can also simply use numbers such as 0 = lowest, 1 = middle and 2 = highest. Remember that these are then not DIRECT costs.
	Cost per working day lost				Insert the total cost for a lost day's work, i.e. include replacement labour also
	Cost of lost days from occupational diseases				Calculated
	Other costs from occupational diseases in time frame (estimate)				
	TOTAL COST OF RISK	0	0	0	**Calculated**

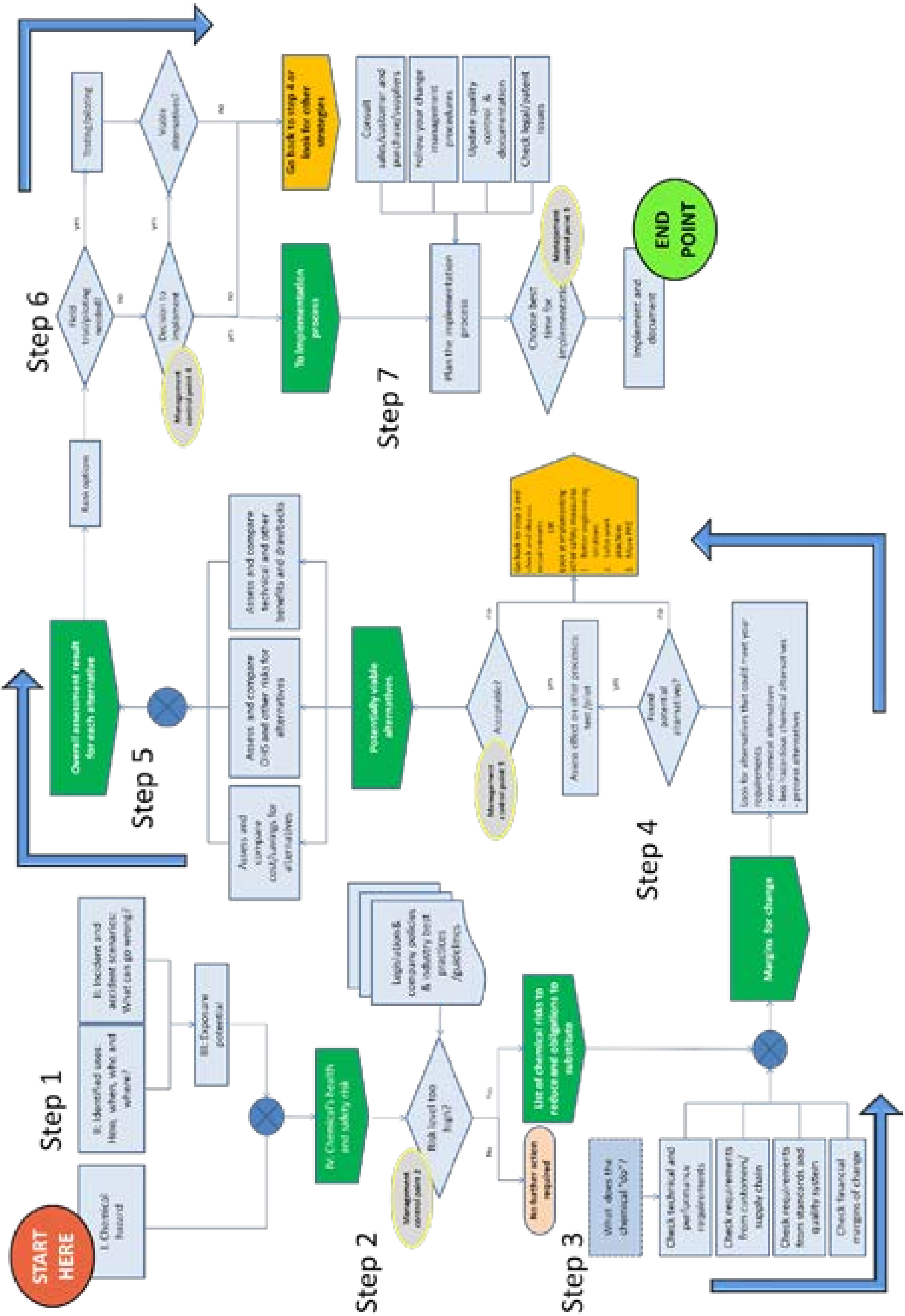
TOTAL COSTS	TOTAL MATERIAL COSTS	0	0	0	Calculated
	TOTAL EQUIPMENT COSTS	0	0	0	Calculated
	TOTAL SAFETY CONTROL COSTS	0	0	0	Calculated
	TOTAL TIME RELATED COSTS	0	0	0	Calculated
	TOTAL WASTE, EMISSION & DISCHARGE COSTS	0	0	0	Calculated
	TOTAL COST OF RISK	0	0	0	Calculated
	TOTAL COST	0	0	0	Calculated

3. Other aspects & results

ASSESSMENT	Current (insert name)	Alternative 1 (insert name)	Alternative 2 (insert name)	NOTES
Technical feasibility				
Workers wellbeing				
Technical safety level				
Performance				
Image				
Environmental permits				
Other considerations				

Risk assessment				From sheet 1
Cost comparison				From sheet 2
Overall assessment				

Appendix 7 Substitution flow chart



PART II

Study Report on identifying a viable risk management measure

Key findings

The study results indicate that main drivers to substitution are legislation as well as pressure inside the supply chain and from within the company. A key issue identified is that substitution is often associated with bans and lists of substances of high concern produced by national or EU authorities or industries. Such substitution tends to be hazard based. **Within this study, the approach to substitution was risk based and the focus was firmly on substitution as an occupational health and safety risk management measure at the workplace level**. A common issue identified by authorities was that the use of substitution within companies is difficult to enforce and relatively poorly monitored. Therefore, it was found that to enhance the use of substitution at the workplace level, a concentrated effort of both providing guidance and follow-up through monitoring and enforcement is needed.

There are many existing guidances and tools to aid companies working through substitution projects. None of these, however, is truly practical or easy to implement, especially for SMEs working outside the industries where chemicals are part of the key processes. During the work, a key question was whether a common guidance for all EU workplaces would be beneficial and whether it would be feasible to construct such a guidance document. The results indicated that:

- A common guidance targeted at SMEs, whilst still providing help for companies where chemical risk assessment expertise is not core knowledge, was without exception felt to provide value.
- The need for substitution guidance for large companies with core expertise in chemicals was found minimal.
- The vast majority of companies within the EU do not have the expert knowledge or resources to undertake state of the art evaluations. An easy-to-use guidance accompanying a step-by-step process describing a “substitution for beginners” type of simplistic yet scientifically sound approach was identified as a key target.
- Risk assessment of chemicals at the workplace is a task where many companies struggle. In order for any substitution guidance to be effective, it was found that an overview and guidance to how to conduct a risk assessment as well as tools for doing this had to be included.
- Basic prioritisation following risk assessment was found to need to be addressed in order to support identification of substitution priorities based on relative risk levels.
- Substitution is a change, and therefore the assessment and implementation of any substitution should be approached through methods suitable for change management.
- Providing tools and guidance on how to assess overall costs and benefits and relating these to chemical functionality and performance requirements and risk was found highly desirable.
- To be effective, the guidance will have to be accompanies by targeted dissemination. Potential partners for dissemination of the final Guidance document are national authorities, industry associations, occupational health centres, trade organisations, professional organisations as well as the DG website and other EU level organisations.
- The Draft Guidance document is recommended to be distributed through a website. This will give the opportunity to keep any links up to date and add new information as needed.

Principales conclusions

Les résultats de l'étude indiquent que les principaux moteurs pour la substitution sont la législation, ainsi que la pression dans la chaîne d'approvisionnement et au sein de la société. Une clé essentielle identifiée est que la substitution est souvent associée aux interdictions et listes de substances très préoccupantes produites par les autorités et industries nationales ou européennes. Ce genre de substitution est à tendance dangereuse. **L'approche de la substitution est basée sur l'étude des risques et l'accent a fermement porté sur la santé au travail et sur la mesure de gestion de risque en matière de sécurité au niveau du lieu de travail**. Un point commun identifié par les autorités a été que l'utilisation de la substitution au sein des sociétés est difficile à mettre en œuvre et qu'elle est contrôlée de manière relativement faible. C'est la raison pour laquelle, il s'est avéré que pour renforcer l'utilisation de la substitution sur le lieu de travail, des efforts concentrés aussi bien pour fournir à la fois une orientation et un suivi par le biais du contrôle et de la mise en application sont nécessaires.

Il existe de nombreux outils et stratégies disponibles pour aider les sociétés à travailler par le biais de projets de substitution. Cependant, aucun de ceux-ci n'est véritablement pratique ou facile à mettre en œuvre, en particulier pour les PME exerçant leurs activités à l'extérieur des industries où les produits chimiques font partie des processus principaux. Pendant le travail, une question clé a été soulevée, à savoir si une stratégie commune pour tous les lieux de travail dans l'UE serait bénéfique ou s'il était plus faisable de dresser un document d'orientation.

- Une stratégie commune ciblée pour les PME tout en fournissant une aide aux sociétés où l'expertise en évaluation des risques ne constitue pas une connaissance fondamentale, ou qui a échoué à apporter de la valeur ajoutée.
- Le besoin pour une stratégie en substitution s'adressant aux grandes sociétés disposant de compétences fondamentales dans le domaine des produits chimiques s'est avéré minimal.
- La grande majorité des sociétés au sein de l'UE ne disposent pas de l'expertise ou des ressources pour entreprendre des évaluations utilisant des techniques de pointe. Des conseils faciles à utiliser accompagnant un processus étape par étape décrivant un type de « substitution pour débutants » simpliste, mais reposant sur un fondement scientifique ont été identifiés comme un objectif clé.
- L'analyse de risques relative aux produits chimiques sur le lieu de travail est un point avec lequel de nombreuses sociétés ont des difficultés. Afin de permettre une stratégie de substitution efficace, il a été constaté qu'un aperçu et une stratégie sur la manière de mener une évaluation des risques, ainsi que les outils pour la réaliser doivent y être inclus.
- Une priorisation de base suivant l'évaluation des risques s'est avérée nécessaire pour soutenir l'identification des priorités de la substitution. Cette identification est basée sur les niveaux de risque relatif.
- La substitution constitue un changement, et pour cette raison, l'évaluation et la mise en œuvre de toute substitution doivent être abordées par le biais de méthodes appropriées pour la gestion de changements**.**
- Fournir des outils et une stratégie sur la manière de gérer les coûts et avantages globaux et de faire des liens avec la fonctionnalité chimique et les exigences en matière de performance et les risques se sont avérés être hautement souhaitables.

- Afin d'être efficace, cette orientation devra être accompagnée d'une diffusion ciblée. Les partenaires potentiels pour la diffusion du document final d'orientation sont les autorités nationales, les associations industrielles, les centres de la santé au travail, les organisations de commerce, les organisations professionnelles ainsi que le site web de la DG et les organisations au niveau européen.
- Il est recommandé que le projet de document d'orientation soit distribué par le biais d'un site web. Ceci fournira l'opportunité de maintenir tous les liens à jour et d'ajouter de nouvelles informations, si nécessaire.

Wichtigste Erkenntnisse

Die Studienergebnisse zeigen, dass die hauptsächlichen Treiber zur Substitution sowohl die Gesetzgebung als auch der Druck innerhalb der Lieferkette und im Unternehmen selber sind. Ein wichtiger in der Studie ermittelter Kernpunkt ist die häufige Verbindung der Substitution mit den durch nationale oder EU-Behörden oder Branchen erstellten EU-Verboten und Listen besorgniserregender Stoffe. Diese Art von Substitution bezieht sich meistens auf Gefährdungen. **In dieser Studie erfolgte die Herangehensweise zur Substitution risikobasiert und der Schwerpunkt lag auf Substitution als eine Maßnahme des betrieblichen Gesundheits- und Sicherheitsrisikomanagements auf Arbeitsplatzebene.** Ein von den Behörden festgestelltes gemeinsames Anliegen war, dass die Verwendung von Substitutionen innerhalb von Unternehmen schwierig durchzusetzen ist und relativ schlecht kontrolliert wird. Daher wurde festgestellt, dass zur verstärkten Nutzung der Substitution auf Arbeitsplatzebene kombinierte Anstrengungen sowohl für die Bereitstellung von Beratung wie auch zur Weiterverfolgung durch Überwachung und Durchsetzung notwendig sind.

Den Unternehmen stehen viele Leitfäden und Mittel zur Verfügung, um Substitutionsprojekte durchzuführen. Nichts von alledem ist jedoch wirklich praxisbezogen oder leicht umsetzbar. Dies vor allem für KMUs, die außerhalb von Branchen tätig sind, in denen Chemikalien in den Kernprozesse eingesetzt werden. Während der Studie wurde die Schlüsselfrage formuliert, ob ein gemeinsamer Leitfaden für alle EU-Arbeitsplätze nützlich und ob die Erstellung eines solchen Dokumentes machbar wäre. Die Ergebnisse anzeigen dass:

- Es herrschte die Auffassung, dass ein auf KMUs zugeschnittener gemeinsamer Leitfaden, der Unternehmen ohne Expertenwissen über die Risikobewertung von Chemikalien unterstützt, wertvoll wäre.
- Der Bedarf an einem Substitutionsleitfaden bei großen Unternehmen mit Expertenwissen im Bereich Chemikalien wurde als minimal eingestuft.
- Die große Mehrheit der Unternehmen innerhalb der EU verfügt über kein Expertenwissen oder keine Ressourcen, um dem neuesten Stand der Technik entsprechende Bewertungen durchzuführen. Als ein Hauptziel wurde ein benutzerfreundlicher Leitfaden inklusive Schritt-für-Schritt-Anleitung bezeichnet, der "Substitution für Anfänger" zwar einfach aber mit wissenschaftlichem Ansatz bietet.
- Die Risikobewertung der Chemikalien am Arbeitsplatz ist eine Aufgabe, die vielen Unternehmen Mühe bereitet. Es wurde festgestellt, dass ein Substitutionsleitfaden eine Übersicht, Leitlinien über die Risikobewertung sowie die Anleitungen zu deren Umsetzung enthalten soll, um wirksam zu sein.
- Eine auf die Risikobewertung folgende grundlegende Prioritätensetzung muss thematisiert werden, um die Identifizierung der auf relativen Risikoniveaus basierenden Substitutionsprioritäten zu unterstützen.
- Substitution ist eine Veränderung. Daher sollten die Bewertung und Umsetzung jeglicher Substitution mit geeigneten Methoden aus dem Change Management unterstützt werden.
- Die Bereitstellung von Mitteln und Leitfäden zur Evaluierung der allgemeinen Kosten und Nutzen und deren Verknüpfen mit chemischer Funktionalität, deren Leistungsanforderungen und Risiken wurden als äußerst wünschenswert empfunden.

- Damit der Leitfaden seine Wirkung erzielt, muss er anschließend gezielt verbreitet werden. Potentielle Partner zur Verbreitung des endgültigen Leitfadens sind nationale Behörden, Industrieverbände, betriebliche Gesundheitszentren, Handelsorganisationen, Berufsverbände sowie die DG-Website und andere Organisationen auf EU-Ebene.
- Es wird empfohlen den Leitfadenentwurf vorgestellt, über eine Website zu verbreiten. Dadurch können alle Links auf dem neuesten Stand gehalten und neue Informationen je nach Bedarf hinzugefügt werden.

Executive summary

This report presents the work undertaken and results reached in a study on the practical implement-tation of substitution of chemicals at workplaces across the EU. The focus was on substitution as a risk management measure for reducing the risk to workers' health and safety from chemicals at the workplace. Substitution has throughout the work been approached through a risk management perspective. The study's main objectives were firstly, to find out if there was a need for a common guidance on substitution across the EU and, secondly, if needed and seen as a possibility, to develop a common approach to substitution and present this in a draft guidance document. The results indicated that a common guidance across the EU would be welcome; hence the majority of this work was directed towards developing a common approach and presenting it as a guidance document.

The objective of the developed approach presented in the draft guidance is to provide workplaces across the EU with a systematic process for identifying chemicals that could or should be substituted to reduce risk. The identification process is firmly based on risk assessment results. Substitution can be a complex process, and in large organizations the potential to substitute may be evaluated by a large team of different specialists. In the vast majority of smaller or non-chemical industrial workplaces, one person will have to manage all these aspects. The main target audience of the developed framework and accompanying guidance are such workplaces, where there may be limited knowledge of and/or scarce resources allocated to chemical risk management.

The work was carried out by a multidisciplinary team that included technical experts (chemistry, industrial hygiene, toxicology, ecotoxicology and medicine) as well as management, risk management and decision making experts. The combination of the multidisciplinary team with an extended validation round aimed at producing a robust yet practical and widely applicable approach to substitution.

Within the study, several methodologies were applied in multiple work packages with specific targets. Primary data collation included interviews and web surveys across the EU, Norway and Switzerland. An iterative literature review that included looking at substitution approaches developed around the world was carried out. Preliminary results were subjected to critical review in an interactive multi-stakeholder workshop and refined based on the comments. Three pilots to test the developed approach as well as the completeness and user friendliness of the accompanying draft guidance were carried out. Finally, validation of the work was done through inviting comments and critique from a wide set of stakeholders across Europe. The draft guidance presented as the main outcome of the study was modified to take into account these comments.

Requirements from legislation in the EU was analysed both at the EU level and through a more in-depth analysis of the legal framework and supporting policy and guidance available on substitution in five case countries (Finland, France, Germany, the Netherlands and UK). There were marked differences on both the level of tools and guidance provided on substitution and the requirements to follow certain methodological approaches between these countries. This study aimed to identify and integrate the "best parts" both from a practical and a scientific point of view into a common framework. As the target was to develop a reasonably short and easy to read guidance document to explain and support a common approach, this has inevitably lead to simplification as well as exclusion of some very good national or industry specific approaches from the draft guidance document. This study report contains a more detailed review.

The barriers, drivers and motivators to substitution were analysed in the early part of the work, with the aim to find the most important obstacles to overcome within a common approach. Both societal and internal organisational factors influencing the use of substitution as a risk management measure at workplaces were reviewed. Areas where conflicting influences were evident are high-lighted in this report. The development work focused on addressing practical issues identified as potential barriers to the wider use of substitution of hazardous substances at workplaces across Europe. These practical challenges were initially approached through a closer look at the challenges, differences and commonalities within ten industrial sectors: the automotive, chemical, construction, engineering (mechanical and electronic), food, plastics and rubber, hospitality/cleaning, mining, metals and minerals and textiles and clothing industries. Early on the results from both the country and sector studies indicated that, although some sector specific aspects would be worth of addressing, the main need was for a simple approach to substitution that would address commonly identified decision points and evaluation methods on a very concrete level. It became evident that clear differences in the needs for guidance more clearly relate to the position in a value chain than to specific industry sector. The initial sector specific approach was then modified towards a value chain based analysis in order to provide more widely applicable findings. This approach was adopted for the remaining study and hence detailed sector specific conclusions are not presented in this report. Instead, the findings are discussed based on the different chemical value chain positions. The generic and much simplified value chain was depicted through four main positions: Chemical manufacturing; Chemical blenders and service companies; Process industry; and Chemical users.

There are, of course, many differences that can be identified within different industries and different size organisations within these value chain positions. However, when viewed against the main target audience of a potential common approach for substitution, a broad categorisation was seen as sufficient. Significantly, there is a potential correlation between the value chain position and the level of detail the common approach can depict. In particular, workplaces representing chemical end users commonly appear to require a highly simplified step-by-step process. Based on interview results, the messages received from authorities implied that if the guidance to substitution does not provide guidance to risk assessment also, the developed approach would not meet the requirements of the target audience. Therefore, the draft guidance includes a step-by-step guidance on how to carry out a risk assessment of both chemicals in use and potential alternatives.

The risk assessment approach presented has been constructed based on several national approaches and is in places much simplified. It is acknowledged that there are many public reports and a vast number of risk assessment methodologies and tools available. The key target audience of the work is SMEs and companies with limited knowledge or experience of chemical risk management. Organizations with internal expertise and large R&D focuses on chemical safety were not an identified target audience. Therefore no attempt to produce guidance for experts has been done. As the risk assessment step was found to be one of the main parts where help and tools are needed, a considerable part of the developed approach addresses how to include comparative consideration of the basic principles of hazard identification and risk assessments. The chosen risk assessment approach draws heavily on the perhaps most well-known tool for assessing risk, the risk matrix.

In order to enable the approach to substitution developed remain a flexible tool and to demonstrate that substitution need not be a complex task to undertake a two-layered substitution process based on the PLAN-DO-CHECK-ACT change management model was developed. These two approaches are:

1. A much simplified **4-step approach**, where the target audience is workplaces where either relatively few chemicals are used, or where chemicals used are not directly part of the products produced. Knowledge and experience of chemical risk assessment and management may be very limited. Tools aimed to help during risk assessment, data collation as well as for the overall assessment of the implications and potential benefits and drawbacks of substitution are given. The target audience includes, but is not limited to, workplaces and industries such as maintenance and repair, construction, painting and decorating, cleaning, offices and food industry.
2. A more detailed 7**-step approach**, where the target audience is workplaces were chemical use is either more complex or wider and chemicals may be used as part of the products produced. At these workplaces, there is perhaps more knowledge and experience of chemical risk assessments. The 7-step process contains more detailed tools and a depiction of the work flow for how to approach, evaluate, implement and monitor chemical substitution at the workplace.

The decision to adopt a two-layered approach reflects the differences in the existing levels of expertise in chemical risk management across workplaces. It also allows users to choose to conduct a more thorough review or to start off with a broader evaluation.

1. Introduction

1.1 Chemicals are a vital part of today's society

Chemicals are a fundamental and lasting part of our society. Much of our welfare is built on harnessing chemical reactions to make a variety of things from pharmaceuticals to water purifiers and from paints to plastics. In 2007, chemicals sales in the EU amounted to €537 billion and within the union, the chemicals, plastics and rubber industries create some 3.2 million jobs in more than 60 000 companies.[27]

At the same time, chemicals are often associated with undesirable effects on health, the environment or the safety of a particular operation. Many of us remember immediate disasters such as Toulouse or Bhopal, we are also familiar with the highly detrimental long term effects of DDT and frequently hear about how asbestos has claimed many victims. These long term effects were originally not understood sufficiently well, legislation did not target these substances until after the effects were understood and therefore detrimental conditions were allowed to develop. Immediate disasters have many reasons, some include various combinations of non-planned events and often human errors or bad management practices. Many of these highly publicised long term effects and immediate disasters have lead to stricter legislative requirements.

Strict legislative requirements combined with effective control methods are prime societal instruments for achieving better protection of workers health at the workplace. Within the EU, health and safety policy plays a key role in improving health protection standards. EU and member state regulations, legislation and various policy instruments as well as their effective enforcement are of prime importance in enhancing the protection of EU's workers health and safety. Another important policy instrument that authorities can use is to provide guidance on how to interpret and best apply regulatory requirements. The need for this type of guidance is particularly strong in areas that may be outside the normal sphere of knowledge at the workplace. Good and widely disseminated guidance can have a high practical impact in increasing health and safety at individual workplace as well as helping to meet health, safety and environmental objectives of the EU. Note that the focus of this work is firmly on occupational health and safety, but environmental concerns are considered as part of the overall regulatory and practical scene.

Despite tightening legislative control within the EU, stricter enforcement and many voluntary measures by industry, some 167,000 workers has been estimated to die in the EU-27 of work related conditions a year. More than 95% of these deaths are from occupational diseases. Nearly half of these deaths are attributed to exposure to dangerous substances. Long-term effects such as work-related cancers are among the main causes.[28] According to the EU-OSHA, chemicals and hazardous chemicals or other materials used in the workplace may be the cause of up to 70 000 deaths a year in the EU[29]. Most of these are from long term exposure and asbestos still contributes significantly.

[27] DG Enterprise & Industry, webpage

[28] EU-OSHA (2009)

[29] http://osha.europa.eu/en/publications/factsheets/84

According to European Trade Union Institute (ETUI), approximately one out of every three occupational diseases recognised annually in Europe can be ascribed to exposure to hazardous materials[30].

In comparison, about 10 000 people die annually as a consequence of drink driving[31] and, in 2006, a total of about 43 000 people died in road accidents in the EU[32]. The road fatalities where alcohol plays a role (10,000 deaths on EU roads[33]) is 7 times less than occupational health diseases potentially attributed to exposure to hazardous materials.

It is therefore clear that despite the, by global standards, strict EU occupational health and safety regulatory regime, improving risk management practices and the implementation of safer working conditions also require the use of instruments that enhance the understanding at the workplace level of how to make the workplace safer. This is true for many occupational health and safety areas and is certainly pertinent in relation to management of risk from hazardous materials**.**

Guidance and other instruments that aim to enhance the practical risk management of hazardous materials at our workplaces therefore play an important role in promoting the use of less hazardous substances and safer working practices.

1.2 Legislation sets the basic requirements for chemical risk management

Legislation is a primary instrument for controlling risk to workers from chemicals. Legislation addressing chemical risk ranges from specific restrictions of the use of highly dangerous chemicals or hazardous materials, such as asbestos[34] to more general occupational health and safety legislation**;** from environmental regulations to specific major accident hazard legislation or the extensive regulatory framework for transport of hazardous chemicals.

The Framework Directive 89/391/EEC for Occupational Health and Safety contains a basic requirement for a systematic, integrated, proactive and participative approach towards occupational safety and health management at the workplace. Risks must be assessed, controlled and integrated into all activities at all hierarchical levels. The risk assessment obligation *de facto* requires a proactive approach to occupational health and safety management, i.e.

> "*All hazards to the safety and health of workers should be identified and risks arising from them eliminated or controlled in order to prevent occupational accidents and work-related diseases*".[35]

Legislation specifically directed towards controlling chemical risk at the workplace contains a clear principal requirement to consider and, where possible, apply substitution. This requirement is in-

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[30] http://www.etui.org/Topics/Health-Safety/Chemicals-and-REACH

[31] http://www.etsc.eu/documents/Fact_Sheet_DD.pdf; European Transport Safety Council (2008)

[32] http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Road_safety_statistics_at_regional_level

[33] European Transport Safety Council (2008)

[34] Council Directive 83/477/EEC on the protection of workers from the risks related to exposure to asbestos at work

[35] EU-OSHA (2010)

cluded in both the Directive for Chemical Agents[36] and in the Directive for Carcinogens and Mutagens[37]; in both a clear obligation to substitute where technically possible is stated.

These requirements to use substitution to control chemical risk apply to all types of enterprises in all EU countries. Nevertheless, shortcomings in implementation of the requirements at the workplace level as well as shortcomings in the enforcement of substitution and risk control were seen as being common, even prevalent, by the authorities interviewed during the course of this work. This understanding of the situation in the field is mirrored in the Community Strategy on Health and Safety at Work for the period 2007-2012[38], which emphasises the need to strengthen the implementation of the EU legislation in the Member States.

Occupational health and safety legislation often emphasises chemical risk management through the company's own risk management systems. However, unlike under environmental legislation or chemical major accident hazard legislation, there are neither occupational health and safety chemical permits nor strictly prescriptive consent conditions that need to be met. Perhaps as a consequence of this, substitution to decrease chemical occupational health risks is a risk management instrument that is not widely applied. Risk management trough substitution is also seen as a requirement that is particularly challenging to enforce.

Environmental legislation has a long history of restricting or banning the use of highly hazardous chemicals and, in the EU, rather effectively controls the release of any substances to the air, water or soil. **Chemical major accident hazards** are also tightly controlled through the EU Seveso II Directive[39] that imposes strict safety demands on operators of major accident hazard potential installations**.**

Umbrella chemical legislation such as the REACH regulation[40] brings further obligations to manufactures and users to assess and control risks to workers, the public and the environment. REACH together with the CLP[41] is expected to improve on the quality and uniformity of safety data sheets, giving more consistent data on hazards and risks and enabling more consistent risk assessments.

Chemical risk management cannot be only a task for experts. An expert forecast in a recent study recognised 8 different chemical risks as strongly emerging in the workplace[42]:

1. nanoparticles and ultrafine particles;
2. **the risks resulting from the poor control of chemical risks in SMEs;**
3. **outsourced activities performed by subcontracted workers with poor knowledge of chemical risks;**
4. the increasing use of epoxy resins;

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[36] Chemical Agents Directive 98/24/EC

[37] Council Directive 2004/37/EC - carcinogens or mutagens at work

[38] Eur-Lex, webpage

[39] Seveso II Directive, Council Directive 96/82/EC on the control of major-accident hazards incolving dangerous substances; Directive 2003/105/EC of the European Parliament and of the Council of 16 December 2003 amending Council Directive 96/82/EC

[40] REACH Regulation 1907/2006/EC

[41] 1272/2008 CLP Regulation

[42] EU-OSHA (2009)

5. the exposure to dangerous substances in the treatment of domestic, clinical and industrial waste;
6. dermal exposure leading to skin diseases;
7. diesel exhaust;
8. isocyanates.

Control of chemical risk in SMEs was seen as the second highest emerging risk, followed by outsourced activities – often also to SMEs. In SMEs, expertise in chemical risk management is not commonly held in-house. The sheer complexities of taking a truly scientific approach to chemical management can make the task of practical chemical risk management so daunting that the task is, in effect, not even attempted. In order to increase workplace health and safety through reduction of chemical risk by applying substitution, substitution cannot be a task only for experts. The real need for guidance and help is within the workplaces where there is little or no chemical risk management expertise.

Reflecting this target audience, whilst innovation and product development work aiming for safer products and process are acknowledged as vital, the developed guidance does not in detail address substitution of, for example, substitution of reagents in chemical reactions or more complex cases where substitution requires extended research and development work. Substitution can be a complex process and in large organizations substitution potential would often be evaluated by a large team with members from quality control, engineering, production, R&D, purchasing, safety, environment, occupational hygiene, maintenance and management as well as workers who carry out the actual handling of the material. In the vast majority of enterprises, one person will have to manage all these aspects. **The main target audience of the guidance is companies where chemical risk management tends to be the responsibility of one person, who may have limited possibility to reach and maintain high scientific understanding of chemical risk.**

Substitution of very hazardous chemicals is, as indicated in the previous section, a firm part of the regulatory framework in the EU, through for example the Carcinogens and Mutagens Directive or the authorization process for substances of very high concern under REACH. Substitution may also be an element in each company's day-to-day product stewardship, product development and innovation activities. Both processes may lead to substitution but are quite distinct in nature. This study focuses on substitution as an element of day-to-day risk management.

Managing chemical risk effectively is a task that often requires knowledge, determination and sustained effort towards better practices. An understanding of how chemicals affect health and how to minimise negative impacts can however be hard to come by. The effects of chemicals on humans, the environment or other material are often due to complex interactions at a molecular, cellular or sub-cellular level. Equally effects can be seen at the ecosystem or global level. The scientific or expert literature dealing with chemical health effects is often very technical and chemical risk management is consequently both a vast, difficult and rapidly evolving subject. Legislation can be highly technical and the text both detailed and complex. This complexity is perhaps the inevitable result of a quest for better knowledge, better control and better understanding of chemical effects. Nevertheless, it clearly also makes it a very challenging subject for the non-expert to approach.

Practical chemical management is never an isolated task, but a balancing act with the target of finding the best possible solution that minimises risk to health, safety and environment yet is both practically possible and financially viable. Much effort by authorities and organisations ranging from the United Nations (UN) to European Trade Union Confederation (ETUC) has been directed towards translating chemical properties into easy to understand classes and symbols of risk, such as the European Risk Phrases[43] or the Globally Harmonised System's (GHS) Hazard statements and warnings[44] as implemented in the EU through the CLP regulation. **The existence of relatively user-friendly data is however not enough: The user must also have a degree of knowledge of how to use this type of data. Here there is a clear need for more tools, guidance and practical help.**

1.3 Substitution as a preferred risk reduction measure

The hierarchy of preferred measures to reduce chemical risk[45] are firstly elimination, secondly substitution and thirdly, protection. Despite this, in the majority of workplaces, the most widely used measures are some form of protection from chemical risk, including engineering solutions, protective equipment such as ventilation equipment, organisational measures such as procedures or use of personal protective equipment (PPE).

Stopping the use of the chemical (elimination) obviously effectively removes the chemical risk, but it is not always a possible solution. One example of elimination that has had quite an uptake is the introduction of cleaning methods which remove dirt without using chemical. At the same time, this may come at the expense of increasing some other type of risk, for example pressure spraying may bring risk of noise and vibration. Elimination should therefore not be made without considering the overall implications. The same issue of risk type transferral could occur as a result of substitution: the potential of increasing other risks and the consequences to overall risk levels must therefore always be taken into account.

Promoting substitution as a potential risk reduction measure requires workplaces to change the way they work, which may raise resistance (e.g. why should we change). Substitution is generally viewed as a difficult task requiring specialists or something authorities do (e.g. by banning certain chemicals). In many workplaces, substitution may never have been even considered as a potentially viable risk management measure. Should substitution perhaps be described as a theoretically applauded and promoted way of reducing chemical risk that more seldom is put into practice? During the study

[43] Dangerous substances directive i.e. Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances

[44] United nations (2009) Globally harmonized system of classification and labelling of chemicals (GHS); CLP Regulation 1272/2008

[45] Council Directive 98/24/EC; Article 6: "substitution shall by preference be undertaken, whereby the employer shall avoid the use of a hazardous chemical agent by replacing it with a chemical agent or process which, under its condition of use, is not hazardous or less hazardous to workers' safety and health, as the case may be. Where the nature of the activity does not permit risk to be eliminated by substitution, having regard to the activity and risk assessment referred to in Article 4, the employer shall ensure that the risk is reduced to a minimum by application of protection and prevention measures, consistent with the assessment of the risk made pursuant to Article 4. These will include, in order of priority:

(a) design of appropriate work processes and engineering controls and use of adequate equipment and materials, so as to avoid or minimise the release of hazardous chemical agents which may present a risk to workers' safety and health at the place of work;
(b) application of collective protection measures at the source of the risk, such as adequate ventilation and appropriate organizational measures;

(c) where exposure cannot be prevented by other means, application of individual protection measures including personal protective equipment" undertaken, it was found that there is an almost polarised view of substitution as a risk management measure: Substitution is seen by some as something continuously done as part of R&D, others raise their hands in defeat and state it is not possible to even consider substitution in their line of business or that all potential changes have already been made. Yet examples of these views may be found within the same industry segment. This has the immediate practical implication that, whilst implementation of and searches for ever better protective control measures continues and is taken "for granted", the step towards routinely even considering substitution as a practical, viable risk management measure is one taken by far fewer workplaces.

1.4 Data interpretation and requirements for tools

A fundamental aim of the work undertaken was to describe and analyse substitution from a workplace, i.e. company perspective in order to evaluate whether a common EU guidance to substitution is needed and if it is seen as helpful. Questions addressed were:

- What makes substitution difficult
- What, if any, makes substitution easy
- What are the constraints for making substitution a practical alternative

The target was to develop an objective view of how and when substitution can be used to reduce chemical risk at workplaces and what type of help, tools and data is needed to enable this.

Not surprisingly it was found that the smaller an enterprise, the less ability or knowledge it generally has to devote to systematic risk reduction. Substitution is often ignored as a potential measure because substitution is either not even identified as a potential measure to consider or it is seen as far too complex a process. One barrier to wider use of substitution clearly emerging from the study was the lack of initial identification of chemicals or work processes or tasks that could – or should – be a primary target for substitution. Much of this is due to a basic need for better understanding of what data related to chemical hazard means and how different choices of work practices or processes can affect risk levels. The main hurdles identified here are:

- **Hazard data interpretation:** Data on what the effects of using the chemical may be is generally presented in the chemical safety data sheet (SDS) through description of the chemical's inherent properties, i.e. through hazard statements or risk phrases and chemical-physical data, backed up by test results. To fully understand what type and extent of effects a chemical may have on a worker or the environment when exposed to the chemical, an ability to interpret the hazard data given in the SDS is essential. This ability is not always available at the workplace.
- **Risk assessments:** To assess the risk from chemical use, the person carrying out the assessment needs to be able to relate the identified hazardous properties to how the chemical is used, i.e. to determine the exposure potential. Variables such as process temperature and ventilation rates, how often the chemical is used and in what kind of amounts and by whom and how these variables may increase or decrease the risk to workers must be identified and assessed in order to arrive at a reasonably accurate estimate of the risk level at the workplace.

- **Control effectiveness assessments:** The control measures in place should be evaluated for how well these reduce risk and what potential there is for a control measure to malfunction or be forgotten. Only then will a full overview of the risk level be achieved.

If a company already has difficulties in carrying out these fundamental steps of chemical risk management, it is not hard to see why chemical substitution is not more widely used as a risk management measure. Within the research undertaken for this study, a main target was to evaluate whether it is possible to develop a simple enough approach to substitution that would enable more workplaces to consider substitution. In view of the identified barriers, such an approach would need to include a way of making chemical risk management more accessible to companies of all sizes and with different levels of internal expertise on chemical risk.

Starting with an assessment of technical performance and efficiency of alternatives or comparative cost-benefit analyses may be possible for some companies. However, for perhaps the majority of EU workplaces, chemical substitution will not and cannot be approached until risk assessments are made easier. Whilst there is indeed much guidance and many tools available for risk assessment, it was considered that for the substitution guidance to be effective, basic components of hazard identification, exposure potential estimation and risk assessment must be included within the same document, enabling a complete overview of the entire process described in a manner that is easy to apply and does not require expert knowledge. Therefore, the early parts of the developed draft guidance deals in detail with how to do a comparative hazard, exposure and risk potential analysis and how to use this information to identify, assess and implement substitution.

1.5 Report structure

This document progresses from a presentation of the methods used in the research to the results obtained. Chapter two of the report presents the aim and objectives of the study as well as the analytical framework. The used materials and methods are explained in chapter three. Chapters 4-7 present the results that have been obtained through interviews, surveys and literature and web searches. This is followed by a discussion on the feasibility and boundaries for development of a common framework as well as the development process (chapter eight). Finally, conclusions and recommendations are expressed in chapter nine. A Draft Guidance to substitution of chemicals is presented with this report.

1.6 Steering group

The work was initiated by the European Commission's DG for Employment, Social Affairs and Inclusion (DG EMPL) and supervised by a steering group consisting of Antonis Angelidis, Alick Morris and Dr. Alicia Huici-Montagud from the DG EMPL. The steering group provided valuable input into all stages of the work, in particular, to the success of the workshop and through extensive and highly expertise review of the document in hand. The steering group met three times during work, once to initiate the work, for a midterm review and for a final meeting for discussion and approval of the conclusions and the project output.

1.7 Disclaimer and acknowledgements

The objective of the work carried out was to, if possible, provide workplaces across the EU with a systematic process for evaluating chemical risk and identifying chemicals that could or should be substituted and guidance on how to carry out the substitution process. The viewpoints of different stakeholders heard during the research were divided on the subject of how feasible this is or in what format a potential process should be presented. Specific care has therefore been taken to present all viewpoints as well as the objective review of facts. It is acknowledged that the guidance simplifies scientific knowledge. In places, there are details that could be debated. Indeed, details in the guidance can and should be refined in future editions. A target of this report is to provide a stimulus to further research and debate. If any bias is perceived, this is wholly unintentional and the sole responsibility of the authors.

The guidance document does not attempt to produce new science or reveal major new ways of thinking about substitution – it aims to translate scientific considerations of hazard, risk and risk reduction through substitution into something more easily accessible for the target audience. The vast majority of companies within the EU do not have the expert knowledge or resources to undertake state of the art evaluations. Wherever there are simplifications, the authors hope the scientific community and experts in chemical risk management aspects will accept this simplification as a necessity in the effort to reach a larger potential audience and make substitution a more widely used risk reduction measure.

"....Seeking perfection [in methodology] will only ensure that the prevention of work-related disorders will not be achieved for the majority of the world's work force...".

David M. Zalk; Deborah Imel Nelson:

History and Evolution of Control Banding: A Review. Journal of occupational hygiene, 2008

The authors gratefully acknowledge the continuous support and constructive criticism received from the many participating organisations, in particular from the extensive reviews and suggestions provided by the HSE in the UK and the ETUI.

2. Study focus, definitions, aim and objectives

2.1 Focus of the work

The focus of the undertaken work was on chemical substitution from a workers' health and safety protection perspective and firmly founded on the requirement to protect workers' health through effective risk management. The study addressed the objective of the EU Health and Safety Strategy 2007-2012 to achieve a sustained reduction of occupational accidents and diseases in the EU through attempting to provide a practical non-binding instrument[46] that can help organisations and companies to apply substitution and reduce chemical risks to workers. The target set for the work was to reach beyond theoretical studies or list of chemicals to be substituted[47] and to find and analyse potential practical solutions and daily challenges faced by managers contemplating risk reduction through substitution approaches. The work has been a multifaceted undertaking drawing on several scientific and technical disciplines. The focus was throughout firmly on the practical considerations of applying substitution at the workplace. Management sciences and tools such as cost benefit analysis provided fundamental inputs into the work.

Chemical substitution conducted at the workplace can be confused with the Substitution of Substances of Very High Concern (SVHC) which is a distinct process under the REACH Regulation (Annex XVII)[48]. The REACH Regulation also encourages users to substitute with less harmful chemicals when possible. **In chemical substitution based on the Chemical Agents Directive and general occupational health and safety concerns, the prime motor for substitution is a desire to reduce the risk at a particular workplace.** There are however many similarities stemming from the application of the basic principles of substitution as seen in Table 1, where a brief comparison of some key aspects of substitution under REACH (substitution at the EU level) and substitution under CAD (Substitution at company level). **In this work, the focus is firmly on substitution at the workplace level, from a risk reduction objective.**

Table 1: Comparison between approaches to substitution in OSH and REACH

Aspect	Substitution in this project	REACH authorisation process and substitution
Initiator	Risk level or hazard level	Hazard level
The analysis of alternatives or any substitution plan	Technical, risk, feasibility at company level	Technical, risk, feasibility at societal level
Hazard information	Standard data from SDS	In-depth toxicology data

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[46] See for example DG EMPL web pages http://ec.europa.eu/social/main.jsp?catId=151&langId=en;

[47] Santos et al. (2010)

[48] REACH Regulation (EC) No 1907/2006

In the following sections, a brief overview of the vocabulary used is first given, followed by the specific aim and objectives of the study.

2.2 Definition of substitution

Substitution is often understood as referring only to the replacement of the chemical itself. Risk management measures, such as process modification or organisational measures may not always be recognised as adhering to the principle of substitution. Taylor *et al* (2010)[49] defines substitution as "*the replacement of a substance, process, product or service by another that maintains the same functionality*" and emphasise that substitution should take into account effects over the entire life cycle of the replacement product in order to ensure that no unintended negative impacts on human health or the environment take place. They also point out that "*substitution will only be successful where the socioeconomic requirements of all the stakeholders can be satisfied*".

Semantic issues may skew the understanding and it was recognised that such a broad definition of substitution may not be immediately acceptable to all. However, as the context of this report is to support practical risk management at the workplace, it was considered vital to not be too narrow in the definition of what substitution is. Please also see the list of the terms and abbreviations used in this report that is provided at the back of the report. **In this document, substitution** covers risk reduction at source through[50]:

- **Changing the chemical used** to a less hazardous one or eliminating the chemical altogether through use of a different process. If a less hazardous chemical is used in exactly the same way as the one it replaces, this will reduce the risk. If the process is changed at the same time, care should be taken to ensure no new risks are introduced.
- **Changing the physical form of a chemical** to another, that is less likely to lead to exposure. One example is using pellets or slurries instead of powder to minimise dust and reduce inhalation risks.
- **Changing a process or task** to a safer one like using e.g. lower temperature process

Only once it has been established that risk cannot be reduced at source using any of the above means should controlling risk management measures such as the following be considered.

- **Engineering controls such as alarms, safety valves, double skinned tanks and others.** These are often very good options for controlling the risk, but they will not remove the cause of the risk.
- **Administrative controls** such as workplace procedures and training are very important, but while reducing it, do not completely protect from human error.

[49] Chemical Stakeholders Forum (2010)

[50] e.g. as per European Commission (2005); also Council Directive 98/24/EC Article 6: "substitution shall by preference be undertaken, whereby the employer shall avoid the use of a hazardous chemical agent by replacing it with a chemical agent or process which, under its condition of use, is not hazardous or less hazardous to workers' safety and health

- **Personal Protective Equipment (PPE)** will only provide a barrier against exposure to a particular hazard and does not reduce the potential for harm of the hazard itself.

Note that none of the above three measures is to be considered as substitution measures.

2.3 Aim and objective

The aim of this work was to evaluate existing approaches in EU member states and whether it is possible to develop a common approach for conducting substitution of hazardous chemicals within the EU and if so, present such a common approach in a guidance document. Henceforth the term "**common approach"** is used to refer to the overall core steps that must be included in the consideration, evaluation and implementation of substitution. If seen as desirable and feasible to construct, the main output of the work was to be a draft guidance document for chemical substitution that can be used as a "*step-by-step*" guide for identifying, evaluating and implementing practical substitution at the workplaces across the EU. Certain criteria were set for the common approach, e.g. it should:

- Consist of practical methodologies, processes and/or tools for chemical risk management and implementation of chemical substitution principles at workplaces
- Meet the requirements of different industries and different Member States
- Satisfy good scientific practices

The aim of this work has been to address substitution in a way as to support substitution at a practical level. The main outcome of the work is the draft guidance document, for which there were specific set objectives. **4 objectives were set for the provision of a common approach to substitution and guidance:**

1. Provide an overview of successful substitutions
2. Identify and provide examples of practical applications of effective substitution for different types of substitution processes
3. Assess the potential for developing a common approach to substitution at the EU-level, including development of generic or more specific approaches (e.g. substance specific, sector specific, process specific etc.) and, if feasible, propose a common approach/approaches to substitution across the Union
4. Develop practical guidelines for applying the principle of substitution in workplaces, suitable for use by both workers and employers

There were also objectives set for the overall background study. These were set for substitution at a practical level as well as addressing substitution at the policy and societal level. **Objectives related to the substitution process at the policy and societal levels were:**

5. Collate, compare, contrast and evaluate existing approaches to substitution within the EEC area, including generic, substance specific or sector or chemical specific approaches
6. Identify and analyse the policy level drivers (motivators) and barriers to chemical substitution and relate these to industry sectors and company size

7. Analyse the process of substitution from different stakeholder views and identify any relevant sector specific issues and recommendable processes

Objectives related to the substitution process at the practical level:

8. Identify, describe and evaluate the different scientific, financial, technical and management aspects that impact on the substitution process
9. Identify, describe and evaluate the different practical aspects related to chemical substitution processes, identifying common and contrasting elements and their impacts (positive and negative) on the company applying the principle of substitution
10. Identify the key aspects contributing to challenges and success in chemical substitution processes
11. Identify and analyse how substitution decisions are made and which key factors influences these, including cost considerations
12. Analyse the degree of worker participation and the influence of workers in the implementation of substitution
13. Identify the key motivators to substitution

These three groups of objectives were further broken down into research questions addressed in specific tasks. This allowed the use of a clear task based approach during the work whilst ensuring each objective was equally and sufficiently addressed.

3. Study framework and methodologies

3.1 Research boundaries

The substitution of truly hazardous chemicals has largely been legislatively driven. Legislation and socio-cultural settings each contribute to providing the boundaries within which companies operate and determine the minimum level of “acceptable safety”. The emphasis society puts on preventing risk to workers health and safety has an impact on how much companies are expected to do over and above legislative minimum demands. **Whether substitution is used as a risk reduction measure at the workplace is nevertheless firmly in the hands of the workplace itself.**

Existing literature shows a multitude of well researched examples of why substitution should be undertaken in specific cases and legislation places substitution as second only to elimination in the hierarchy of risk management measures to consider. The overall reasons for why substitution should be undertaken have therefore not, as such, been addressed.

Substitution in this work is considered from a practical workplace level. Hence the central focus is on a company’s internal processes that influence substitution decisions. The research boundaries were set to limit the focus to aspects considered likely to directly influence specific substitution decisions within a company. The research boundaries are shown in Figure 1.

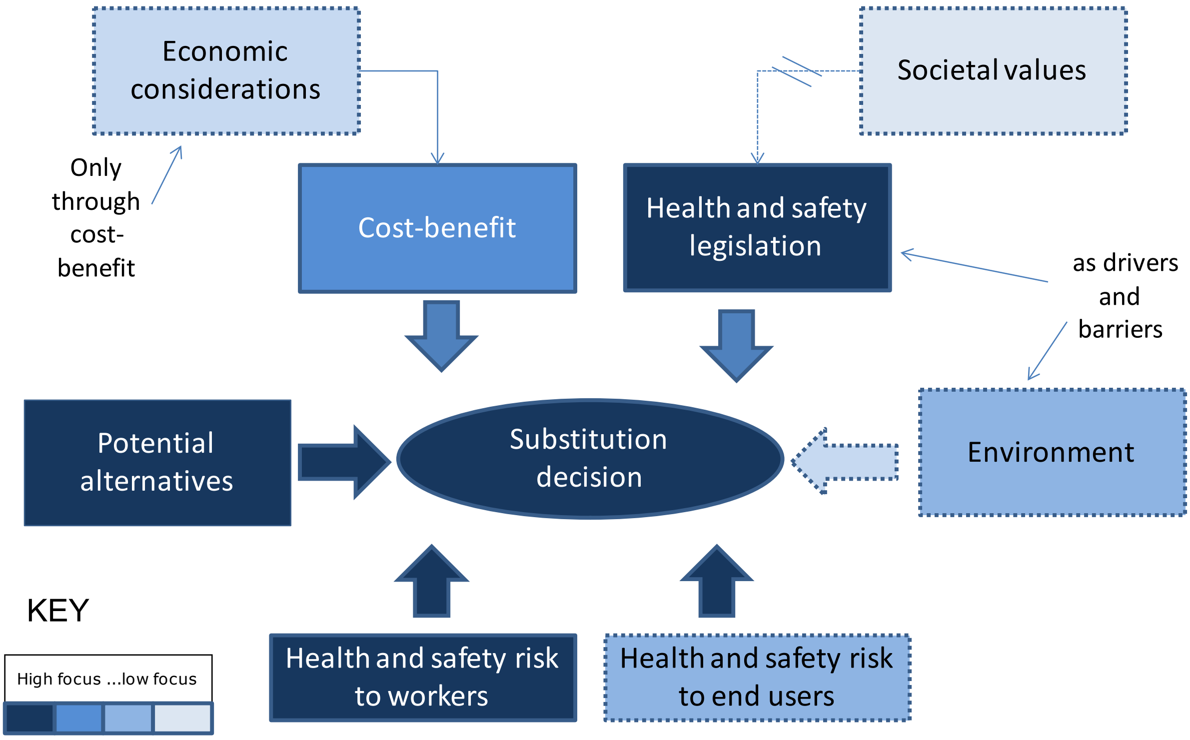

Figure 1: Research boundaries

Health and safety legislation was analysed both as a driver for substitution but also as a passivating force, e.g. whereby authorities are “expected” to carry out substitution evaluations and prescribe which compounds are to be substituted and by when. **Environmental** concerns have only been addressed in terms of drivers or barriers and in relation to potential conflicting influences on occupational health. Environmental risk was not, *per se*, addressed.

When a company sells its product to a customer that is another industry/workplace, the customer's concern for the health and safety of workers or the final end user can be a major motivator for risk reduction (market driven substitution). Therefore some considerations of **health and safety risk to end users** were included within the research. To be able to substitute, **technically feasible alternatives** have to be available. **Cost considerations** are part of a company's reality and a vital consideration when evaluating the viability of different alternatives. Macro-level economics were not included in the scope of this work. Monetary aspects were included only in terms of **direct cost-benefit** structures relevant to the specific decision in hand – i.e. not general economic trends or even company overall financial status.

3.2 The analytical framework

Chemical management approaches taken by a company can be seen as the product of influences within the companies acting conjointly with external influences. The various external and internal influences may form highly complex patterns of interdependency, although this pattern has not, as such, been analysed here in any great detail. Within this work, the focus was on determining **how** different external and internal influences act, not on the more complex interactions and interdependencies. The way these influences act were then analysed to find key challenges, setting the requirements any common approach would have to meet in order to fit in and support practical decision making in companies.

No processes can be seen as undertaken in isolation and both internal and external influences must be taken into account. Both internal influences (within company), external (from society) influences were mapped. The **external influences outside the company** are predominantly, although not always, seen as drivers for enhanced risk management, but the type of force these exert may differ according to country, industry and size of enterprise, to name a few.

Company internal influences form the practical framework within which each management decision must be taken: Funding, strategic priorities, input from workers, level of knowledge of how to evaluate substitution as well as experiences from previous accidents and incidents. Internal influences may include opposing ones; e.g. the company policy is to minimise risk but no funding is allocated to carry out evaluations and/or risk reduction measure implementations. Certain internal positive influences can also be described as motivators, exerting a pull towards substitution through opening a potential for achieving benefits (e.g. better competitive position, savings potential etc.).

The framework for the overall study was constructed around the central point of chemical management within a company or organisation. This process was further broken down into individual steps that precedes or succeeds substitution decisions. The identified steps are shown in Figure 2 in the central pillar. The actual technical implementation of these, i.e. what to do; what data to include and how to actually evaluate alternative options, may have surprisingly strong influences on how often and to what extent substitution is considered within a company. The framework allowed a targeted analysis of each step of the chemical management process and relating this to drivers, motivators and barriers, aiding understanding of what type of guidance may be needed at each decision point.

The relative focus on each of the different aspects is given in Figure 2 using colour coding (see key in top right corner of the Figure).

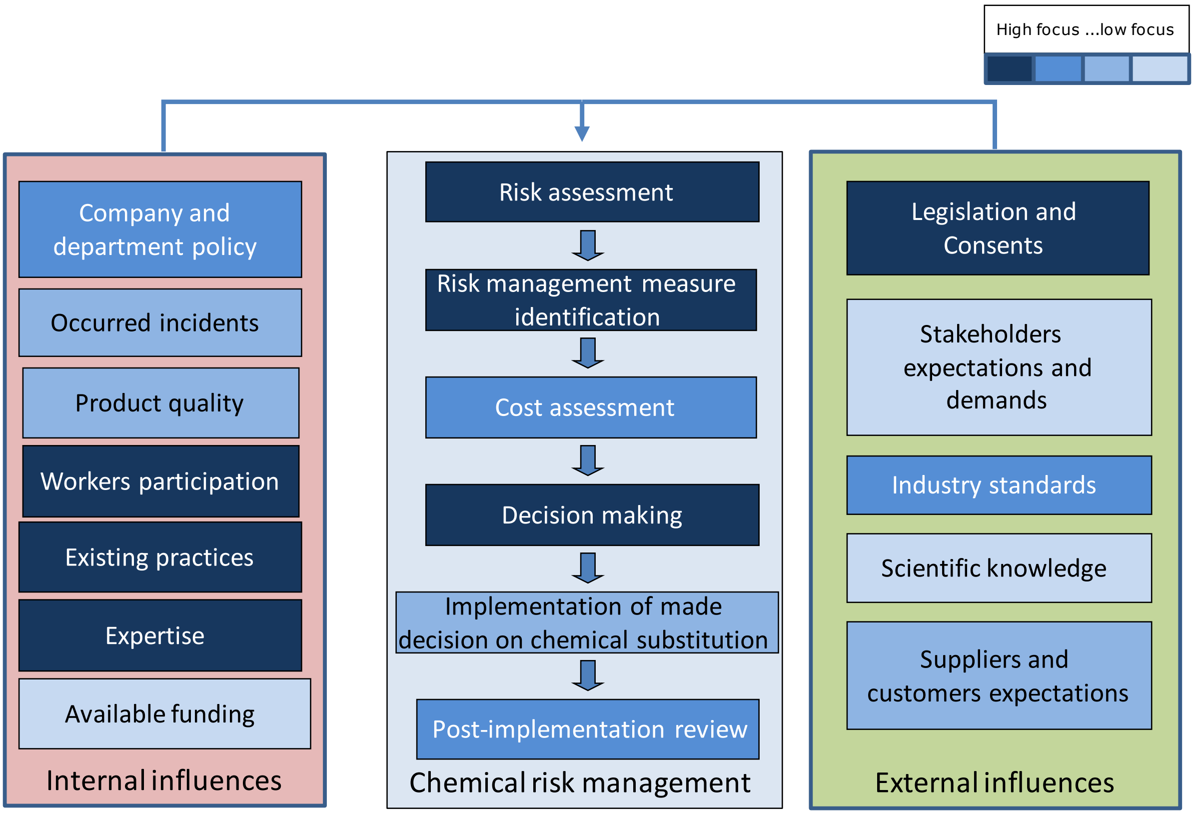

Figure 2: The analytical framework for substitution as part of the chemical risk management process

3.3 Overview of methodologies used

The scope of the study required a combination of different methodologies for data gathering, data analysis and evaluation and identification of necessary elements to include in a potential common approach or framework for chemical substitution. Methods from several different disciplines were combined to give an overall palette of multidisciplinary working methods.

The different methodologies applied are depicted in Figure 3. These can be divided into four different methodological groups: Data collation methods, analytical methods; evaluative and forecasting methods and process development methods. The process development built on the results from earlier work stages. The developed processes were then evaluated for practicality and integrity using the same analytical processes as in the earlier stages.

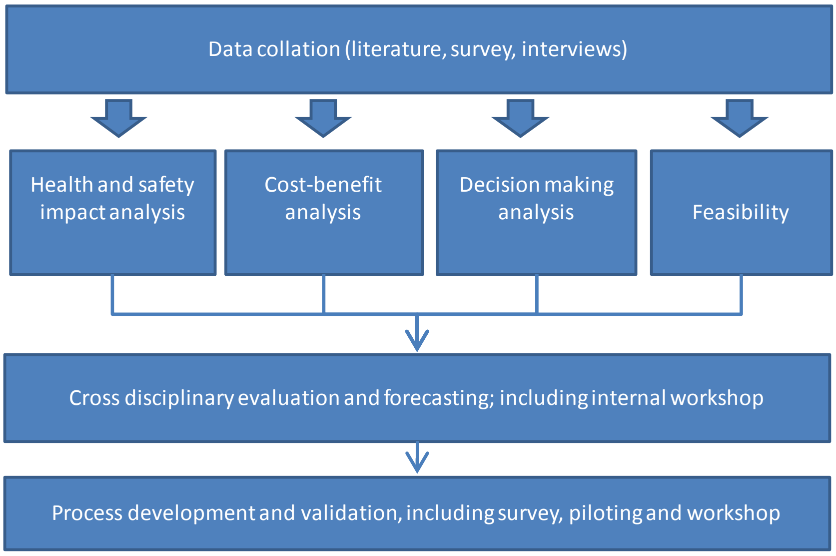

Figure 3: Overview of methodological approaches

The work plan included several iterative stages in order to enable filling in any potential data gaps. In the following sections, the various methodologies are described in more detail.

3.4 Data collation

3.4.1 Data collation overview

The primary data collation included four steps, as illustrated in Figure 4.

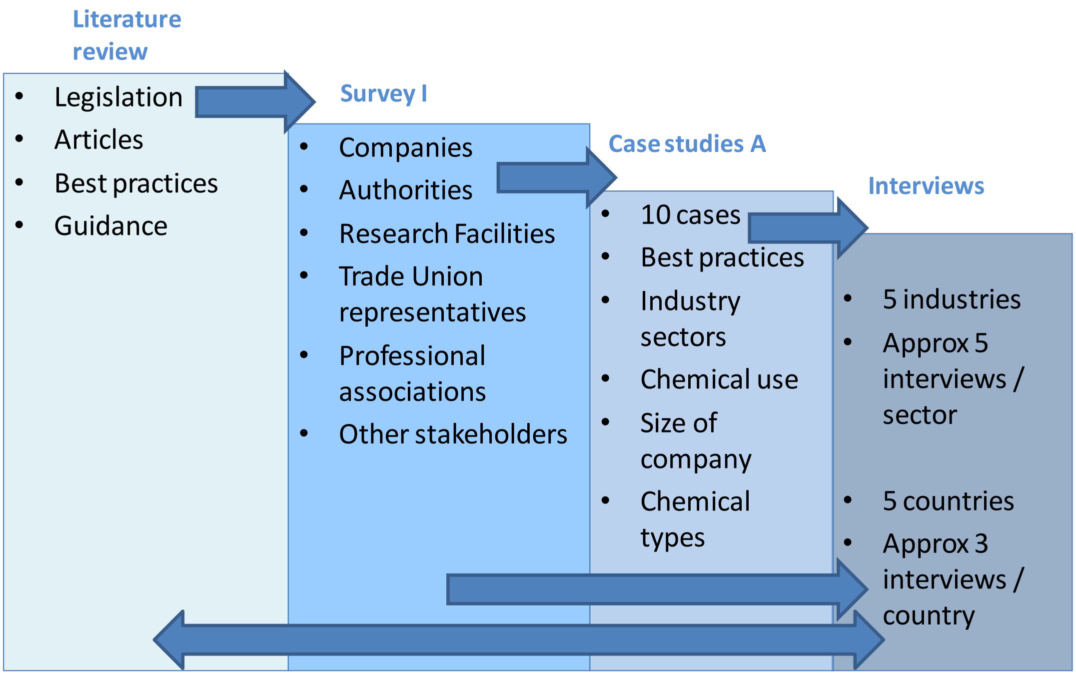

Figure 4: Overview of data collation methodologies used

In order to produce a coherent overview of the existing situation and the requirements for a common approach, the data collation covered the EU and EEA area and relevant legislative frameworks as well as a wide selection of industries. As can be seen in Figure 4, the data collation was iterative, allowing results from later steps to lead to, for example, further literature review. In the following, more specific details for each activity are given. Most of the objectives presented in chapter 2.3 were addressed within data collation – only analysis, assessment or preparing practical guidelines (objectives no 3, 4, 7 and 12) were addressed in later work stages.

3.4.2 Literature review

A review of the existing literature focused on establishing what types of practices for substitution are required, recommended or adopted voluntarily. The geographical scope of the overall work as on the EU and EEA[51], the literature search cast the information gathering net larger. In addition to the overview of existing approaches, examples of existing successful substitution practices and substituted chemicals were collated[52]. The focus was on determining what is required to succeed. Both successes and challenges recognized in the literature in relation to substitution were analysed in order to ensure practical obstacles were considered in the process development.

Publicly available material, mainly on the internet, such as legislation, survey results, reports, scientific articles and guidance material from industry, trade unions and professional associations was reviewed. The aim was to firstly establish a clear overview of legal requirements and recommendations and secondly, to gather background material for the process development on current practices and challenges[53]. The review was conducted using English search words. However, material in other languages was taken into account to a certain extent, but no actual translation of material was undertaken as part of the work. A listing of the documents and other material reviewed is found at the back of the report.

[51] See chapter 2.3; Objective to Collate, compare, contrast and evaluate existing approaches to substitution within the EEC area, including generic, substance specific or sector or chemical specific approaches

[52] See chapter 2.3; Objective to Identify, describe and evaluate the different practical aspects related to chemical substitution processes, identifying common and contrasting elements and their impacts (positive and negative) on the company applying the principle of substitution; Objective to Provide an overview of successful substitutions and Identify and provide examples of practical applications of effective substitution for different types of substitution processes and the Objective to Identify and provide examples of practical applications of effective substitution for different types of substitution processes

[53] See chapter 2.3; Objective Identify, describe and evaluate the different scientific, financial, technical and management aspects that impact on the substitution process; Objective to Identify, describe and evaluate the different practical aspects related to chemical substitution processes, identifying common and contrasting elements and their impacts (positive and negative) on the company applying the principle of substitution; Objective to Identify the key aspects contributing to challenges and success in chemical substitution processes; Objective to Identify and analyse how substitution decisions are made and which key factors influences these, including cost considerations and Objective Identify and analyse the policy level drivers (motivators) and barriers chemical substitution and relate these to industry sectors and company size

3.4.3 Data

Stakeholders targeted

Ten industry sectors were initially selected for closer scrutiny. The decision was taken to allow answers to be clustered and industry specific responses compared. The chosen industries represented a cross section of European Industries and different types of workplaces and dominant gender of work force was considered. Importance was placed on covering differences in how chemicals are used (using REACH process categories, PROCs) and what type of chemicals are used. The included industries are given in Table 2. A few of the sectors, namely chemicals, mining and minerals, engineering, automotive and cleaning and textile, were later chosen for an even closer look.

During the work, it became apparent that the hospitality industry was not easily engaged into the discussion. In addition, it was also considered that the industry's main use of chemicals is likely to relate to cleaning and potential maintenance which was already included as a separate industry. It was therefore decided during the midterm review to not focus effort on reaching this industry. At the same time, it was decided to include more data from the construction industry through a second survey.

The EU is the world's largest motor vehicles producer**,** and the **automotive industry** represents Europe's largest private investor in research and development (R&D)**[54]**. The automotive industry is a large employer, and the number employed has increased over time, especially in relation to employment in manufacturing. In 2008, the European automotive industries employed directly around 2.2 million people, and additional 9.8 million in closely related sectors.[55]

The European chemical industry produces some 30% of the world's chemicals and for example the 29 000 CEFIC members employ approximately 1.3 million people.[56] There is a number of SMEs that engage in chemical production. In the EU, there were nearly 40 000 chemical industry SMEs in 2007 compared with less than 1500 larger enterprises. The chemical SMEs employed more than 600,000 people and generated €386bn in sales.[57]

The construction sector is a strategically important industry in the EU, and the largest sectoral employer as well as a major contributor to Gross Capital Formation in Europe[58]. The sector employed some 14.8 million persons in 2007 and generated nearly 10% of the EU's non-financial business economy's value added (some 562 billion Euros)[59].

The European **electrical and mechanical engineering sectors** together employ over 4.5 million people. In terms of number of enterprises, the mechanical engineering represents one of the largest

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[54] European Commission web pages, http://ec.europa.eu/enterprise/sectors/automotive/index_en.htm

[55] European Automobile Manufacturers´association web pages, http://www.acea.be/index.php/news/news_detail/the_auto_industry_in_2008_recession_strikes/

[56] CEFIC, web pages

[57] ICIS, web pages

[58] DG Enterprise and Industry, web pages

[59] Eurostat data from 12/2009, web pages

industrial sectors in EU, with around 169 000 companies which are mostly SMEs. About 90 % of the European engineering industry's companies are small and medium-sized enterprises. [60]

Table 2: Industry selection (NACE code)[61], description and expected Chemical use processes and main source of information

Industry	**NACE code**	**Brief description**	**Expected Chemical use processes (PROC)**	**Survey 1, 2, interview, workshop**
Automotive	C29	Large workforce; big companies, many chemicals - any impact has large impact within EU H&S	PROC 5, 7, 13, 14	Survey 1 Interviews
Chemicals	C20.1.2 C20.1.3 C20.1.4 C3	Producer & user; large workforce; key area for HS is chemical safety, key for finding best practices; also data on consumer demands (i.e. from customers)	PROC 1, 2, 3, 4, 5	Survey 1 Interviews Workshop
Construction	F	User of chemicals; perhaps little knowl-edge, which would make for a good benchmarking for other industries that use chemicals as a secondary process	PROC 8, 10, 11	Survey 1 Survey 2
Engineering (mechanical and electronic)	C26 C27	Large employer; different chemicals	PROC 14, 22	Survey 1 Interviews
Food industry	C10	Large number of people and companies; female work force well represented	PROC 8, 9, 14, 15, 19	Interviews
Plastics and rubber	C20.1.6 C20.1.7 C22	Substitution issues also from substances in articles	PROC 5, 9, 14	Survey 1 Workshop
Cleaning	N81.2	Female work force well represented, covers many small and micro size compa-nies	PROC 8, 9, 16, 19	Survey 1 Interviews
Mining, metals and minerals	B C24 C25	Very large chemical use, also invested heavily in H&S due to high risk activity, may be good source for best practice	All of the PROCS (except 12)	Survey 1 Interviews
Textiles and clothing	C13	Diverse, large employer, large female work force, covers many small and micro size companies	PROC 5, 8, 13, 15	Interviews

[60] European Commission, web pages

[61] http://epp.eurostat.ec.europa.eu/portal/page/portal/nace_rev2/introduction

Food industry processes and packages products for human and animal consumption. There are some 308 000 companies within this sector, employing over 4.6 million people, of which some 62.5% in SMEs. [62]

Plastics and rubber is generally considered together with the chemical industry. In 2004, there were over 65000 companies in the plastics and rubber sector in the EU, generating some 243 000 million Euros in turnover and employing some 1.7 million people[63]. In this work, the plastics and rubber industries are in general considered together with the chemical manufacturing industries.

The **cleaning** sector in Europe represents one of the most important service industries. The cleaning sector employed about 3.6 million workers in 2006. However, the real figures are considered to be higher due to the high number of unregistered workers in the profession. The sector is mainly composed of small and very small companies. In 2006, about 89% of the cleaning companies had less than 50 employees.[64] Characteristic of the cleaning sector in terms of employment is the high proportion of women. At the European level about 75% of cleaning workers are women. [65]

Mining, metals and minerals sector was in this work approached trough the oil& gas sector, where vast amounts of chemicals are used on a daily basis. **The oil & gas sector** in fact consists of three sectors: Exploration and production, refinery and retail. The retail sector is not dealt with in this study. Hydrocarbon refineries are highly complex examples of process industries, where large volumes of chemicals are used. **The exploration and production** of oil & gas in the EU is most commonly associated with the North Sea, although many other sites also exist. Despite being largely located offshore, EU legislation applies,[66] and based on the high-risk environment an oil platform or drilling rig is, specific legislation on minimum health and safety provisions also apply. [67]

The **textile and clothing industry** is a diverse and heterogeneous industry which covers a number of activities from the transformation of fibers to yarns and fabrics to the production of a wide variety of end products. In 2006 the textile industry employed 2.5 million people and there were approx. 220.000 companies.[68]

The way companies approach substitution was shown initially to appear to be value chain dependent. It was therefore decided to analyse the differences and similarities between various sectors and industries through a value chain approach rather than a specific industry based approach. This allowed for some generalisation and a potentially wider applicability of the results. The industry sectors chosen for the study focus are depicted in Figure 5 in the value chain. Note that the positions of individual parties may vary in specific value chains.

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[62] Eurostat data from 2006, web pages

[63] Eurostat, 2005 Chemicals, plastics and rubber, web pages

[64] EU-OSHA, The occupational safety and health of cleaning workers, web pages

[65] European Federation of Cleaning Industries, web pages

[66] Oil platforms are regulated under the Directive (94/9/EC). Workers on oil platforms are protected under the Framework Directive (89/391/EEC), which applies to all sectors.

[67] Council Directive 92/91/EC

[68] European Commission, web pages

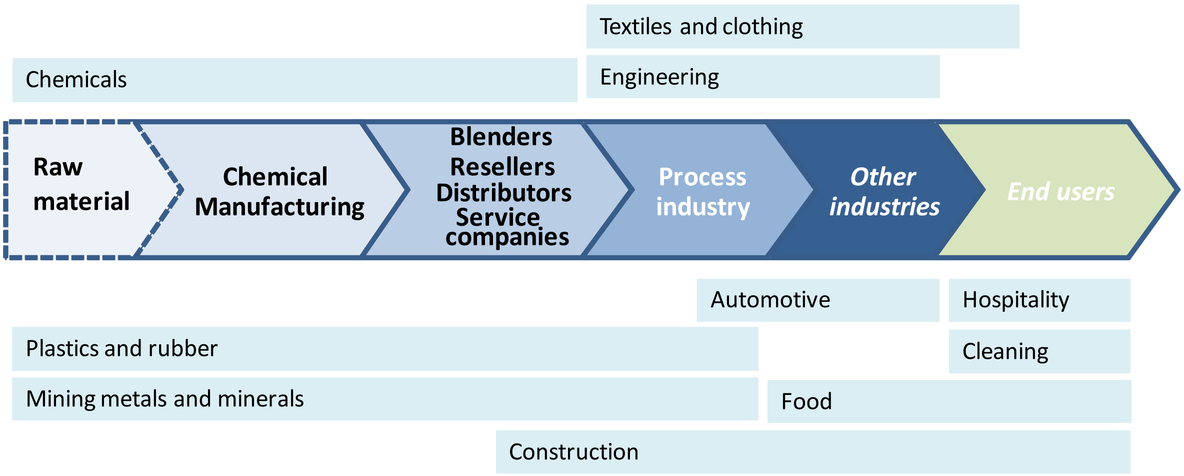

Figure 5: The value chain used and examples of industry positions

As a rule of thumb, the more important a specific chemical or material is in terms of functionality, the less easy it will be to substitute. If it is not of vital importance to specific processes, then a slighter pressure will lead to substitution. For a manufacturer, substitution may require changing an entire process (line or factory) whereas for a retailer or end user, this may just entail changing your supplier or making demands for your supplier to change their processes. The different positions in the value chain therefore have different drivers and different readiness to substitute.

In this study, **raw material suppliers** are discussed only in relation to the impact raw material supply can have on substitution. **Chemical manufacturers** include both very large companies and smaller, specialised companies that produce chemicals utilising different chemical reaction pathways. Both were included. **Blenders, resellers and distributors** have yet a different outlook on substitution from chemical manufacturers. They do not make chemicals through chemical reactions and often aim for added value through providing specific chemical service solutions. Resellers and distributors are shown in the same value chain position as blenders; in reality they may also occupy later positions in the value chain. This segment provided some very interesting results and case studies. **Process industry** is here used as a term to describe industry where chemicals are used within the processes themselves to perform a specific function, such as within the paper and pulp industry. This may or may not include chemical reactions but often require very specific chemical or molecular functionality. **Other industries** represent industries where chemical functionality is less specifically determined, but the chemical is still incorporated into an end product, such as paint in the automotive industry. Note that in reality other industries are in effect in the same value chain position as process industries, but for the sake of clarity have here been depicted as a separate position. **End users** are companies or organisations that actually **consume the end product** of the earlier value chain, e.g. a cleaning company using cleaning chemicals or a painting and decorating company using paints. Consumers such as private persons or companies buying cars were not included in this study. Neither were resellers such as hardware stores or supermarkets included, although their potential influence, mainly as motivators to supply less hazardous chemicals is briefly discussed.

Other stakeholders included representatives from European workers federations and industry associations but also professional organisations and research organisations. The study also included occupational health authorities and authorities concerned with chemical safety in a broader meaning (including industrial process safety, environmental safety, end product safety and chemical safety to workers).

Surveys

An internet survey using the webropol tool (www.webropol.com) was conducted in the spring of 2010. Targeted mailing lists were generated by CEBUS[69], through professional networks of the authors and through the review of the literature. Recipients were sourced from each EU country, Norway and Switzerland.

The survey was sent out to over 5000 recipients covering the target groups shown in Figure 5. Company recipients for the survey included enterprises of all sizes. The survey was sent to either the HSE manager /director, to workers HS representatives or, in smaller companies, to the managing director. The recipients were encouraged to send the survey to other potential interested persons and the project website included an open invitation to participate in the survey.

The survey questions were designed to allow current practices, requirements, challenges and motivations to be analysed. The survey was also a mean of identifying best practice case studies of substitution and piloting companies. Specific care was taken to ensure that gender-related views and information was gathered. Questions on unsuccessful substitution cases were included to gather information on potential cases in which substitution did not work. The survey questions were divided into six main groups as follows:

1. Substitution at policy and societal level
2. Guidance to substitution
3. Substitution at a practical level: Current state of play
4. Substitution at a practical level: Decisions
5. Substitution at a practical level: Experience
6. Substitution at a practical level: Future

A summary of the survey results are given in Annex 2 of this study report. The further analysis of the results is included in the discussion in Chapters 5-7.

The survey was not successful in soliciting responses from companies. The most likely cause of this was the attempt to use a commercial provider to send out the link to the survey in order to approach a large number of recipients. This may have caused too many of the emails to be marked as junk mail. Another highly likely cause was the excessive length of the survey, caused by the requirement to cover the multitude of objectives set for the work. Although several short cuts from questions were allowed, the inclusion of all objectives and sub-objectives resulted in the overall time taken to go through the survey was too long. The overall responses obtained represented a very low response percentage. The analysis of responders concluded that this represented a relatively good response from authorities (20 answers). From companies, a far too low a rate of answers was obtained. To compensate for this, additional interviews were carried out, specifically targeting such industries were response rates were low. Additional information about substitution practices within

[69] See www.cebus.net

the construction sector was also collated through a short gallup type survey in the UK and Finland (in person and by telephone). Altogether 45 answers were obtained. This survey was much more successful in reaching the intended target organisations. The results are shown in Annex 3.

Case studies

Originally the study plan included the preparation of a number of case studies representing best practices of chemical substitution. However, during the work it became evident that the need for and benefit of selected case studies is low for the general audience. Specifically during the workshop, it was concluded that it would be of more practical value to provide generic, illustrated examples of how to proceed through a specific step in the developed process. Especially the early risk assessment steps were seen as needing “worked examples”. Therefore the chosen case studies focused mainly on how to proceed through a specific work step in the overall substitution process and the results are shown as a part of the guidance document. The worked examples are from companies of different size and industry sectors. They also cover different types of chemical uses and different types of substitution approaches. The main research questions for the case studies are presented in Figure 6.

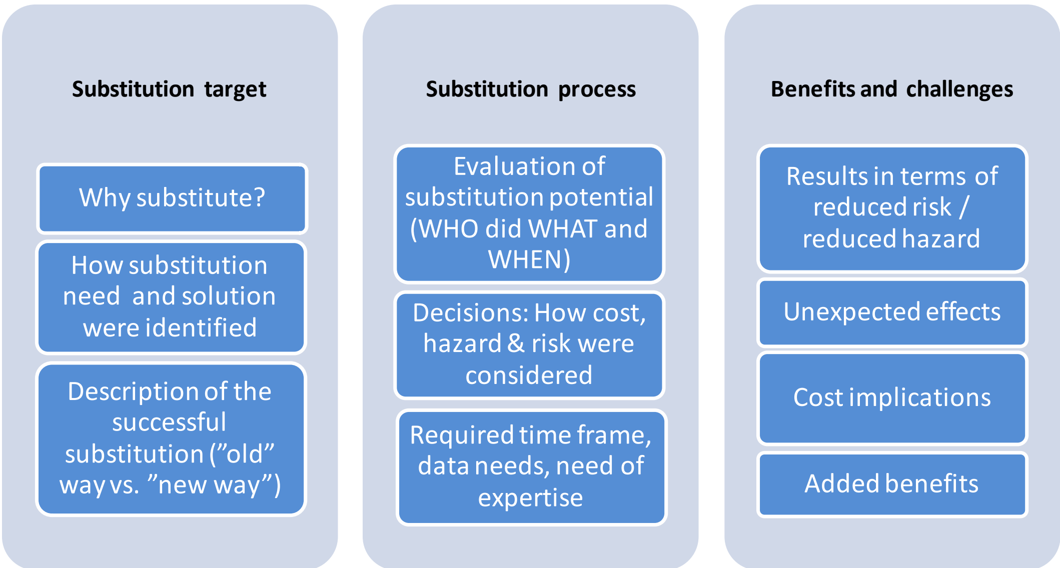

Figure 6: The case study research questions

Interviews

Interviews were conducted face-to-face, via the phone or by writing. Altogether 62 persons were interviewed and the list of these interviewees can be found in Annex 1. Some of these people were interviewed several times and some of the interviews were in-depth interviews (see Chapter 3.3.3). The original target was for 40 interviews, and the decision to increase interviews was done in agreement with the steering group in order to compensate for the low survey response rate. The aim of the interviews was to give a more in depth overview of selected countries and value chain positions to allow valid conclusions that relate to practical issues and to ensure relevant societal issues were identified. The research questions were the same as for the survey, albeit allowing a more detailed examination of a particular segment of industry or a country.

Industry specific interviews: Five industrial sectors were selected for closer examination. The selection criteria included company size; relevant REACH process categories; geographical coverage of industry within the EU; worker gender balance; chemical use intensity; relative chemical risk associated with industry; balance between short term safety issues and long-term exposures leading to occupational health diseases; relevance of chemicals in primary processes (i.e. needed as part of main production or used for maintenance only) and relative number of workers within that industry. The potential for finding best practices was also considered.

The selected industries were engineering, textile, cleaning, chemical, and a specific part of the mining, metals and minerals sector, the oil & gas sector. For each of these, approximately five interviews were carried out and each included interviewees from different sized companies in different geographical sectors. Representative of a workers federation or a workers' health and safety representative in a large company and representatives of the industry organisations were also interviewed.

Country specific interviews: To get a more in-depth overview of approaches, drivers and barriers within specific countries, five different countries were selected. The selection was based on differences in occupational health regulative regimes, different types of industrial background, and the relative effort put into the area by authorities in recent years. The selected countries were: Finland, France, Germany, the Netherlands and the UK. All of these are recognised as active within the field and all have a slightly differing distribution of responsibilities between the relevant authorities within the country. Fifteen interviews were carried out, three interviews per member state. The interviewees were first and foremost from the occupational health and safety authorities, which are slightly differently organised in different member states. These first contacts were then asked to name other experts or specific organisations in their country.

Other stakeholder interviews: In addition, interviews with other stakeholders were carried out. These included ETUI, OSHA, ECHA, ILO, ISTAS, WWF and IVL.

3.5 Analysis and evaluation

3.5.1 Overview

The analytical and evaluative work of the collated data was carried out in several stages. In the first stage, the external and internal influences on companies and organisations depicted in Figure 7 were analysed. The analysis was iterative and initial conclusions drawn from the literature study were subjected to validation via survey 1 and discussed in the interviews. This is described in Section 0. Secondly, the existing approaches were analysed from several points of view and subjected to cross-disciplinary evaluation in an internal workshop by the team. During the course of the work, a proposal for a common approach was built up stage by stage in an iterative manner (Section 0).

3.5.2 Assessment of drivers, barriers and motivators

A core objective of the study was to identify the drivers and barriers to chemical substitution[70] and, to a lesser extent, the mechanisms by which these act. Such drivers and barriers are often not manifested through easily measurable objective impacts. These difficult to quantify variables can be among the most important factors influencing final decisions. Societal trends and expectations act not only from the outside of the company, but also format the mindset of the people making decisions within the company. In this study, the focus was on identifying and, where possible, providing a means of estimating the relative impact of internal and external drivers (and motivators) as well as barriers to substitution (see Figure 7).

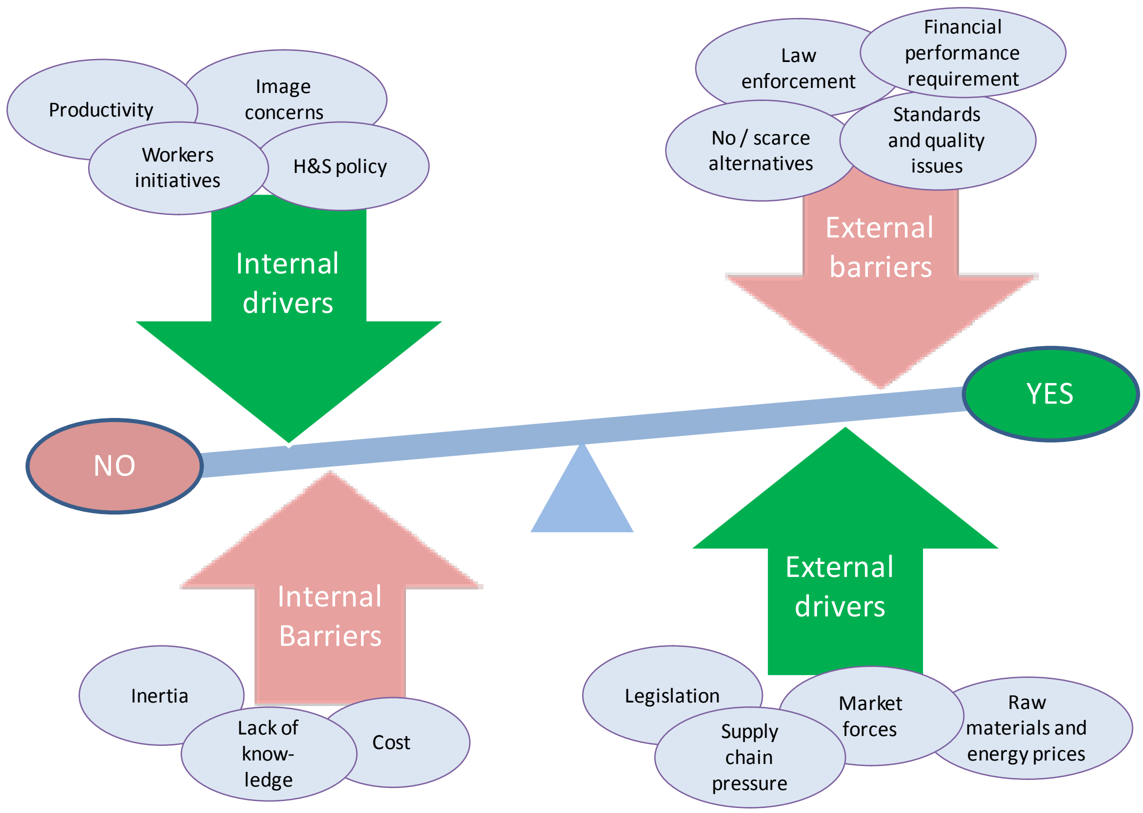

Figure 7: Examples of some potential external and internal drivers and barriers to substitution

The assessment of the relative impact and impact mechanism of drivers/barriers as policy instruments were, however, outside the scope of this study. The analysis initially aimed to categorize and list the barriers and drivers and also addressed the relative importance of these and potential variation in relation to the key variables: Company size, country, industry, chemical use (type of chemicals, amounts used, processes used in). However, as the number of answers to the survey was not

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[70] See chapter 2.3; Objective to Identify, describe and evaluate the different scientific, financial, technical and management aspects that impact on the substitution process; Objective to Identify, describe and evaluate the different practical aspects related to chemical substitution processes, identifying common and contrasting elements and their impacts (positive and negative) on the company applying the principle of substitution; Objective to Identify and analyse how substitution decisions are made and which key factors influences these, including cost considerations; Objective to Identify the key motivators to substitution and Objective to Identify and analyse the policy level drivers (motivators) and barriers chemical substitution and relate these to industry sectors and company size

sufficiently large to allow for statistically significant conclusions, this analysis of relative importance was not included in the final work.

3.5.3 Assessment of existing approaches and development of requirements for a common approach

Overall evaluative approach

The objectives addressed through the evaluations undertaken were:

- Evaluating approaches, or models, that exist at national or EU level[71]
- Identify and evaluate the existing cases of substitution, including listing the successful cases[72]
- Evaluating successes and challenges of the practical implementation of substitution and the contribution to this process from the key stakeholders[73]
- Developing an argumentation, to describe whether a common approach to substitution can be developed at EU level[74]
- Evaluating the impact of applying the principle of substitution on work organisation and competitiveness of employers[75]
- Evaluation whether specific approaches can be recommended for particular groups of chemicals or specific employment sectors or company size[76]

Firstly, the different areas that influence substitution decisions were identified and further data collected on existing approaches and requirements for how to approach substitution. These were subjected to separate analyses by experts in health and safety, toxicology, ecotoxicology, risk assessment, technical assessment and management decision making. The preliminary findings were then subjected to a cross-disciplinary examination in an internal workshop for the experts. A proposal for the steps to be included in a common core approach to substitution was then developed and subjected to external evaluation in a work-shop for industry and authority representatives. As

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[71] Chapter 2.3; Objective to Collate, compare, contrast and evaluate existing approaches to substitution within the EEC area, including generic, substance specific or sector or chemical specific approaches

[72] Chapter 2.3; Objective to Provide an overview of successful substitution

[73] Chapter 2.3; Objective Identify, describe and evaluate the different practical aspects related to chemical substitution processes, identifying common and contrasting elements and their impacts (positive and negative) on the company applying the principle of substitution and Objective to Analyse the process of substitution from different stakeholder views and identify any relevant sector specific issues and recommendable processes

[74] Chapter 2.3; Objective Assess the potential for developing a common approach to substitution at the EU-level, including development of generic or more specific approaches (e.g. substance specific, sector specific, process specific etc.) and, if feasible, propose a common approach/approaches to substitution across the Union

[75] Chapter 2.3; Objective to Identify, describe and evaluate the different practical aspects related to chemical substitution processes, identifying common and contrasting elements and their impacts (positive and negative) on the company applying the principle of substitution

[76] Chapter 2.3; Objective to Assess the potential for developing a common approach to substitution at the EU-level, including development of generic or more specific approaches (e.g. substance specific, sector specific, process specific etc.) and, if feasible, propose a common approach/approaches to substitution across the Union

part of the final analysis and evaluation after the workshop, a data gap analysis was undertaken and any identified missing data sought using interviews and further literature searches.

The overall evaluation of the necessary requirements for substitution approaches is depicted in Figure 8 and described in the following sections.

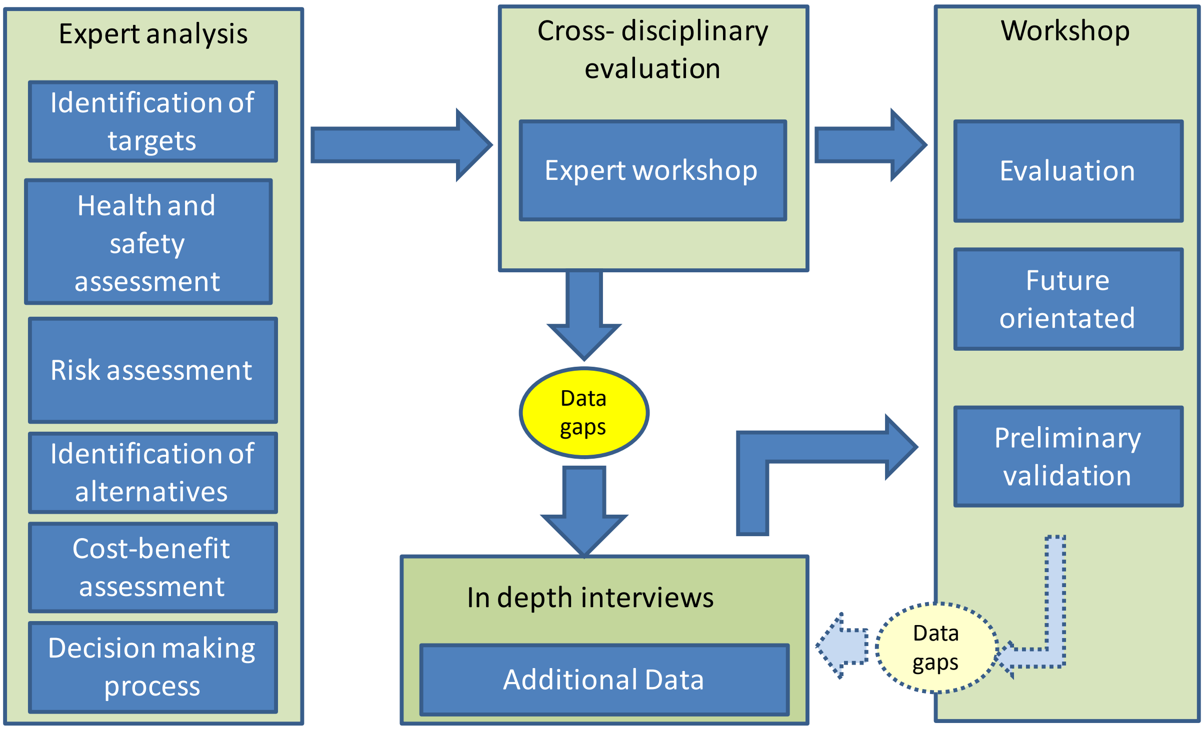

Figure 8: The analytical and evaluative work stages

In the following, each of these work stages is described in more detail.

Expert analysis of requirements for a common approach

The collated data from the literature and primary research was analysed through the views of several different disciplines and approaches. The review included two considerations, namely:

- what is done in existing approaches
- what should be done in an ideal approach to substitution and
- which steps are absolutely essential for all substitution assessments and which ones are more industry specific

The analysis addressed six different areas:

1. **Identification of targets,** i.e. how is and how should identification of need to consider substitution of specific chemicals be done.
2. **Health and safety assessment;** i.e. what are the hallmarks of reliable results from a toxicological, medical and occupational hygiene point of view, how should potential uncertainties be taken into account and how aspects of ecotoxicology and chemistry are incorporated. At the same time, the requirements for a scientifically valid process were debated.

3. **Risk assessment**; looking at how chemical risks are and should be assessed in order to utilise the data for targeted substitution.
4. **Identification of alternatives;** e.g. looking at how alternative applications to specific hazardous chemicals or processes are and should be identified and assessed.
5. **Cost-benefit assessment**, where the approaches and requirements to evaluate the overall costs and benefits of substitution with specific alternatives was scrutinised both from a shorter and a longer time perspective.
6. **Decision making process;** where the potential for companies to use particular methods/ approaches or guidance documents was analysed from a management point of view, looking to find out if it supports companies to assess the practical feasibility of carrying out particular substitution

The approach to each analytical area is described in more detail in the following.

Identification of targets for substitution

Identification and prioritisation of high risk chemicals or processes are fundamental steps in any successful chemical management scheme. The questions addressed were:

- How systematically are priorities identified and what is required from a prioritisation process?
- What aspects are taken into account and which ones are essential?

A specific area of interest in this part is whether the identification of targets is risk or hazard based. All so called lists of chemicals to substitute are based on absolute hazards. **In this work, the approach is risk based and consideration of substitution is seen as a vital step in all chemical risk management assessments, not as a function initiated solely by hazardous properties.**

Health and safety assessment

The approaches for substitution identified in the case study countries were analysed from a health and safety assessment point of view. The analysis for each of the identified approaches was done through a discipline based review. The different aspects analysed concentrated on finding strengths and weaknesses and the specific research questions were:

- **Workplace health: Toxicology, medicine and occupational hygiene**
    - Are effects on humans through inhalation, ingestion, dermal or eye contact considered?
    - Are long-term health (occupational diseases) as well as short term health & safety impacts considered?
- **Relationship to environmental risks and hazards: Environment and ecotoxicology**
    - **Does the approach take into account effects on environment** and how are these taken into account in relation to health and safety effects?

- **Workplace safety: Chemistry and chemical safety**
  - Are the risks dependent on the physical form (solid, liquid, gas etc.), and e.g. vapour pressure and boiling temperature of the chemical taken into account?
  - Are potential risks related to chemical reactions considered?
  - Are safety risks included (e.g. explosion risks etc.)

The results on existing approaches were noted down in a standard format. These were then used as a basis for process development and in the cross-disciplinary evaluation. Notably, the differences were not so much related to the details, such as whether inhalation or dermal risks were taken into account, but rather to whether a clear risk based format of assessment was taken or not. Therefore the analytical discussion in later chapters focuses more on the approach to risk assessments.

Risk assessment

The way risk assessments are carried out and how the results of these are taken into account in deciding whether there is a need to reduce risk and consider substitution is of prime importance. Approaches to substitution were assessed in relation to the following:

- **Risk assessment**
  - How should the assessment include estimation of risk through hazard and exposure potential? What examples are there?
  - How is or should exposure potential be defined?
  - How are effects of risk control measures taken into account?
  - What are the identified potential challenges and benefits of the risk assessment when viewed from a risk management point of view and how are these addressed?
- **Substitution as a chemical management measure**
  - How are alternatives to existing chemicals or processes identified and prioritised?
  - How are the alternative assessed?
- **Technology considerations in chemical risk management**
  - Are technological constraints taken into account?
  - How are different technological alternatives assessed?
  - Is this part of the chemical management or wider management process?

Particular attention was paid to acknowledged challenges. The results from this analysis were highly relevant for defining how a common approach could or should be constructed. The consideration of how technological solutions and constraints are taken into account was included here, as if this is not part of the chemical risk management approach, there is a danger of decoupling broader substitution potential considerations from the daily chemical management issues.

Cost-benefit assessment

For a company, cost is a prime consideration, and this holds true for the cost of chemical management. Cost in itself is however not enough, but has to be related to the potential benefit an outlay can bring (e.g. what is the profit potential). Ideally, the cost of applying various chemical risk management measures should be related to benefits achieved from each.

As a minimum, the cost-benefit assessment needs to take into account differences in operational costs and savings. Ideally, the cost of risk should be taken into account. There are no existing widely used standard methods for assessing direct and measurable costs and benefits of risk reduction from chemical substitution, although there are several approaches to costing risk in general [77]. Often this may be an aspect which receives less attention in the overall substitution assessment[78]. The benefits from taking the overall cost potential into account are, amongst others, related to the fact that it makes it easier to compare alternatives and therefore, eases the decision making process.

The analysis included assessment of whether cost-benefit analyses were included in existing approaches as well as analysis of how practical, accurate and encompassing any cost-benefit analysis approach was, and included the following research questions:

- What is required to be known about the cost of substitution?
- What weight is given to costs and benefits in decision making?
- Are direct and indirect consequences of applying the alternatives included and quantified (e.g. cost of risk)?
- What are the challenges related to this aspect of chemical management?
- Is the approach comparative (e.g. business as usual vs. substitution approaches)?

Initially, the objective was to compare approaches for including calculations for intangible benefits through monetisation or used to calculate net present values in some other manner. However, as this was not found in any existing approaches and most interviewees deemed it too difficult to be included, this aspect has only been briefly touched upon.

Decision making process

Prior to any decisions, the company will need to undertake an assessment of the feasibility of implementing potential technical and organisational solutions. Such a feasibility assessment is dependent on specific chemicals, industry, processes and company in questions. In this work, analysis of the actual feasibility of implementing any particular substitution was not included. Instead, the analysis focused on how the feasibility of implementing different substitution solutions is or should be assessed, based on data from the literature and existing guidance as well as from the case studies. Here, feasibility assessments undertaken that did not lead to substitution were of equal interest, as identification of the variables to take into account when making decisions was the primary focus. The assessment undertaken focused on what type of requirements for a framework for feasibility

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[77] Gilbert et al. (2008a)

[78] Gilbert et al. (2009a)

assessments can be identified and how such a framework could be constructed. Related to the study objectives of "*Identify and analyse how substitution decisions are made and which key factors influences these, including cost considerations*" and to "*Analyse the degree of worker participation and the influence of workers in the implementation of substitution*", the following research questions were addressed for existing approaches:

- Have criteria for decision making been clearly defined or described?
- Are cost benefit analysis, risk assessment and feasibility assessment results assigned relative importance in the overall decision criteria?
- Who is included in the decision making process and how are worker representatives heard?
- What is the presumed length and overall timeframe for the decision making?

3.5.4 Interactive methods: Cross-disciplinary evaluation and workshop

Cross-disciplinary evaluation

The results from the described analyses were collated and cross-reviewed. This allowed assessment of whether there were any potentials for conflicts, i.e. for example whether risk assessment fed into the cost-benefit analysis or if these are considered separately as well as whether the potential for conflicting impact on environment (ecotoxicological) and humans (toxicological) as well as interactions between different types of risks to health and safety are considered and how these are addressed. The various properties considered are summarised in Figure 9.

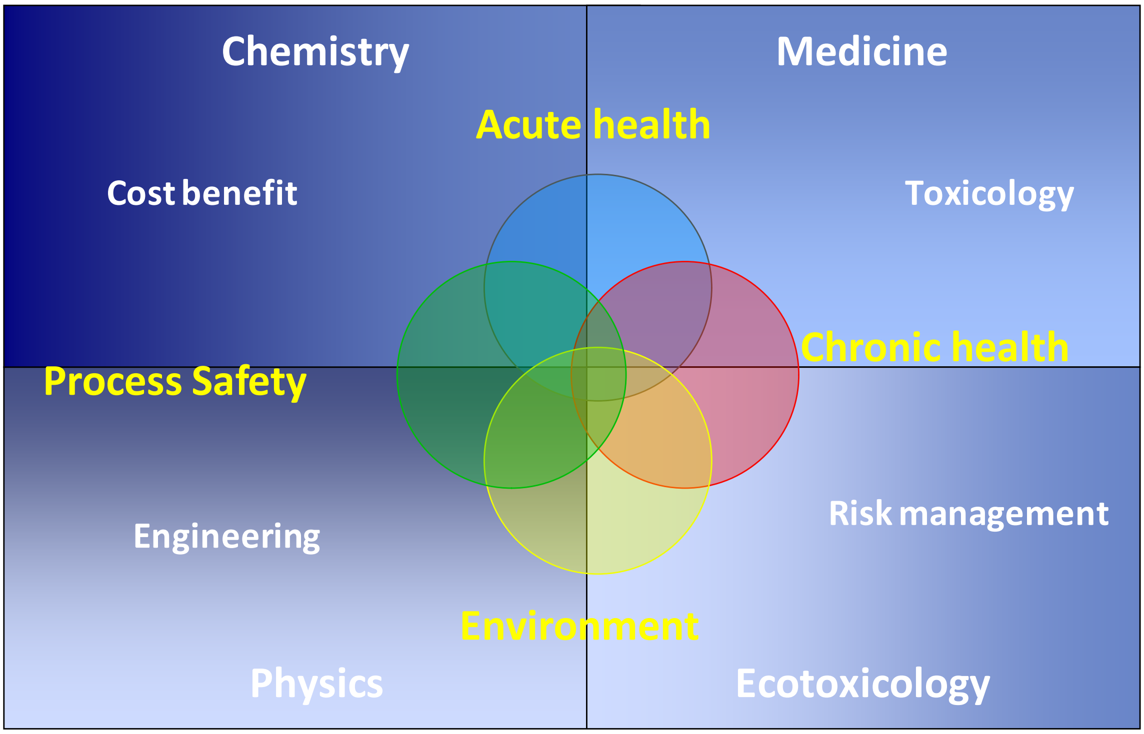

Figure 9: Cross-disciplinary evaluation subjects

The approach enabled creation of an overall picture of the current status as well as of what is required from any process developed. The cross-disciplinary evaluation also considered how to approach measuring the success of substitution in such a manner as to be useful for future decision making in each company.

The results of the cross-disciplinary reviews were further processed in a facilitated working session for the experts, where the aim was to:

- Assemble an overall picture of each evaluated approach, concentrating on the benefits and gaps identified when compared to the requirements as obtained from interviews and survey.
- Identify approaches and tools, which have the most potential for being useful to a wide audience and debate the relative merits.
- Use the results to define the boundaries for a potential model that could address all areas and may have the potential to be used as EU wide recommended common approach to substitution.

The findings were related to the study framework, to policy and to the practical process in a company. The expert working session then concentrated on conducting a cross-disciplinary benefit-drawback evaluation of the tentative early modelling work, specifically with the view of simplifying the common approach so that it meets the requirements of SMEs. The results of the session were used to refine the modelling work and to provide background material to the workshop.

External stakeholder workshop

The results of the analysis and the cross-disciplinary workshop were presented for critique and initial validation in a workshop held in Brussels 28.9.2010. The aim was to clarify and validate the intermediate results, develop initial recommendations and carry out future orientated work. The results of a workshop are highly dependent on the participants and the 26 participants represented EU level organisations, national authorities, recognized experts, workers organisations, enterprises and various industry organisations. A list of participants is contained in Annex 1.

The workshop objectives were to:

- Scrutinise the results critically and refine/validate conclusions
- Evaluate the benefit and drawback potential of a common EU approaches
- Carry out future oriented work (e.g. discussions on what would a common EU approach look like)
- Evaluate and potentially amend a draft proposal for a common EU core process for substitution

Based on the results from the interactive stages, the development criteria for a common approach were refined.

3.6 Developing a common approach

3.6.1 Development work

The development work focused on using the initial results to evaluate whether there is a potential to develop a common approach to substitution. The development work was in particular based on the answers to research questions belonging under objectives "*Identify, describe and evaluate the different practical aspects related to chemical substitution processes, identifying common and contrasting elements and their impacts (positive and negative) on the company applying the principle of substitution*" and "*Identify and analyse how substitution decisions are made and which key factors influences these, including cost considerations"* (see chapter 2.3). These questions were:

- How are chemical substitution decisions made currently and how should they be made?
- What are the practical steps of the process?
- What are the key criteria to be taken into account in identifying, evaluating and introducing a substitute chemical or process?

The main focus was on developing or finding a framework, tools, methods or processes that support practical aspects of substitution at the workplace. The process development was iterative and overlapped in time with the data gathering and utilised both expert modelling and validation stages (e.g. workshop and cross-disciplinary analysis as described in earlier sections). The results are presented in the Draft Guidance document.

The results from the primary data gathering indicated that the companies that are the main target audience for any guidance do neither require nor would they use theoretical guidelines. Instead, a simple step-by-step approach to successfully tackling chemical substitution is needed. The overall substitution process was therefore approached from a very practical angle, using the research framework as a starting point and addressing all variables required for informed decisions. The variables to consider were identified earlier in the work and the process development focused on putting together all the pieces in a coherent yet simple enough overall approach. Despite this attempt to find a simple enough level, it became apparent during the work that the ability of companies to carry out chemical risk management is at such very different levels that two different presentations of the overall approach are needed: a very simple one where the target audience is companies with little or no knowledge in chemicals and a more detailed one for guiding more experienced chemical risk managers through the process. Note that providing guidance for experts in chemical risk management has not been attempted as it is outside the scope of the study.

3.6.2 Validation

The validation process aimed to ensure that the developed approach and the manner in which it is presented (e.g. the draft Guidance Document) are easy to understand, reflect actual needs and enable users from a variety of sectors to successfully undertake the overall process of substitution. The validation process was also used to clarify and discuss means and boundaries for broad dissemination of results to the target audiences.

The validation was done in several stages: In the previously described external workshop, the conclusion from earlier stages that a common approach is desirable and feasible although challenging to construct was validated. A rough outline of the process was also subjected to pre-validation during the previously described workshop. Following this initial validation, a refined process was subjected to commenting by the Working party "*Chemicals at the workplace*"[79]. After this, the process was further refined and constructed into a draft guidance document, which was evaluated through a short survey. The survey questions addressed the practicality and applicability of the proposed guidance. In addition, a possibility to comment or edit the guidance as a whole was given. The survey was sent to approximately 300 persons representing national authorities, companies, industry organisations and workers federations. 50 separate replies were gained, including 24 survey answers and 26 email replies. Notably, the emails and commented versions of the guidance document draft received back were in the majority commented on by several persons.

Finally, the practicality of the developed approach was tested in piloting sessions with three companies. These enterprises were of different sizes and from different industries, in order to assure the proposed methodologies are suitable for different types of organizations. The piloting companies represented

1. end-users of chemicals (e.g. offices where cleaning and maintenance products were the main area of interest);
2. Industry where use of chemicals is not a main part of the process; and
3. A heavy industry where chemicals are used in large numbers as part of processes.

As some of the piloting companies expressed a wish to remain anonymous, the names are not disclosed in this report. For each pilot, the entire approach developed was worked through, from identifying targets for substitution through to analysis of benefits and drawbacks for a specific case for substitution. This included face-to-face evaluation of the process from a practical point of view with the three piloting companies, and the focus here was on identifying any requirements for clarification or modification. The validation through piloting was an iterative process, i.e. refinements /amendments to the process were done during the piloting. The piloting progressed through the following steps:

1. Pilot companies identified
2. A preliminary draft guidance document was sent to the pilot companies
3. Pilot companies assembled the necessary data for testing the process
4. A site visit was undertaken, during which the process was run through in its entirety and feedback on its practicality was taken
5. Required amendments and clarification were done

Based on the validation results, the overall process was finalised.

[79] During meeting for the Working party "*Chemicals at the workplace*" 20.10.2010 in Luxembourg

3.7 Reporting

The reporting included a research report (in hand) and the development of a draft Guidance document. The study report content follows traditional research report content and contains the details of the work undertaken, the results had and the development process as well as a discussion on the potential benefits and drawbacks from applying the process. It is intended to shed light on the development process and record the decisions made and reasons why as well as to provide a critical review of existing approaches. Most of the effort was however placed on the Draft Guidance document. The objective of the Draft Guidance document is to communicate and promote good practice in effective chemical substitution across the EU. It presents a number of practical steps and is intended to be used as a framework tool to enable employers and workers to apply the principle of chemical substitution in EU workplaces. The Draft Guidance includes supporting case studies i.e. practical examples of substitution.

4. Policy, legislation and information sources

4.1 Introduction

4.1.1 Relevant policy and legislative areas

Chemical risk reduction is a topic that is addressed in several different legislative and policy areas. Most prominent of these are occupational health and safety, process safety and environmental protection. National and EU policy is in turn influenced by work undertaken and recommendations by certain supranational organisations, of which the UN and OECD are the most prominent.

In this Chapter, the supranational organisations work in the chemical risk management arena is addressed first, followed by an overview of EU level policy and legislation. National approaches in the selected five case study countries are presented after the EU legislation. The actors considered in this work are depicted in Figure 10.

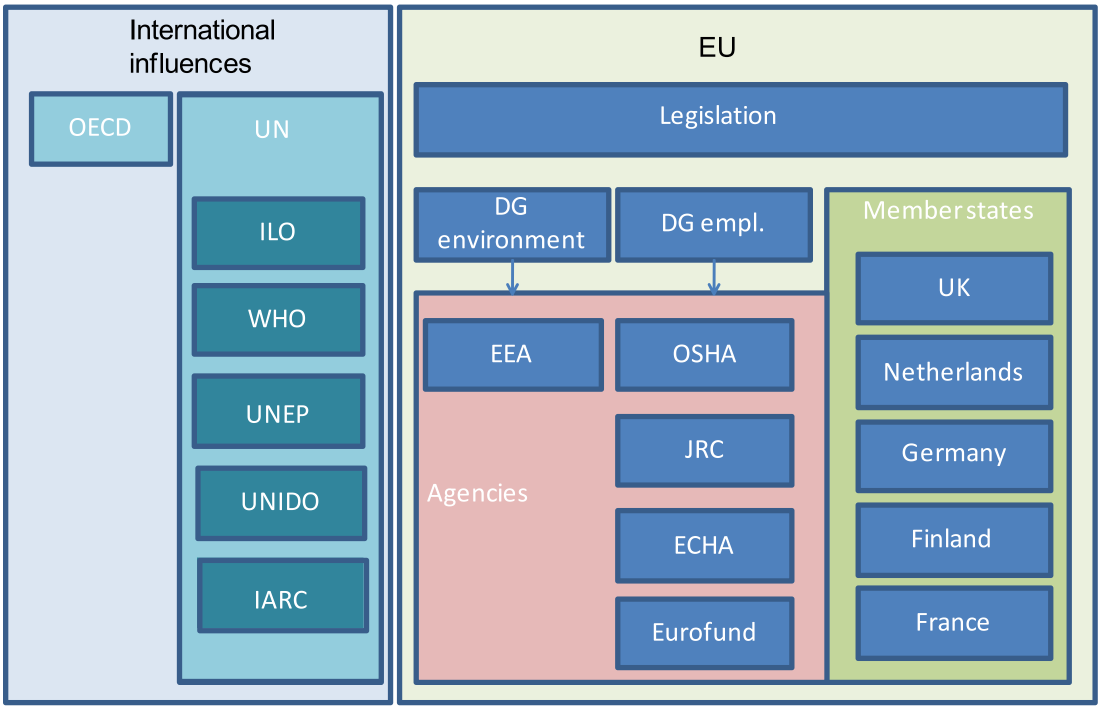

Figure 10: The actors considered

In the EU, the legislation is largely harmonised but implementation of for example directives may differ at the Member State level. In some countries the legislation or practises can be highly elaborate and use very specific approaches to promote the principle of substitution.[80] Viewed from an industry point of view, the different types of approaches used both globally and within the EU Mem-

[80] Lissner (2006)

ber States, it can be highly challenging to ensure the various national requirements are satisfied whilst still maintaining a companywide approach to chemical risk management.

4.2 Supranational organisations

4.2.1 United Nations – promoter of chemical safety

The United Nations (UN) is a prime force in **promoting** chemical safety. At a direct legislative level, transport of dangerous goods is perhaps the area where the UN has most direct influence. Transport of dangerous goods is an area where detailed regulations on safety are needed, if there were different regulations in every country and for different modes of transport, international trade in chemicals would become very difficult and the transport itself potentially unsafe. In order to ensure consistency between national transport and other chemical regulatory systems, UN has developed mechanisms for the harmonization of hazard classification criteria and hazard communication tools as well as aligning many transport requirements conditions between different modes for transport. The GHS-system is an UN product, translated into mainstream in the EU under the CLP regulations.

The UN organisations are also influential trend setters and tool providers for occupational health protection and chemical risk reduction. Particularly relevant UN organisations are ILO (International Labour Organisation), UNEP (United Nations Environment Programme), WHO (World Health Organisation), IPCS (the international programme on chemical safety) UNIDO (UN Industrial Development Organisation) and IARC (the International agency for research on cancer).

As such, clear guidance on chemical substitution is not issued by any of the UN bodies. Instead a large amount of data has been collated and is mostly available free of charge on the internet. A factor hindering effective UN data utilisation by companies is the multitude of sources and sometimes overlapping datasets, which do not immediately provide helpful guidance on how to compare different chemicals or different processes.

IARC Monographs identify environmental factors that can increase the risk of human cancer. These include chemicals, complex mixtures, occupational exposures, physical and biological agents, and lifestyle factors. IARC Monographs publishes lists of evaluated and classified carcinogenic compounds, which can be very useful sources of information. [81]

ILO is a tripartite UN body, concerned with, amongst other things, occupational health and safety. A prime goal is to facilitate access to facts needed to prevent occupational health problems, a task widely carried by the **International Occupational Safety and Health Information Centre (CIS).** CIS monitors world literature on occupational safety and health and disseminates the most important information electronically and in print. CIS maintains the ILO's Encyclopaedia of Occupational Health and Safety, available free of charge through its Internet site.[82]

[81] IARC Monographs, webpage

[82] ILO SafeWork, webpage

UNEP is a primary driving force in the UN system for international activities related to the sound management of chemicals. The aim is to promote chemical safety and provide countries with access to information on toxic chemicals. UNEP work also includes implementation of the **Strategic Approach to International Chemicals Management** (SAICM). The current state of knowledge on High Production Volume chemicals are summarized in the Screening Information Data Set (SIDS), which are available free of charge on the internet.[83]

UNIDO is also working with chemicals, including SAICM, and has recently started promoting chemical leasing as a sustainable business model. This approach however focuses more on reducing environmental impacts than on reducing health hazards. [84]

WHO is the directing and coordinating authority for health within the United Nations. The agency is responsible for "*providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends*".[85]

The International Programme on Chemical Safety (IPCS), established in 1980, is a joint programme of three Cooperating Organizations - WHO, ILO and UNEP, for implementing activities related to chemical safety. WHO is the Executing Agency of the IPCS. The main targets of IPCS are to establish the scientific basis for safe use of chemicals, and to strengthen national capabilities and capacities for chemical safety[86]. In 2009, the IPCS programme covered seven areas, of which two are particularly relevant from the point of view of substitution: the applied Risk Assessment and the Risk Assessment Methodology (including the IPCS Harmonization Project; Environmental Health Criteria Documents)[87]. The output of the IPCS is very useful, but as such, more suited to experts.

4.2.2 OECD – information provider

The Organisation for Economic Co-operation and Development (OECD) has a strong chemical programme. The main objectives of the OECD Chemicals Programme are to improve chemical safety, make chemical policies more transparent, and prevent distortions in the trade of chemicals. As part of the overall work on chemicals, a clear focus is on improving chemical risk management. OECD has not published specific guidelines on chemical substitution; safety indicators[88] and chemical risk management is however addressed. 24 Emission scenario documents (ESD) have been developed and are freely available on the internet. The OECD is also active in the scene of chemical testing guideline development, and also provides several useful databases on chemicals, including:[89]

- eChemPortal (hazard data): eChemPortal is a free public access portal that gives information on the properties of chemicals (physical and chemical properties, environmental fate and

[83] UNEP Chemical Information Exchange Network, SIDS-database

[84] UNIDO Resource Efficient and Cleaner Production Programme, webpage

[85] WHO, webpage

[86] WHO IPCS, webpage

[87] WHO (2009)

[88] OECD (2008)

[89] OECD, Chemical Safety, Directories and Databases on Chemicals

behaviour, ecotoxicity, toxicity and GHS classification) as well as to hazard and risk assessments. eChemPortal can be used to simultaneous search multiple databases, and it gives also access to data submitted to government chemical review programmes at national, regional, and international levels.

- OECD's New Industrial Chemicals Information Directory (data on requirements for industry)
- OECD List of High Production Volume (HPV) Chemicals: Serves as the priority list from which chemicals are selected for SIDS (Screening Information Data Sets) data gathering and testing and initial hazard assessment. The criteria for the selection of these HPV chemicals are production in one OECD Member country in quantities above 10,000 metric tons (22 million lbs) per annum or above 1,000 metric tons (2.2 million lbs) in two or more OECD countries. The HPV list contains 4,638 substances and is based on submissions of eight national inventories and that of the European Union. The SIDS Program involves the collection of all existing test data for the HPV chemicals. The data collation is done by the sponsor country that also determines whether or not additional testing is needed to complete the SIDS data set. Needed SIDS testing is conducted and the results incorporated in the SIDS dossier.
- OECD Existing Chemicals Database (chemicals under evaluation): Tracks all High Production Volume (HPV) chemicals through the process of assessment. Each chemical is identified as to exactly which stage it is at in the assessment process, and for those chemicals which have already been selected for sponsoring (i.e. SIDS chemicals), there are links to relevant documents. It shows the results of assessments as well as the actual reports and background information behind them.

As such, there is a wealth of data on substances and their properties, very useful when comparing different chemicals. Interpretation of the data requires some expertise, and for the reader looking specifically for step-by-step guidance on substitution, the OECD does not have many helpful sources.

4.2.3 OSPAR – international agreements for industry specific requirements on substitution

OSPAR is the mechanism by which fifteen governments and the European Community cooperate to protect the marine environment of the North-East Atlantic and amongst others, provides input into national regulations of the offshore oil & gas industry in the North Sea. Whilst OSPAR was founded for protection of the environment and is not in itself applicable to occupational health and safety, this organisation has been included here as a very interesting example of how regulators can - very effectively - steer the market towards using less hazardous substances.

The offshore industry is regulated through common agreements by the offshore industry states under OSPAR. The OSPAR Decision 2000/2 on a Harmonised Mandatory Control System (HMCS) for the use and reduction of the discharge of offshore chemicals is the basis for the regulation covering the use of chemicals offshore throughout the North Sea. The decision defines the regulatory steps and obligates the use of the Chemical Hazard Assessment and Risk Management (CHARM) model for the ranking of chemicals. The OSPAR Commission has published a List of Chemicals for Priority Ac tion and a List of Substances of Possible Concern. OSPAR is progressively moving towards the target of the cessation of discharges, emissions and losses of hazardous substances[90] by the year 2020. The OSPAR countries have committed to phasing out discharges of certain chemicals used offshore and to do so by 2010 for Chemicals for Priority Action and by 2017 for substances identified by OSPAR as candidates for substitution.[91]

The substitution of harmful chemicals is seen as an integral part of the Harmonised Mandatory Control Scheme. Member countries are obliged to implement the policy to replace chemical substances identified as candidates for substitution. An offshore chemical will be flagged with a substitution warning if it is on the OSPAR List of Chemicals for Priority Action; or if it is considered by the authority, to which the application has been made, to be of equivalent concern for the marine environment. There are specific rules that flag a substance as substitutable[92]. Since the application of the HMCS in the early 2000's, the industry use of chemicals discharged has changed markedly. More and more effort is put in by operators to eliminate discharges – and use of chemicals flagged for substitution[93].

4.3 European Union – legislator, policy setter and information provider

4.3.1 Overview and the main actors

Legislation is a primary driver for substitution and chemical substitution forms a core objective of several pieces of EU legislation. EU's broadest chemical related legislation, the REACH Regulation[94], has embedded the principle of identifying candidates for substitution within the overall chemical registration, evaluation and risk management process the legislation enforces. Occupational health and, safety and to some extent environmental legislation requires employers to ensure chemical risk is effectively managed and reduced where possible. The Chemical Agents Directive[95] specifically states the requirement to minimise or eliminate chemical risk to workers. Lists of specific chemicals

[90] Hazardous substances are defined by OSPAR as substances which are persistent, liable to bioaccumulate and toxic (PBT substances), or which give rise to an equivalent level of concern as the PBT substances

[91] OSPAR, Quality Status Report 2010

[92] e.g. if it is inorganic and has a LC50 or EC50 less than 1 mg/l; or has a biodegradation of either less than 20% in OECD 306, Marine BODIS or any other accepted marine protocols; or less than 20% in 28 days in freshwater (ready test); or meets two of the following three criteria: biodegradation: less than 60% in 28 days (OECD 306 or any other OSPAR-accepted marine protocol); or in the absence of valid results for such tests; less than 60% (OECD 301B, 301C, 301D, 301F, Freshwater BODIS); or less than 70% (OECD 301A, 301E); bioaccumulation: BCF > 100 or log Pow ^{3} 3 and molecular weight <700; toxicity: LC50 < 10mg/l or EC50 < 10mg/l; if toxicity values <10 mg/l are derived from limit tests to fish, actual fish LC50 data should be submitted; CEFAS, webpage

[93] Interview data with chemical suppliers, service company, industry association as well as operators

[94] REACH Regulation (EC) No 1907/2006

[95] Council Directive 98/24/EC

to be eliminated or the use of which are to be restricted are included within several pieces of environmental legislation (e.g. WFD[96], WEEE[97] and RoHS[98]).

There are several relevant organisations (Directorates, Agencies and other bodies) at the EU level concerned with different aspects of chemical safety, a short overview of which is given next.

The EU Commission staff is organised in departments, known as 'Directorates-General' (DGs). Each DG is responsible for a particular policy area. These DGs devise and draft legislative proposals, which become official once adopted by the Commission. The main DG for occupational health and safety aspects is the DG Employment, Social Affairs & Inclusion, but there are several other European Commission services contributing. The main players are DG Enterprise & Industry which is in charge of sector-specific legislation on chemicals (e.g. fertilisers, detergents, etc.), DG Environment, DG Health & Consumer Protection, and DG Energy & Transport. In addition, the DG Joint Research Centre, (JRC) is the DG that provides the scientific advice and technical know-how to support a wide range of EU policies. The JRC has seven scientific institutes, one of which is the Institute for Health and Consumer Protection (IHCP). The formerly known European Chemicals Bureau (ECB), whose mission was to provide scientific and technical support to the conception, development, implementation and monitoring of EU policies on chemicals and consumer products, was part of the IHCP. Since 2008, many of these tasks have been taken over by the European Chemicals Agency (ECHA). The remaining tasks of Ex-ECB at IHCP comprise *inter alia* the risk assessment of nanomaterials, the Review Programme on the risk assessment of Biocides, the development of methodology for the future Regulation on the Prioritisation of Chemical Substances and its corresponding environmental quality standards (EQS) and harmonisation of testing methods and non-testing methods (e.g. QSARs).[99]

European Agencies have their own legal personality and are governed by European public law. These bodies are distinct from the EU Institutions (Council, Parliament, Commission, etc.). European Agencies are set up by an act of secondary legislation to accomplish specific technical, scientific or managerial tasks. The most relevant ones for this study are briefly described below.

European Agency for Safety and Health at Work (OSHA) is the EU Agency that provides Community bodies, Member States and interested parties with technical, scientific and economic information in the field of health and safety at work.[100] OSHA is the main agency for health and safety issues and takes a strong interest in chemical management and provides both fact sheets, case examples and a list of available tools for chemical risk management on their website. [101]

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[96] Directive 2000/60/EC of the European Parliament and of the Council on establishing a framework for Community action in the field of water policy (2000)

[97] Directive 2008/34/EC of the European Parliament and of the Council amending Directive 2002/96/EC on waste electrical and electronic equipment (WEEE), as regards the implementing powers conferred on the Commission (2008)

[98] Directive 2008/35/EC of the European Parliament and of the Council amending Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment as regards the implementing powers conferred on the Commission (2008)

[99] European Commissions Joint Research Centre, webpage; Information about ECB, webpage

[100] EU-OSHA, webpage

The European Chemicals Agency (ECHA) is responsible for the coordination of REACH related duties. For many authorities and industry the main current regulatory challenges are the correct implementation of REACH and CLP both of which are managed by ECHA. As part of REACH, a list of substances of high concern is compiled[102]. However, ECHA is a relatively new Agency and whilst their work is specifically related to chemical safety in the workplace, neither REACH nor ECHA have been up and running for long, and many of the efforts at the time of writing are related to administrational issues.

The European Environment Agency (EEA) has a primary role in maintaining and supplying up-dated, specific and reliable environmental information to, for example, decision makers. Although EEA is a European Union agency, it has also other members than the 27 EU Member states, among them Norway. Just as other agencies and bodies, the EEA has no regulatory role.

The European Foundation for the Improvement of Living and Working Conditions (EUROFOUND) aims to assist planning and introduction of better living and working conditions in Europe. Whilst one of the primary areas of interest is health, where risk management is identified as a key parameter, the Foundation does not specifically appear to deal with chemical safety. Contributing to EUROFUND work is the European Working Conditions Observatory (EWCO), which provides regular information on quality of work and employment issues, including trends in workplace risk. However, chemical risk is not a main topic. [103]

4.3.2 Occupational safety and health (OSH) legislation

Occupational safety and health (OSH) in the EU Member States is today largely regulated through EU level legislation. The Asbestos Directive[104] is a prime example of specific substitution of a hazardous material driven directly by occupational health driven legislation. The main framework for occupational health and safety is provided through the Council Directive 89/391/EEC – the "Framework Directive" on the *Introduction of measures to encourage improvements in the safety and health of workers at work.* The Directive emphases risk assessment as tool of OSH. The overall aim is to introduce measures that encourage improvements in the safety and health of workers at work. The Framework Directive lays down the general principles of protection of workers and prevention of occupational accidents and diseases. It contains principles concerning the prevention of risks, the protection of safety and health, the assessment of risks, the elimination of risks and accident factors, the informing, consultation and balanced participation and training of workers and their representatives. The general principles of prevention according to the Framework Directive are: [105]

- avoid and evaluate risks and combat the risks at source
- adapt the work to the individual and adapt to technical progress
- **replace the dangerous by the non- or the less dangerous**

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[101] EU-OSHA, Risk Management Tools

[102] ECHA, Candidate List of Substances of Very High Concern

[103] EUROFUND, webpage

[104] Directive 2009/148/EC

[105] EU-OSHA, Directives webpage

- develop a coherent overall prevention policy and prioritize collective protective measures (over individual protective measures)
- give appropriate instructions to the workers

Other pertinent legislative instruments are:

- **Health and safety at work:** Council Directive 98/24/EC; on the protection of the health and safety of workers from the risks related to **chemical agents** at work (i.e. Chemical Agents Directive, CAD).
- **Exposure to carcinogens and mutagens:** Directive 2004/37/EC of the European Parliament and the Council on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.
- **Occupational exposure limits:** Commission Directive 2006/15/EC; on establishing a second list of indicative occupational exposure limit values; Commission Directive 91/322/EEC on establishing indicative limit values by implementing Council Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work and Commission Directive 2000/39/EC, on establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work. [106]

4.3.3 Control of Major Accident Hazard

Control of major-accident hazards involving dangerous substance is in the EU legislation based on the Council Directive 96/82/EC also known as the Seveso II Directive, and its extension by Directive 2003/105/EC. The main elements of chemical risk control is related to process safety and storage safety – land use planning aspects come into the questions and societal risk reduction is a prime target. Article 7 of the Directive gives requirements for a major-accident prevention policy by the operator, but although the major-accident prevention policy established by the operator "*shall be designed to guarantee a high level of protection for man and the environment by appropriate means, structures and management systems*", it does not specifically require the operator to consider substitution.

However, by providing a rigorous framework for controlling hazardous substances stored or used over and above certain trigger amounts, this directive is a very strong risk reduction driver for the industry to whom it applies. For the purposes of substitution, the Seveso II Directive can provide ideas and indicators of relevant dangers associated with particular chemicals, but nevertheless, it does not address occupational health as such and has therefore not been further addressed in this study.

[106] Note that there are both Council Directives and Commission Directives, where the Council has delegated legislative authority to the Commission. EEC Directives were issued before 1993, when the European Economic Union became the European Union, which issue EC Directives.

4.3.4 Overarching chemical legislation - REACH

The EU has recently renewed its chemical legislation in a massive overhaul of over 40 instruments to create the REACH (registration, evaluation and authorisation of chemicals) Regulation. The overall aim of REACH is to improve the protection of human health and the environment, mainly through providing better and earlier identification of the intrinsic properties of chemical substances in a format that users can utilise. REACH places the responsibility for risk management firmly to the manufacturers and users. Industry will have to provide clear and comparable information on the chemical properties that affect safety, environmental hazards, and occupational health hazards (long term and short).

The REACH regulation is complemented by the classification criteria and labelling rules agreed at UN level, the GHS, which is given in the EU as the CLP Regulation[107]. The CLP introduces new classification criteria, hazard symbols (pictograms) and labelling phrases, while taking account of elements which are part of the earlier EU legislation. Thereby consistency to the basic data on which risk assessments are made is sought – a welcome standardisation that will ease the practical issues of comparing chemical risk and identifying substances that should be substituted and enabling users to compare chemical hazards from the SDS in a more reliable way.

Substitution is a fundamental part of the “spirit” of REACH, calling for the progressive substitution of the most dangerous chemicals when possible. For substances identified as being of very high concern[108] (SVHCs) and listed in the REACH Annex XIV, authorisation requirement applies. The aim of the authorisation part of REACH is to ensure that SVHCs are properly controlled, and progressively replaced by substances or technologies that reduce the risks to human health and the environment. Uses of substances that are subject to authorisation will be banned unless industry can justify continued use through demonstrating either that the risks to human health and the environment are adequately controlled, or that the socio-economic benefits outweigh the risks. Therefore, where a suitable safer alternative substance or technology is available, authorisation will lead to the hazardous substance being removed from the market (enforced substitution). The REACH Regulation also includes former bans e.g. asbestos, certain aromatic amines, benzene, lead white, certain chlorinated solvents, PCBs, PBBs, certain mercury and arsenic compounds, CCA wood preservatives, organic tin, cadmium, pentachlorophenol etc.

In this project, the focus is on enhancing the substitution of hazardous chemicals based on their risk regardless of the absolute hazard. This does not impact on REACH requirements, but should be considered as a separate workplace orientated process that does not specifically target substitution of chemicals on lists of banned or phase-out chemicals.

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[107] European Commission, Environment web pages/GHS

[108] substances that are category 1 and 2 carcinogens, mutagens, and reproductive toxicants (CMRs); substances that are persistent, bioaccumulative, and toxic to the environment (PBTs); substances that are very persistent and very bioaccumulative (vPvBs); and substances that are of an equivalent concern (where there is scientific evidence of probable serious effects, such as endocrine disruptors) are collectively known as “Substances of Very High Concern”, or SVHCs

4.3.5 Environment

Environmental EU level policy and regulations that specifically addresses the substitution of environmentally hazardous chemicals include the following:

- RoHS Directive 2002/95/EC (Electronic equipment) [109]
- Ozone Layer Regulation 1005/2009/EC [110] and Montreal Convention (Substances depleting ozone layer; CFCs, Halons, methyl chloroform etc.)
- Metals Directive 2004/107/EC (Ambient air quality)[111]
- Directive 98/70/EC (Leaded petrol ban) [112]
- VOC Solvents Emission Directive 1999/13/EC (Organic solvents emissions)[113]
- Stockholm Convention 2001 (Persistent organic pollutants)
- Water Framework Directive (Priority substances and other pollutants) [114]

The **Restriction of Hazardous Substances (RoHS)** regulation has had a major impact on the electronics industry. The consequences of the RoHS Directive on occupational health are not as clear cut as it first would appear. The RoHS Directive restricts the use of certain materials (e.g. lead, mercury, cadmium, chromium and polybrominated flame retardants). This has led to for example the replacement of lead solder with lead free solder, which requires a higher working temperature and may need an increased amount of rosin added to the flux. Rosin based fumes have, for example in Britain, been identified as one of the most important causes to occupational asthma, wherefore the rise in the use of the material is of concern.[115] This illustrates what a multifaceted task substitution is and goes some way towards explaining why a simple, good for all cases approach is somewhat challenging to develop.

Ozone layer depleting **CFC substances** (chlorofluorocarbons) have been phased out and substituted largely by HCFC (hydrochlorofluorocarbon) and HFC (hydrofluorocarbon) compounds and also with chlorinated hydrocarbons such as trichloroethylene and tetrachloroethylene. The two latter compounds pose a clearly higher health risk for the workers due to their neurotoxicity. Also gaseous/very volatile hydrocarbons, such as butane and propane (used instead of CFCs in refrigerators) cause an increased safety risk through their flammability.

Biocides and chemical products for plant protection are strictly regulated and the two most important directives being the Council Directive 91/414/EEC of 15 July 1991 concerning the placing of

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[109] Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

[110] Regulation (EC) 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer (recast)

[111] Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air

[112] Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC

[113] Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations

[114] Directive 2000/60/EC

[115] Health and Safety Executive (2007)

plant protection products on the market and the Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market. However, pesticides and agricultural biocides were not included in the project scope and are therefore not further discussed here.

4.3.6 Transport of dangerous goods

Transport of dangerous goods is a very international field and several of the legislative areas stem from UN bodies. Transport of Dangerous goods EU legislation includes 67/548/EEC; 2008/68/EC; 95/50/EC; 1999/45/EC and others. Transport of dangerous goods is not as such within the study focus, sufficient to say that the legislation is highly prescriptive in how substances can be transported, and that the requirements increase in relation to the hazard. This in itself provides a driver towards substitution - it is much easier to deal with the logistics for less hazardous substances than it is for more hazardous ones.

4.3.7 Combined effects

None of the current legislative areas appear to sufficiently cover combined exposure to chemicals from different sources and how these may interact to produce detrimental effects on humans. In December 2009, the Environment Council adopted conclusions on combination effects as follows:

- Experts regard the predominant chemical-by-chemical approach in risk assessment as insufficient to protect against the risks of combination effects. The conclusions therefore call for more research in the area.
- The Commission is invited to assess how and whether existing legislation addresses this problem and to suggest appropriate modifications and guidelines, paying attention to the precautionary principle in future legislation.

The focus is particularly on endocrine disrupters, which act as hormones and may disrupt the endocrine system's[116] normal functioning. Such effects have already been seen in animals, impairing reproduction, development or immunity and several studies have linked multiple endocrine disrupters to effects on human health. Such exposure may occur both at work and as a consumer, through food, plastics, paints and cosmetics and others. Endocrine disrupters can lead to declining sperm counts and quality, genital malformations, retarded sexual development and increased incidences of certain types of cancer. **Any guidance on substitution or any common approach model adopted to aid the assessment of substitution needs should therefore put appropriate weight on risks arising from endocrine disrupters even used in moderate amounts**. [117]

[116] The endocrine system is the internal network of glands and hormones that regulate many of the body's functions, including growth, development and maturation

[117] European Commission, Environment web pages/effects

4.4 National approaches in the case study countries

The following chapters outline the legislative and administrative structure and specific approaches to substitution of hazardous chemicals from an occupational health and safety point of view in the selected case study countries in alphabetical order (Finland, France, Germany, the Netherlands and UK). After this, a short overview of a country where much has been done and which is reported in earlier literature (Denmark) is briefly discussed. Finally, an evaluation of the approaches in the case study countries is presented.

4.4.1 Finland

The administrative structure

There are two Ministries that are the main legislators concerned with occupational health and safety. The most important one is the **Ministry of Social Affairs and Health,** which is responsible for enhancing the wellbeing of the citizens in issues directly related to human health, including occupational health aspects. The **Ministry of Employment and the Economy** is the legislative authority for overall working environment issues and technical safety of enterprises. The **Ministry of the Environment** is responsible for the environmental safety of chemicals.

The Finnish Institute of Occupational Health (FIOH) is a research and specialist organisation that aims at promoting occupational health and safety. FIOH works under the auspice of the Ministry of Social Affairs and Health and provides authorities with information that enhances health and safety at workplaces. FIOH also issues guidance, methods and tools on healthier and safer working conditions, measures occupational exposure as well as carries out research on new occupational hazards.

The Finnish Safety and Chemical Authority (Tukes) is the enforcing authority for the technical safety of products, equipment and services as well as industrial installations under the auspices of the Ministry of Employment and Economy. The specific aim relevant for this study is to protect people, property and the environment from the accident risks related to the manufacture, handling and storage of hazardous materials. For certain larger facilities (the so called large-scale handling and storage of chemicals falling under the Seveso II Directive), Tukes issues permissions for the handling and storage of hazardous chemicals and carries out periodic inspections. The small-scale handling and storage is monitored by municipal authorities. Tukes is also involved in the development of legislation concerning chemicals safety. From the beginning of 2011 Tukes is responsible for most of the chemical control measures in Finland as tasks from SYKE, Valvira (National Supervisory Authority for Welfare and Health) and Evira (Finnish Food Safety Authority) are assembled under one roof.

The Finnish Environment Institute (SYKE) is a research institute working under the Ministry of the Environment. SYKE is responsible for assessing environmental chemical risks and aims at reducing the risks and improving the management procedures. SYKE also participates in the implementation of chemicals-related legislation and is responsible, for example, for the authorisation of some biocides.

The Advisory committee on chemicals (Kemikaalineuvottelukunta, KENK) is a cooperation body working under the Ministry of Social Affairs and Health with members from a wide variety of organisations. All of the previously mentioned chemicals control authorities and institutions in Finland are represented, as well as employees, industry and trade.[118] KENK aims at strengthening the cooperation of the authorities, enhancing overall control of chemicals and providing guidance. The committee has, for example, issued the national chemical profile of Finland in year 2005[119], clarifying the roles of various national actors.

Since 1.1.2010 six **Regional State Administrative Agencies** have taken the tasks of the former occupational health and safety districts and are now the enforcing occupational authorities in Finland. They are responsible for executing all legislative implementation, steering and supervision functions in the regions in Finland. Their detailed task is, for example, to reveal the causes of serious occupational accidents, illnesses and diseases and to prevent them.

Substitution in national legislation

The substitution principle - and especially in relation to workers wellbeing - is embedded in several national acts and decrees. The Chemical Agents Directive has been implemented in Finland as a Government Decree on Chemical agents at work[120]. The substitution principle is described in the decree, which stipulates that the cause of hazard has to be eliminated or substituted and if not possible, the risk has to be reduced to a level that is "as low as possible" by other means.

The employer's obligations for occupational health and safety are also mentioned in the Employment Contracts Act, which specifies that any hazard that endangers the health of pregnant employees or the fetus has to be eliminated and, if not possible, other working duties have to be considered[121]. The Occupational Health and Safety Act also requires the employer to eliminate hazards and harmful aspects and, if not possible, to substitute them[122]. The Chemicals Act stipulates that the least harmful chemical or method has to be chosen – if reasonably possible[123]. However, compliance with any of these obligations is not in practice enforced trough regular controls.[124]

Substitution is also mentioned in the Act on the safety of handling of hazardous chemicals and explosives[125]. The act describes "the obligation to choose", i.e. to prevent the damages from hazardous chemicals and explosives the actors must choose the least harmful chemical, explosive or method – when it is reasonably possible. This obligation has, however, not been controlled in practice[126].

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[118] KENK web pages

[119] KENK (2005)

[120] Government Decree (715/2001), Finland

[121] Employment Contracts Act (55/2001), Finland

[122] Occupational Health and Safety Act (2002/738), Finland

[123] Chemicals Act (1989/744), Finland

[124] Ministry of the Environment (Finland) (2006)

[125] Act on the Safety of handling chemicals and explosives (2005/390), Finland

[126] Interview data

An example of a specific motivating approach to reduce hazards through legislation is the use of the potential for **reducing administrative burdens** as a tool for promoting substitution. In Finland, the substitution of carcinogenic chemicals at workplaces has been promoted since 1979 through an occupational exposure registers (so-called ASA-register[127]) and notification of occupational exposure to carcinogenic chemicals became statutory in 1993[128]. One of the aims was to encourage the employers to substitute these chemicals with less harmful ones and thereby free themselves from the obligation of elaborate record keeping. Finland issued this legislation for registration of workers exposed to carcinogenic substances as one of the first countries. The current Finnish Act dealing with workers exposed to carcinogens is from 2001[129] and the list of carcinogenic substances mainly from 1993 (hardwood dust and environmental tobacco smoke have been added to the list later). In this Act, the substitution of known carcinogens is considered the most important method for prevention. In 2006, about 28000 employees (1,1% of labour force) were registered in the ASA register. The most common exposures included environmental tobacco smoke, chromium-Vi-compounds and nickel compounds especially in welding of stainless steel.[130]

Other instruments to enhance substitution

In other respects the activity of Finnish authorities in relation to enhancement of substitution and specifically in relation to issuing any guidance has been low. Substance and subject specific guidance has been published in Finland only in a few cases. Mostly Finnish industry has carried out specific substitution because of new/coming legislation, often environmental legislation is seen as the prominent driving force, as examples of substitutions tend to include asbestos, CFC-compounds and some solvents. The Ministry of Social Affairs and Health has published guidance on substitution of asbestos and specifically on substitution of asbestos in industrial seals & gasket as well as in friction materials[131]. The fact sheet on substitution of dangerous substances issued by the EU OSHA and translated into Finnish is the only one giving advice on substitution and the process as a whole[132].

A Finnish national chemicals program was launched in year 2006. The initiative and stipulation to prepare such a program came from the Government's Programme 2003 and the work was coordinated by the Finnish Environment Institute. The overall aim of the program was, that chemicals would not cause significant health and environmental harm in Finland in 2020, executing the aim of the international meeting in Johannesburg in 2002 [133]. The harm that chemicals cause to individual consumers, public health, workers health and environment were evaluated taking into account the whole lifecycle of the chemicals. The program proposed a range of measures of which the improvement of know-how and tools for chemical risk management in companies was one of the most urgent ones. It also stated that especially training in SMEs and occupational safety are areas that

[127] Information on the register available at http://www.ttl.fi/fi/rekisterit/asa-rekisteri/Sivut/default.aspx

[128] Act (717/2001) on the register for carcinogenic substances and methods at workplaces: Laki syöpäsairauden vaaraa aiheuttaville aineille ja menetelmille ammatissaan altistuvien rekisteristä (717/2001)

[129] Act (717/2001), Finland

[130] Saalo A. et al (2006)

[131] Humppi (1993a), Humppi (1993b), Humppi (1994)

[132] Euroopan työterveys- ja työturvallisuusvirasto (2003)

[133] Ministry of the Environment (Finland) (2006)

need improvements. Developing guidance was mentioned as one means for promoting the implementation of substitution principle.

For carrying out chemical risk assessments there are some tools and guidance available. The most practical help relating to chemicals management and risk assessment in Finland might be a software tool called Kemi-Arvi. It is a tool available for companies for listing their chemicals information and for estimating the danger to the employees exposed to chemicals[134]. The tool has been created by the Technical University of Tampere together with the Occupational Safety and Health Department of the Ministry of Social Affairs and Health. More information on the tool can be found in chapter 7.3.

Taking into account the rather scarce output of tools and guidance from authorities on chemical risk management and especially the substitution process, it is not surprising that the level of knowledge on chemical substitution issues is not very high in Finnish companies[135,136]. Even the legal obligation to have and maintain a chemical lists have been lacking in many companies. Perhaps innocently, this is something that is "hoped to be improved" due to the requirements set in REACH Regulation. However, there is not yet any information about the impacts of the regulation on the overall level of chemicals related knowledge and risk management activities in companies. Most problems are found within small companies, such as hairdressers and beauty salons that are less motivated and do not have the resources or required knowledge for exposure and risk assessment[137]. These workplaces are also largely unaware of the potential problems. Companies are in general quite willing in principal to substitute the hazardous chemicals by less hazardous, but economic and performance/quality aspects as well as inertia hinder good intensions [138]. **In practice the ASA register has been most probably the strongest driver to substitution in Finland – chemicals that appear on that list are the ones most likely to become substituted[139].**

4.4.2 France

The administrative structure

The French **Ministry of Labour** is responsible for the national public policy on workplace health and safety.[140] It prepares, develops and implements occupational health and safety regulations with respect to chemicals, and manages cooperation with the social partners in the Steering Committee on Working Conditions (COCT).

COCT is an advisory body attached and chaired by the Ministry of Labour, which is consulted on all regulatory legislative proposal concerning the protection and promotion of health and safety at

[134] Tool available at http://kemi-arvi.tksoft.com/index.html

[135] Interview data

[136] Ministry of the Environment (Finland) (2006)

[137] Vainio H. et al. (2006)

[138] Johansson A. et al (2006)

[139] Interview data

[140] The Ministry of Labour (France), web pages. The Ministry of labour is one of the portfolios of the Ministry of Labour, Solidarity and Public Service (Ministère du Travail, de la Solidarité et de la Fonction publique). For web pages, see: http://www.travail-solidarite.gouv.fr.

work, and it also follows statistics on Labour and examines yearly the overall working conditions in France.

The **Ministry of Agriculture**[141] is responsible for all agricultural activities using chemicals. Depending on the ministry there is an inspection unit that controls the companies, and sees that the laws and regulations are followed.

Under the Ministry of Labour, the **Labour Inspectorate** controls and supervises companies, gives information, consults and enforces the legislation and regulations related to health and safety at the workplace.

The National Agency for the Improvement of Working Conditions (ANACT), also supervised by the Ministry of Labour, contributes to the development of research to improve working conditions, collect and disseminate information in this field, offers advice to companies and takes action in the operational area of occupational risk prevention. [142]

*ANSES**,*** the ***French Agency*** for Food Safety, ***Environmental*** and ***Occupational Health and Safety*** is a new legal and operational entity operational from the 1 July 2010. ANSES incorporates the missions, resources and personnel of the previous French Food Safety Agency (AFSSA) and the French Agency for Environmental and Occupational Health Safety (AFSSET). The main mission of ANSES is to provide independent, multidisciplinary scientific consulting to authorities, such as the scientific and technological support needed to develop health protection politics, including the application of risk management measures in their fields. The Agency plays a central role in assessing risks related to chemical substances and coordinating scientific expertise and technical research programmes in the area of environmental and occupational health.[143]

INRS is the French ***National Research*** and Safety Institute for the prevention of occupational accidents and diseases. INRS works in the area of occupational risk prevention, improvement of workers' health and safety and preventing occupational accidents or diseases. INRS is a non-profit association, and its budget comes almost entirely from the **National Occupational Accident and Disease Prevention Fund**. INRS has three main missions; conduct study and research programmes to anticipate future prevention needs, raise awareness of occupational accidents and diseases (via information products and campaigns) and provide technical assistance, and design and facilitate training courses.

CNAMTS, the National Salaried Workers' Health Insurance ***Fund***, and its regional branches (regional health insurance funds) form the other part of the occupational accidents and diseases prevention system in France. CNAMTS has strong cooperation with INRS.[144] CNAMTS manages the National Occupational Accident and Disease Prevention Fund, which is provisioned by mandatory contributions from companies. From this fund CNAMTS compensates occupational accident and disease victims. CNAMTS works to identify occupational accidents and diseases, and defines the means and measures to promote occupational risk prevention in companies. While the Ministries take actions essentially through regulations, CNAMTS is focused on practical recommendations, financial incen-

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[141] The Ministry of Agriculture (France), web pages

[142] ANACT, web pages

[143] ANSES, web pages

[144] INRS, web pages

tives, technical assistance and consultation of companies to implement appropriate prevention measures and training on health and safety at work. [145]

Substitution in national legislation

The legislative main focus in France is on CMR substances, and the principle of substitution is highly underlined in the French interpretation of the legislation as well as in advisory materials provided for workplaces. Prevention rules specific to CMRs are defined in the French Employment Code, le Code de Travail [146] and includes the obligation from the CMR Directive for the employer to replace CMR substances, to the extent technically feasible, with a substance, preparation or process which is less hazardous to health[147].

Other instruments to enhance substitution

As in many other EU countries, companies with over 50 employees must set up a hygiene and safety and work conditions committee (CHSCT) and produce an employment protection plan. Because of this it was considered that health and safety issues gain more attention in medium and large sized companies. Many of these committees are active and push for evaluations and other initiatives to promote workers health. In smaller companies it is up to the management to initiate measures to maintain and improve health and safety at workplace.[148] In the current labour health plan (2010-2014), the objective is to develop actions of chemical risk prevention by substitution, especially focusing on assistance directed to small companies.

Professional industry associations and federations are in France seen as important actors in reaching companies, which do not recognise the need for risk prevention. For example INRS works as much as possible with different industry associations to deliver the message of substitution. In 2004 for instance, there was a prevention campaign with CNAMTS regional branches, occupational physicians associations and hairdressers associations, in which INRS helped to design leaflets about the risks of exposure to chemicals for hairdressers.

The SUMER survey (SUrveillance MEdicale des Risques professionnels, Medical Surveillance of Workplace Risks), conducted in 2002-2003 under the auspices of the Ministry of Labour provides an estimate of occupational exposures of employees. It shows that many employees are regularly exposed to one or more CMR substances in their work. Specifically it shows that 2 370 000 employees (13.5% of the workforce) are exposed in their work to one or more carcinogens. Approximately 186 000 persons (1.1%) are exposed to mutagenic products and nearly 180 000 (1%) to reprotoxic products.

In 2005, at the request of the Ministry of Labour, INRS draw up **an inventory of all CMRs used in France**. In this inventory, it was estimated that a total of 4.8 million tons of chemical agents classified as carcinogenic, mutagenic or reprotoxic, consisting of 324 CMR chemicals and hundreds of

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[145] CNAMTS, web pages

[146] The legislation is available at http://www.legifrance.gouv.fr/initRechCodeArticle.do

[147] More information about the obligation to substitute is available in France at http://www.travailler-mieux.gouv.fr/substitution-des-agents-chimiques.html

[148] Interview data

petroleum products, were used in France during 2005. The numbers of exposed workers were also estimated. All the results of the inventory have been published as a database on INRS website.[149]

A control campaign on the use of CMRs was then undertaken in 2006, organised by the Ministry of Labour and the CNAMTS with the technical support of INRS. In this campaign, the practices of companies in identification of CMR substances, risk analysis, process substitution and preventive measures were identified through a survey.[150] The survey focused on three industry sectors; mechanical industry, manufacturing of paints and plastics, and industry manufacturing a limited number of products: trichloroethylene, Pb compounds, chromates (CrVI), phthalates and refractory ceramic fibres (RCF). The survey showed, as perhaps was to be expected, that large companies are more aware of chemical risk management and the substitution principle than smaller companies, but with two exceptions: Greater awareness was observed in the smaller companies that either use RCFs or are paint manufacturing companies. The better awareness in large companies was partially attributed to many of these recognizing themselves as chemical companies, and to longer traditions of working with chemical risks. All in all, about 2000 companies participated in this control campaign survey and 60% of these companies had tried to substitute CMR category 1 and category 2 substances**. Of these, 70% succeeded, 18% was still experimenting at the time of writing, and only one out of ten had failed in the substitution attempts.** The campaign showed that the successful substitutes were found by using the knowledge inside the company and with the help from the suppliers. Failures were in most cases due to lower performance level of the alternatives and very rarely due to other direct economic reasons.

In 2005-2009, as a part of the Health Work Plan, a study on the substitution of CMRs was commissioned by the Ministry of Labour and conducted by Afsset. In the study, after having determined a suitable prioritization methodology and choice criteria, a priority list of CMRs category 1 and 2 was generated. In the second step further investigations, studies and literature searches to collect data on the properties, uses and alternatives were focused on these priority substances. As a result, a web tool to support and help the industry to manage the substitution process was developed (www.substitution-cmr.fr). The tool is introduced in more detail in Chapter 7.

In 2007 **INRS published a guidance document** on substitution that outlines the obligations of companies and the approach to be implemented for the substitution of CMRs.[151] In this guidance the substitution process has been divided into 9 steps:

1. Identify the substances that should be substituted
2. Create a working group
3. Define specification
4. Search alternative solutions
5. Try out the alternatives
6. Evaluate the consequences of the solution on safety and health

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[149] INRS, database

[150] INRS (2007a)

[151] INRS (2007b)

7. Compare the different options
8. Implement
9. Evaluate and validate the solution

Since 2006, Afsset (later ANSES) has maintained an internet site, which provides information about actions taken, available courses and advanced research in the field of substitution. By offering several levels of information, it aims to help different actors to find alternatives to CMRs. At the moment, examples of substitution of 24 chemicals are available on ANSES website with a target of examples of about 70 chemicals when the project is finalized.

In 2007 INRS joined the CLEANTOOL project[152] and is working together with Cooperation Centre Hamburg and ISTAS - the Spanish Trade Union Institute for Work, Environment and Health, to improve the CLEANTOOL database further and maintaining the national web pages and processes. More information on CLEANTOOL can be found in Chapter 7.

At the time of writing this report**,** a campaign joined by CNAMTS and INRS was ongoing, where the objective was to assist companies in identifying potential carcinogens and finding substitutes by developing practical identification and substitution factsheets. The identification factsheets are developed separately for a specific activity, and the potential carcinogens and exposure scenarios are listed. Substitution factsheets are developed for each chemical, presenting the required actions and the possible substitutes.[153]

The substitution web tool, CLEANTOOL (see Chapter 7) and the factsheets developed by INRS are the main tools developed by the French authorities for practical assistance to substitution. As such, there is a wealth of information available on CMRs, but according to interview data, getting this information to the industry still appears problematic. According to ANSES, it appears that most companies are not aware of the existence of the guidance, and the most challenging segment to reach is SMEs. Therefore the view is that any future guidance or common approaches to substitution should be more targeted to SMEs, and kept simple and aimed at easy comprehension by a wide audience.[154] In general, the interviewed French authorities considered that, in order to achieve broader implementation of substitution, the substitution principle should be included in legislation more efficiently, including penalties as well as provision of means and resources for enforcement and control actions.[155]

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[152] CLEANTOOL is a Europe wide database for parts cleaning, metal surface cleaning, component cleaning and degreasing, which is based on real processes in numerous European companies. CLEANTOOL started in 2001 as a European Innovation Project, and to date more than 100 enterprises have participated in the project. CLEANTOOL, available in four different languages at http://www.cleantool.org/

[153] Identification and substitution factsheets are available in French at http://www.inrs.fr/accueil/header/recherche.html?queryStr=FAR+et+FAS

[154] Interview data

[155] Interview data

4.4.3 Germany

The administrative structure

The three Ministries that prepare legislation relevant to substitution of hazardous chemicals are the ministry for **Labour and Social Affairs** (BMAS) dealing with occupational health and safety issues, the Federal Ministry of Economics and Technology (process safety) and the ministry for the **Environment** (BMU). As Germany comprises of 16 federal states, legislative decisions must be approved not only by the national parliament (Bundestag) but also by the chamber of states (Bundesrat). The federal states are also responsible for enforcement of the legislation. The implementation of chemicals legislation is carried out at the state level while enforcement is under the responsibility of the federal states.

The Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, BAuA) is a governmental research institution that operates at the interface between science and politics, advising the Federal Ministry of Labour and Social Affairs in matters of occupational safety and health[156]. One of the tasks of BAuA is to promote the transfer of knowledge and proposed solutions to companies and thereby into practice. The specific task of the Division for Hazardous Substances and Biological Agents is the evaluation of toxicological and medical risks of chemicals. The focus is on uses, processes and exposure and risk management measures for safer use, handling and storage of chemicals. One of BAuA's divisions, the Federal Office for Chemicals / Authorisation of Biocides, is the competent authority for REACH and responsible for the evaluation and risk management of chemicals, the implementation of the CLP regulation as well as evaluation and authorisation of biocide products.[157]

The **Federal Institute for Materials Research and Testing (Bundesanstalt für Materialprüfung, BAM)** is a scientific and technical institute under the auspices of the Federal Ministry of Economics and Technology. BAM carries out research on materials and develops testing techniques and chemical safety engineering solutions. The Institute's overall aim is to promote chemical safety and knowledge transfer of safer technologies and materials both to the Federal Government and industry. In addition, its tasks cover collaboration in developing legal regulations.[158] The institute also determines and evaluates the dangerous characteristics of materials, material mixtures and goods and looks for technologies that are suitable for reducing the risk.

The Federal Environment Agency (Umweltbundesamt, UBA) is Germany's central federal authority in environmental issues providing scientific support to the Federal Government[159]. One of agency's tasks is to advise on environmental laws, including authorisation of chemicals that are of environmental concern. Especially the Division for Chemical and Biological Safety plays an important role in substitution: it investigates and assesses environmental risks of substances and preparations. Where chemical risk to environment is of concern, UBA develops measures to reduce these risks, for example through bans on manufacture or use.

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[156] BAuA, web pages

[157] BAuA, web pages

[158] BAM, web pages

[159] UBA, web pages

The Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR) is a body working under the auspices of the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV). BfR's objective is to strengthen consumer health protection, including conducting health assessments of chemicals. It also develops methods for testing chemical effects. Consumer protection on a more common level is a task of the **Federal Office of Consumer Protection and Food Safety** (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, BVL).

In Germany the **institutions for statutory accident insurance** and prevention (Berufsgenossenschaften, BGs) are also important actors in the field of occupational health. These sectoral organisations' aim is the prevention of accidents and occupational deceases as well as ensuring the rehabilitation of injured or diseased workers.

The **Institute for Occupational Safety and Health of the German Social Accident Insurance** (Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung, IFA) helps other institutions by addressing scientific and technical problems relating occupational health and safety[160]. It carries out research and investigations and, for example, workplace measurements for **the Social Accident Insurance Institutions.** IFA works on a practical level, giving advice to companies, as well as participating in standardisation and regulation setting bodies. IFA is also responsible for the maintenance and updating of the GESTIS databases on hazardous substances, which is a joint project with the German Social Accident Insurance Institutions for preventing accidents and promoting occupational health and safety. IFA and BAuA cooperate on a scientific and expert level.

Substitution in national legislation

The overarching legislation for workers protection from hazardous chemicals in Germany is the Occupational Health and Safety Act (Arbeitsschutzgesetz). The Occupational Safety and Health Act, stipulates that employers must conduct a hazard assessment for all of their workplaces. The Chemicals Act (Chemikaliengesetz) aims to "*protect man and the environment from the harmful effects of dangerous substances and preparations, in particular to identify them, avert them and prevent their occurrence*" and deals with testing and notification, amongst others.

The use of chemicals at workplaces is addressed in more detail in the Hazardous Substance Ordinance (Gefahrstoffverordnung), which corresponds for the national implementation of the Chemical Agents Directive. It defines the conditions and required actions stating, for example, that the employer has to eliminate or minimize the health and safety risks for workers arising from activities involving hazardous substances: *"In particular, the employer shall avoid activities involving hazardous substances or shall replace hazardous substances with substances, preparations, products or processes that are not deleterious, or less deleterious, to worker health and safety under the relevant application conditions"*[161].

[160] IFA, web pages

[161] Hazardous Substances Ordinance (BGBl. I p. 3758)

Other instruments to enhance substitution

The implementation of the Hazardous Substance Ordinance is supported by the Technical Rules for Hazardous Substances (TRGS) produced by the Federal Ministry of Labour and Social Affairs. The TRGSs have been prepared by **the Committee on Hazardous Substances,** which consists of both national and state level representatives as well as independent experts, trade union representatives and statutory accident insurance representatives in a "tripartite approach". The aim of the TRGSs is to help the employer to comply with legislation and the TRGSs also provide a benchmark for the enforcing authorities.

The TRGS guiding the implementation of the substitution principle, TRGS 600 Substitution[162], is a framework guidance that is complemented with several other TRGSs with more detailed guidance on specific chemicals and specific uses and their potential substitutes. TRGS 600 includes a flowchart and examples and has four major themes under which guidance is given or additional sources are pointed out:

1. determination of substitution possibilities
2. guiding criteria for the pre-selection of substitution possibilities with good prospects
3. decision on substitution
4. documentation

The TRGS 600 also takes into account other than occupational health and safety factors such as cost and environmental concerns and provides models (column and effect factor models) for comparative assessment of the health and safety hazards. **The column model** for comparing the properties of different chemicals is discussed in more detail in Chapter 7. Other framework TRGSs exist, e.g., for risk assessment (TRGS 400) and using control measures (TRGS 500).

There are also sector specific substance databases, guidance and tools available that can help in finding alternatives and comparing them (e.g. CLEANTOOL, Gisbau, see Chapter 7).

Substitution solutions have also been supported by branch specific activities, initiated by the **statutory accident insurance.** Communication of risks was seen as something that need strengthening, as one German study pointed out that over half of the employees answering a survey stated that no risk assessment had been carried out at their workplace[163]. This result does not exclude the possibility that risk assessments have actually been done, but it indicates that employees are not aware of either risk assessments or their results.

In practice, implementation of the substitution principle in companies is not on a very good level. According to interview data, companies are not very active in substituting and many appear to not understand the perhaps somewhat complicated technical rules. The implementation of the rules requires skills that especially SMEs do not have. In particular, it was mentioned that the potential of an SME to carry out a new substitution (e.g. a substitution not done before) was seen as not likely.

[162] Committee on Hazardous Substances, AGS (2008)

[163] BAuA (2008)

4.4.4 Netherlands

The administrative structure

The **Ministry of Social Affairs and Employment** is the main policy-making body and regulator for occupational health and safety. The main aims of the Ministry's occupational safety and health policy are to prevent absence due to illness and occupational disability and to provide the legal framework for the health and safety at work. The Ministry regulations set targets that state the levels of protection which employers must provide for their employees.[164]

The Labour Inspectorate (Arbeidsinspectie), under the Ministry of Social Affairs and Employment, is the Dutch workplace health and safety enforcing authority. The Labour Inspectorate monitors and supervises compliance with statutory regulations regarding health and safety at work, looking at working conditions, working and rest periods, wages and illegal work. The focus is on sectors where the risks are high and/or where the chances of violations of the Act(s) are higher[165]. The Labour Inspectorate's working area includes all companies and commercial and non-commercial (both private and public). If the Labour Inspectorate finds violations in complying with the various laws and decrees with regard to labour protection, they can immediately impose a penalty. A penalty can also be imposed to employees, if they do not comply with the regulations. The major duties of Labour Inspectorates related to chemicals are:[139]

- **Supervision of the Working Conditions Act:** The Labour Inspectorate supervises that employers and employees comply with Working Conditions legislation, taking severe actions in the case of serious violations.
- **Supervision of the Major Hazard Control Act:** The Labour Inspectorate supervises compliance with Major Hazard Control Act that implements the Seveso II Directive via inspections and a comprehensive assessment of processes, organisational and technical measures, safety reports and additional risk assessments and evaluations. All companies that store, transport or work with large quantities of hazardous substances are periodically inspected by the Labour Inspectorate.
- **Investigating industrial accidents:** The Labour Inspectorate investigates all accidents requiring notification, and in case of violations, sanctions will be imposed.
- **Investigating complaints by employees about their working conditions:** Employees can file a complaint with the Labour Inspectorate if their employer does not comply with the Working Conditions Act or other laws regarding labour protection.

The National Institute for Public Health and the Environment (RIVM) is a leading centre of expertise and research, and gives advice and supports policy-makers and professionals in safety issues related to public health, environment, products and food.[166] The tasks of RIVM include, amongst others:

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[164] Ministry of Social Affairs and Employment, web pages

[165] Arbeidsinspectie, web pages

[166] RIVM, web pages

- **Product safety:** assessing and calculating exposure to substances, deposition of information on e.g. composition of products with a danger symbol (based on dangerous preparations directive)
- **Health:** Advice on acute and chronic poisonings, risk assessment
- **Environmental pollution:** environmental monitoring, population studies, modelling, assessment of environmental impacts of accidents and disasters
- **Food safety:** determining which concentrations of substances can be ingested without risk to health
- **Technical safety:** prevention and management of incidents and accidents (e.g. major disasters)

The **Ministry of Housing, Spatial Planning and the Environment** (**VROM)** creates regulations and distributes subsidies for improving the country's living environment.[167] VROM focuses on sustainability and the environmental dimensions of consumption, and is the competent authority for environmental risk assessment. Working under VROM, the **Directorate General for Environmental Protection** co-ordinates and oversees national environmental policy, and is responsible for the enforcement of environmental laws.

The VROM Inspectorate enforces laws, regulations and policies that fall under the responsibility of the Ministry of Housing, Spatial Planning and the Environment. Their activities include investigation, primary supervision, secondary supervision, policy enforcement, and observation, identification and notification. Environment related regulations that are relevant in this context are the Environmental Management Act (WM), the Pollution of Surface Waters Act (WVO) and the Environmentally Hazardous Substances Act (WMS).

The Interfaculty Environmental Science Department (**IVAM**) of the University of Amsterdam is an independent research and consultancy organization that carries out research, provides advice and training, and supports companies, trade associations, authorities and NGOs in several areas including environmental problems and occupational health and safety risks. [168]

TNO is an independent research organization that works intensively in the area of chemicals risks and workers health. The focus of TNO is to look at substitution more broadly; as something more than just replacement of hazardous chemicals. Working with the entire supply chain and ensuring efficient communication to reduce risk is considered highly important.[169]

Substitution in national legislation

The main legal instrument related to the safe use of chemicals in the workplace is the Working Conditions Act supported by the Working Conditions Decree and the Working Conditions Regulation.

[167] VROM web pages

[168] IVAM, web pages

[169] TNO, web pages

The new Working Conditions Act came into force on January 2007, placing obligations on the employer to have a policy in place that limits the risks for safety and health for employees. This also applies to the situations in which hazardous substances are used.

The Working Conditions Decree contains a number of obligations in the area of the risk and exposure assessment, registration, packaging, designation and safe storage of hazardous substances. In the decree the responsibility for working safely with chemicals is firmly assigned to the companies. The Ministry of Social Affairs and Employment only set limit values for a small group of substances and the companies themselves are in the first instance responsible for setting their own limit values for chemicals, which should then be used to assess possible health risks. The ministry provides subsidies for employers and employees for developing systems to facilitate reliable value setting and safe working conditions.

According to the Ministry of Social Affairs and Employment, one of the current enforcement challenges is created by the obligation to substitute carcinogens and mutagens on the basis of the EU carcinogens Directive.[170] This is seen as very difficult for authorities to enforce and, as a consequence, not considered to be well implemented into practice in the Netherlands.

Other instruments to enhance substitution

The VASt programme was established by the Dutch Ministry of Social Affairs and Employment to assist SMEs in reinforcing the working condition policy and hazardous substances management. In the context of this program a large number of research and consultancy projects were conducted and partly funded by Dutch Government. A web-based tool, Stoffenmanager, is one of the instruments that were developed during this programme.[171] A more detailed description of this tool is presented in Chapter 7.

Notably, funding for substitution projects concerned with new process development is available from the Ministry of Economic Affairs.

TNO has developed a Substitution Guide that can be used to support the process of chemical substitution.[172] The work was funded by the Ministry of Social Affairs and Employment, and the objective was to support companies in complying with the legal obligations to substitute CMR substances. The aim of the guidance is to provide help particularly for the process of comparing the risks of different substances. The guidance does not include substitution of chemicals within products. The guidance consists of two parts; a cycle that can be used to make the substitution process transparent,[173] and a module for integrated assessment of risks before and after substitution. A ten step cycle is used to describe a successful substitution process.

- **Identify the substances** that needs to be substituted (focus on CMRs)

[170] Directive 2004/37/EC. In this directive it is stated that “the employer shall reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, preparation or process which, under its conditions of use, is not dangerous or is less dangerous to workers’ health or safety, as the case may be”.

[171] Stoffenmanager tool is available in Dutch and English at https://www.stoffenmanager.nl/

[172] TNO (2007)

[173] The cycle is partly base on the 7-step model: Dorward A. (1994)

- **Mobilize stakeholder support and commitment:** Broad support from all stakeholders is needed for successful substitution process.
- **Form a steering group:** A multidisciplinary steering group should include representatives of management, purchase, R&D, customer, supplier, HSE experts, engineering, maintenance and employees.
- **Functional analysis:** Analyse the purpose of using the dangerous chemical.
- **Find requirements/barriers:** The requirements and barriers can be divided into functional, process-based, physic-chemical, quality, logistical and economic.
- **Find and evaluate alternatives:** In cooperation with suppliers and R&D department find and evaluate suitable alternatives.
- **Risk assessment:** To make a good choice, comparison of risks before and after is desirable. For example possible shifts from health risks to risks to environment should be considered. The risk assessment should start from the chemical risks to human health. Stoffenmanager is recommended for the assessment of inhalation risks, and Riskofderm[174] for the evaluation of dermal risks. The extent of the risks to the workers should also be evaluated; e.g. how many workers are exposed etc. In addition to chemical risks, environmental, security and other working condition risks should be assessed.
- **Testing in practice:** To ensure acceptance and determine the effects on production, business and the product itself, potential alternatives should be tested.
- **Implementation:** Based on the testing results, the steering group decides whether the alternative should be implemented. Communication during this step is crucial to avoid confusion and resistance.
- **Evaluation:** Examine whether the objectives have been achieved. If not, the cycle should be restarted.

This ten-step cycle has quite successfully gathered all the necessary components that are needed for a successful substitution process, and it also gives the important message that the process should be an ongoing cycle. However, to render it more useful for SMEs, which are unlikely to have the resources to gather a multidisciplinary steering group of experts, some modification would be needed. As with many other guidances, the main focus is on CMRs, and the risk assessment targets comparison of the risks of possible alternatives against the original CMR chemical.

In addition to the Substitution Guide, TNO has developed a range of material and guidance, to help reduce exposure to chemicals and to avoid and reduce health risks. A TNO project, "*Examples of reduction of dangerous substances*" was targeted to encourage companies to use a more broad approach for substitution; all the way from substitution of hazardous chemicals to new process and

[174] For more information see TNO web pages: http://www.tno.nl/index.cfm?Taal=2. See also Warren, N. D. Marquart, H. Christopher, Y. Laitinen J. van Hemmen, J. J. Task-based Dermal Exposure Models for Regulatory Risk Assessment, Ann. Occup. Hyg. 2006, vol. 50, 491-503.

product design, by introducing examples of good practices.[175] Other guidance and brochures by TNO address for example toxic use reduction, risk reduction and communication in the supply chain.[176]

A web portal, Stoffencentrum, offers employers and workers practical information about dangerous chemicals and safe work practices.[177] The portal also contains information about legislation and links to tools and practices such as Stoffenmanager, PIMEX[178], Guide for safe limits and safe practices[179] and AWARE[180] .

TNO has also been working on several research projects on substitution, where instruments and guidance have been developed for companies. However, the companies are apparently not using substitution as a risk management approach to any great extent, and the interviewees commented that even though there are several guidances available in the Netherlands, these are apparently only in little practical use.[181]

4.4.5 The United Kingdom

The administrative structure

The main authorities in the UK of interest are the **Health and Safety Executive (HSE)** and the **Department for Environment, Food and Rural Affairs (Defra**). The Environment Agency (England, Wales) and SEPA (Scotland) are enforcement orientated. Other notable organisations concerned with substitution are the **Royal Society of Chemistry (RSC)** and as an example of a research orientated organisation, the **Institute of Occupational Medicine (IOM).** Several informal networks in the UK actively promote sustainable chemistry, such as the Chemistry Innovation Knowledge Transfer Networks and the Green Chemistry Network[182] launched by the RSC in 1988 and now funded on a project base.

The Department for Environment, food and rural affairs (Defra) is responsible for policy and regulations on the environment, food and rural affairs in the UK, including environmental chemical legislation and REACH. Defra is also a very active government department in the field of overall chemical

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[175] Hertsenberg A. et al (2008)

[176] These and other brochures and further information is available in Dutch at http://www.tno.nl/index.cfm?Taal=2

[177] See http://www.arboportaal.nl/stoffencentrum

[178] PIMEX (Picture Mix Exposure) is a tool for improving awareness of the risks of exposure when using a chemical in certain activities. It shows how exposure changes when alternative working methods or personal protection equipments are used. For more information in Dutch, seehttp://www.arboportaal.nl/onderwerpen/gevaarlijke-stoffen/veilig-werken/pimex.html

[179] Guide for safe limits and safe practices is a digital tool that helps in making a correct and safe choice from a wide range of existing limits and safe work practices. For more information in Dutch, see: http://www.arboportaal.nl/onderwerpen/gevaarlijke-stoffen/veilig-werken/grenswaardestelsel/grenswaarden.html

[180] AWARE (Adequate Warning and Air Requirement) is a two digit-code for solvent-based products such as coatings, cleaning agents, adhesives and thinners, and was designed to help manufacturers and suppliers to calculate, store and retrieve the AWARE-codes of their solvent-based products. The AWARE offers manufacturers a clear insight in the contribution of the different ingredients, and provides a tool for comparing products regarding their potential and health-related hazards. For more information in English, see: http://213.206.93.221/aware/

[181] Interview data

[182] Green Chemistry Network, web pages

safety, and the Defra chemicals pages are a good source of information on chemical risk management in general[183].

The Health and Safety Executive (HSE) is the UK regulator for occupational health and safety. The mandate covers shaping and reviewing regulations, producing research and statistics and enforcing the law. The HSE is responsible for all aspects of chemical safety, bar environmental safety. The HSE's mandate covers health and safety in the manufacturing, storage, supply, carriage and use of chemicals in the workplace[184]. The HSE's work in the chemical field is organised around the following areas:

- **Industrial use[185]**
- Marketing and supply of chemicals
- Carriage of Dangerous Goods
- Chemical waste
- REACH enforcement

The concentration of most chemical regulations enforcement into one agency has the benefit of providing a very clear and easy to use framework for occupational health and safety in relation to chemicals.

Substitution in national legislation

Specific references to substitution in national legislation follow EU legislation, apart for the case of offshore industry, where a very interesting case of implementation of legislation with a requirement to substitute is the Offshore Chemicals Regulation. In the UK, the Centre for Environment, Fisheries & Aquaculture Science (CEFAS) provides a list of chemicals that are approved to be used in the offshore industry in the UK North Sea[186]. No other chemicals can be used. The system is however wholly based on environmental considerations. All chemicals are ranked based on their hazard to the environment and the ranked lists are available on the internet. Chemicals of high concern are marked as candidates for substitution in accordance with the OSPAR Hazardous Substances Strategy[187], which sets the objective of preventing pollution of the maritime area. In addition, specific risk assessments have to be carried out for any chemicals discharged to the environment, using the PON (petroleum operators notice) system. This type of hazard ranking provided by an authority is somewhat unique, and has provided a clear system of choosing alternative chemicals. The ranking is also used by the oil & gas companies for example to define purchasing policy through specific clauses referring to acceptable ranking in calls for tender.

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[183] Defra, web pages

[184] Health and Safety Executive, web pages

[185] including Control of major accident Hazards, which falls under the COMAH legislation (national implementation of the Seveso Directive) and is overseen by HID (Hazardous installations directorate); Chemical manufacture and storage, which falls under the Chemicals Industry Division of the HSE ; and the Use of chemicals, which falls under the Control of Substances hazardous to Health (COSSH) legislation (Chemical Agents Directive)

[186] See http://www.cefas.defra.gov.uk/industry-information/offshore-chemical-notification-scheme.aspx

[187] See http://www.ospar.org/content/content.asp?menu=00200304000000_000000_000000

Other instruments to enhance substitution

The HSE and the Environment Agency meet for discussions in relation to chemical management, often together with industry and trade bodies. Contacts are often informal and/or project based. Often the EA and HSE also sit together on committees. More formal meetings are held in relation to regulatory development, where for example the ban of CFCs was jointly considered. This type of joint working is however limited to special projects. Partnering between the HSE and industry /trade bodies to tackle specific areas of interest is a typical way of interaction (working together towards common goals).

The HSE has been very active in providing well written and clear guidance on different aspects of chemical safety, freely available on the internet.[188] The HSE programs related to chemical risk in workplace are built around the aim of achieving less exposure to hazardous chemicals. Substitution is one of the options, but the overall aim is to achieve less exposure. Whether substitution is part of this depends on the process looked at, the economics and the control systems.

The guidance in relation to the COSHH legislation (control of substances hazardous to health) is of particular interest. Here the HSE has developed both a web based tool for undertaking risk assessments in relation to workplace occupational risks from chemical use (the COSHH Essentials web tool)[189] as well as written fact sheets of guidance on different subjects. However, particular guidance on substitution on its own is not given. Instead, the need to consider substitution is frequently mentioned in different leaflets and other guidance on how to manage particular aspects of chemical safety. Examples include the guidance on "*Dust and fume control in the rubber industry*"[190]; "*Chemical vapour deposition (CVD)*"[191] etc.

In 1999, the UK Chemicals Strategy was initially published by Defra, setting out voluntary action for managing chemical risk in the UK. An important outcome of the strategy was the establishment of the Chemicals Stakeholder Forum, with the task to provide advice on general chemical policy but also on how to implement the strategy aims. This Forum has 21 members and includes representatives from industry, environmental and animal protection and conservation organisations, trade unions, consumer groups and the scientific community[192]. The Forum has identified a list of chemicals of concern and a list of less hazardous chemicals that still pose a concern. In more recent years, the forum has taken on an additional advisory role to Government on REACH and moved away from detailed examination of individual substances towards encouraging more rapid industry action on groups of substances.

From the point of view of this work, of specific interest is the "*Guide to Substitution*"[193] that the Chemicals Stakeholder Forum has produced. The work was initiated after the first publication of the

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[188] see http://www.hse.gov.uk/coshh/resources.htm

[189] COSHH Essentials, web pages

[190] Health and Safety Executive Publications, web pages

[191] Health and Safety Executive (2008)

[192] Defra, web pages

[193] Chemical Stakeholder Forum (2010)

ETUC's research institutes ETUI's priority list[194] and also in response to the failure of the industrial forums such as The Green Chemistry network to produce any concrete help for companies. In line with so many other UK guidance's and fact sheets, this document approaches the subject pragmatically and through a practical point of view. It deals with four main topics and gives example cases of successful substitutions:

- What is substitution?
- Why does substitution take place?
- How is substitution managed?
- A glance into the future

The guide does not attempt to provide a single approach towards substitution, but presents the drivers and barriers to "*help focus thinking, identify opportunities and address significant obstacles as part of the process of drawing up workable plans for substitution*". The guidance summarises the seven areas to address when thinking about substitution as:

- **Functionality**: Can an acceptable functionality be delivered?
- **Compatibility:** Is the substitute compatible with all other aspects?
- **Availability**: Is it available in sufficient amounts and is the supply secure?
- **Depth of knowledge**: Is the level of knowledge of the substitute at least as good as that of the original?
- **Human & Environmental Impact**: What are the respective impacts on human health and the environment of the original and the alternative?
- **Efficiency of resource utilisation:** Does the substitution lead to any changes in resource utilisation including quality and quantity of waste production?
- **Socio-Economic Consequences**: What are the socio-economic consequences of the change to the end consumer and to all the other actors in the supply chain?

The guidance builds on work done by the Chemistry Innovation Knowledge Transfer Networks work on Chemistry Innovation Sustainable Design Guide.[195] The Chemistry Innovation Knowledge Transfer Network is a remarkable resource for overviews of practical case studies, with over 100 listed on their website.[196] Although these are named sustainable design cases, a large number are in fact substitution cases. However, the focus is on the wider concept of sustainability and to find specific occupational health and safety related data requires a determined effort. According to Defra[197], producing the guidance will not be enough, but a mechanism is needed whereby you are able to come back every 12-18 months to ask industry "*where are you now*" and "*how have you used the guidance*" and "*has it been helpful*". Another mechanism much needed is a way for industry to share information – for this, Defra is looking to the sector bodies (industrial organisations) that can actively engage with their members.

[194] Santos et al. (2010)

[195] Chemistry Innovation KTN, web pages

[196] See https://connect.innovateuk.org/web/chemistryinnovationktn

[197] Interview data

In the interviews with the UK organisations, the need to include the consideration of costs of substitution in any approaches to substitution was emphasised. Promoting substitution without giving industry the tools for assessing costs and benefits was seen as futile. It was also raised that there appears to be a lack of reliable methods aimed at allowing especially SMEs to calculate overall impacts of changes over a longer period of time.

4.4.6 Some additional notes from Denmark

An example of a Member State where much has been done for substitution is Denmark, where both specific legal approaches and development of practical tools for industry to find substitutes for specific applications have been applied. Note that an overview of Danish approaches has already been published (e.g. Lissner, 2006) and therefore Denmark was not included as a case study country. However, the following three approaches are particularly noteworthy.

1. A legislative approach of interest is the Danish so called MAL-code labelling system, which was established as a means of promoting protection of workers to chemical risk. If a product is used for professional purposes in Denmark, a MAL code has to show both on the package and in the Safety Data Sheet (SDS) of the product. The MAL code consists of 2 figures with a hyphen in between, e.g. 3-5. The first number characterises the level of necessary protective measures for inhalation exposure, based on volatility of the ingredients and their occupational exposure limit values. The second number characterises the necessary protective measures needed for skin, eye, inhalation of dust or droplets and accidental ingestion protection[198]. The MAL code system has also served as inspiration for similar systems, such as German GISCODE for construction products[199].

2. There is a separate Danish Product Register, whereby any chemicals used professionally in Denmark have to be reported to provide an overview of what is used in the Danish workplaces and in what amounts. This knowledge is used by authorities for various purposes including prioritising of work, control, risk assessments, supervision, statistics and mass flow analyses.[200]

3. The Danish output includes the provision of the Catsub database, originally financed by the Danish Working Environment Authority and the European Agency for Safety and Health at Work[201]. (See also Chapter 7.4).

[198] Danish working environment service (2005) Executive order on the determination of code numbers; accessed at http://arbejdstilsynet.dk/en/engelsk.aspx

[199] e.g. Eurofins; accessed at http://www.eurofins.com/en.aspx

[200] Danish Working Environment service, accessed at http://arbejdstilsynet.dk/en/engelsk.aspx

[201] Available at www.catsub.dk

4.4.7 Evaluation of existing guidance to substitution in the case study countries

Comparative overview of these guidances to substitution

There is a mixed set of guidance available on substitution in the five case study countries, ranging from none (Finland) to guidance provided by the legislator (Germany, France), by a research organisation and funded by the authorities (the Netherlands) and guidance produced by a stakeholder forum (UK). Each of these are summarised below:

- **In Finland,** there is no guidance developed for substitution
- **In France,** the guidance focuses on CMRs and is built around nine steps: 1) Identify the substances that should be substituted, 2) create a working group, 3) define specification, 4) search alternative solutions, 5) try out the alternatives, 6) evaluate the consequences of the solution on safety and health, 7) compare the different options, 8) implement and 9) evaluate and validate the solution. A web tool to support and help the industry to manage the substitution process of CMRs has also been developed (www.substitution-cmr.fr).
- **In Germany,** the substitution principle is clearly addressed in the legislation and through the provision of a rather detailed technical guidance/tool for the substitution process, the Technical Rule for Hazardous Substances (TRGS) 600 Substitution, which aims to help the employer to comply with the Hazardous Substance Ordinance. It is a framework guidance based on chemical risk, complemented with several other TRGSs with more detailed guidance on specific chemicals and specific uses and their potential substitutes. TRGS 600 includes a flowchart and is constructed around four themes: 1) Determination of substitution possibilities, 2) guiding criteria for the pre-selection of substitution possibilities with good prospects, 3) decision on substitution and 4) documentation. The guidance addresses occupational health and safety factors, cost and environmental concerns and recommends models to use for the comparative assessment of the health and safety hazards.
- **In the Netherlands,** TNO has produced guidance to substitution in two parts: a ten step cycle for the substitution process and a module for integrated assessment of risks before and after substitution. The ten step cycle consists of: 1) Identification of the substances, 2) mobilisation of stakeholder support and commitment, 3) forming a multidisciplinary steering group, 4) functional analysis of why the chemical is used, 5) finding requirements and barriers (functional, process-based, physic-chemical, quality, logistical and economic), 6) finding and evaluating alternatives, 7) risk assessment (health, safety, environment and risk shifts), 8) testing in practice, 9) implementation and 10) evaluation.
- **In the UK,** the guidance has been very recently produced by Chemicals Stakeholder Forum under the auspices of Defra. It does not provide a clear step by step guidance, but rather raises the questions that need to be addressed and discusses barriers and drivers for substitution. The guidance is divided into four themes: 1) What is substitution? 2) Why does substitution take place? 3) How is substitution managed? and 4) A glance into the future, providing also case examples of successful substitutions. Within the “how is substitution managed” part, the focus is on seven different areas of consequences of substitution, namely: 1) Functionality, 2) compatibility, 3) availability, 4) depth of knowledge, 5) human & environmental impact, 6) efficiency of resource utilisation and 7) socio-economic consequences to the end consumer and to all the other actors in the supply chain.

The guidance available in some countries focuses on CMRs, and whilst some provide practical tools and models (France, Germany, and the Netherlands) for example the UK guidance is more of a discussion paper, including discussion around the theme of why to substitute. The two guidances that provide a direct cyclic step by step approach (France, the Netherlands) do not contain detailed information, and are better suited to large companies with internal resources to provide multi-disciplinary steering groups. None of the guidances are specifically easy to interpret suited for SMEs with limited knowledge and experience of chemical risk management or substitution, but in particular the German and Dutch guidances are accompanied by several tools to help companies carry out risk assessments and find substitutes.

In all of the case study countries, the interviews with authorities indicated that the uptake and practical implementation of substitution was poor. In particular, where guidance is provided without accompanying tools but more importantly, without accompanying campaigns or sustained efforts to raise substitution onto the agenda, there is little success and few companies utilise the guidances in practice. In the successful campaign of substitution of CMRs, organised by the French Ministry of Labour, CNAMTS and INRS, of some 2000 participating companies, 60% had tried to substitute CMR category 1 and category 2 substances**.** Of these, 70% succeeded, 18% was still experimenting at the time of writing, and only one out of ten had failed in the substitution attempts. The results indicated that the successful substitutes were found by using the knowledge inside the company and with the help from the suppliers. Failures were in most cases due to lower performance level of the alternatives and very rarely due to other direct economic reasons.

The current situation in the case study countries can be summarised as follows:

- None is directly providing specifically smaller companies with practical help, although the German solution is here perhaps the easier one for small companies to use.
- The guidances are more expert than management orientated, which makes it particularly hard for SMEs to utilise the existing knowledge or tools to any great extent.
- Risk assessment as a starting point is only part of one of the guidances, the German one, where the technical rule for substitution is supposed to be used for all chemical uses that are identified as in need of risk reduction.
- Pulling together the overall evaluation results of alternatives is either something not included in the processes or described in a too complex manner to have practical value for smaller companies.

From the point of view of this study objective to find out if there is a need for a common guidance across the EU, directed specifically at SMEs, the answer must be yes. In order to find best practices and areas that particularly need addressing, the approaches to substitution guidance in the five case study countries were assessed in relation to the following three topics:

- Use of risk assessment; including for example identification of targets for substitution and health and safety assessment
- Taking technical and cost considerations into account
- Linking substitution to chemical management

Use of risk assessment in guidance

The way targets for substitution are identified is considered to be of prime importance, and it is argued that the identification should be based on risk. The way the evaluated guidances discuss and guide the company through risk assessments and how risk assessment results are taken into account in the decision on whether to substitute varies between the countries. A comparison of the approaches in those case study countries where substitution guidance is provided is given in Table 3.

Table 3: A comparison of the use of risk assessment in the guidances to substitution

Risk assessment / country	**France**	**Germany**	**Netherlands**	**UK**
Estimation of risk	Focus on CMRs. Risk estimation discussed, but no detailed guidance.	Substitution guidance refers to TRGS 400 Risk assessment for activities involving hazardous substances, complemented with guidance for the assessment of specific risks.	Included. Recommends using specific tools such as Stoffenmanager.	Not included
Exposure potential	Not included	Part of risk assessment, i.e. TRGS 400; TRGS 401 and 402.	Part of risk assessment, using tools such as Stoffenmanager.	Not included
Risks covered	CMR, others not specified	Inhalation, dermal and physic-chemical risks.	Environment, inhalation, ingestion, dermal and safety risks. Also risk-shifts mentioned.	Environment mentioned, risk shifts; technical compatibility.
Risk control measures	Focus on substitution, others not discussed.	In TRGS 400 substitution is the primary measure, other control measures are referred to in TRGS 500.	Substitution is the primary measure. Other control measures are included in the Stoffenmanager tool.	Discussed in general terms, no specifics.
Risk management	Not included	Covered to some extent in the TGRS 400.	Discussed in general terms.	Discussed in general terms, no specifics.

Taking technical and cost considerations into account

Technical considerations are included in all of the guidances in various degrees. The German substitution guidance provides a list and examples for comparing and identifying the relevant aspects, but does not provide clear guidance on how to identify these. The UK guidance discusses technical considerations at a general level, and provides some examples of how these have been assessed and overcome. In the French guidance, technology barriers and cost is discussed in some degree.

Table 4: A comparison of technical and cost considerations in the guidances to substitution

Technical and cost consideration/ country	**France**	**Germany**	**Netherlands**	**UK**
Technology constrains and technical assessments.	Discussed in terms of functionality and efficiency.	Yes, covers technical requirements, suitability in process and whether realisable at current premises.	Functional analysis of why the chemical is used, and finding requirements and barriers (functional, process-based, physic-chemical, quality, logistical and economic).	Discussed in terms of functionality, compatibility and availability of alternatives; no specific assessment of technology.
Cost of substitution	Discussed in general terms, no specifics.	Tables provided for calculating costs using a comparative approach (increase or decrease) covering insurance, material, equipment, labour, transport, storage, disposal and protective measures.	Economic impacts e.g. short and long term costs and benefits and investment requirements are discussed. The guidance contains a checklist for possible business impacts.	Discussed in terms of efficiency of resource utilisation and socio-economic consequences to the end consumer and to all the other actors in the supply chain. No specifics.
Direct and indirect consequences, e.g. costs of risk.	Mentioned briefly	Comparative increases or decreases through reduction. Risk not covered by costs.	Discussed shortly, no specific guidance.	Discussed in general terms, no specifics.

Linking substitution to chemical management

Ideally, chemical substitution should be directly linked to the company's chemical management approach. Here the UK guidance is perhaps the best example of a discussion paper, where the challenges and barriers related to substitution are discussed from an overall risk management point of view. However, this guidance does not specifically address risk management in the company, but approaches it more from an overall societal viewpoint. In the German guidance risk management is included as an overall idea in the TRGS 400 on risk assessment, but is not very clearly presented.

The identification of alternatives is addressed in all of the guidances. Most recommend talking to suppliers and internally within the company. All of the guidances also guide the user to carry out comparative assessments of business as usual versus alternatives. Most discuss the potential of risk shifts (e.g. from environmental to health etc.), but no help for comparing or prioritising the different types of risks is given. In the German and UK guidances the importance of assessing the depth of knowledge, i.e. how much is known about the potential substitute is mentioned, although no clear rules on how to assess this is provided. The German guidance provides tables for carrying out overall cost-benefit analysis, whereas the French and Dutch approaches do not address this in much detail and the UK guidance takes a societal perspective, encouraging the user to assess costs and benefits at the societal level – yet without providing any specific tools for this.

The UK and German guidances do not specify who should be included in the decision process, whereas the French and Dutch guidances call for multidisciplinary steering groups. None mention the hearing of workers representatives. The presumed length and overall timeframe for the decision making is not addressed in any of the guidances.

Summary review of the case study country guidances

Overall, many excellent elements are provided in the various guidances. The German guidance is perhaps the most detailed one and best suited for smaller companies, but its structure is cumbersome and laborious to read, including highly technical elements best suited for expert evaluations. Especially the division of risk assessment and substitution guidance into totally separate documents, and both having complementing documents, makes it very difficult to read them and to understand the entirety they are forming. The UK guidance does not provide practical support, but rather discussed the overall approach on a higher level. The French and Dutch guidances have initially been constructed to support substitution of CMRs and require multidisciplinary expert groups to evaluate the substitution potential – hence these are not directly suited to SMEs.

It is however considered that there are very good elements in all of the guidances, that can be re-used and perhaps modified to provide a unified, step-by-step guidance document suitable for all workplaces, including SMEs that do not have the resources or knowledge for elaborate evaluations. Specifically the following elements were identified as highly relevant for any developed guidance at the EU level: The German column model approach, the Dutch and French models' cyclicity and focus on continuous improvement, and the UK requirement to address effects over the entire supply chain.

5. Substitution drivers, barriers and motivators

5.1 Overview

Drivers are influences that "push" companies towards substitution. **Motivators** on the other hand "pull" companies towards substitution, i.e. it creates a desirable advantage for companies to substitute. **A barrier is** a term that is here used to describe any influences that hinder or make it difficult for companies to substitute. All three of these types of influences can be external, i.e. created by society, the market place, specific legislations or policies, or internal, arising from within the company. These influences can act co-jointly or as opposite forces and can sometimes lead to conflicts of interest.

Although the analysis in this report is based on the legal framework of today, regulative requirements change with time and therefore future trends in relation to compliance and liabilities are also probed. The boundaries for decisions on which chemicals to use in what manner are created by societal and company expectations, often in conjunction with personal beliefs and experiences, as illustrated in Figure 11.

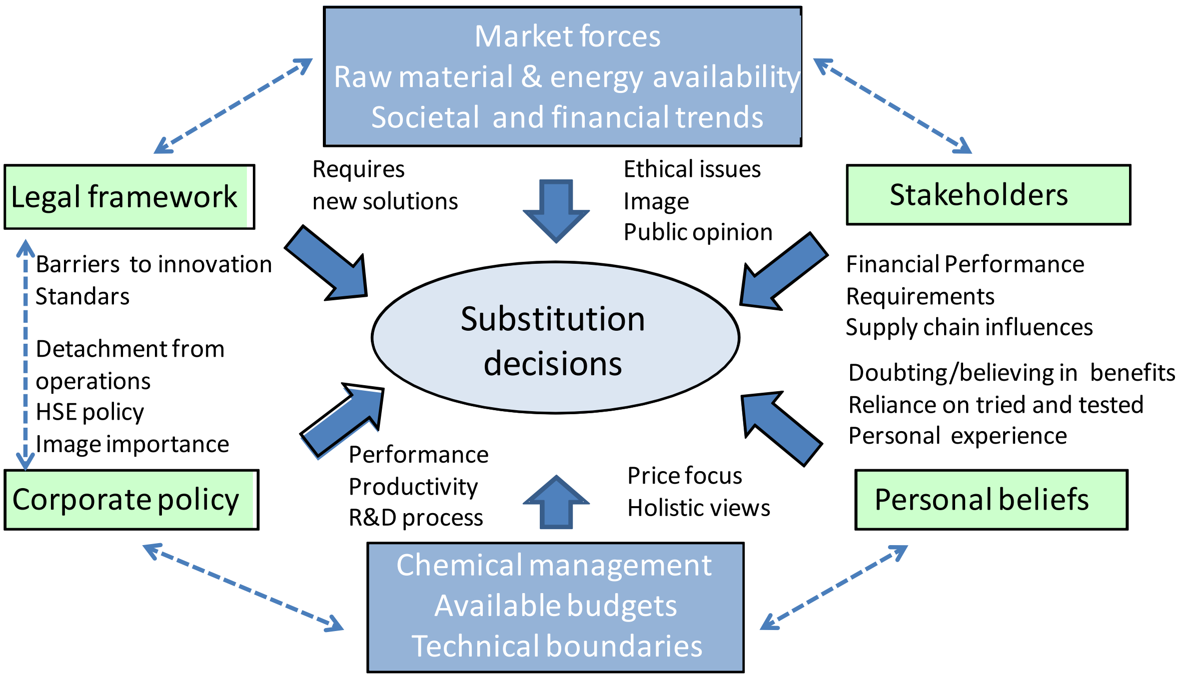

Figure 11: Drivers and barriers to substitution

One of the most influential overall drivers is indubitably legislative demands. This driver is also consistently acting on all companies. Company policy guidelines for how HSE properties should be taken into account are often based on regulative boundaries and definitions. Other forces are also interlinked, and the motivation to reduce chemical risk through substitution is for example based on a combination of, amongst others, market trends, customer demand, performance goals, tendency to inertia and personal beliefs. These influences may vary with time, location, corporation and person making the decisions.

In this chapter, the external influences are first examined separately and as creators of the societal boundaries for obligatory, acceptable and desirable behaviour of businesses. Secondly, the internal influences acting on the companies' policies and actions are discussed. After this, the relevant value chain characteristics of external and internal influences are presented. Finally, the potential for creation of conflicting interests that these various forces have, are examined through a look at the consequences of substitutions undertaken based on specific, dominant influences.

5.2 External influences

5.2.1 Types of influences

External influences on substitution decisions have been described for example by Taylor *et al* (2010) as including, but not being limited to the following types:

Drivers:

- Regulative restrictions or requirements, including coming restrictions and requirements
- New relevant alternatives brought to the market
- Pressure from the supply chain or users
- Availability of raw materials and energy
- Liability and litigation potentials

Barriers:

- Requirements for new /renewal of permits etc.
- No alternatives available in market
- Possibility to relocate (out of regulatory requirement area)
- Conflict with contemporary political expediencies
- Lack of regulatory or supply chain pressure
- Competition and confidentiality needs hinder cooperation and communication

Lohse *et al* (2003)[202] in turn identified communication and social factors, risk information and the regulatory framework as key external influences. Lohse *et al* further conclude that legislative drivers may also lead to "*substitution as a side-effect*", e.g. when substitution is not the primary goal. The general tendencies towards resistance to change and reluctance to experiment with the unknown are identified as other prime barriers. Notably, the authors identified that the "*motivation of companies to substitute specific substances differs significantly from other stakeholders' attitudes*".

The external drivers and barriers have here been grouped as per Figure 11 and are further described in the following sections.

[202] Lohse J. et al. (2003)

5.2.2 The legal framework influencing substitution decisions

Overview of regulatory influence

Health, safety and environmental concerns within society can when combined with chemicals make for a volatile emotional cocktail in the public eye, as chemicals may be automatically perceived as dangerous. In a democratic society, legislators will focus on such areas that are the concern of voters. Consequently, the HSE aspects of chemicals are subject to increasingly tight regulatory control[203,204] and increasingly stringent statements of intent. This is reflected in the fact that whilst the specifics may vary in different legislative areas and between countries, the requirement to substitute chemicals with less harmful substances is being brought into more and more legislative eas[205,206,207]. Whilst the intent is spelled out, detailed specifics on what substitution means and how it should be approached is somewhat lacking, specifically in health and safety legislation. Environmental legislation has been more successful in implementing substitution of specific chemicals, or, through the application of permit requirements, the reduction of overall high risk chemical use. In the occupational health and safety legislation, substitution requirements are often not rigorously enforced, may be unclearly specified or hidden within complex technical regulations and consequently do not act as strong drivers for substitution.

Regulators and authorities are in general seen as playing an important role in goal setting and promoting substitution as a relevant option for risk reduction. In addition to the role as preparers of legislation, the authorities have a large influence on the use of substitution in companies through sending more informal signals to industry in the form of guidance and recommendations.

General requirements to "**use less harmful substances*****" were not seen as a strong driver. In fact, such terminology was seen as an expression of "*****regulatory optimism*****" with negligible impact on practical decisions.*** Calls for more detailed consideration, even prescriptive use of substitution requirements were voiced by authorities and companies alike. Parallels were drawn to many successful environmentally derived bans on certain chemicals. The example of banning the use of VOC substances indoors in Netherlands is a prime example of effective regulatory push. At the same time, such regulatory lead requirements to find alternatives were also seen as having the potential to lead to conflict of interest, i.e. banning a chemical substance on environmental grounds may introduce alternatives with higher occupational health risks.

Legislation as a driver for substitution

One of the strongest influencing factors for chemical risk reduction is legislation and the boundaries of acceptable risk this creates. There are however large differences in how strong an influence a

[203] Garland E. (2005)

[204] Selin H. and Van Deever, S. (2006)

[205] REACH Regulation (EC) No 1907/2006

[206] OSPAR Decision 2000/2

[207] Act on Safety, etc. for Offshore Installations for Exploration, Extraction and Transport of Hydrocarbons (Offshore Safety Act)

specific legal instrument has on substitution decisions, strongly correlating to the degree of enforced actions it requires.

The impact of a particular legal instrument on substitution decisions within a company also varies according to the size of the company, the industry and the position of the company in the value chain. The early part of the value chain is more heavily regulated than the latter part due to differences in the overall risk level. Such companies are often risk aware and often have the required expertise in-house for chemical management challenges. Heavy industrial users and manufacturers of hazardous chemicals are perhaps most heavily regulated. This does not, however, necessarily mean that weak legislative drivers for substitution would be stronger towards these companies, as the actual substitution of a chemical may be much more intricate and difficult than for actors closer to the end of the value chain.

The emphasis enforcing authorities puts on substitution and the degree to which they monitor and enforce substitution has a strong impact on substitution decisions. If little or no enforcement of substitution requirements occur, the legislative impact decreases substantially. The focus of enforcing authorities varies between countries: for example, in the UK, much monitoring is directed towards SMEs, whereas in Finland, occupational health and safety inspections are somewhat more biased towards larger workplaces. The relative emphasis enforcing authorities place on occupational health and safety issues related to chemicals also vary between industry sector. Whilst in the chemical industry this is one of the key targets in many countries, for the food industry, the main occupational health and safety focus tends to be on ensuring safe use of equipment and maintenance of hygiene standards, whereas for the construction industry the focus is often on preventing falls. Therefore, one could almost state that the more knowledge of chemical management and chemical risk reduction a company has, the more emphasis is placed on it, although one has to bear in mind that the relative risk from chemicals is also indubitably generally higher the closer to the early part of the value chain a company is situated.

Specific legal requirements are, in contrast with most occupational health and safety legislation, often associated with environmental legislation. Environmental regulation bans on specific chemicals are an obvious way of ensuring substitution takes place, but stringent consent conditions also often successfully encourage the entire supply chain, and in particular chemical manufactures, blenders and service companies towards innovation to facilitate their customers implementing substitution. This is due to consent conditions often being a primary driver for reducing risk for the customers of these companies. A prime example is the oil and gas offshore industry in the North Sea, where consent conditions are strict and have led to many of the companies developing chemical risk reduction targets (See also Chapter 4.4.5). In order to be able to supply the customers (oil and gas companies), suppliers actively work towards formulation of environmentally less hazardous substances and overall, the use and discharges of the most hazardous compounds has seen a steady decrease since the OSPAR regulations were introduced. Other prime examples where environmental legislation has had a marked effect on chemical substitution is the electronics industry, e.g. through the RoHS Directive restricting the use of materials hazardous to environment and health and the WEEE Regulations promoting re-use, recovery and recycling of components. Environmental requirements are seen as, in general, stricter and more thoroughly enforced through permits than occupational health legislation.

Some occupational health and safety regulatory areas contain direct requirements to substitute (e.g. CMR directive). Regulatory influences in the form of specific requirements that follow from the use of hazardous substances are in general considered the strongest external driver towards substitution. Indeed, some of the interviewees even considered legislation as the only significant external influence. On the other hand, the opinion was also voiced that regulatory requirements and legislation only acts as a background influence that supports certain actions and decisions motivated by other issues.

In general, interviewees were of the opinion that **the less specific the regulatory requirements for substitution is, the less likely it is to drive risk management measures towards substitution**. Overall, the primary data collated indicate that legislative measures acting as drivers for substitution can be put into an order of influence as follows:

1. Explicit bans on the use of certain substances, mainly used in environmental legislation, but will also increasingly arise from REACH
2. Restrictions and consent conditions that require certain levels of risk management based on the quantities and hazardousness of substances used, mainly used in Seveso II Directive implementation
3. Specific requirements for substitution of chemicals with certain properties, e.g. CMRs
4. Specific requirements for occupational health and safety measures and standards to be achieved (e.g. German TRGS system)
5. Un-specified requirements for best practices and application of the general principle of risk reduction through substitution (e.g. Chemical Agents Directive)

Regulatory motivators

Avoiding increased obligations is an example of regulations acting as motivators. There are mechanisms whereby legislation drives companies towards substitution through for example easing the administrative burden (e.g. the Finnish ASA-register, see Chapter 4.4.1). Environmental legislation in particular can also to some degree be seen as influencing the customer's willingness to pay, as "*environmentally well performing*" products may be more expensive yet still achieve market success – although this is not always the case.

Avoiding increased obligations is seen particularly in industries where chemical volume and hazard based consents are required (e.g. Seveso II Directive upper tier requirements such as Safety Reports, discharge consents etc.). Consent conditions and legislation are definitely seen as encouraging substitution and risk management in general. It simply "makes life easier" to reduce the risk as much as possible.

Financial incentives to look for alternative substances or to develop new processes with less risk were seen as particularly desirable regulatory motivating instruments, although few examples are found. In the Netherlands, the Department of Economics has some funding available for substitution projects. This funding however is directed more towards process development projects, and not as much towards chemical-chemical substitution. A good example of using taxation as an instrument to encourage substitution trough creating end-user demand for the safer product is the case of introducing unleaded petrol. Here taxation was used as an instrument to ensure the price at the pump was cheaper for unleaded petrol. This created a natural demand for the safer product.[208] In Denmark, the government participated in funding a substitution project of NKT Cables, to level the costs of developing a safer alternative for PVC.[209]

Regulatory barriers

The biggest regulatory barrier to change occurs when innovation or change requires lengthy paperwork, changes in standards or specific consents. Such barriers are however at the same time seen as necessary safeguards to ensure sufficient knowledge of alternative compounds or processes are amassed prior to change.

5.2.3 Stakeholders: Supply chain influences

Stakeholder influences as drivers and motivators for substitution

Some suppliers are investing into providing their customers with alternatives that reduce risks and actively promote these alternatives, i.e. acting as drivers of substitution.

Pressure from the chemical users is among the most effective **motivators** for the chemical industry and other suppliers to change product lines and provide safer alternative products. Customers looking for safer alternatives do however have varying success. The pressure this demand creates correlates firstly to the relative importance of the customer, e.g. a large user has more influence with his supplier and can effectively direct the suppliers R&D towards providing safer alternatives. Secondly, the impact of user demand is related to the degree of ultimatum the customer gives: For example, where large car manufacturers have put together list of substances they will not buy, this has a direct effect in stimulating the suppliers to look for alternatives.

Another example comes from several large engineering companies / manufacturers having constructed lists of substances that they do not allow to be used in their products or processes,[210] thereby effectively “killing” the market for certain substances. On the other hand, if a small metal workshop does the same, they will most likely have to find other suppliers and will not affect product sortiments on their own. By default, the more chemical compounds a user consumes, the more influence that company has on the suppliers.

Stakeholder influences as barriers to substitution

Some manufactures on the other hand may demand that certain, technologically proven products are used even if there are safer alternatives, acting as barriers to innovation and substitution. Interviewees also identified resistance of suppliers/producers of chemicals to supply alternatives as one of the most important external barrier, quoting instances of difficulties in convincing suppliers to supply alternative, less hazardous products or products that can be used in an alternative, less risky manner. Even where functionally equivalent substitutes are readily available, economically viable

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[208] interview data

[209] Interview data

[210] Interview data

and proven to be less hazardous, their introduction in a certain process or product is often hampered by the fact that complex communication along the supply chain is a prerequisite for implementation. Never-the-less, there are of course also examples, just as with users, of some suppliers resisting change and holding on to old ways.

Examples of users resisting change and transferral to new safer products or operating methods are abundant. For the chemical supplier, this is an external barrier, whereas for the chemical user, this is obviously an internal barrier. In particular, this was seen in the traditional engineering industries (oil & gas, car industry, construction, engineering etc.). On the other hand, such resistance often stem from internal influences, e.g. quality control demands in aerospace industry. Sufficient to say is that not all users welcome the notion of change, and user inertia can create huge barriers to commercial success of safer alternatives, particularly until the alternative has become a tried and tested solution within the industry.

5.2.4 Market forces: Raw materials and energy use

The availability and price fluctuations of raw materials and energy can act both as a barrier and as a motivator for substitution. As well as the direction of influence, the magnitude varies with market prices. This is illustrated for example by the strong trend towards energy saving initiatives that are seen when energy prices rise. Likewise, if a company uses large amounts of a specific chemical /raw material, any increases in market price or scarcity of the material will motivate the company to look for alternatives.

The type of market also influences what type of innovations the market fluctuations lead to. In a commodity market with several suppliers competing on the same market, increased price of raw materials will stimulate process innovation, i.e. how to produce the end product more effectively in order to gain a competitive advantage. A market where substances are sold based on customer benefit or specific functionality (e.g. completion for effectively meeting end user needs) is generally favourable to innovation looking for alternative solutions and thereby more favourable for substitution approaches.

In general, the availability of less hazardous and environmentally friendly products on the market is increasing and prizes are becoming more competitive. However, some of the alternative products (e.g. cleaning agents) still tend to be more expensive and some are – or are perceived to be – less effective, making it difficult to justify a substitution.

The conservation of natural resources through operation optimisation and decreased raw material consumption was seen as a faint motivator in all but one case: Chemical Leasing[211]. This business model is based on the supplier getting paid for the benefit created, and the amount of chemicals used does not influence the overall bill. Hence the supplier has a strong incentive to ensure that the minimum amounts of chemicals are used. Chemical leasing is a business model that has been tried

[211] For more information, see http://www.chemicalleasing.com/

and used in the oil & gas industry, in the municipal water industry and current work by UNIDO is to broaden the scope of sectors through piloting programs.

The effect of market fluctuations in raw materials is strongest at the beginning of the value chain. Energy price fluctuations on the other hand impact most on industry that uses relatively large amounts of energy. For companies nearer the end of the supply chain, e.g. end-users, retailers etc. this type of influence is primarily indirect and felt mainly through relative prices of potential products.

5.2.5 Legal framework and standards and quality control

Industry standards, quality control and insurance procedures were recognised by interviewees as potential barriers to substitution. For example, analytical testing laboratories may not be able to introduce substitutes as tests have to conform to standards or the results will not be acceptable and comparable. To make changes in a testing standard is both a complex and lengthy process. Changing a standard has however direct influence on many users and is an effective way of ensuring widespread substitution.

The degree of influence industry standards have on the substitution process divides opinions and is very clearly linked to the industry itself. Heavily regulated industries also often have very high requirements for quality control, such as in the aerospace industry or the pharmaceutical industry. Such requirements in effect stifle or at least pro-longs innovation to some degree, as each change requires lengthy approval procedures. For example, the use of biofuel in commercial aircraft is subject to an approval process, and not something a company can decide on themselves.

Chemical manufacturers have a particularly strong industry led drive towards better health and safety management through the Responsible Care® initiative. In this global voluntary initiative chemical manufacturers work together with the national chemical industry associations to continuously improve HSE performance. Communication of products and processes to various stakeholders form an important corner stone of this approach.[212] There is therefore a strong industry specific driver to reduce risk to workers. HSE performance and specifically improvements and best practices are often relatively openly communicated within the industry. Accidents, incidents and chronic illnesses are recognised as high cost items and consequently the emphasis is firmly on prevention.

Insurance companies may also demand customers to use certain technically proven materials. One example is the use of certain cleaning agents for fire alarm maintenance – if the maintenance does not conform to this, and for example uses freon free cleaning agents, the insurance will be rendered invalid in the case of fire if the fire alarm malfunctions. Obviously this hinders the use of these less hazardous chemicals.

[212] e.g. Responsible Care, web pages

5.2.6 Stakeholders: Public opinion and company image

Public opinion acts in two ways on substitution decisions: firstly, general trends in public views are often created by media and NGOs around specific substances or uses. Secondly, the image of a specific company in the eyes of stakeholders such as shareholders and employees are more dependent on specific performance of that company. Both can act in unison. The closer to the end-user a company is, the more weight public opinion and image concerns have in relation to potential substitution decisions. Large companies are also more likely to react to public opinions and are also particularly concerned about protecting their image. Sectorally, the influence is particularly strong for companies where brand image is important and directly or readily related to chemicals: for example manufacturers of cleaning products or the oil and gas operators. On the other hand, brand image is less readily associated with chemical use in industrial sectors such as the food sector or the hospitality or construction sector, where other aspects are more prominent influencers of brand image.

The interviewees indicated that public opinion is particularly important in relation to environmentally based substitutions. Environmental concerns attract more attention both by the media and by NGOs than occupational health and safety issues. Chronic health issues, such as carcinogenic compounds are, however, an exception to the general focus of the public on environmental issues. This is particularly true for chronic health effect potentials of consumer products. Overall, the increasing trend of raised awareness about health issues is on a general level pushing industry towards safer use of chemicals.

Public opinion also shapes policy and creates input into what is regarded as acceptable risk levels. The more obscure a process is, i.e. the less that is known about chemical use within that industry, the less it generally attracts attention by the public[213]. This can easily lead to skewing of the public opinion towards specific issues, creating the potential for conflicts between for example societal pressure and lack of scientific knowledge in relation to specific substitutes.

Competitive edge and image were usually mentioned together, and considered overall encouraging for substitution. Image was seen to have an influence in both directions in the supply chain. More and more both the suppliers and the customers are demanding greater devotion to health issues and the environment, which has to be taken care of to maintain competitive. Achieving a competitive edge through enhanced image was considered to encourage substitution, particularly in the industries near the end of the value chain. For example enhancing competitiveness and improving company image were considered to be one of the major reasons for the companies to join the Green Office network. In Spain, for example, municipal purchasing policy also requires the use of greener and safer chemicals from the service provider, and competitiveness can be increased if such services can be provided.

5.2.7 Summary of external forces

Based on the results the most important external drivers, motivators and barriers are summarised in Table 4.

[213] interview comments

Table 4: A summary of some relevant external influences

Origin of influence	Driver	Motivator	Barrier
Legal framework and regulatory influences	Bans on specific chemicals Consents and restrictions increase with hazard /risk of chemicals used	Less restrictions or administrative burdens achievable Financial incentives to substitute or apply better risk management	(Excessive) standard requirements for changes Lack of specific requirements Lax enforcement
Legal framework: Standards and quality control	Conformance with voluntary agreements (e.g. Responsible care) and availability of industry specific support	Being regarded as a fore runner	Strict requirements on quality (e.g. medical industry, aerospace) require lengthy time and testing for any changes
Market forces: Raw materials and energy	Limitations in supply of current material	Availability of alternatives (price, supply logistics etc.) Reduction in energy use Price increases in existing raw materials	Lack of alternatives (with sufficient performance) Increase in energy use
Stakeholders: Supply chain	Pressure from end-users to provide safer alternatives	Potential for differentiation as supplier	Competition and confidentiality needs hinder cooperation and communication Lack of knowledge of alternatives
Stakeholders: Public opinion and company image	Public opinion trending towards responsibility NGO lead campaigns on certain materials General awareness of potential for harm Press coverage	Better image /image protection Potential for higher market share	Not a clear barrier, although occupational health is not high profile in public opinion unless specific accidents or long term illnesses (e.g. asbestos related) bring it into media focus, many companies therefore do not "see the value" of enhanced public opinion

Overall, any guidance developed should take into account these influences, but perhaps most importantly, the effect and dissemination success of the guidance should be monitored and the guidance itself actively promoted by authorities.

5.3 Internal factors influencing the use of substitution

5.3.1 Types of influences

The internal influences act from inside the company, depicted in the bottom part of Figure 11. Certain distinct value-chain dependant trends could be recognized, but the overall influences are largely company-dependent, and most of the factors were seen both as drivers and barriers. There are a number of issues that influence the use of substitution as a risk management measure that act inside the company. Taylor *et al* (2010) lists, among others, influences such as relative yields of alternatives, resistance to change, costs, desire to reduce HSE impacts, concern for worker welfare and potential to increase market potential. In addition, the company policy sets the general framework for risk management and R&D. Neither should it be ignored that final decisions often come down to personal beliefs, experience and knowledge levels. In reality, it is often difficult to separate the corporate policy from personal beliefs and values.

Occurred incidents within the company – and in industry – can also have a considerable impact, although this divided opinions. The results of the interviews and surveys conducted indicate that there are three distinct types of internal influences: the R&D process, technical considerations and management considerations (including financial considerations). On all of these, there are influences stemming from company policy, technical and financial restraints, risk management approaches and personal beliefs. As it was commonly considered to be a combination of a variety of internal aspects that encourages the companies to substitute, these are in the following discussed under the three main areas (R&D, technical considerations and management considerations). Some value-chain dependant trends could be recognized in particular in relation to the R&D process. The magnitude of influence technical considerations have was largely related to the industry and to the type of optimisation the substitution aims for (process, functional or customer benefit optimisation). The overall influences are largely company-dependent, and most of the factors were seen both as potential drivers or motivators and barriers.

5.3.2 The R&D process

The target of R&D is to make better products and generate more profit for the company: more efficient products, better yielding reaction pathways or processes. Thereby R&D acts both as a driver (find new ways) and as a motivator (achieve better market shares) and can indeed also act as a barrier (the amount of R&D required is too much to undertake or not a priority).

The level of knowledge and overall research that the substitution of an existing compound or process requires has considerable influence on the likelihood of substitution. The type of substitution considered also has direct bearing on the R&D requirements. If a new molecule is required for molecular functional optimisation, the R&D process is generally lengthy and expensive, often taking years. The earlier in the value chain the company is, the more R&D processes verge towards process or molecular functional optimisation. For chemical manufacturers as well as for some of the process industry, the research process aims for optimisation of yield and function. This blurs the distinction between substitution related R&D and general R&D. In fact, many of the interviewed companies regarded the entire research process as always being part of substitution efforts, although this terminology is seldom used.

There are trends discernible in the type or research undertaken and increasingly better HSE performance is regarded as a basic target for any new substances or processes. HSE performance is also clearly a criterion against which the research success is judged. Notably, this does not limit itself to the reduction of hazard. Other aspects that decrease overall HSE impact over the life-cycle of the product are:

- Less use of energy in the manufacturing or use process
- Less use of raw materials, i.e. better yields
- Safer working methods, such as closed loop systems
- Less creation of waste or less hazardous waste

An interesting example of taking into account the HSE properties and directing efforts towards better performing products is the eco-efficiency analysis carried out by BASF on many of their products[214]. The analysis looks at performance over the entire life-cycle and relates this to cost. The analysis is comparative and allows pinpointing the differences for targeted R&D to improve on specifics. To date, more than 400 such analyses have been conducted. Another example of targeted R&D is found in the service companies to the oil & gas sector, such as M-I Swaco, where data from the field is used to trigger research for substitutes. Field engineers provide data on particular properties that are undesirable from a health and safety point of view, and this leads concentrated research on how to overcome these properties. Notably, these undesirable properties can also be technical.

The available R&D budget can be a significant barrier to research, in particular where lengthy research projects are foreseen. On the other hand, the relative readiness to engage in research is often related to the chemical manufacturer's market strategy. Manufacturers of commodities and bulk chemicals compete on cost and are more likely to engage in research for process optimisation. Other manufacturers aim to be market leaders through providing the best functionality of chemicals, these companies also direct their R&D processes towards chemical function optimisation. Finally, service orientated chemical suppliers and manufacturers tend to focus on how they can provide better overall customer benefits. A prime example of the latter is the use of Chemical Leasing as a business model, done by for example Safechem (a subsidiary of Dow Chemicals), Cabot Speciality Fluids and Nalco.

Further along the value chain, the relative intensity of the required R&D process diminishes. However, at the same time, the ability to influence the R&D processes of the chemical manufacturers may increase. The retail industry has a considerable potential to influence substitution through targeted purchasing policy (for example, decisions on what is kept in stock). Industries where chemicals are used tend to focus on optimising the process of using the chemical, with less emphasis on finding new alternatives. This can also be related to the level of specialist knowledge in chemistry required to find substitutes for certain processes – and the perceived complexity of finding substitutes for other processes. Any guidance should attempt to lower this perceived complexity by mak-

[214] BASF, web pages

ing the substitution process more accessible by breaking the overall process of substitution into more manageable and easier to implement pieces.

5.3.3 Technical and practical considerations

Technical and practical considerations were seen not as barriers or drivers but rather as **enabling factors.** The first consideration when looking at risk reduction through using a new chemical or process is to ensure it is technically viable and can be implemented at a reasonable cost. If a substitute will not give the desired technical performance (e.g. yield) at less or at least almost the same cost, substitution is seldom further considered.

The technical constraints are perhaps biggest in the beginning and the middle of the value chain. If for example the entire factory is designed to accommodate a specific chemical reaction pathway, the barrier to change this is considerable. Similarly, if substituting one substances creates a need to change an entire recipe, e.g. to find new alternatives for also the other chemicals that are used, this will create a substantial barrier to substitution. Technical and practical considerations are therefore perhaps best seen as forming the framework within which substitution is possible rather than as separate influencing forces. Whilst it is clear that development of new techniques can open up previously unachievable processes, the engineering profession is often conservative and resistance to change with unproven benefits over time is often high.

On the other hand, if a new substance or process can be adopted within the given technological framework, resistance to change is considerably lower. Small changes therefore appear easier to accommodate. Never-the-less, new and revolutionary designs in process chemistry can lead to considerable savings and if this can be proven, the barrier to substitute is significantly lowered.

At the end of the value chain, technical considerations often move towards becoming practical considerations. Instead of contemplating having to change a whole factory line, the consideration is more work step related. The relative easiness of trying out new methods lowers the relative barriers. For many end-user industries, the precise chemical function (e.g. how it cleans) is of much less importance than the outcome of the use of the chemical (that it cleans well). The less hazardous the average chemical used is, the less knowledge the company is likely to have about the chemical HSE properties. The knowledge base within such industry about potential substitutes or how to assess the substitution potential is relatively speaking quite poor, resulting in high reliance on suppliers for information and new ideas. In particular, service orientated chemical suppliers and manufacturers selling solutions i.e. customer benefits, have a very important role to play in initiating substitutions within this sector. A prime example of this is the cleaning industry. New methods will be tried and embraced based on how well the alternative performs the desired function. For example, a comparison of floor cleaners may not so much be based on for example toxicological information or even risk assessments, but rather on how well and how fast the floor can be cleaned. It is seldom that the company itself has in-depth knowledge of chemical properties, and the reliance on the supplier to recommend safer alternatives is quite high.

Any guidance developed should take into account technical considerations. As the technical considerations relevant to any one company are very specifically related to the activities of the company, this should take the form of a framework for identifying and evaluating technical considerations.

5.3.4 Management approaches

Workers wellbeing and occupational safety and health management: Due to rather strict regulations in occupational health, workers health is in general relatively high on management agendas and reducing accidents have for long been an important objective of companies. Especially in the chemical industry, workers wellbeing is a prime motivator for risk management, although it would appear that there is a tendency to use technical or procedural improvements rather than elimination or substitution[215]. The degree of influence that workers wellbeing has on substitution is related to the degree of "risk management sophistication" of the company. For chemical blenders, workers wellbeing is seen mostly through the customers eyes, although here service providers may also supply field engineers and in this case workers wellbeing in the own company becomes more important.

In other value chain positions, enhancing workers health and reducing accidents are also seen as important motivators – by some interviewees, this was seen as the overall biggest motivator for substitution decisions. Others acknowledged that the reason workers health and safety is high on the agenda is not purely done for the sake of ensuring workers' wellbeing and health, but also because accidents and occupational illnesses can lead to significant costs to the company.

Interestingly, authorities and experts in the area of substitution considered that workers health concerns seldom work as the sole motivator for substitution. Company representatives themselves on the other hand, regardless of the position in the value chain or position in the company, often listed workers health concerns as the crucial factors driving substitution. This apparent conflict in understanding may reflect a more cynical view of authorities, or perhaps more likely, the fact that authorities considered actions whereas companies may have considered intentions when assessing this question. The authorities' views are of course also based on experiences of many companies.

Employee *commitment* was seen as a valuable component. Employees with true interest and commitment in safety, to whom the company's management give both the required resources and the authority to accomplish changes, were seen as vital. It would however appear that HSE professionals often are at disadvantage when presenting cases for change to management. This often has to do with inability to convert HSE reasons into reasons that make business logic. When decisions to change a process or chemical require management approval, this can be hard to obtain if the case is not also presented from a business point of view.

Occurred incidents: A clear albeit unfortunate motivator to substitution is occurred incidents: it is easier to justify any money spent on change if there is a tangible reason for this. Company representatives often quoted examples of substitution cases that were initiated as a result of accidents occurred in production site. Another motivator is a proven linkage to chronic health problems, e.g. cancer inducing compounds or mutagens, which also have stricter regulatory requirements.

Knowledge management: A clear area of concern is the influence that lack of knowledge can have on decisions. Lack of knowledge can act both as a barrier and as a driver to substitution. Neither is preferable. Lack of knowledge about the properties (e.g. toxicological impacts) of a potential substitute can lead to the use of an alternative chemical that in fact constitutes a higher risk than the

[215] Interview data (Several authority interviews)

original compound when looked at over the life-cycle. Substances which have been used for a long time may have a more complete set of hazard information available than newer potential substitute, where this level of information simply does not exist. As there still are a lot of gaps in our knowledge about the chemicals and their effects on health and the environment, situations where for example a carcinogenic substance is substituted but the substitute might for instance lead to much higher acute risk to workers than the original substance are possible. Also, there might be a considerable imbalance between the available risk information. Lack of knowledge can lead to overseeing for example occupational health impacts if the substitution is instigated from an environmental point of view. Lack of knowledge can also simply lead to non-consideration of substitution as an option, as it is deemed “too difficult for us”. Particularly here the role of good guidance could help companies take the step towards substitution by lowering the barrier of perceived difficulty.

Scientific knowledge was considered to play a role in all parties of the value chain, however clearly increasing towards the beginning, being most influential within chemical manufacturing. The lack of easily available, good scientific information and documentation was considered to be an effective barrier for substitution. For example, when higher concentrations of less harmful chemical has to be used to have the same result as with the more harmful chemical, the actual positive effects to health and environment are difficult to assess. Shifts of risk from one area to another are another difficult to assess issue, as there are ethical value considerations as well as scientific understanding of the risk shift to take into account.

Lack of awareness of chemical risk management and the substitution principle was seen as a barrier to substitution. New solutions for how to share the knowledge more effectively and make it more broadly available were seen necessary, and here step-by-step guidances both towards risk management in general and substitution could help.

Risk management: Risk level and product hazard concerns were also mentioned as internal drivers to enhance the use of substitution as a risk management measure. If a company has a clear policy for occupational risk management, this often includes the principle of substitution. Existing risk management approaches in general increase in thoroughness towards the beginning of the value chain. For example, OHSAS 18001 or ISO 31000 using companies or companies working to these principles usually have reasonably good practices for risk management. This may include commitment to promoting the use of substitution. However, it would appear that very seldom are structured processes in place for systematic substitution potential identification and assessments. In fact, existing practices for managing chemical risk can act as barriers to substitution as such practices are often oriented towards risk reduction through finding engineering solutions or increasing PPE.

Viewed from a risk management approach, it is clear that substitution is best seen as one option in a palette of risk management options and not as a separate target. Although substitution is regarded as the second most preferable risk management measure after elimination, in practice the consideration seldom follows this hierarchy of preferred management options. Instead, the most common method is still to look for better engineering, more automation or increased PPE. These are often measures that fall within the company’s sphere of knowledge comfort, whereas alternative chemicals or reaction paths may be seen as more difficult. It should be noted that this is not always the case, and many companies are both innovative and actively promote the use of substitution as a risk management measure.

To be able to use substitution as a risk management measure, it would appear that several considerations have to be satisfied:

- the original use of the chemical has to be identified as a relatively high risk operation
- substitution has to be identified as a route to risk reduction
- viable alternatives have to be identified, tested and their relative costs and benefits compared with the challenges to implement the change

Companies with comprehensive risk management policies are more likely to actively look for safer alternatives. This often correlates with the relative risk of the industry in general, but not in a straight forward manner. High risk industries are often near the beginning or in the middle of the value chain and technological restraints towards substitution can be considerable. There is also a high degree of inertia built into many companies, i.e. a reluctance to change anything that is proved to work. Finally, the step from comprehensive risk assessments to holistic risk management is one that many companies have not yet taken.

There are many examples of companies where the overall management decision to reduce risk has lead to open thinking and innovative approaches to new and safer ways. Other companies have translated their risk management policies to clear lists of allowed purchases. However, management approaches are perhaps still more of a barrier than a driver or motivator to substitution. A considerable part of this comes down to the real or perceived cost of substitution. Substitution is, often without specific knowledge or comparisons, regarded as an expensive and unknown route to reduced risk. Where a guidance can provide help, is in how to present overviews of total consequences to management and, even more importantly, to provide a clear overview of how to collate all relevant consequences and assess them for overall impacts. One of the biggest factors influencing management decisions is the consideration of cost, which is discussed in more detail in the following section.

5.3.5 Financial considerations

Financial considerations can be divided into costs and benefits. Benefits arise through increased market share or increased profits and cost savings. Finding solutions to cut costs and save money are always motivating for companies. Equally, higher costs are barriers to implementing new methods or chemicals. Some of the interviewees considered financial issues to be the biggest barrier for substitution. Especially in the absence of other robust drivers, such as legislation, short term financial considerations are often the main barrier for substitution[216].

Just as technical considerations, financial impacts of a substitution are a fundamental question where certain conditions have to be met. Firstly, substitutions that considerably lower profits are not generally undertaken unless there is a specific legal demand for this. Secondly, either sufficient savings or other notable benefits have to be demonstrated in order to justify the costs of change, i.e. the cost of substitution. However, less hazardous and environmentally friendly products are sometimes more expensive, which makes justification difficult. Especially when process changes are needed, resistance from management based on cost was seen as a common barrier. In many cases,

[216] e.g. Lohse et al. (2003)

the existing process is seen as well known and understood, but "one cannot be sure how it will work with the substitute" was an often voiced comment.

Often the only costs considered were the relative direct costs of chemicals or processes. Other costs seen as barriers were related to research and development, testing and quality assurance, and training. On the other hand, some companies took a more long term view. An acceptable justification for higher costs of less hazardous chemicals was in some cases the potential for even higher costs from the use of hazardous chemicals in the future (e.g. liability, regulatory requirements). The potential for cost savings through better workers health and reduced accidents were also seen as important motivators.

Closely connected to the costs, available time was considered a significant barrier for substitution. Time is a very limited commodity in the business world, and the ever increasing demand for higher productivity does not help the situations.

Opportunity to save money is a motivator for substitution – if only these opportunities are recognised. For example, if the need for extensive and costly ventilation systems can be eliminated when less hazardous chemicals are used, this saving should be balanced against the cost of implementing and operating the substitute process/chemical. Here a clear problem is that the direct costs in general ***are*** easier to identify and quantify than the benefits, and therefore receive most attention. To assess the value of substitution by ***quantifying financial impacts, this should include consideration of long-term effects on several factors and operations, such as*** improved performance and efficiency. To reduce the pressure imposed by cost consideration, calls were made for ***political*** support through incentive ***funding and tariffs***.

A core requirement for any cost-benefit assessments for chemical substitution is that it should take into account risk reduction. There are both practical and theoretical challenges with calculating the true cost consequences of risk reduction. Nevertheless, in order to make management decisions based on overall impacts of substitution, understanding both relative operational costs and uncertainties or risks related costs of chemical use are basic requirements[217]. There are many formats used in other areas of management, such as Activity Based Costing (ABC)[218] which has a background in cost accounting and the analysis of production costs in the manufacturing industry. This was an area where there was an interesting polarisation in the answers: The UK authorities and industry in general saw this as a particularly difficult task, and that the lack of tools for assessing true relative costs is a barrier to substitution. Other authorities and for example CEFIC saw this as something routinely done by companies any way. What would appear clear is that financial considerations cannot be ignored in any developed guidance, and if possible, it should include a detailed review of total costs of operation, certainly not stopping at evaluation of relative material costs only.

[217] Teale et al. (2003)

[218] Kaplan and Bruns (1987), Kaplan and Atkinson (1998)

5.3.6 Summarising internal factors

In opposite to external factors influencing chemical risk management, internal factors are obviously much more company specific. Certain distinct value-chain dependant trends could however be recognized. Most of the discussed factors are seen as capable of acting both as barriers and motivators: some, in particular the management system itself, is seen as a very important driver. It is not possible to give an overall ranking of the relative importance of these factors, but an attempt to summarise the most important ones is given in Table 5.

Table 5: A summary of the most important internal drivers, motivators and barriers

Origin of influence	Driver	Motivator	Barrier
The R&D process	Potential to find better ways of working	Potential to achieve better market shares	Lengthy process High costs Uncertain outcomes
Technical considerations	New more efficient technology enabling safer chemical use	Savings in for example technical risk management measures	Large changes needed in certain cases (e.g. the entire factory is designed to accommodate a specific chemical reaction pathway)
Management considerations	Company's risk management and an existing policy for occupational risk management Committed employees	Workers wellbeing and occupational safety and health management Occurred incidents	Lack of management knowledge by experts Lack of scientific knowledge on hazards and behaviour of substitute Lack of awareness of chemical risk management and substitution principle
Financial considerations	Potential cost savings through better workers health and reduced accidents	Market share increase potential and improved competitiveness	Cost of substitution Available time

5.4 Conflicting influences

Conflicting influences arise frequently and most substitution decisions are a balancing act. A prominent and often quoted conflicting external influence to OSH arises from environmental considerations or legislation. More environmentally "friendly" products can be more harmful to humans. This was seen as a particular problem for the legislator, and more cooperation between occupational health experts and environmental regulators was called for.

In general the society was considered to be a strong driver to substitution, but it can also cause contradictions. The green movements are strongly pushing for substitution, but mainly through a hazard based approach[219], which conflicts with the general principle of risk reduction rather than hazard reduction.

Conflicting influences can also arise from different aspects of safety, and for example between legislation and required industry standards. A good example is brominated flame retardants (BFR) that have been traditionally widely used in electrical and electronic products as well as in textiles, furniture etc. BFRs are effective in preventing fires and often required by industry standards. Concerns of BFRs' properties including their persistence, bioaccumulation, and potential for toxicity have been growing. At the same time, industry standards require the use of equipment and spare parts compliant with fire prevention requirements. Fire safety was a prime concern that led to the initial exclusion of BFRs in 2006 from the RoHS Directive, which restricts the use of a limited number of hazardous substances in electronics. In a recent Committee meeting (June 2010), the commission adopted a draft[220], whereby "*permission to use noncompliant spare parts is extended to equipment benefitting from an exemption when placed on the market, to prevent premature withdrawal of equipment from use"*. Today, it is seen that there are safe alternatives available and many companies have moved beyond legislation and have phased out, or are in the process of phasing out, brominated flame retardants and other hazardous substances [221] . Many leading electronics companies and environmental organizations have in fact urged EU to include e.g. brominated flame retardants on the RoHS-list of restricted substances to further drive substitution. This example highlights the dilemma that not only legislators but also companies may face (e.g. toxicity, persistence vs. fire safety) and which may be solved through more knowledge and assessment of alternatives.

Conflicting influences can be regarded as a problem arising from a too narrow a focus during the evaluation of consequences of substitution. This is also obvious in legislation. Society rarely takes a holistic approach to consequences, which can lead to wholly unintended consequences. For example, the EU Biocide Directive was introduced to promote the use of safer biocides, but according to the Royal Society of Chemistry interview data, what has happened is that all research has effectively stopped.

Sometimes substitution can lead to problems in other areas of sustainability, for example through greater resource use or greater energy use. A good example is the case of classification and labelling of ethanol. Ethanol should be classified as a teratogenic[222] when used in relatively high concentrations. This would mean that ethanol could not be used under EU Solvents Directive[223] (CMRs may not be used). This in turn would lead to the fact that the current trend of using ethanol as a substitute for "nastier"/less appropriate solvents would no longer be possible, and the whole effort to move towards solvents with less risk would go in reverse.

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[219] For example the SIN List is an NGO driven project intended to speed up the transition to a toxic free world, see http://www.chemsec.org/list

[220] European Parliament Environment, Public Health and Food Safety Committee (2010) About the subject in European parliaments Legislative Observatory, see: http://www.europarl.europa.eu/oeil/FindByProcnum.do?lang=2&procnum=COD/2008/0240

[221] ChemSec (2010)

[222] Able to disturb the growth and development of an embryo or fetus

[223] Solvents Emission Directive 1999/13/EC

Other cases highlight the danger of substituting without proper research. A good example here is the substitution of chlorinated insecticides (bio-accumulative) in favour of organophosphor, which do not accumulate, but impact on humans directly. The organophosphors were in turn phased out by the use of pyrethroid insecticides, which despite their otherwise good toxicology profile are very toxic to aquatic life. When used in sheep dips this creates problems, highlighting the fact that substituting for something better in one area can lead to subsequent problems in other areas unless a thorough holistic view of all consequences is taken. Any developed guidance must highlight the importance of taking a holistic view of risks and to consider risk transfer from one type of risk to another.

6. Substitution in practice

6.1 Actors and the value chain

6.1.1 Taking the value chain approach

The overall message from companies, authorities, organisations and experts working with risk management was that available guidance on substitution is in general far too theoretical to have practical application especially for SMEs. As the main target group for a potential guidance and common approach to substitution developed in this work are SMEs, specific emphasis has been put on analysis of how a common framework or approach to substitution can be made more accessible, user friendly and easy to implement in practice.

This chapter focuses on how substitution is viewed and tackled in practice. As discussed in earlier chapters, there are numerous factors influencing the application of substitution. How strong a force these influences exert varies from company to company, but there is an apparent correlation between the relative importance of these factors and the position of the company in the value chain. **Therefore this chapter has been structured around the value chain positions rather than differences and similarities between different industries. It is considered that this will also give a wider application of the analysis.**

6.1.2 The role of authorities

Authorities are seen as having a dual role in promoting chemical risk management. Firstly, they **create the boundaries of acceptable operations** through defining the legal requirements. At the same time, authorities interpret the legal text and define how enforcement and monitoring is taking place as well as execute enforcement. Secondly, authorities are viewed as a **significant source of knowledge** and are expected to provide guidance for how to best achieve risk reduction. Despite this, a common finding was that there is much to be done in enforcement of legislation and in information provision.

6.1.3 The role of companies

Companies are obviously the **executors of substitution decisions**. Companies also act as **suppliers of alternative products and knowledge**. Other companies exert pressure on suppliers to come up with new and better alternatives. Companies **change the market** through innovation and creation of new business models. The different roles that companies have are analysed in relation to the position in the value chain in this chapter. The sectors chosen for a closer look were: Chemicals, plastics and rubber, mining, metals and minerals, engineering, automotive, cleaning, textile and clothing, food and construction.

6.1.4 The role of other organisations

Other organisations also influence the use of substitution. Industry organisations, trade organisations and professional organisations are **important sources of knowledge** and also **shapers of public**

opinion and industry standards. Independent research institutes and consultants are seen as **providers of enabling information.**

NGOs and public pressure groups are important **shapers of policy and societal opinion**. At the moment, the main emphasis on hazardous chemicals tends to be on the environmental properties and chemicals with potentials for chronic health impacts. Product safety from a consumer aspect is another widely discussed issue.

6.2 Chemical manufacturing

6.2.1 Overview

The industries included in the research that fall under this position are chemicals, plastics and rubber and mining, metals and minerals (See Figure 12). **Mining, metals and minerals** are however considered in the process industry, as in this particular research, the focus is more on chemical use than mining of raw materials or oil production. Therefore, these companies will be discussed under that heading of process industries. Never-the-less, it should be born in mind that the boundaries are not exact and that many companies indeed stretch over several value chain positions, depending on the specific role considered. Blenders, resellers and distributors are considered separately, as the forces acting on them are often different from those acting on traditional chemical manufacturers.

The chemical, plastics and rubber industries manufactures chemicals that range from base commodity chemicals to very specific formulations for example for the pharmaceutical industry. The plastic and rubber industry can also be regarded as a process industry or as other industry (e.g. when making moulded plastic goods etc.). Here, it has mainly been treated as a manufacturer.

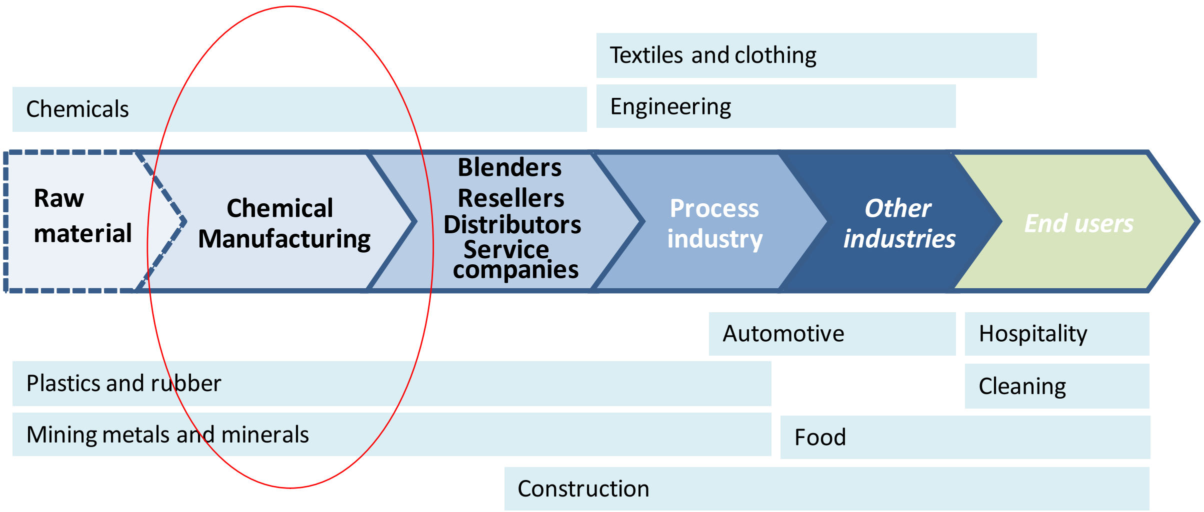

Figure 12: Raw materials and chemical manufacturing

The R&D processes conducted tend to be dependent on the type of manufacturing they are engaged in. Consequently, their R&D processes are targeted towards bettering either the yield of their products (making more profit through less operational expenses) or towards better products (gaining market share). Innovation in chemistry has long been geared towards finding more sustainable solutions and there are specific networks for “green chemistry”[224].

6.2.2 Current practices

Substitution *per se* is not been addressed as a risk management measure in industry guidance. Instead substitution is largely approached as related to REACH and the authorisation process. It is therefore hardly surprising that the industry tends to view substitution as something highly complex and well beyond the realms of SME’s. Indeed it was even mentioned in some interviews that “*all simple substitutions have already been done*”. This focus on substitution as something highly complex is perhaps obviously directly related to the fact that substitution within the chemical industry mostly requires extensive R&D. This different viewpoint lead to some interesting discussions during the project work, even to a point where the “*wisdom to promote substitution to SME’s*“ was questioned.

At the same time, the chemical industry is very active in promoting risk management measures and the European Industry Organisation CEFIC has for example recently (June 2010) launched a Responsible Care toolbox for SMEs offering a large number of instruments that can help SMEs to better manage occupational health, process safety, transport safety and chemical management, amongst other issues.[225]

Worker involvement in substitution varied significantly from company to company. For example in BASF, employees are actively encouraged to continuously put forward suggestions for improvements, safer practices or safer products. The suggestions are then evaluated by experts and topics include suggestions for how to deal better with safety, energy reduction or workload optimisation. A benefit calculation done for the suggestions implemented every year clearly indicate that workers are making a valuable contribution.[226] In other chemical companies, the management did not recognise any activity on part of workers to suggest or engage in substitution work.

The relative priority of the process where the chemical is used in is the key element, e.g. an intermediate or raw material is much more difficult to replace than a solvent. Chemical manufacturing plants are fairly standard yet can be highly complex, and changes that can be done within the same engineering structure are easier to achieve. The more important the chemical is to the process outcome the more difficult it is to substitute as changes may lead to requirements to change for example the whole production line technology – or even the entire plant structure. Substitution can therefore be both time consuming and expensive.

Process design becomes more challenging when trying to institute a change in an existing process than when starting something new (e.g. plant or production line). In the process design, balancing the alternatives values – energy, water, raw materials and costs against efficiency of the manufacturing process (e.g. yield) is seen as crucial.

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[224] e.g. Green Chemistry Network, web pages

[225] CEFIC, toolbox web pages

[226] interview data

6.2.3 Requirements

The requirements of the chemical industry in relation to substitution are quite complex. Firstly, there are a vast number of different types of chemical companies, with different lines of chemistry, different sizes and different business logics. The needs highlighted during this study were directed towards in-depth examples of successful substitutions, better data-bases and information exchange with users and other industry. Substitution is seen as part of the overall risk management approach and any attempt to view substitution as a separate entity was strongly condemned.

For the chemical industry, it is hard to separate the core R&D processes from substitution efforts. Large chemical companies are well versed in the thinking of producing safer products in safer manners. **Therefore it is not considered possible to, within this scope of work, produce a simplified approach or framework for substitution that would be of direct use to for example the larger chemical companies.**

SMEs in the chemical sector have an advantage over other SMEs in that they generally have a working knowledge of the chemistry involved and are therefore better primed to consider the potential effects of any substitution. However, as previously mentioned, risk management in chemical industry SMEs has been recognised by the Industry body CEFIC to benefit from tools and approaches. It is therefore considered that some chemical industry SMEs could benefit from adopting a structured approach to substitution.

The biggest role for the chemical industry in relation to substitution in the context of this study is found to be as information providers to downstream users of their products. The chemical industry can therefore be seen as:

1) **information providers** to the downstream users of chemical products and
2) **innovators** of safer products and practices.

With REACH and CLP, the quality and breadth of information provided "automatically" by chemical manufacturers and suppliers to downstream users should increase. However, for substitution, the need for information about alternatives is as important as the need for information on a specific chemical. A proactive approach to promoting the company's own alternative brands (e.g. often so called "green line" or "eco products") is desirable. For more complex cases of substitution, a joint "problem solving" approach together with the customer can be very beneficial. Such active customer care is often related to the degree of service provided. Here chemical blenders and specifically chemical service companies have an important role to play.

6.3 Chemical blenders and service companies

6.3.1 Overview

Many chemical manufactures also perform the role of importers and act as service companies. Chemical blenders are also often acting as chemical service companies and are in general classed as chemical companies. The main difference between a chemical manufacturer and a chemical blender is often in whether actual reaction chemistry is involved or not. Resellers and distributors are not in the focus of this research. Nevertheless, a brief discussion has been included in the end of this chapter, as they often exert strong influences on chemical manufacturers and blenders.

As well as participating in the interviews and survey, one of the piloting companies represented a global chemical service company. Chemical companies or blenders are often strongly service orientated. The more service oriented the company is, the more likely it is to react to customer demand. The innovation and R&D process is often more orientated towards increased functionality and effective application rather than manufacturing process enhancement. Technical understanding and service orientation is used to create market advantages, for example through providing technical support and advice to users.

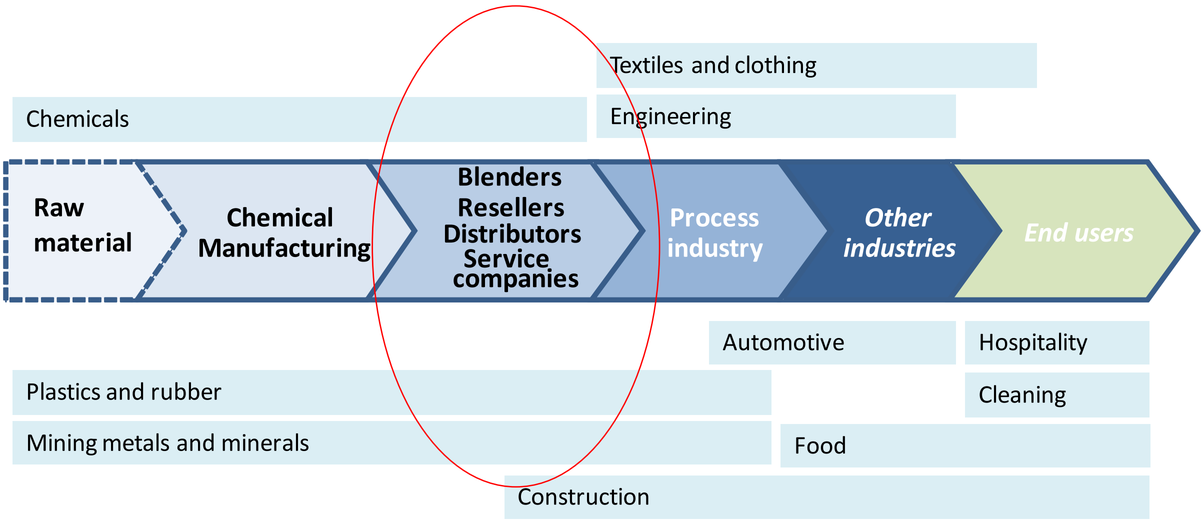

Figure 13: Blenders and service companies

Environmental regulations and consent conditions of end customers often influence the product lines carried and innovation activities undertaken by these companies. As the companies are themselves buyers of chemicals, they are also in a better position to try to find safer ingredients or products than traditional chemical manufacturers. Blending of different components mostly requires less complex production systems and actual chemical reactions are generally not involved. This leaves these companies more agile in their reaction to changes in demand and also more likely to proactively try to find solutions together with end users to enhance safety. This segment of the value chain therefore has a particularly active role to perform in the overall use of substitution as a risk management measure.

6.3.2 Current practices

In **business-to-business sales** the buyers own management system objectives are important, especially in companies that produce reports which are open to public scrutiny. Here image and stakeholder considerations are a strong influencing factor, driving the user towards safer alternatives. This is however dependent on the customers industry branch. In industries where there is a potential for more severe exposure to workers, the drive to find safer materials and processes is clearly stronger and also communicated to the supplier. For example, much of the R&D work done by a particular chemical blender is to find alternatives that reduce the amount of aromatic compounds in products, thereby decreasing product volatility and lowering the potential for inhalation exposure.

Increased knowledge about chemical risk is also seen as increasing the demand for safer alternatives. For example, in the case of toluene, as overall knowledge of the properties of the chemical increased, the labelling requirements increased. This in turn brought the understanding of the hazards and risks to a higher level and drive users towards finding a substitute – this has apparently not yet been successfully solved.

Occurred accidents/incidents or occupational diseases will spur customers and service companies towards substitution. For example, one of the large service companies for the oil & gas industry has a policy of reporting all incidents as well as a system for managing the reports, which includes a questionnaire on for example skin irritation incidents. A reported incident leads to a re-evaluation of the risk and within this evaluation, the need and potential to substitute is analysed. If the need to substitute is identified as high, a more thorough investigation will be launched. The service provider also state that they have reformulated chemicals due to occupational health reasons. If a specific compound or chemical is identified as a cause for concern from an H&S point of view, then the effort will be put into reformulation or substitution of that component to make the chemical less of an occupational health hazards. Initial screening (HSE assessment and laboratory testing for working conditions exposure) is failed by perhaps 10% of all products. Based on occupational health risks, this service company has terminated the use of chemical systems, chemicals and compounds in perhaps a dozen cases over the last ten years. In addition, some 50-60 reformulations of products have been done based on occupational health and safety issues over the last ten years.

Similarly another blending and service company has worked with customers in some cases over a couple of years to reformulate products or come up with entirely new solutions that reduce risk. Cost is of course a factor, as if the safer solution is too expensive, not many customers will buy it.

This segment is strongly driven by market demand and possesses a good degree of agility to react to changes in market demand. If market demand for safer products increase, the supply as well as R&D of this sector will quickly react and attempt to provide what is needed. At the same time, the understanding of chemical safety influencing factors is relatively high – although there are clearly wide differences between companies and inevitably, there will be SMEs with little knowledge of either substitution or risk management. For example, it would appear that some of the service companies have a working process for taking chemicals to the market, that would *de facto* work equally well for substitution. A service company reports using the following screening process for compounds before taken to market[227]:

1. Identify if a component/compound/chemical is hazardous and if risk need to be better managed
2. Look at the possible chemistries with better environmental or occupational health profiles for similar chemistry that can be expected to do the required technical job and identify potential substitutes.
3. Screen costs to see if carried by the market

[227] Interview data

4. Test formulation prepared on laboratory scale
5. Test the formulation in laboratory for technical performance
6. Screen for HSE properties
7. Conduct testing if required (skin irritation etc. as well as environmental)
8. Test the formulation in field for HSE and technical performance
9. Review data
10. Reformulate if necessary and repeat steps 1-7
11. Work up product line and take to market

Within the companies interviewed and from the survey answers, **workers participation** is seen as essential. For example, in a case of working with substitution with a boat yard on solvents, the process was modified by feedback from workers, who were asked to evaluate the practical aspects of the suggested substitute. Workers participation is in overall seen as important, as if workers are not engaged in the change process, problems with resistance to change may arise. Cases where the testing in laboratory conditions have indicated that a substitute is performing well may give rise to for example skin irritation in field conditions. **Existing practices for managing chemical risk** are seen as becoming less set, i.e. there is increasing willingness to accept and instigate new manners of managing risks. **Expertise** within company related to health and safety management can be used by the supplier as a marketing advantage, e.g. provision of technical support and HSE advice.

Workers are in general seen as becoming more and more aware of chemical safety being linked to their own wellbeing and are consequently participating more actively. This is however dependent on the company policy on communication and encouragement to bring forwards suggestions. Most feedback from workers is suggestions on how to improve things, although this is seldom directly linked to using different chemicals.

6.3.3 Requirements

The value of a common process towards substitution is mostly seen by this sector as supporting a potential sales argument for going through the need for safer products with the customer. The role of these companies would therefore very much be that of an advisor to the users, **e.g. working with the user in an almost consultative role to find best possible solutions.** As blenders and service companies are not so strongly tied to specific manufacturing processes or chemical raw materials, they are in fact ideally placed as information sources and partners in substitution efforts.

In this context the difference between distributors and resellers is mostly concerned with how close the party is to the consumer. The resellers are here associated with being close to the consumer and hence more susceptible to societal forces and pay more attention to issues such as image, stake-holder perceptions and competitive edge through "safer" solutions. An interesting trend observed by several interviewees were that for example **high street retailers** are driving suppliers more and more towards using less hazardous materials. Here, the drive for substitution is both direct end user pressure but also avoidance of potential conflicts with NGOs, as image is very important to such retailers. For example changes in materials used for printing T-shirts was mentioned in interviews as originating from the wish to pre-emptively avoid potential conflicts with NGOs.

6.4 Process industry

6.4.1 Overview

Within the process industries, there is a kaleidoscope of different industries, here characterised by the use of sometimes complex processes where chemicals used may or may not undergo reactions. A process industry engages in treating or preparing raw materials in a series of stages. Process industries included in this work are the **automotive**, **mining, metals and minerals**, **textiles and clothing**, and the **engineering** industries.

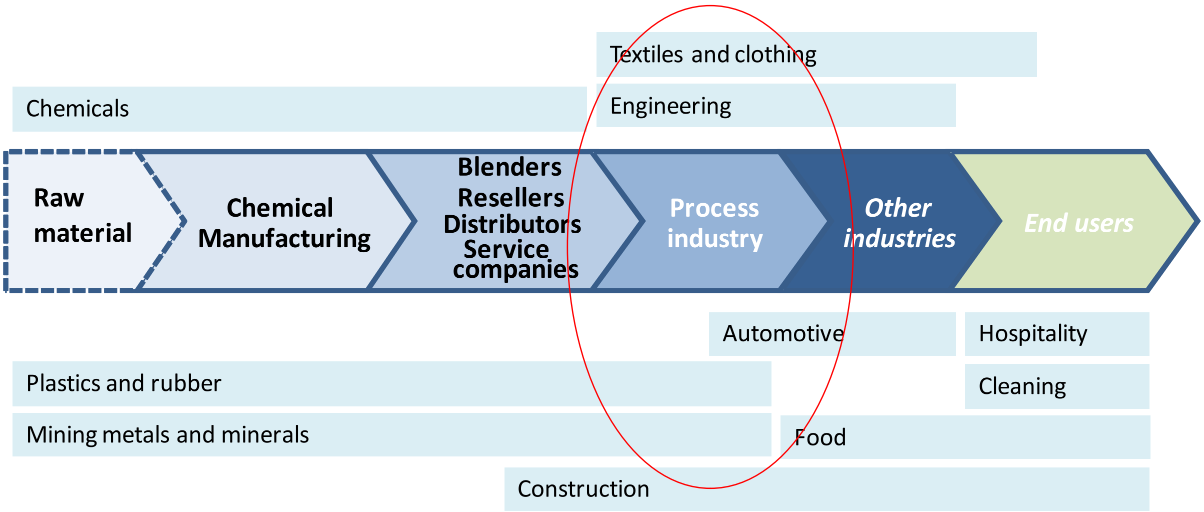

Figure 14: Process industry

Note that the classification of the selected industries is by no means absolute and has here been done purely from a workers occupational health and safety point of view. For example, the automotive sector may be considered a process industry, equally it could be regarded as part of other industry (assembly lines), and can also be considered as a user of chemicals for specific, isolated treatments of parts and dealt with as an end user. Nevertheless, automotive has been discussed here as a process industry. Similarly, the food industry is indeed engaged in preparing raw materials into products in a step-wise process, but the use of chemicals can be divided into two main parts: Chemicals used in the production itself and chemicals used in supporting functions such as hygiene, maintenance or refrigeration. As the substitution of chemicals used within food products is subject to stringent legislation and outside the scope of this work, within this study the food industry has been classified as a user of chemicals.

6.4.2 Current practices

Legal requirements and consent conditions, particularly the stringent environmental consents also encourage substitution in other process industry sectors. The automotive industry is a highly regulate industry in Europe. Car manufacturers have for some time actively worked to reduce the environmental impact of their products and manufacturing processes.[228] Similarly, legislation also has a major influence on the engineering industry. In particular in the electrical and electronic ***industries,*** the WEEE[229] and the ***RoHS directives***[230] ***have had considerable impact.*** The RoHS Directive restricts the use of materials hazardous to environment and health while the WEEE Regulations promote re-use, recovery and recycling of components.

Environmental legislation is very influential for the oil & gas sector, and particularly the upstream exploration and production, however, particularly in production, where workers are more permanent rather than the project type exploration activities, **occupational health and safety** is increasingly important. Efforts to find and substitute carcinogens have increased and there have also been some questions of liability in this respect. Companies tend to be large, often multinational players, although some smaller companies are found in the exploration and production sector. Due to the high risk environment of work, safety is a prime concern and companies tend to have clear policies that safety and well-being of people is paramount.

Some companies, particularly in the oil and gas sector have **specific chemical strategies** and for example, in one of the companies interviewed, before a new chemical is bought, it will be assessed for occupational health, safety and environmental risk levels. A clear goal is to find chemicals with least risk, taking into account how it will be used. Each time a more thorough risk evaluation for specific work is done, an evaluation of the potential to substitute is also carried out. Some oil & gas companies have a **company policy on occupational risk management and substitution**, which has a strong influence on what type of chemicals are used. In other industry sectors such company policies were few, but when existing, a specific company policy was considered to be both influential and acting as a driver for substitution.

Lists of restricted substances are common in the automotive, textile and engineering industries, especially in the larger companies. The automotive industry has even developed a global automotive declarable substances list (GADSL), which contains more than 2000 individual substances.[231]

Product hazard concerns influences chemical management in oil & gas companies, mainly where the company is engaged in producing products for the end user market (e.g. oils and lubricators etc.) Oil & gas exploration and production companies typically use service companies for supply of both chemicals and engineers for any particular job. The oil & gas company specifies what type of chemicals can be used and which health and safety criteria have to be met. The rigour with which this is done varies between companies. For example the Norwegian based company Statoil is well known in industry for applying very stringent HSE criteria. The push from the users to find products with less hazard and/or risk tend to considerably stimulate the service companies search for alternatives. In the car industry, end users also exert pressure towards more “environmentally friendly” vehicles.

The data collated from textile, automotive and engineering industries, identified **education and training** increases as the most important internal factors that would enhance wider use of substitu-

[228] European Commission Enterprise and Industry Directorate-General (2006)

[229] Council Directive 2008/35/EC

[230] Council Directive 2008/35/EC

[231] For more information about GADSL, see: http://gadsl.org/

tion. This was not the case in the oil & gas sector, which reflects the high degree of chemical awareness already existing in this sector. Comprehensive education for both the workers and the management is needed in order to have appropriate skills to e.g. assess available information, make the right decisions and to communicate efficiently with suppliers. The problem for the other than oil and gas companies in this supply chain position is related to not having personnel with a background in chemistry, chemical engineering or chemical risk assessments. There are exceptions, but in general chemical risk management is neither a priority nor an area of expertise. This is reflected by the fact that companies are less actively applying substitution. Changing recruitment policy for example in relation to HSE personnel to include expertise in chemicals and risk management, and give authority to efficiently do the required changes and improvements would most likely significantly enhance the use of substitution as a risk management measure. However, if a company goes down this route, it should take care that other HSE aspects that require specialist knowledge do not suffer.

Government-funded research and development programmes were considered to be an important tool to support substitution, especially when extensive resources are required and/or the subject is significantly removed from the core business competencies.

Workers participation was seen to encourage the move towards safer chemicals. Ensuring workers participation was considered highly important by all within this value chain position. The increasing level of concern about risks to workers' own health and general heightened risk awareness was seen as a main driver for substitution. The workers were seen as a source of practical knowledge and expertise of processes. In many companies, the experience was that when employees are being listened, it also encourages further participation as well as commitment to maintaining safety levels.

It was generally agreed that management commitment is essential for achieving good results and maintaining an ***atmosphere of continuous*** development. In the oil & gas sector workers participation is seen as one of the most effective drivers, and is actively encouraged. High risk awareness and well trained people tend to encourage consideration of substitution. Within the engineering and automotive industries, workers have been actively included in substitution processes. In practice, different ways and levels of participation exist. Educating the workers about chemicals, their risks and safe use is seen as the baseline that enables workers to participate in substitution processes. One simple method of participation is through feedback and development proposals. In practice the workers are mostly involved when new potential substitutes are tested and screened. In some cases the workers were also actively included in other steps such as setting boundaries and finding alternatives.

Existing practices for managing chemical risk vary in influence. For some companies, the inertia is high whereas others actively encourage open and innovative thinking.

A simplified description of **a substitution process** that has been successfully used in some of the food industry companies consists of three steps:

1. The chemical and its effects to environment and workers health are evaluated based on data in the SDS
2. If the hazard is seen as too high, a need to substitute is identified and alternatives are searched for and tested.
3. The substitute is compared to the original substance, taking into account performance, efficiency and costs.

In the engineering industry the RoHS enforcement guidance document[232] has been used by for example Nera Networks as a model for a substitution process. In one successful substitution project the target was to achieve a lead-free product. First the RoHS directive was thoroughly studied and information was gathered. After convincing the management that substitution was necessary, the project was started in 2004. The project was also a part of a Scandinavian project in lead free production[233]. In this project data about the costs were not collected, however, as the project lasted for four years, the overall costs are likely to have been high.

6.4.3 Requirements

The awareness of existing guidance is relatively low and some sectors and companies have developed their own processes. In general, most of the guidance included in variety of directives from EU was considered to be unpractical and obscure. In order for the regulation to be applicable, more understandable language, targeted to a larger non-expert audience, would have to be used. Overall, a pressing need for a **common comprehensible approach to substitution** accompanied by understandable guidance was voiced. In general, the requirements tended to include user-friendly and as simple as possible guidance, with no so called "legal or scientific jargon". At the same time it should be sufficiently flexible that it can be adapted by individual companies to meet their specific needs and requirements.

Most of the company representatives (some 80%) considered that **industry sector specific guidance is not needed**, although some of the oil & gas sector companies declared it "would be nice but not excepted". Any industry specific guidance could be specifically targeted towards certain "difficult" chemicals and take into account the exact way and technical restrictions there are for use. Quite a few of the interviewees considered **industry specific databases** beneficial. Such databases should contain information about the possible substitutes together with substitution examples and best practices. As such, successful substitution examples from within the own industry was seen as a good potential source of "new ideas and inspiration". Provision of such industry specific database is perhaps best tackled by industry associations.

A variety of aspects were seen as difficult regarding substitution. Broadly the difficulties can be divided into information, operations and economics. A common difficulty was the **lack of information** about the possible substitutes and their risks in different uses. Some interviewees considered it difficult to **identify chemicals that should be substituted** to begin with. Common challenges related to operations included finding technically suitable alternatives that meet quality criteria. Some companies stated that finding time to dedicate to a potential substitution process was a limiting factor. Establishing changes required in the overall processes or a need to "alter the whole recipe" to maintain the performance of the product and communicating the change in the supply chain were also mentioned as difficult issues. Most of the interviewees considered it difficult to predict whether the desired result and outcome would justify the investments made.

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[232] RoHS Enforcement Guidance Document available at http://www.epa.ie/

[233] See also http://www.nordicinnovation.net/

Predicting and establishing the possible changes that are needed in the overall processes was seen as most difficult aspect overall. This is also seen as something that carries potentially the highest costs. **Efficient cooperation** in the entire supply chain was considered to be extremely important, and necessary for implementing a successful substitution process. Sharing existing and evolving knowledge, not only inside the company and the supply chain members, but more broadly through **databases and forums** was considered very important. If in the future comparable risk-related information on conventional substances and their substitutes are to be available; this was considered to hold significant potential to accelerate substitution of hazardous substances in products and processes. Some of these data needs will hopefully be met through the new REACH and CLP Safety Data Sheets. It is considered that this wish for comparable information is also related to the need to enhance the ability of the people concerned with chemical management to better comprehend the various data supplied.

Issues mentioned as challenging were also those high on the list to be included in any guidance, which should ideally provide practical help for companies to work through the following:

1. Which chemicals are harmful, e.g. how to recognise priorities for substitution
2. Finding alternatives
3. Assembling sufficient information about potential hazards and risks of alternatives
4. Comparing and prioritizing the dangers and risks
5. Comparing and assessing the costs and benefits between the alternatives.

6.5 Chemical users

6.5.1 Overview

The end users of chemicals covered by this study are the cleaning and hospitality sector, the food sector and the construction industry sector, as indicated in *Figure 15*. In addition to the initial survey and interviews, a mini-survey for the construction industry was carried out (see Annex 3). Two of the piloting companies also represented end-users (food industry and office using cleaning and maintenance chemicals).

This sector is perhaps overall the sector where the initial knowledge and understanding of chemical risk was expected to be lowest. It also represents a large number of SMEs in the EU, therefore representing a large part of the target groups of the undertaken study.

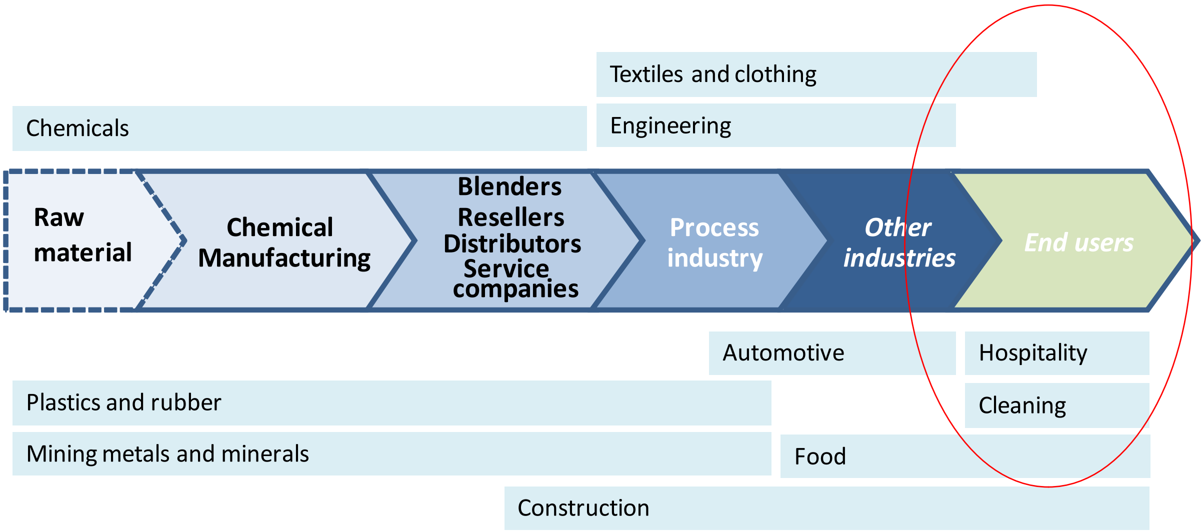

Figure 15: End users of chemicals

6.5.2 Current practices

The mini-survey directed at construction sector SMEs indicated that the level of understanding of chemical risk to health and safety is very low, although some examples of risk based assessment were found. Some 10% of the survey participants indicated that risk influences buying decisions (See Figure 16).

In general, the overall chemical selection is based almost purely on cost and performance, although some end customers may specify materials to work with. In experiences from the construction industry, it should be noted that the main effort of both companies and authorities tend to go towards preventing physical damage to workers (e.g. falls), and dust and noise have also received attention. This is however a sector that uses many hazardous chemicals, often in quite uncontrolled environments, where the specific chemical functionality is of less interest than the results (e.g. adhesives, paints, paint strippers) and therefore a wider selection of potential substitution alternatives could potentially be considered.

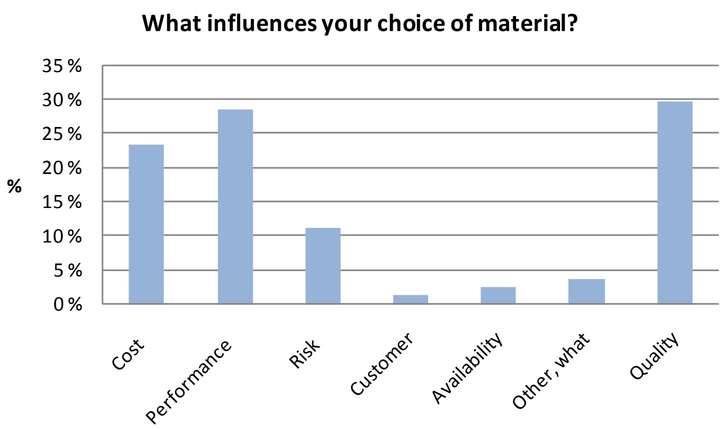

Figure 16: Survey results from the construction industry on product choice influences

Within the food sector, workers participation was not seen as particularly relevant in chemical risk management. Risk management efforts tend to concentrate towards ensuring the used chemicals are suitable for using in food manufacturing premises, and other considerations are not so much taken into account. As such quality and liability issues are particularly important for food industry and finding possible substitutes that fulfil the technical and quality criteria can be extra challenging. As with the construction industry, food manufacturing OSH efforts are often directed towards avoiding physical injuries from equipment. Dust, especially in the bakery sector is an important issue. Chemical management levels and understanding of chemical risk was found to be low, although the data set for this sector was very limited.

Within the **cleaning sector**, a higher degree of awareness than in the other two considered sectors in this value chain position was in general evident. In the cleaning industry there are multiple examples where cleaning agents have been replaced with micro fibre clothes, decreasing the use of chemicals substantially during the last years. Efficiency improvements and optimisation of cleaning processes can also help to either decrease the volumes of strong and hazardous chemicals used or changing these for less hazardous alternatives. In some cases, chemicals can be eliminated altogether. Note that in the piloting process, it was evident that whilst there was some degree of chemical awareness at the management level, this had not trickled down to the user level, and for example the explanation of what R-phrases are and what a carcinogen means had to be established first – notably once this hurdle was overcome, the response was rapid and the identification of products with highest risks using the proposed guidance document progressed smoothly.

In the cleaning sector, workers participation in the substitution projects was considered to be very important by some companies although not all, and it was mentioned that workers should be included into the process in different phases. Some companies encouraged workers to identify risks and consider better alternatives actively and continuously. Other companies did not see this as a relevant requirement and considered management commitment and actions as the most important factor in promoting substitution. Whilst most interviewees agreed that workers must be listened to and given real possibilities to influence; the reality is that particularly in smaller companies, workers initiatives are sometimes discouraged by the employer because of short sighted cost reasons.

In some of the companies interviewed the workers are efficiently included in chemical management. The workers are also almost always the ones who **carry out the actual testing**.

6.5.3 Requirements

Most of the interviewees were not familiar with any guidance to substitution, although some participants had expert level knowledge of tools, databases and guidance. Most interviewees did not see the need for industry specific guidance.

Within the construction sector, the largest need for help is among the vast numbers of micro and small enterprises and one-man companies, who have neither the awareness nor the expertise to consider chemical risk. The role of responsible suppliers in offering safer products is therefore particularly relevant. For the food industry, the need to take into account whether the chemicals are allowed to be used within food preparation areas is a vital requirement that limits some of the choices. One of the most common challenge for the cleaning industry was to find alternatives with less risk that are still effective enough so that there is no need to increase either the required volume of chemicals used or time taken to achieve the set standards. In particularly the time taken was seen as very relevant to whether the change would be economically viable.

Less hazardous chemicals were perceived as still tending to be more expensive. Overall comparisons between alternatives, including time, costs and risk as well as end results and performance were seen as challenging. As such, substitution was in many cases seen as hard to justify to the management. There are usually several different but overlapping products used by a cleaning company, which can make the substitution process laborious. Lack of knowledge about possible substitutes was considered to be an obstacle, and just as in the construction and food industry, proactive suppliers informing about alternative products and their benefits were seen as vital.

Overall, companies in this value chain saw a clear need for a common guidance, which should contain information about the entire substitution process, not only about the chemicals and their possible alternatives. Any guidance or tools must be simple to use and easy to understand. To really assess the benefits between one and the other chemical was seen as the hard part. For the micro- and small companies in all of these three sectors, a very short check list type document could help – including references only to hazards found on for example the chemical tin labels and a simple assessment of exposure potential on a scale of 1-3 or 1-5.

A common wish was for future legislation to be accompanied by guidance documents written in a manner that allows even complex issues to become accessible to the non-experts.

6.6 Summary of current practices and existing challenges in the supply chain

Based on the undertaken research, the position in the supply chain appears to be a very important factor influencing how companies approach substitution. It also correlates with the degree of complexity that a substitution process would entail. A summary of the needs for guidance and specific roles within substitution in relation to data, innovation and alternatives are presented in relation to the value chain in Figure 17, followed by a summary of the current practices per industry sector in Table 6.

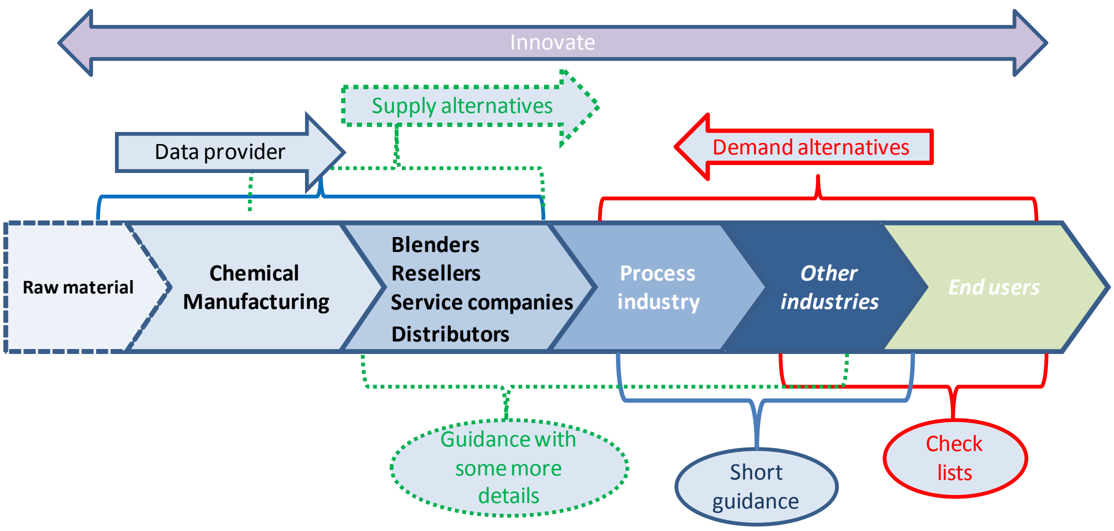

Figure 17: Roles and requirements in the value chain

Table 6: A summary of sector specific experiences

Industry	Current practices in relation to substitution
Chemicals	**Manufacturers** Strictly regulated industry and environmental consents and Seveso II Directive, the industry's own Responsible Care program is very influential Substitution process is very dependent on type of manufacturing and is in most chemical and rubber and plastics companies seen as being part of the R&D process Processes may be complex and changing requires technical changes that may include a whole process line ➔ expensive Worker participation in risk management high but in actual substitution processes less **Blenders and service companies** More agile than manufacturers in ability and willingness to change, R&D focus often on application and functionality as well as on overall services Source components globally, exert pressure on suppliers and reacts to downstream users demands quickly **Crucial role as information provider and companion in substitution process, engage with workers of customers to find best practices** *Note: Some chemical manufacturers also harness the role of blenders and service companies*
Plastics and rubber	Plastics is an industry with a lot of SMEs, just as the fragmented general rubber goods industry. Tire industry is formed of a few large actors Requirements to substitute come mainly from the legislation and official lists or bans, but increasingly due to customer requirements and the end consumer and NGO pressure Focus is mostly on consumer or environmental protection
Mining, metals and minerals, subsectors oil & gas	Strictly legislated high risk industry with high chemical risk awareness, high volume chemical users Exploration and production industry in particular use service contracts with chemical suppliers Environmental legislation is the prime driver for substitution, refineries and production have also high focus on chronic illnesses Worker participation is seen as important
Automotive	Strictly legislated industry ➔ used to applying substitution among other as a risk management measure Workers are actively included in substitution processes Long development times and long mass production times make substitution extra demanding Strict industry standards and chemical ban lists are common
Engineering	Focus more generally in process to process substitution Making changes in processes can be expensive ➔ costs are important barriers to substitution The main difficulty is how to find all the needed changes in the processes Because of RoHS, substitution is not a new approach for electronic engineering More experts in chemicals and chemical risks would be needed to enhance substitution

Industry	Current practices in relation to substitution
Food industry	Quality and liability are important ➔ It is challenging to find possible substitutes that fulfil the technical and quality criteria Little information available about the possible substitutes and their risks in a specific process Controlling risks by more traditional methods such as PPE is common Public concern and influence is an important driver, this however focuses on the chemicals and additives used in the food itself
Textiles and clothing	Awareness of chemicals and chemicals risks is usually quite low Guidance and instruction is needed in every aspect of chemical management and substitution Customer demand is a particularly important driver
Cleaning and hospitality	Performance is the main criteria for selecting used materials ➔ The difficulty is how to find less hazardous alternatives that would still be effective Requirements for using certain types of products or products with certain properties (e.g. scented products) comes bottom up in the supply chain Substitution is relatively easy to assess and consequently fairly frequently done in the cleaning sector Workers are sometimes actively included in the substitution processes; problems in worker's health may often be the initiators for the process Specific chemicals (e.g. disinfectants) lack widely known or efficient enough alternatives
Construction	Awareness of chemical OHS risks is generally low Cost, performance and quality are the main criteria for selecting materials. Including cost – benefit in guidance would make it more attractive Pressure for less risky materials is minimal in the supply chain, especially from SMEs working for private clients Sustainable design is an up-and coming area that encourages substitution at the planning stage Substitution in the whole branch (e.g. asbestos) as well as at individual working places (e.g. less dusty products) has been made Some guidance and lists of potential alternatives are available, but the problem is how these could reach the numerous small actors in the sector For SMEs, the level of knowledge is very low, and any guidance will have to be firmly focused on really simple examples and methods

7. Tools and databases supporting practical substitution

7.1 Overview

Information on available databases and tools that would support the implementation of the substitution principle was gathered through the survey, interviews and in the literature review. However, an exhaustive listing and description of tools and databases as such was not found to bring added value for the study. There also is a concurrent EU funded project that specifically focuses on forming a database on information for substitution purposes[234] (see Chapter 7.4).

In order to get a better overview of the available tools and information sources as well as what type of activities these support, the following categories have here been used to group the material:

1. Databases with **substance information** only
2. Databases, guidance and tools mainly targeting **chemical risk assessment,** with some or no substitution specific parts
3. Databases, guidance and tools specifically on **substitution**
4. Cost-benefit assessment approaches and tools

7.2 Databases with substance information only

There is a plethora of different databases available for general information about substances (group 1). It was not in the focus of the current study to list and review all such databases. Databases such as these are useful for finding specific information relating to inherent chemical properties, toxicological and ecotoxicological effects and can be used as a data source for example when collating data for comparative reviews of potential alternative substances. This group of data sources are not discussed further in this chapter, as they are to be considered as pure information sources rather than tools or a guidance that would be useful when approaching substitution. Note that many – if not all – of the databases are better suited to expert use than for a relative novice to chemical assessments. In expert hands these are, however, very useful and rapid sources of information, although care must be taken to ensure data comparability between for example data from different databases.

7.3 Existing tools for chemical risk assessment

These types of tools were reasonably common and include both country and sectoral approaches. The description of the tools within this chapter also includes an overview of the benefits of using the tools and the target user groups. Note that the review is by no means exhaustive and there is likely to be several other tools available, particularly from sources outside the EU. A list of some of the publically available risk assessment tools is contained in Appendix 2 of the Draft Guidance.

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[234] SUBSPORT – SUBStitution support PORTal

COSHH Essentials [235] is a relatively easy-to-use tool developed for the HSE in the UK, and designed for SMEs for chemical risk assessment. The web-based tool basically consists of a series of questions about the chemical used and how it is used. The results are given as bands (A-E). It does not allow input of risk management measures but gives you the so called gross risk banding. It gives risk level results for selected tasks, but if you do not feel that any of the selected tasks are applicable, you still get general advice. The results are given as pre-prepared fact sheets and, if the chemical use is deemed as high risk, a list of specialists that can be contacted for advice is given. COSSH Essentials currently only work on R-phrases, not the new CLP Hazard statements. COSHH Essentials only deals with risks to health and does not cover safety or environmental risks, which, if the tool is used as the sole source of risk assessment, can result in safety and environmental risk effectively being ignored.

Whilst relatively easy to use, there is no clear tie-in for how to assess the risk in relation to management measure. Notably, according to the HSE, there is a high rate of interrupted assessments shown in the user statistics, indicating that the tool is too difficult to use for the target group of SMEs. On the other hand, the tool has also been used by over a million users.

When a potentially high hazard chemical or suite of chemicals is entered (e.g. “high hazard group of E), the tool prompts to consider using a less harmful chemical and provides a link to “Seven steps to successful substitution”. This link has however not worked when tried out. You also have to be a subscriber to HSEdirect, but no links were easily available on how to subscribe. Notably the booklet for the “Seven steps to successful substitution” was published already in 1994 and not easily located on the web.

Kemi-Arvi is a Finnish program for chemical risk assessment. The latest version of Kemi-Arvi (Kemi-Arvi 3.1) is an IT program for helping companies in compiling chemical lists and assessing workers exposure risk[236]. It was developed as a joint project and financed by the Finnish Ministry of Social Health and Affairs, the Ministry of the Environment, Tukes and the Finnish Work Environment Fund. The program is designed to help especially SMEs in risk assessment and on how to avoid risks. The latest version also takes into account occupational and environmental effects of accidents. The risk assessment is based on the properties of the substance (R-phrases), the route of exposure and the handling of chemicals. Technical control measures or personal protective equipment (PPE) implemented, and other organisational measures in use can also be taken in to account. Exposure and risk assessment are however done using check list technique (risk managed or not managed), which is quite limited, and certainly does not help if you do not know whether the risk is managed or not. The program does not cover emission of chemicals very well and the exposure assessment is quite limited. Thus more accurate risk assessments may be needed to complement the results from Kemi-Arvi in certain situations. The program is most useful for storing information and managing chemical data. However, Kemi-Arvi is not very user friendly and requires down loading certain components, which may be a real issue for some companies (e.g. IT security issues). The program and all the guidance is only available in Finnish and a license is needed for its use.

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[235] Available at http://www.coshh-essentials.org.uk/

[236] Available at http://kemi-arvi.tksoft.com/

PRIO[237] is a web-based chemical risk reduction tool developed by The Swedish Chemicals Inspectorate (KEMI)[238] .The tool contains a guide and a database with about 4000 dangerous chemicals that the Swedish government has identified as being of high concern. These chemicals are classified in two groups. The "phase-out" chemicals, that should not be used and "risk reduction" chemicals for which a risk assessment and evaluation of exposure should be done. To assess chemicals that are not found in the PRIO database, the user needs to compare the properties of the chemical to the PRIO criteria, and determined whether it fits into either of the two category or not. This can require considerable expertise. The tool does not consider exposure and safety hazards such as flammability and explosiveness. It is best for screening and prioritising hazardous chemicals for substitution, but is does not directly provide information on possible alternatives.

Stoffenmanager is a Dutch, public and freely available web-based tool for chemical exposure assessment and control with more than 10 000 users.[239] Compared with the user figures for COSHH essentials (over a million) this is relatively modest. The tool was developed by Arbo Unie, BECO and TNO with funding from the Dutch Ministry of Social Affairs and Employment. The Stoffenmanager was initially developed to assist small- and medium-sized enterprises to prioritise and control health risks of handling chemical products. To best fit the needs of SMEs in the Netherlands, the Stoffenmanager was built based on previously developed approaches in Europe, combining elements found useful from different sources.[240]

The hazard band of each substance is based on R-phrases of a product, following the UK COSHH Essentials scheme[241]. Exposure bands are calculated based on the rationale of the underlying exposure model. Inhalation exposure model to both inhalable dust and vapour is based on the source-receptor approach developed by Cherrie and Schneider *et al*[242,243]. The model uses process information, physic-chemical characteristics, and mass balance to assess exposure[244]. The results from hazard and exposure band are combined in the Stoffenmanager tool to calculate a risk band, or priority band, which gives a relative ranking of risks.

After its development the Stoffenmanager inhalation exposure model was validated with approximately 250 exposure measurements and adapted accordingly for the specific scenarios.[245] The newest version (version 4.0) includes a model for estimating inhalation exposure to vapours, aerosols of low volatility liquids and inhalable dusts emitted from solid objects (presently only stone and wood). The model has been extensively validated in daily practice and the database is still growing to allow future validations and updates of the model. In addition to the inhalation exposure tool, Stof-

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[237] Available at http://www.kemi.se/templates/PRIOframes____4045.aspx

[238] KEMI, web pages

[239] Stoffenmanager tool is available in Dutch and English at https://www.stoffenmanager.nl/

[240] Marquart et al. (2008)

[241] Brooke (1998)

[242] Cherrie et al. (1996)

[243] Cherrie and Schneider (1999)

[244] Tielemans et al. (2008)

[245] Schinkel et al. (2009)

fenmanager also contains a risk banding module RISKOFDERM[246] for dermal exposure, which is based on a large number of dermal exposure measurements in real work situations. The Stoffenmanager has been accepted under the EU-REACH guidance, and it contains a specific REACH section.

When the priority band has been assigned, Stoffenmanager enables the user to design a control scenario for risk reduction. The tool gives a list of possible control measures that are presented in the order of the so-called "STOP-principle" (substitution, technical measures, operational measures, personal protection). There is only a limited amount of specific information available for alternative chemicals in the case of substitution. The tool gives general guidance for different control measures and calculates the effect on the risk level. The tool provides the user with a choice of different control measures, from product elimination to adaptation of the workers situation. For the non-experts, this feature is probably desirable as a first indication of control measure effect. Once inputs are modified based on the control measure, a new priority band can be calculated to give an indication whether the chosen measures would be effective in reducing the risk. Stoffenmanager also gives information and guidance regarding storage of dangerous substances and enables the user to assess explosion risks according to the European ATEX guidelines.

For the more expert user, Stoffenmanager is a good tool. However, the control measure suggestions are generic, and should not be used as a sole source of identifying potential controls. Stoffenmanager does not take environmental impacts into account, so a separate risk assessment is needed to assess the risk for environment. Also the tool can only be used to assess exposure and risk during normal use, incidents and accidents are not covered (except explosion risks).

7.4 Existing databases and tools for finding and comparing alternatives

This chapter describes a selection of databases and tools that are available for finding substitutes and some which facilitate comparing alternatives. A list of tools and databases for substitute identification and comparison can be found in Annex 2 of the Draft Guidance.

The German Column Model (Spaltenmodell) as described in the Technical Rules for hazardous chemicals (TRGS 600 Substitution) is a tool for simple comparison of the differences in the substances hazards and risks[247]. It can be used to create the risk profiles of the currently used chemical and the potential alternative(s).

The simple one page model is based on the classification of hazards into five risk categories ranging from very high risk to negligible risk. The hazard classes (i.e. columns) considered are acute health hazard, chronic health hazard, environmental hazard, fire and explosion hazard, hazard due to release behaviour and hazards due to process.

In the first four columns the assessment of hazards is mainly based on information found on the safety data sheets, e.g. the R-phrases. The release behaviour column takes into account the physical state of the substance as well as the vapour pressure. The last column of the model classifies differ-

[246] Goede et al. (2003)

[247] Advice on risk assessment is provided in TRGS 400.

ent ways of using the substance (mainly open working vs. closed system). Based on the model, systems with closed tight system should be considered to be of negligible risk. This means that the model does not take into account the possible consequences of accidents and incident.

The format of a one sheet form is practical and easy to understand and in case of substances with consistent results the model is easy to use. Thus the target audience, namely SMEs, could use this model relatively easily. However, in cases where there are varying risk rankings from column to column, there is no advice how to proceed. Therefore it leaves room for interpretation, which for SME's and the non-experts can be challenging. The column model has also been implemented as an easy-to-use electronic version at least by the Institut für Arbeitsmedizin, Sicherheitstechnik und Ergonomie e.V. (Institut ASER)[248] and IFA has launched the first update to comply with the GHS[249].

Catsub[250] is a Danish database that contains case examples of substitution of hazardous chemicals. Depending on the case different information are given, e.g. description of the substitution, technical requirements the product must fulfil and assessment of the solution. The examples are provided by companies, occupational health services and the Danish Working Environment Authority. Catsub aims to provide information about completed substitution cases to provide examples of what can be done and stimulate new ideas. Many of the Catsub examples that originate from Denmark refer to Danish MAL codes. The Danish MAL code system is a simple two- party numerical code system that describes a product's effects on health (See Chapter 4.4.6). **There are more than 300 substitution examples in Catsub, some of them available in different languages (English, Danish, French and German).**

CLEANTOOL is a Europe wide tool with an accompanying database for finding alternative chemicals for parts cleaning, metal surface cleaning, component cleaning and degreasing[251]. The examples are based on real processes in numerous European companies. One of the objectives of the website is to enhance communication, which is encouraged by allowing users to submit data (feedback, reports on own experience and presentation of new challenges) and receive guidance and recommendations. CLEANTOOL can be used to assess the cost, technology, quality, occupational health & safety and environmental aspects of alternative chemicals and processes. However, it is not intuitively easy to use, and especially for smaller companies looking for alternatives, the database can be quite hard to work. For example, although there are several fields for specifying your own process which are well presented the search only really return data on very generic fields, such as selecting the metal type. More specific searches often return no results. The reduction in risk is not specified, and finding the criteria for the different classes of evaluation results is quite hard. The cost assessment is laid out in a very dated format, which is not intuitive to use. Evaluative results are displayed in an extremely large sheet, which makes it very hard to read. The tool however has all the right components in it and provides an interesting overall approach to substitution.

SUBSPORT – SUBStitution support PORTal The goal of the SUBSPORT project, which at the time of writing is ongoing, is to raise awareness and develop an internet portal on safer alternatives to the

[248] ASER, web pages

[249] IFA, web pages

[250] Available at http://www.catsub.dk/

[251] Available at http://www.cleantool.org/en/reinigungssuche.php

use of hazardous chemicals[252]. The developers and funders of SUBSPORT are aiming for it to become the leading database for substitution worldwide. The portal will provide information on alternative substances and technologies, but also of tools and guidance for substance evaluation and substitution management. The portal will support companies in meeting substitution requirements of EU legislation, and provide different level of access to information for other stakeholders. In addition, the project aims to create a network of stakeholders, assisting in the content development and ensuring a sustainable update and maintenance.

The French approach to support the substitution of CMR substances, **www.substitution-cmr.fr**, is a website that contains different levels of information, methodologies, datasheets for CMRs and their alternatives and success stories, to give help in a substitution process. The website is intended to address more than 80 substances. At the moment of writing, 25 substances were covered. For the moment the tool is available in French only, but it will be translated into English.

"Green" alternatives Wizard is a web-based databank that gives general information about possible substitutes for certain substances[253], and can be used to find and compare potential substitutes. The databank is especially designed for reducing the hazardous wastes in research laboratories. The Wizard allows the user to search from a list of solvents commonly used in the laboratory, by the chemical or the process you wish to replace or modify, or by an alternative chemical or process. The Wizard identifies less hazardous and more environmentally benign chemicals or processes and provides references to journals and other information sources.

Pollution Prevention Options Assessment System (P2OASys)[254] is a tool for checking whether already identified potential alternatives may have unforeseen negative environmental, worker or public health impacts. The tool has been created by the Toxics Use Reduction Institute (TURI) in the United States. The tool allows the comparison of the total environmental and occupational impacts of process changes and not just those of chemical changes. Both quantitative and qualitative comparison parameters are included. As a result the tool provides numerical hazard scores – both for the current process and the alternatives - which can then be used in decision making. Additional information includes for example case examples from companies. This set of tools could be very useful especially when combined with TURI's **CleanerSolutions database**.

CleanerSolutions by TURI gives alternatives to hazardous solvents used in surface cleaning[255]. This database provides a wealth of information on potential alternatives[256]. The database allows among other properties searches for alternatives taking simultaneously into account for example the contaminant and equipment used. Two sections yield search results based on laboratory testing for specific client situations. The Vendor section will let users search and browse information supplied by over 100 product vendors. In the "Replace a solvent" site one can search for a tested alternative chemistry to replace the current solvent cleaner. Contaminant, substrate and equipment criteria can

[252] Available at http://www.subsport.eu/

[253] Available at http://ehs.mit.edu/greenchem/

[254] Available at http://www.turi.org/

[255] Available at http://www.cleanersolutions.org/

[256] Available at http://www.turi.org/

be added to narrow your search. This is a useful tool for a relatively narrow section (surface cleaning).

7.5 Existing cost benefit approaches and tools

There are a multitude of different tools available on the financial side for making decisions based on costs and benefits. However, if one views this from a small company's point of view, it is doubtful that they would have the knowledge, time or interest to delve into operational cost assessments from a theoretical point of view. The clearly biggest gap in current tools and methods for substitution is in how to estimate the costs and benefits. At the same time, costs and savings are a key barrier /driver for substitution.

The German TRGS 600 contains a simplified worksheet for estimating costs and benefits, but it does not include any calculation methods. Some of the web-based tools, such as Cleantool and to some degree Stoffenmanager (see Chapter 7.4) contain cost evaluations, but for example the Cleantool cost part is quite difficult to work and understand.

7.6 Analysis of existing tools and databases

Several different, publically accessible tools and databases on chemical risk assessment, comparison of chemical properties and substitution have been developed in EU countries.[257] The information is however scattered and although many address the steps necessary in a substitution evaluation and implementation process, there are no practical tools to help an SME through the entire process. Some of the tools are industry or task specific and as such not useful for all companies.

Tools for chemical risk assessments

There are many tools and data banks available that can be used in the risk assessment step. However these tools rarely give assistant for other parts of the substitution process. Several databanks containing chemical hazard information are available. These databanks give essential information that can be used in risk assessments, and are a welcome aid for the experienced chemical risk assessor. However, for users with little experience and knowledge such databanks are somewhat hard to use, and they do not provide help towards carrying out the risk assessment in practice.

The easiest risk assessment to use is perhaps the German Column Model, which – although it has not been specifically designed for risk assessments but for substitution, – also gives a good methodology for the risk assessment. The accompanying guidance could, however, be written in a simpler way to help non-experts tackle the subject. Several countries have developed online tools for carrying out risk assessments. The UK COSSH essentials and the Dutch Stoffenmanager are particularly efficient and easy to use tools that can also be used for risk assessments. The biggest problem is that neither includes all types of risk (e.g. acute health, chronic health, environment, safety) and as such, will need to be complemented by other risk assessments.

[257] Further details on databases, tools and guidance are listed in Annex 2 of the draft guidance document.

Tools for identifying and assessing technical constraints

Requirements from the supply chain, technical and legal requirements - also from other than occupational health and safety aspects - have to be considered when approaching substitution. No tools or guidances where all of these are addressed were found. In the German TGRS 600 issues that should be included are identified, but the assessment is relatively basic.

Identification of potential alternatives

Databanks containing chemical hazard information are also valuable sources for finding possible alternatives, if one knows what to look for. There are also examples such as Catsub and Cleantool which are databanks containing specific information about alternatives and substitution success stories, which can be used to find not only exact solutions but also ideas and inspiration to challenging substitution projects.

Cost-benefit assessments

The results from this study indicate that both authorities and companies considered cost-benefits as a crucial part of the evaluation of substitution potential. This was echoed in the survey, where cost-benefit tools, cost assessments and decision making support where identified as the most needed tools. In the workshop, it was concluded that the comparison of different alternatives is perhaps the most difficult but also essential step to undertake. It is therefore considered that this lack is perhaps one of the areas were most help is needed.

Assessing the costs and benefits – or savings – is relatively straight forward, although sometimes time consuming. Whilst it is true that any methodology used to assess overall impacts should ideally be able to compare all benefits and drawbacks in kind, monetisation of for example health and safety benefits is notoriously hard and fraught with ethical dilemmas. Therefore, it is considered that a potential, workable solution could be to use cost benefit analysis in stages of increasing detail, starting with some very simple and basic calculations. This is particularly relevant for smaller businesses, where complex or lengthy analytical methods simply would not be used. Nevertheless, it is considered that any methods should be available to all businesses, therefore, as stage wise evaluation of costs and benefits meets all these requirements.

In the workshop, some very basic excel-based tools (see Chapter 9.3.6) were tested. These were initially commented on as being too complex, but after consideration and working through, these were seen as representing the bare minimum of what is necessary to consider. Whilst it was concluded that for a majority of companies, this may be a task where specialist help will be needed, such tools could be very useful to many companies were the substitution is perhaps more complex. This type of tools were also seen as providing a good decision making framework, in line with for example the much more complex socio-economic analysis as per REACH legislation. This type of approach was also seen as providing particularly useful help when looking at CMR alternatives where there are many other risks.

Summary

The current situation in relation to the existing tools and databases can be summarised as follows:

- The majority of the available tools and databases screened in the study are useful for risk assessments.
- The existing tools for risk assessment mainly target intended use of chemicals and the risk of incidents are rarely included. This is however a prime motivator for companies and should therefore be included.
- The assessment of all types of risk is a weak point in most tools. Neither is the user helped to assess whether sufficient information of alternatives is available to do a comparison.
- The overall substitution process is covered through a combination of available tools, but these are not applicable to all industries and not all brought together into one core process.
- Very few address costs and benefit calculations, which is the perhaps the single most influential area for companies. Technical and practical assessments of whether a substitute would meet functional requirements and fit the practical constraints within a company are also scant.
- The overall evaluation of alternatives is either something not included in the tools or described in too complex a manner to have practical value for smaller companies.

In the following Chapter, the feasibility of developing a common approach for drawing together all the existing knowledge in a manner easily accessible to all kinds of companies is discussed.

8. The feasibility of a common approach

8.1 Substitution as a risk management measure

Substitution of very hazardous chemicals is part of the regulatory framework in the EU, through for example the authorization process under REACH and the Carcinogens and Mutagens Directive. The REACH authorisation process also identifies substances of high concern. Endocrine disrupters may be a specific type of chemicals increasingly scrutinized in the future in a similar legislation lead approach to substitution of the most hazardous chemicals. The legislation lead process is quite distinct in nature and there appears to be a general tendency to associate substitution as being solely something that is applicable to such high hazard chemicals.

It is commendable that the combination of published implication of long term effects from exposure with this hazard driven listing has made the substitution of these chemicals a primary target for many industries. It can nevertheless be argued that this reliance on public policy and listings for substitution priorities may, in certain instances, lead to a somewhat disproportionate effort towards finding substitutes for intrinsically hazardous substances without taking into account the proportional risk these pose to workers (or environment) in that particular company and at that particular use. A more intrinsically “benign” chemical, used in a manner that creates high exposure levels (e.g. by spray painting), often presents a much higher risk to the worker than, say a highly hazardous chemical used only in small amounts or infrequently through less exposure creating methods (such as for example applying lube oils trough brushing on, or direct injections into closed loops) [258]. **Therefore, whilst elimination and reduction of high hazard chemical use remain a primary objective across industry and at national and supranational level, the overall risk reduction for a particular company and its workers may be much higher, if the priority is clearly set as substituting the use of high risk chemicals rather than high hazard chemicals.**

There is also a clear weakness in how the implementation and enforcement of the requirement to substitute certain chemicals wherever technically possible. For example, the Carcinogens and Mutagens Directive[259] states that where technically possible, substitution of chemicals classified as Car1, Car2, Mut1 or Mut2 level[260] chemicals should be carried out, and an assessment should be made. Many of the interviewed authorities identified this as a particularly poorly enforced area (e.g. Netherlands, see Chapter 0) and consequently an area where practical risk reduction through substitution is still relatively scarce. This is therefore an area where sustained effort to enhance substitution within the companies should be applied by authorities.

In addition to sustained efforts to substitute legally recognised highly hazardous chemicals such as carcinogens, companies must **identify** which chemical use risks could be reduced through substitution. In order for substitution to act as a risk lowering measure, this step is crucial. Yet far too often

[258] Gilbert Y. et al. (2008b)

[259] Corrigendum to Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC)

[260] Known to be carcinogenic, Should be regarded as carcinogenic, Known to be mutagenic, Should be regarded as mutagenic

industry appear to initiate substitution evaluations only for such compounds that have been listed as a target or candidate for substitution on authority released “official” designations or listings made by NGOs or for example the ETUC or their customers (e.g. automotive industry).

As chemical risk is, as pointed out previously, often associated with less hazardous substances used in greater volumes and in less controlled environments, it is argued that first and foremost substitution should be viewed as a risk management measure. As such, it is much underutilised.

This work has focused on establishing whether there is a need for a common approach and accompanying guidance for **substitution as an element of risk management**, as part of the company’s day-to-day business, with a target group that includes all industries and all sizes of companies in EU.

8.2 The relative complexity of substitution

When the feasibility of a common framework process was looked at in greater detail, the following specifics were noted:

- The size of company or industry is not a prime variable, but substitution is more process type dependent (e.g. why a company uses chemicals and for what).
- A vital issue affecting the practical substitution process is the position of the company in the value chain and how the chemical is used, affecting firstly the complexity of the substitution process and in most cases, the level of knowledge of chemical risk and risk management held within the company.

It is vital to acknowledge that substitution is not always a simple process, yet it does not always have to be a complex one either. During the work, it became apparent that the degree of complexity varies according to two main variables: The reason the chemical is used or manufactured and the availability of tried and tested alternatives.

The reasons the specific chemical is used can be divided into three groups, as given below and illustrated in relation to the relative number of potential solutions in Figure 18.

- **The exact chemical (molecule) is required**
  If the exact chemical is required, for whatever reason, and no other molecule will do, substitution can be approached through process substitution: The process or reaction may be changed to produce or use this specific chemical more efficiently and more safely, i.e. through different reaction pathways or through modification of the process used. This type of substitution aims to achieve **production optimisation** whilst minimising occupational health and safety impacts.

- **A very specific chemical functionality is necessary**
  In this type of substitution, the desired product is the specific function that the chemical performs, for example the function of a biocide is to kill for example algal growth. If this is the case, substitution can be approached through finding out if any other chemical could perform the same function or perform it more efficiently whilst the use or manufacturing process is made safer (e.g. different types of active ingredients in biocides). The functionality does not require a specific molecule, but the functionality is for example tied to specific reactions. Changing the chemical can therefore be done, but this most probably requires a lengthy R&D process (**chemical function optimisation**).

- **The chemical is used more generically to achieve a certain benefit**
  If the benefit of using a chemical can be directly related to an end-use that can be achieved in many ways, including non-chemical solutions, there are more options open. For example, if the reason a chemical is used is to clean a floor, this can be achieved in many ways, and it becomes a question of finding the safest and most efficient way to do this. This can be approached through customer benefit analysis. The customer benefit is the clean floor, which can be achieved in many ways: with different chemicals that all perform the same job (e.g. different brands, different active ingredients), but also through elimination of the chemicals, i.e. using steam or just scrubbing with brushes and water etc. (**customer benefit optimisation).**

In all of these approaches to substitution is important to include evaluation not only of the chemical risk reduction, but the effectiveness of the approach (how long does it take to scrub the floor; what is the process yield) as well as potential changes in other risks (e.g. noise, strains, vibration etc.).

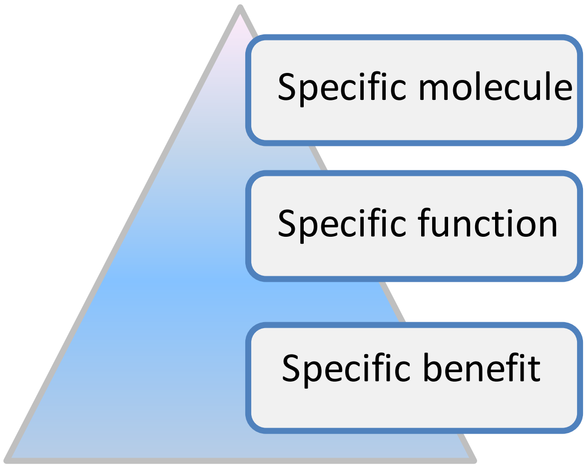

Figure 18: The relative number of possibilities available for different types of chemical use

These different types of substitution can also be partially directly related to the position of the company in the value chain. The earlier a company is in the value chain, the higher up on the pyramid in Figure 18 it is likely to be in relation to specific reasons for the use or manufacture of a chemical.

Substitution can also be classified based on the relative amount of effort needed for finding viable alternatives:

1. **Non-proven alternatives.** Cases where new potential alternatives require extensive R&D and piloting are the most complex and time consuming ones.
2. **Substitution of a chemical with an alternative that will also require process changes**. This type of substitution is complex and will require detailed evaluation. The process changes have to be carefully evaluated and related to overall risk, cost and process efficiency. The alternatives may be generally available, but the threshold to carry out a substitution is high as changes would require in depth assessment of process changes.
3. **Tried and tested alternatives available and none or minor process changes needed.** If there is already knowledge and experience about alternatives available for example within the in-

dustry that can be used without major changes to processes, no lengthy testing or piloting is required. Such alternatives may be recommended by suppliers, by colleagues or by authorities.

Here, the complexity decreases from top to bottom. If these are put together you get a matrix of increasing complexity as shown in Figure 19. The types of companies undertaking specific types of substitution can also be, albeit loosely, related to the position in the value chain, as indicated in Figure 19. **Note that this is a generalisation that does not apply to all companies.**

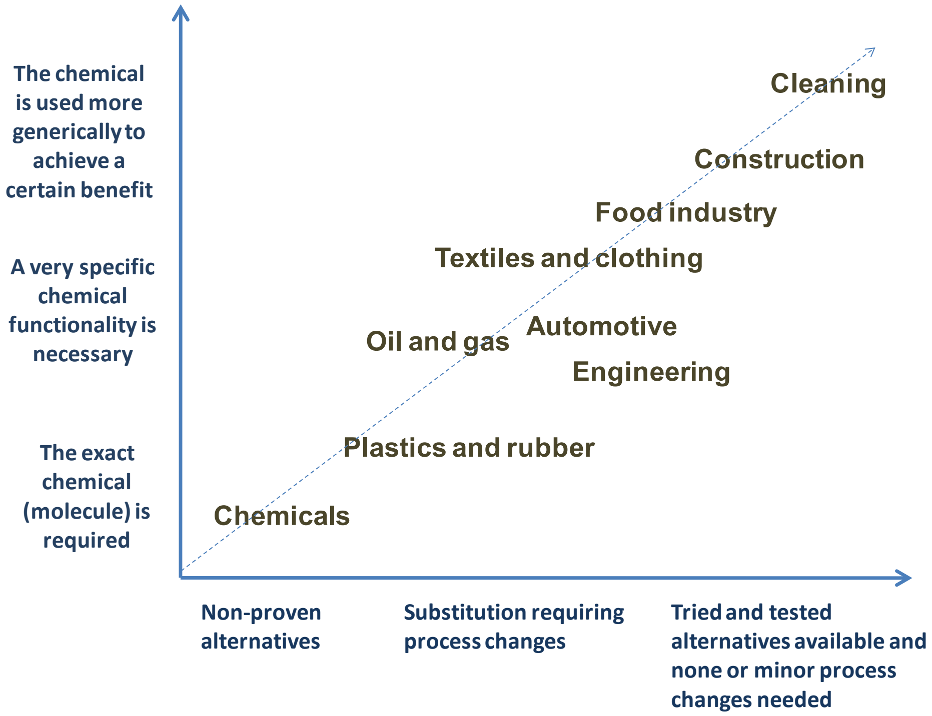

Figure 19: Substitution complexity as a function of alternatives and chemical requirements. Complexity decreases in the direction of the dotted arrow

When looking at the complexity of substitution, it is clear that there are several instances where finding alternatives is very complex, time consuming and requires specific R&D effort. On the other hand, there are also less complex cases (top right hand corner), where substitution could be relatively simple and not require a great deal of effort. SMEs may often be in this area, and it is here where a common guidance and a common framework across the EU member states could really provide benefit, helping to reduce risk at the workplaces.

8.3 Requirements for the common approach

An effective substitution process requires several evaluative steps and a determined effort to find alternative chemicals or processes. The research indicates that one of the key issues that need to be addressed is how to identify the potential for risk reduction through substitution.

Whilst the theoretical aspects or step-wise sequence required to perform a successful substitution evaluation are quite easy to construct, the overall process can be highly complex in practice. It was stressed in both interviews and the workshop that to be of any real value, a common framework would have to successfully simplify the overall process to a level where small businesses with no full time experts in the areas can utilise it (e.g. specifically industries in the top right-hand corner of Figure 19). It was also considered essential that substitution should be discussed in the overall framework of risk management and not as a separate issue. This includes providing a common process for risk identification and assessment as well as identification of alternatives, comparisons, testing and implementation. In particular, it was noted that systematic risk assessments of chemical use is still a concept that is seen as difficult in many companies. Therefore any developed process would have to provide step-by-step guidance on how to conduct a risk assessment. Comparisons of cost and benefits as well as identification of potential other risks were also highlighted as key areas to address.

According to the primary data as well as the overview of existing approaches, there appears to be a clear need for a common framework for substitution, although some opinions in favour of industry specific guidance were voiced. The most pressing needs were recognised for presenting all of the main tasks within a substitution process in a coherent manner. The main tasks – or steps – within a substitution process are the same regardless of the company or the industry sector. The complexity, time and data requirements as well as relative importance of each step naturally vary between companies and between substitution cases. The most commonly voiced requirements for any process can be grouped as follows:

1. How to find adequate information about the chemicals they are using
2. How to identify the most dangerous chemicals based on hazard and use cases
3. How to prioritize the chemicals for risk reduction through substitution
4. How to find alternatives
5. How to compare the properties and risks of identified alternatives

There is a clear need for **one single portal** for access to all the existing databases and tools. Ideally, this type of forum should provide both guidance and relevant information sources needed in the substitution process. Case examples, best practices, legislation specific guidance and easy to access information about alternative chemicals or non-chemical solutions would enhance the value of such a forum. A current EU project (SUBSPORT, see Chapter 7) aims to create such a common portal for different case examples. **Therefore listing of alternatives or successful substitution cases has not been duplicated in this work. Instead the more useful approach of providing links to existing sources of successful substitution cases and databases and tools for finding alternatives are provided in Appendix 2 of the Draft Guidance document. This way the user has access to several hundred cases rather than a few.**

It is considered vital that a common process on how to approach substitution should be agreed on between the EU member states and competent authorities. Such an agreement would make the practical work for companies much easier, as they could utilise all the existing information in the knowledge that the approach is essentially "approved" by authorities. Linking each step to current tools and information sources would also better utilise the existing approaches, as for example providing translations to existing tools is certainly easier and less expensive than building new ones in each Member State. This is particularly important in the case of CMRs. Here the French website **www.substitution-cmr.fr** provides a valuable, yet apparently underutilised resource. In particularly the difficulty of enforcing substitution of CMRs (see Chapter 7) in combination with the fact that the French survey (see Chapter 4) indicated that some 70% of respondents were able to successfully find substitutes for Carcinogenic compounds, indicate that such information sharing across the EU is very much needed.

8.4 Risk assessment tools

It would appear that despite many available tools on the web and a plethora of academic papers as well as guidance and fact sheets from various authorities and other organisations that the basic risk assessment still represents a major difficulty.

A proposal for a risk matrix is contained in Appendix 3 of the draft guidance document. The risk matrix has been constructed based on several different approaches found in the literature as well as practical considerations. There are several approaches to risk matrices in common use, ranging from a three by three matrix to a seven by seven or even more complex matrix used in some companies. It was decided that a five by five matrix of hazard (y-axis) and exposure potential (x-axis) is the most useful and also the perhaps most universally used approach.

In current tools and models for occupational health and safety assessments, the exposure potential is generally addressed only through exposure from normal use. In companies, the likelihood of accidents and incidents are however often the starting point for risk assessments. Therefore it was decided to include exposure potentials from both normal use and accidents and incidents. Many tools, such as PRIO and COSHH Essentials only deal with health risks. As companies often have to conduct environmental and safety risk assessments also, these risks were included. This was felt to be particularly important in relation to substitution, as the overall risk should be considered whenever a substitution is assessed.

As the current classification and labelling system is in the process of changing from the old R-phrases to the new CLP hazard statements, it was decided to include both systems for the hazard categories. The German column model (Spaltenmodell) as described in the Technical Rules for hazardous chemicals (TRGS 600 Substitution) was used as a base line comparison for the assignment of the R-phrases and Hazard Statements to the five hazard categories. The categorisation of R-phrases proposed is shown in Table 7. Here those R-phrases which have been assigned a different category from the German column model (Spaltenmodell) as described in the Technical Rules for hazardous chemicals (TRGS 600 Substitution) are shown in red.

Table 7: Categorisation of R-phrases

Category	R-phrases
5	**Acute hazards:** R26, R27, R28, R32
	Chronic health hazards: R39, Carc. Cat. 1 and Carc. Cat. 2 + R45 or R49, Mut. Cat. 1, Mut. Cat. 2 + R46, Repr. Cat. 1 + R60, R61
	Environmental hazards: N + R50, R51, R53, R54, R55, R56, R57, R58, R59
	Safety hazards: R1, R2, R3, R4, R6, R17
4	**Acute hazards:** R23, R24, R25, R29, R31, R35, R41, R42, R43, R64
	Chronic health hazards: Carc. Cat. 3 + R40, Repr. Cat. 2, + R60, R61, Mut. Cat. 3 + R68; R48
	Environmental hazards: R52 and R53, R53
	Safety hazards: R5, R9, R12, R14, R15, R16, R18, R19, R30, R44
3	**Acute hazards:** R20, R21, R22, R34
	Chronic health hazards: R33, Repr. Cat. 3 + R62, R63
	Environmental hazards: R52
	Safety hazards: R7, R8, R11
2	**Acute hazards:** R36, R37, R38, R65, R66, R67
	Safety hazards: R10
1	No R-phrases

The justification for each of these differences is as follows:

R1 - Explosive when dry; **R4** -Forms very sensitive explosive metallic compounds; and **R6** - Explosive with or without contact with air have been placed in category 5. It is considered that all explosive hazards, including these associated with certain conditions are very hazardous and should be treated with extreme care.

R7 – May cause fire. Assigned to category 3. The German model assigns this to category 4. It is considered that the safety hazards have to be differentiated between in order for companies to find the risks that are the highest. Therefore this R-phrase as well as the following 3 R-phrases **(R8, R11 and R10)** have been assigned one category lower than the German model. This is based on practical work with companies, where any priorisation work requires clear differentiation between relative hazards and risks rather than absolute measures of the hazard. This categorization has therefore been seen as appropriate in this context.

R12 – Extremely flammable. Assigned to category 4 safety. The German model assigns this to category 5. However, from a practical point of view, this R-phrase indicates a lower risk than explosives or spontaneously flammable materials. It was therefore considered a category 4 was more appropriate.

R33 – Danger of cumulative effects. Assigned to category 3 chronic health. The German model assigns this to category 4 chronic health hazards. However, on its own, it does not specify what type of effects may be caused by accumulation or long term exposure. It was therefore considered to represent less risk than for example R 48.

R39 – Danger of very serious irreversible effects. Assigned to highest chronic health hazard category. This R-phrase is not classified at all in the German column model.

R41 – Risk of serious damage to eyes. Assigned to category 4 of acute health hazards. The German model assigns this to category 3. It was considered that serious eye damage warrants a category 4 as splashes or dust often may come in contact with eyes, especially in businesses where for example safety goggles are perhaps not used as a norm. The consequences are serious, as it will significantly affect a person's ability to lead an independent life through causing a potentially permanent disability.

R52 – Harmful to aquatic organisms and **R53** – May cause long-term adverse effects in the aquatic environment. This combination is assigned to a category 4 whereas in the German model, these are assigned to category 3. This is based on the importance of the potential long-term adverse effects and also provides differentiation between the environmental effect categories.

R64 – May cause harm to breastfed babies. Assigned to category 4. The German model assigns this to category 3. However, in view of the specific obligation to protect pregnant and breastfeeding workers from exposure to chemical dangers[261], the effects can be serious for unborn or very young children when received through their only source of nutrition.

R48 – Danger of serious damage to health by prolonged exposure, generally given with specifying R-phrase. Assigned to category 4 chronic health. This R-phrase is not classified in the German column model as such. In the column "acute health hazards" a special feature must be noted for the R-phrases 20, 21, 22, 23, 24 and 25: if these R-phrases arise in combination with R48, the relevant substances/products are assessed as being one risk stage higher. This then involves chronic health hazards.

The classification of the Hazard statements (See Appendix 3 of the Draft Guidance) has, as far as possible, been harmonised with the categorisation of the R-phrases.

The other dimension of risk is the exposure potential. The categorisation proposed is shown below in Table 8.

[261] Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding

Table 8: Categorisation of exposure potential

Category	1	2	3	4	5
Quantity used	Very small; grams or millilitres Examples are lock sprays, certain additives in laboratories	Small; less than 1 kg or litre	Medium; between 1-10 kg or 1-10 litres	Large; over 10 kg or over 10 litres	Very large; over 100 kg Often chemical use is measured in tonnes or cubic metres
Physical properties affecting exposure	Vapour pressure of liquid is below 2 hPa	Vapour pressure of liquid is 2-10 hPa	Vapour pressure of liquid is 10-50 hPa	Vapour pressure of liquid is 50-250 hPa	Gases; Liquids with a vapour pressure over 250 hPa
	Non-dust-generation	Low dust generation	Some dust created	Increased dust generation	Very high dust generation, aerosols
Working / process conditions	**Fully enclosed system** -> No possibility of direct skin contact -> No possibility of exposure by inhalation	**Closed system,** with small possibility of exposure during some work steps such as decanting or sampling -> Low possibility of direct skin contact -> Low possibility of inhalation	**Semi-enclosed system** or open system with automatic ventilation and control barriers -> Some possibility of direct skin contact -> Some possibility of inhalation	**Open system,** passive ventilation and protective barriers -> Medium possibility of direct skin contact -> Medium possibility of inhalation	**Open system,** no ventilation -> High possibility of direct skin contact -> High possibility of inhalation
Frequency or duration of use	Rarely, a few times a year Very short use, minutes	Occasional, monthly Short use, less than 1 hour	Frequent, once a day, several times a week Medium use, 1-2 hours at a time	Very frequent, several times a day Use for more than 2 hours at a time	Continuous process
ACCIDENT potential	Very unlikely	Unlikely	Could happen, has occurred in industry	May happen	Very likely, has happened before at our work place

As probabilities are notoriously difficult to assign, a qualitative approach was adopted. The scales for exposure potential takes into account both physic-chemical properties and the use cases. There is also a scale for accident potential. From the categories 1-5, it was initially considered that the categories should be presented more of a continuous shift of potential exposure from 1 to 5. This was based on the notion that a too close description of the categories would require a more exhaustive description and there would still be a danger of not describing the exact situation within a company. Leaving the categories more open was considered to allow for more flexibility. However, in view of the wishes from the piloting studies and the steering group for a more detailed guidance on which categories to choose, these were added. However, it should be noted, that before using the categories, each company should first ensure that the wording is easy to understand and relates to actual situations within their workplace. If necessary, the wording should be amended.

8.5 Identification of alternatives

Identification of alternatives is a stumbling stone for many companies considering substitution. However, the alternatives are very specific for each use, and as such, are not yet gathered into one specific database. The current EU project Subsport should however bring some help in this area (see Chapter 7.4). Therefore the identification of substitution is considered to be best served through providing some general pointers to where such alternatives are already available. This is done in Appendix 2 of the Draft Guidance.

8.6 Feasibility and overall costs and benefits

An assessment of technical feasibility, practicality and functionality as well as compatibility with existing other processes, materials and control measures was seen as clearly required. Here it was indicated that a consistent process highlighting all the issues that need to be considered would be most helpful. Specifically, a change management planning tool was called for in some of the interviews.

A specific wish from the interviews and the workshop was for tools for comparing costs, savings and other benefits. The people engaged in a substitution process may not be the same people as are contemplating the business side of the company. A clear overview of what any change will cost or save or what other obligations it may change will help to, for example, convince management of the necessity for change.

The cost of risk can also be taken into account in terms of direct costs, such as additional PPE or control measures required. This type of calculation gives an indication or relative cost structures and may, in itself, be sufficient. For more detailed cost calculations, tools were constructed and shown in Appendix 6 of the guidance document. Such a tool could easily be provided for example as a downloadable Excel spreadsheet. Note that a web-based calculator is not recommended, as these have at least in the past have had a tendency to become too awkward to use.

Cost of risk is a particularly useful tool when assessing benefits and drawbacks of different alternatives. Therefore a simplistic version of calculating cost of risk has been included in the tool in Appendix 6 of the Draft guidance document. An overview of the approach is illustrated in Figure 20.

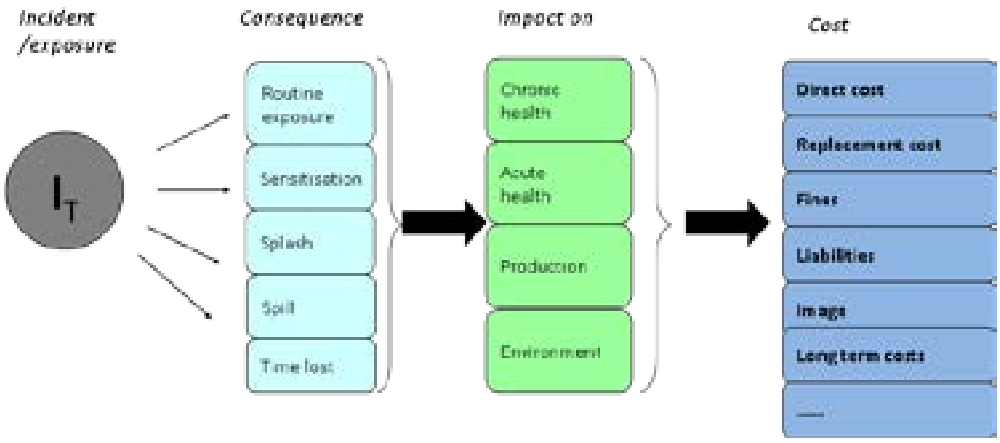

Figure 20: Taking into account the cost of risk in relation to incident or exposure potential.

Presenting cost calculations can often be difficult for non-financial personnel. In the first stage rough estimates of costs for alternative approaches or business as usual are assessed. Here, the comparative tool shown in Table 9 below was constructed to provide a working example of how to compare overall costs and benefits of a potential change.

Table 9: Will change be good? (with fictional worked example)

COMPARE ALTERNATIVES	CURRENT	ALTERNATIVE
Will chemical risk be lower?		
Hazard: Are there differences in hazard?	R34 Causes burns/ Skin Corr. 1B, H314	R38 Irritating to skin/ Skin Irrit. 2, H315 => LESS HAZARDOUS
Exposure normal use: Is it possible that we breathe the chemical or get it on our skin/eyes/mouth during normal use?	Yes	Yes
Exposure time: How often do we use this chemical?	Same	Same
Exposure long term: Are there any hazards indicated for long term use?	No	No
Protection: Are there more control measures or PPE needed for either?	Yes, this one	
Environmental risk: Are there differences in risk to the environment?	R53 ***May cause*** long-term adverse effects in the aquatic environment/ Aquatic Chronic 4, H413	no environmental risk phrases => SAFER
Accident likelihood: Is there a difference in how the chemical is used that could increase/decrease the chance of an accident?	no	no
Chemical risk: Which of the chemicals has higher risk level?	This one	
What are the other benefits and drawbacks?		
Other risks: Are there other than chemical risks from this use (e.g. vibration, noise, strains etc.)?	Yes, ergonomics	Yes, noise slightly higher; ergonomics less
Legislation: Are there any specific legal obligations for this chemical that impact on us, and what?	No	No
Costs: What are the material costs?	1000 €	1050 €
Costs: What would the change to alternative cost? (potential changes in equipment, PPE, training needed, storage requirements etc per annum)	–	100 €
Time: How long does it take to do the task done with the chemical?	30 min	25 min
Supply – is the supply secure, i.e. will we get this chemical when we need it?	Yes	Yes
Waste: Does the use of the chemical create waste that needs special treatment? (YES / NO)	**Yes**	**No**
Environment: Are there differences in discharges to water or emissions to air?	**No**	**No**
Which is better?		This one
CHANGE OR NOT?		**YES**

8.7 Common guidance to a common approach

In order for the process to actually impact on risk levels in companies, the framework would have to be worked into a common guidance document and widely disseminated across the EU. It was generally agreed that a common EU wide guidance on a substitution framework would be useful, although some scepticism was voiced especially by the chemical industry.

A common guidance targeted at SMEs, whilst still providing help for companies where chemical risk assessment expertise is not core knowledge, was without exception felt to provide value.

In particular, the wish to see an easy-to-use guidance accompanying a step-by-step process was voiced. As part of this, a “substitution for beginners” type of very basic framework for decisions related to changes was called for. A specific wish was for the guidance to contain tools for mapping out the decision points (e.g. flowcharts) and assessing cost and benefits. Basic prioritisation following risk assessment was also seen as something needed to be addressed in order to support identification of substitution priorities. **As there are already numerous databases containing examples of substitution cases, it was considered that it would be more useful to direct readers to these and to provide worked examples of each step in the guidance instead of new cases.**

There were varying opinions regarding the needs for different languages. Whilst translation of some of the current tools, especially into English, was seen as a priority by some, others felt it was more important to ensure any developed common framework was available in all European languages in order for companies to be able to access the information. Such translations are however outside the scope of this project and it is hoped that this possibility would be assessed at a later stage and, if feasible, implemented.

It was acknowledged that there are different types of guidance and support needs for small companies and those with little knowledge on chemicals when compared to others. **The need for substitution guidance for large chemical companies was considered minimal. Instead their role would be advisory in the supply chain**.

Thus, if a common approach or framework for substitution could be created and presented in two ways - or levels of engagement – it would be suitable for most types of companies. Thus the substitution process development and guidance preparation focused on these two levels. The study output presented in the next Chapter has been geared towards enabling informed choice, through providing a coherent framework for evaluating chemical risk from multiple angles and aid the identification of clear priorities.

9. The proposed common approach

The results indicate that whilst a common framework is called for, it is necessary to provide a simple, shorter version for substitution and at the same time, meet the requirements of slightly more complex cases. Therefore a core process, which can be followed through two different paths, is proposed: one simplistic, suitable for easier types substitutions (known alternatives, customer benefit) and one more detailed that will be suitable for more detailed evaluations.

The existing approaches to substitution that recommend certain steps or cycles all follow a similar path, all showing various permutations of the sequence: identify – prioritise – evaluate – test – implement – check. There are many similarities with the, from change management systems well known, Plan-Do-Check-Act cycle. From a risk management point of view, the necessary issues to consider are also quite self-evident: Level of hazard and exposure, alternative risks, costs and benefits and potential to lead to unwanted consequences in the process or task under consideration as well as further along the line. The challenge is therefore not in constructing a step-by-step sequence, but in paring it down to the essential core and linking each step to existing best practices, tools and databases.

Substitution is in effect making a change and will consequently require a change management approach to be successfully delivered. This suggests that the well-known change management model of Plan-Do-Check-Act could be utilised to provide the overall framework for the substitution process. This was tested in the workshop and it received a positive response. The developed framework is illustrated in Figure 21. The simpler version is here shown in the middle, with the more detailed process shown on the outside.

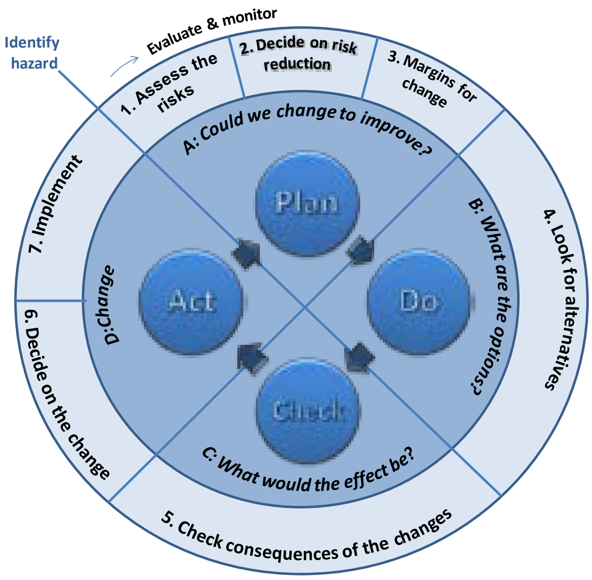

Figure 21: The overall framework for managing substitution changes

The basic Plan-Do-Check-Act model lends itself very well to substitution, and in the simplest version four steps are sufficient. To carry out the substitution consideration process, the companies will also need tools for comparing consequences, tools for comparing risks as well as pointers to where more data can be found or whom to contact for more information.

10. The proposed Draft Guidance document

The set-up of both streams around the Plan-Do-Check-Act model allowed inclusion of easy transferral from less to more detail when wanted. In the 7 step model, flow charts with explanatory text form an integral part of the overall guidance to each step. Worked examples or cases to illustrate how each step is done are provided in Appendix 5 of the Draft Guidance Document. Links and pointers to further reading, databases and tools available in the public domain are given in Appendix 2 of the Draft Guidance. The proposed guidance has the following overall structure:

1. Part I - Introduction
2. Part II – Change for health and safety in four steps
3. Part III – Change for health and safety in seven steps
4. Appendices
    - Appendix 1 Hazard signs and CLP pictograms
    - Appendix 2 Tools and further reading
    - Appendix 3 Risk matrix
    - Appendix 4 Tables for the 4 step process
    - Appendix 5 Case studies
    - Appendix 6 Comparison tools for the 7 step process
    - Appendix 7 Substitution flow chart

One of the key findings from the validation survey and piloting of the Draft Guidance was that the overall guidance seemed to repeat certain things. This is inevitable when there are two parallel processes that can be used. It is therefore proposed that the guidance is disseminated through a website, where the different parts are presented as different documents. This would make it more user-friendly.

The 4 step process focuses on basic concepts and guides the user through hazard and risk assessment as well as prioritisation and evaluation of alternatives. The 7 step process has been illustrated through flow charts, using the universal symbols used by engineers, managers and chemists around the globe.

Companies with more knowledge or more complex tasks may already have done some of the steps included in the core process. They will also need to decide whether substitution is applicable to them or not and where to start. Therefore a set of simple questions to guide the user into the overall reading of a guidance document is included in the 7 step process. The absolute order in the process is not vital, but can be changed.

During the work, it was prominently evident that a main issue will be to get companies to look at the guidance. Therefore the overall context taken is one of seeking to change for better and approaching the issue through a benefit evaluation. The seven questions in Table 10 are proposed to be used as a check list to entice companies to look at substitution.

Table 10: Should we consider substitution?

Question	Yes / No	Note
1. Are we using chemicals?		Using less hazardous chemicals or stopping the use altogether (eliminating) can **increase safety and reduce cost**. You can also apply the same type of thinking to any other hazardous materials or processes. **Make sure that you do not have many chemicals for one job – reducing the number of chemicals will also help you reduce risk.**
2. Could we/should we reduce the risk to workers health and safety from our chemical use?		By law, you must know and control risks from chemicals you use[262] . **Changing to less hazardous chemicals or reducing the number of chemicals could simplify the paperwork done for permits/ authorities.**
3. Do we have a legal obligation to substitute?		If you use chemicals classified as Cat 1/2 carcinogenic or mutagenic, you must replace them so far as is technically possible[263]. **If it is not possible, you have to discuss the implications with the authorities.**
4. Are hazardous fumes or dust created at our workplace?		Even if the materials or chemicals themselves may not be hazardous, you may be using them in such a way that there is a risk to workers. **Changing the source of fumes or dust, the processes or working practices can increase safety and reduce cost.**
5. Do we use chemicals often and /or in large amounts?		If you use chemicals in large amounts and/or repeatedly, this increases the chance of harm to you, your workers and/or the environment. **Finding alternatives or different ways of working can help you reduce the amount of chemical you use or how often you have to use the chemical.**
6. Do we use control measures to reduce chemical risks?		You may be using technology, automation, procedures or personal protective equipment to control risks. Control measures are specified by the supplier for each chemical – look at the safety data sheet to check you are using these. Changing to less hazardous chemicals or changing the way you work can reduce the need for control measures, **protect workers health and safety** and enhance wellbeing. **You might also be able to reduce the cost of controlling chemical risk**.
7. Do we want our image and competitive edge to be better?		Increasingly, companies are looking for safe and sustainable solutions. Changing to safer chemicals or working practices could help you meet your customer's criteria and give you **competitive advantage. Innovative safer solutions may give you a powerful sales argument.**

[262] For legislative requirements, check your national legislation. See also Chemical Agents Directive 98/24/EC

[263] Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

11. Validation of the proposed process

11.1 Validation process

The proposed common approach has been subjected to validation by a number of experts in order to ensure that the overall approach is correct and scientifically sound. Expert input was collected in a specific workshop[264], and in hearing the Working party "Chemicals at the workplace”[265] . Finally, the overall process and the supporting draft guidance document were subjected to critique through a survey. The practicality of the approach was then tested in three piloting sessions. All of the findings were incorporated into the draft guidance document and used to further clarify the proposed process. Finally, the team of experts conducting this study made a final evaluation of the overall soundness of the proposed process from a technical, scientific and management point of view.

11.2 Workshop

A workshop for stakeholders (See section 0) concluded that a common framework for aiding the requirement of using substitution, as given in the Chemical Agents Directive and the Carcinogen Directive, in practice would be valuable. It would help to structure substitution, make the legislation more understandable and give a clear starting point for enterprises to address the issue. It could also enhance the workers involvement.

The workshop discussions supported the results gained from interviews, survey and literature, i.e. that a concrete, easy to understand process described in a short guidance using simple language is needed. The format should be clearly structured and give a framework that would also support in-depth and branch specific information to be added on by different organisations or national authorities. The framework process should firmly link risk assessment to substitution and pay attention to the different types of uses of chemicals. The workshop participants agreed on the proposed dual process concept being suitable as a framework for a common approach. The suggestions for amendments put forward have been taken into account in the draft guidance document.

11.3 Hearing at the Working party "Chemicals at the workplace”

The Working party found the substitution process developed a good attempt to address the difficult issue. A clear definition of the scope was seen to be needed, i.e. making obvious whether hazard or risk based decision making is meant here. Also the target audience was felt to be in need of clarification. The development of a common process presented in a common guidance was seen as an opportunity to put substitution back into context, i.e. being one way of managing chemical risks at the company level. Some opinions were voiced that substitution must also be set in the wider context of REACH and that the potential for substitution targets to be a driver for research and innovation must be made clear. These aspects were elaborated on in the presented Draft Guidance Document.

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[264] Workshop held in Brussels 28.9.2010

[265] Hearing at the meeting for the Working party "Chemicals at the workplace” on 20.10.2010 in Luxembourg

In preparing the process and accompanying guidance document, SMEs and their needs should be a particular focus. Substitution can be a very complex process and motivation of SMEs to consider and apply substitution was seen an important aspect. Highlighting cost, savings and benefits was felt to be a potential way of promoting the overall use of substitution. A concrete guidance with specific supporting tools and databases was seen as a good idea. Examples would be one way of motivating, but confidentiality and competition issues can hinder the use of most interesting cases. Therefore the inclusion of many examples was not felt necessary.

11.4 Validation survey

A summary of the survey results can be found in Annex 4. The majority of the respondents found the proposed process as well as the text within the guidance practical and easy to understand. The overall layout and structure was considered practical. The applicability of the proposed guidance was also considered rather good as the respondents found that the guidance sufficiently takes into account companies in the whole supply chain. However, the draft was seen as lacking in acknowledgement of differences in requirement that different industries and companies of different sizes do have. This is however felt to be expected for a generic guidance document.

In addition to the generic comments in the survey, highly specific comments on wording, lay-out, examples etc. were provided via email. Many of the organisations participating in the validation had collated comments internally from several people. Not all of the people who commented on the text in detail participated in the survey. Hence the actual number of commenting people is difficult to estimate, but it would be closer to 100 than to 50. The comments obtained by the survey as well as by email were all analysed and taken into account in preparing the final Draft Guidance Document.

A specific difficulty in taking into account all the comments relate to the expressed wishes by some commentators to include more references to legal texts, more scientific discussions and more highlighting of uncertainties. As the original target was to provide an easy to use process, it was decided to not include scientific or legal discussions. There are other media and reports that address this, and partially this has been addressed in this study report.

11.5 Piloting

The piloting results were encouraging, particularly for the simpler 4 step process. In the 7 step process, the most welcome tools related to the comparisons of the overall costs and benefits, and the risk assessment approach was regarded as sound. The process was seen as logical and easy to follow, without the need for much explanation by the facilitator for the piloting. Particularly the risk matrix and the cost benefit tools were seen as practical and much welcomed. During the work, it became evident that the ranking and interpretation of the different hazard statements and R-phrases was something seen as very hard. Here the risk matrix helped enormously. This also resulted in inclusion of a complete list of the R-phrases and hazard statements as a separate Appendix (1) of the Guidance document. The testing of the approach and the guidance document with non-native English speakers lead to further simplification of the text.

12. Summary of results for set objectives

Based on the undertaken work, it can be concluded that a common approach to substitution is both feasible to develop and needed. In the following, each of the set objectives is analysed in light of the findings.

4 objectives were set for the provision of a common approach to substitution and guidance for it:

1. **Provide an overview of successful substitutions**. There are literally hundreds of cases of successful substitution available on various sites and databases as well as in the literature. A few are discussed in this document. As there is a concurrent EU project with the specific target of building a database of successful substitution cases, it was considered that in this work, the overview of successful substitution cases would provide little if any added value. Specifically, a generic guidance cannot contain cases for all. Instead the approach to provide links to existing sites, from which the reader can gain access to several hundreds of cases was adopted. It also became clear during the work that specific substitution cases are of limited value to users, as the substitution is often highly specific to a particular company. Other companies regard their successful substitutions as trade secrets.
2. **Identify and provide examples of practical applications of effective substitution for different types of substitution processes**. Wide discussion around the subject of examples and cases versus targeted illustrations of how to proceed in each step of the proposed process was held both in the interim meeting with the steering group and in the workshop. The conclusion was as above, that as there is a concurrent EU project for a common database on substitution, more value would be added by this project if the main effort targeted the differences between substitution approaches and concentrated on finding the parameters to include in a generic approach. This is discussed in detail in Identification of targets for substitution in section 0; as well as in section 5.3 and section 6.
3. **Assess the potential for developing a common approach to substitution at the EU-level, including development of generic or more specific approaches (e.g. substance specific, sector specific, process specific etc.) and, if feasible, propose a common approach/approaches to substitution across the Union**. Developing a generic approach was seen as feasible and the majority of interviewees regarded it as desirable (see discussion in Section 8). The common approach to substitution is presented in the Draft Guidance Document.
4. **Develop practical guidelines for applying the principle of substitution in workplaces, suitable for use by both workers and employers**. This has formed the main part of the work and the results are presented in the Draft Guidance Document.

There were also objectives set for the overall background study. These were set for substitution at a practical level as well as addressing substitution at the policy and societal level. **Objectives related to the substitution process at the policy and societal levels were:**

5. **Collate, compare, contrast and evaluate existing approaches to substitution within the EEC area, including generic, substance specific or sector or chemical specific approaches.** This was addressed in detail and formed a main part of the literature study (See Sections 4, 6 and 7.). There are many different approaches, but a common thread appears to be that substitution is currently discussed mainly through the eyes of the chemical and process industries. Another common practice is to equal substitution to the REACH requirement of authorisation process for certain high hazard chemicals. Much less is available on using substitution as

a risk management measure, especially not for such SMEs that are mainly using chemicals as part of their work and not as a core process component. Therefore the proposed generic approach targets the use of substitution as a risk management measure for SMEs and non-chemical industries. The role of the chemical industry is in this approach more of an information and knowledge provider.

6. **Identify and analyse the policy level drivers (motivators) and barriers to chemical substitution and relate these to industry sectors and company size**. This discussion can be found in Section 5. Main drivers for substitution are not surprisingly legislation and the requirement to ensure workers' safety. Environmental legislation with its associated permits as well as outright bans on certain substances is in general more effective in driving companies towards substitution than occupational health and safety legislation. A particular cause of concern is the apparent low level of substitution of CRMs. A motivator for substitution can be the lessening of administrative burdens, but again this is mostly related to environmental permits. Transport legislation (ADR, RID, IMO) can also act as a main driver for companies to find safer materials. In these cases, the administrative burden is also linked to a cost factor. There are no real differences that can be directly related to company size, unless one includes the fact that large companies tend to use more materials and may be more often subject to permits or authority monitoring. More important external factors are the industry position in the value chain and above all, the amount of hazardous materials or chemicals the company uses as this determines the level of legislative requirements such as permits.

7. **Analyse the process of substitution from different stakeholder views and identify any relevant sector specific issues and recommendable processes.** This discussion can be found in Section 6. During the work, it became apparent that the key influencing factor on substitution is the position of the company in the value chain (see Figure 5: The value chain used and examples of industry positions). The further along the value chain a company is, the knowledge level of substitution or chemical risk management generally decreases, but at the same time, the relative effort required to find alternative chemicals also decreases. The developed generic processes are too generic to be used for substitution that is based on chemical functionality requiring lengthy and specific R&D, therefore it is considered that the developed framework process does not meet the requirements of the chemical manufacturing industry as an entity, although smaller companies may still find the approach useful.

   Some interesting differences in the views of different stakeholders were found.

   Firstly, the authorities tended to regard substitution as something far too difficult for companies and call for very simplistic processes. On the other hand, experts and specifically some chemical companies and industry associations were very reluctant to disregard any scientific information and called for more detailed analysis. As the target group for the potential guidance are SMEs and companies without high level knowledge of industrial hygiene or chemical risk management, a simplifying approach was adopted.

   Secondly, some of the industry associations regarded cost and cost-benefit analysis as something done automatically by companies, whereas the companies themselves saw this as one of the main difficulties. Hence the cost-benefit and comparative tools were included prominently.

   Thirdly, there are clear differences between national level guidance and tools available. This does not, however, according to interviewed authorities; appear to influence the overall use of substitution as a risk management measure very much. However, more statistical data would be needed to further analyse this.

Overall, the process required for identifying, evaluating and implementing substitution is closely related to generic change management processes. Therefore a change management model (Plan-Do-Check-Act) was adopted to structure the overall substitution process. This renders the process applicable to all sectors, and including two levels of assessment (simple and slightly more in-depth) allows the same process to be applied generically across industries, company sizes and member states.

Objectives related to the substitution process at the practical level:

8. **Identify, describe and evaluate the different scientific, financial, technical and management aspects that impact on the substitution process.** This formed the core of the work undertaken. The findings are discussed in detail in Sections 4, 5, 6, 7. The findings were used to construct the generic process and to identify the most urgently needed tools.

9. **Identify, describe and evaluate the different practical aspects related to chemical substitution processes, identifying common and contrasting elements and their impacts (positive and negative) on the company applying the principle of substitution**. The approach taken has been to find the practical aspects that must be taken into account when evaluating substitution, and then develop a systematic process for assessing the potential negative and positive impacts on the company. The developed tools can be found in Appendices to the Draft Guidance Document.

10. **Identify the key aspects contributing to challenges and success in chemical substitution processes.** The key practical aspects that contribute to whether a substitution will become a success or not are included in the developed process. A key aspect to take into account at the outset is inevitably the level of expertise of the assessor, as this will determine how in depth an assessment can be done. No complex substitution should be attempted based solely on the 4 step model. The cost and benefit aspects must be carefully compared over a period of time, taking into account not only direct material costs but also all the other associated cost items. The comparison of risk levels must extend to include not only chemical risk, but also risk from changes in the process or tasks, such as for example safety risks, strains, slips, falls, ergonomics, noise, vibration and continuity risks. Finally, the assessor must include an assessment of uncertainty – i.e. it is not recommended to make decisions based on incomplete data.

    However, it is considered that the overall key aspect that will contribute to instigation of successful substitution is the overall "marketing" of substitution as a risk management measure to a wide audience. Authorities should also more actively monitor that substitution assessments are undertaken for CRMs according to the Directive requirements.

11. **Identify and analyse how substitution decisions are made and which key factors influence these, including cost considerations**. The work undertaken was from the beginning structured around management decisions and how these should be taken into account in the process. In the proposed 7-step process, the key management decision points are given. A potential barrier to substitution is the sometime evident lack of ability to condense risk assessments into the required information to enable management to make informed decisions. To help in this, tools for the assessment of overall effects and implications of a change are presented in Appendices 4 (4-step process) and 6 (7-step process) of the Draft Guidance.

12. **Analyse the degree of worker participation and the influence of workers in the implementation of substitution**. The degree of worker influence on substitution varies according to company size, industry and the type of substitution under consideration. The chemical industry does not so much involve workers in substitution, as it is considered more of an R&D subject. However, once reaching the implementation stage, worker feedback is sought. In general, the smaller the company, the more involved workers may be with substitution decisions and implementation. In larger companies, substitution may be considered in committees, where workers often are represented. In the Nordic countries, worker involvement in any change, including substitution, appears to be the norm. Worker involvement was considered to be desirable but often the practical task of engaging workers in substitution was seen as difficult. Inertia and resistance to change were important factors that must be overcome in any successful substitution.
13. **Identify the key motivators to substitution.** The key motivators for substitution are clearly to increase safety, comply with legislation and reduce cost. The motivators are discussed in detail in Section 5.

13. Conclusions and recommendations

The study results indicate that a common generic approach to substitution is needed and feasible to construct. The proposed common approach has been based on substitution being a change. Therefore the assessment and implementation of any substitution is considered to be best approached through **methods suitable for change management**. The adopted methodology for the processes is the perhaps best known change management model, the Plan-Do-Check-Act model.

There are very different understandings of what substitution is and what it is not. This study has not addressed the authorisation process of REACH, or the substitution recommendations by OSPAR, or any generic lists of high hazard chemicals. The use of substitution as a risk management measure in companies for their daily work is the main focus of this work. This use of substitution is underutilised by companies and often regarded as highly complex and difficult.

Whilst innovation and product development work aiming for safer products and processes are vital, the proposed Draft Guidance does not in detail address substitution of, for example, reagents in chemical reactions or more complex cases where substitution requires extended research and development work.

It is acknowledged that the proposed Draft Guidance simplifies scientific knowledge. In places, there are details that could be debated. Indeed, details in the guidance can and should be refined in future editions. In particular, further simplification of the 4-step process should be attempted after some practical experience of using the guidance has been collated. There has been no attempt to produce new science or reveal major new ways of thinking about substitution. The focus has been firmly on how to translate scientific considerations of hazard, risk and risk reduction through substitution into something more easily accessible for the target audience.

The vast majority of companies within the EU do not have the expert knowledge or resources to undertake state of the art evaluations. Wherever there are simplifications, it is hoped the scientific community and experts in occupational hygiene and chemical risk will accept this simplification as a necessity in the effort to reach a larger potential audience and make substitution a more widely used risk reduction measure.

In order for the proposed Draft Guidance Document to stimulate the use of substitution across the EU and EEA; the following recommendations are made:

1. Dissemination of the generic process as contained in the Draft Guidance document should be planned and implemented. If no dissemination plan is made, it is highly likely that the guidance will reach very few of the target audience, hence rendering the impact of the work negligible. Potential partners for dissemination of the final Guidance Document are national authorities, industry associations, occupational health centres, trade organisations, professional organisations as well as the DG website and other EU level organisations. The proposed framework allows easy tailoring to specific industries, groups of chemicals or tasks and can therefore also be tailored by the distributers by adding specific examples etc. relevant to the industry or references to national legislation (authorities).

2. The Draft Guidance document has been split into two processes and several appendices as well as definitions and an introductory part. This was based on feedback of the need to make sure the user does not see the two streams (4 step and 7 step) as duplication of information but as alternative processes to follow. Therefore the Draft Guidance document is

recommended to be distributed through a website. This will give the opportunity to keep any links up to date and add new information as needed.

3. In order for the process to be fully accessible to all parties in the EU, it is recommended that any final Guidance document is translated to the EU languages.
4. The risk matrix in Appendix 3 of the Draft Guidance document would benefit from a round of validation and adoption as good practice recommended by the DG. It is not considered that the German Column model in its own is suitable to take as a direct EU wide risk assessment concept, as it refers to some national legislation as well as in some cases not providing a sufficient scale for differentiation between safety hazards. It is also considered that the potential for incidents and accidents must be taken into account better.

Terminology and abbreviations

A common approach	The overall core steps to include in the consideration, evaluation and implementation of substitution
ABC	Activity-Based Costing
Acceptable safety	The level of risk that the company is willing to take; the consequences are slight, benefits (perceived or real) are great and the likelihood small
AEGL	Acute Exposure Guideline Levels
AFSSA	Food Safety Agency (France, prior to ANSES, Agence Française de Sécu-rité Sanitaire des Aliments)
AFSSET	Agency for Environmental and Occupational Health Safety (France, prior to ANSES, the Agence Française de Sécurité Sanitaire de l'Environnement et du Travail)
ANACT	National Agency for the Improvement of Working Conditions (France, Agence pour l'amélioration des conditions de travail)
ANSES	Agency for Food Safety, Environmental and Occupational Health and Safety (France)
ATEX	DIRECTIVE 94/9/EC on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially Explosive Atmospheres (ATEX=atmosphères explosibles)
AWARE	Adequate Warning and Air Requirement
BAM	Federal Institute for Materials Research and Testing (Germany, Bundesanstalt für Materialforschung und -prüfung)
Barrier	Any influence that hinders or makes it difficult for companies to substi-tute
BAuA	The Federal Institute for Occupational Safety and Health (Germany, Bundesanstalt für Arbeitsschutz und Arbeitsmedizin)
BfR	Federal Institute for Risk Assessment (Germany, Bundesinstitut für Risikobewertung)
BG	Institutions for statutory accident insurance and prevention (Germany, Berufsgenossenschaften)
BMAS	Ministry for Labour and Social Affairs (Germany, Bundesministerium für Arbeit und Soziales)
BMU	Minstry for the Environment (Germany, Bundesministeriums für Umwelt, Naturschutz und Reaktorsicherheit)

BVL	Federal Office of Consumer Protection and Food Safety (Germany, Bundesamt für Verbraucherschutz und Lebensmittelsicherheit)
CAD	DIRECTIVE 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (CAD=Chemical Agents Directive)
Carsinogens	A substance, radiation or radionuclide directly involved in causing cancer
CAS	Chemical Abstracts Service (USA)
CCA	Chromated Copper Arsenate
CEFAS	Centre for Environment, Fisheries & Aquaculture Science (UK)
CEFIC	European Chemical Industry Council
CFC	Chlorofluorocarbons
CHARM	Chemical Hazard Assessment and Risk Management
Chemical	A chemical is basically anything made of matter - liquids, solids, gases. Water is technically speaking a chemical – but generally the word is used to refer to manmade compounds.
Chemical manufacturers	Very large companies and smaller, specialised companies that produce chemicals utilising different chemical reaction pathways
Chemical reaction	A chemical reaction is a process that leads to the transformation of one set of chemical substances (reactants) into another (products).
Chemical risk	Generally, chemical risk is associated with the possibility that a chemical either through normal use in certain ways or through accidental release can cause harm to persons, the environment or property.
Chemical risk management	A process used within an organisation to manage risks from the transfer, storage, use and disposal of chemicals.
Chemical use processes	Are processes in which chemicals are either used as solvents or additives or to achieve a chemical reaction.
CHSCT	Hygiene and Safety and Work Conditions Committee (France, Le comité d'hygiène, de sécurité et des conditions de travail)
CIS	International Occupational Safety and Health Information Centre
CLP	A European Community Regulation (EC No 1272/2008) on classification, labelling and packaging of substances and mixtures
CMR	Carcinogenic, Mutagenic and Reprotoxic substances

CNAMTS	National Salaried Workers' Health Insurance ***Fund (France, Caisse nationale de l'assurance maladie des travailleurs salariés)***
COCT	Steering Committee on Working Conditions (France, Conseil d'orientation sur les conditions de travail)
COSHH	Control of Substances Hazardous to Health
Cost-benefit	An analysis where costs are related to the potential benefit an outlay can bring
CSF	Chemicals Stakeholder Forum (UK)
CVD	Chemical Vapor Deposition
Dangerous chemicals	Dangerous chemicals are chemicals which due to their intrinsic properties may cause damage to health, the environment or property
DDT	Dichlorodiphenyltrichloroethane
Defra	Department for Environment, Food and Rural Affairs (UK)
DG	Directorates-General
DG EMPL	The European Commission's Directorate-General for Employment, Social Affairs and inclusion
Driver	Influence that "pushes" companies towards substitution
EA	Environment Agency (England, Wales)
ECHA	European Chemicals Agency
EEA	European Environment Agency
EEC	European Economic Community
Elimination	Elimination of chemicals is the most effective way of minimising chemical risk, a good example of which is the introduction of cleaning methods which remove dirt without using chemicals.
End users	Companies or organisations that actually consume the end product of the earlier value chain, e.g. a cleaning company using cleaning chemicals or a painting and decorating company using paints
ESD	Emission Scenario Documents
ETUC	European Trade Union Confederation
ETUI	European Trade Union Institute
EU	European Union

EU-OSHA	European Agency for Safety and Health at Work
EUROFUND	European Foundation for the Improvement of Living and Working Conditions
European Risk Phrases	Risk (R) phrases are indications of the substance's hazard and of safety measures relating to that substance. They are set by the directives of the European Community. They are used in the labelling of the packages and in safety data sheets to warn and guide the use of the dangerous goods and preparations. Risk phrases are standardised presentations of the potential risks of the product in normal handling and use, for example R21 'Harmful in contact with skin'. (Source: http://osha.europa.eu/en/sector/agriculture/ds)
Evira	Finnish Food Safety Authority (Finland, Elintarviketurvallisuusvirasto)
EWCO	European Working Conditions Observatory
EXICHEM	Existing Chemicals Pointer Database
Exposure potential	Possibility to become exposed to chemicals (e.g. skin contact, inhalation)
External influences	Influences from society; outside the company
FIOH	Finnish Institute for Occupational Health
GHS	Globally Harmonized System of Classification and Labelling of Chemicals; addresses classification of chemicals by types of hazard and proposes harmonized hazard communication elements, including labels and safety data sheets. Provides a basis for harmonization of rules and regulations on chemicals at national, regional and worldwide level, and is an important factor also for trade facilitation.
H&S	Health and Safety
Hazard	A situation with the potential to cause harm
Hazard labels	Labels are used to communicate substances hazardous properties; labels according to CLP include hazard pictograms, signal words and hazard statements
Hazardous chemicals	Substances that fulfill the physical, health, environmental or ozone layer hazard criteria (CLP) i.e. substances and materials that have the potential to harm people or the environment
Hazardous substances or hazardous chemicals	Substances that fulfil the physical, health, environmental or ozone layer hazard criteria (CLP). To put is more simply: Substances and materials that have the potential to harm people or the environment
HCFC	Hydrochlorofluorocarbons
HFC	Hydrofluorocarbons

Hierarchy of measures	European Council DIRECTIVE 98/24/EC; Article 6: “substitution shall by preference be undertaken, whereby the employer shall avoid the use of a hazardous chemical agent by replacing it with a chemical agent or process which, under its condition of use, is not hazardous or less hazardous to workers' safety and health, as the case may be. Where the nature of the activity does not permit risk to be eliminated by substitution, having regard to the activity and risk assessment referred to in Article 4, the employer shall ensure that the risk is reduced to a minimum by application of protection and prevention measures, consistent with the assessment of the risk made pursuant to Article 4. These will include, in order of priority: (a) design of appropriate work processes and engineering controls and use of adequate equipment and materials, so as to avoid or minimise the release of hazardous chemical agents which may present a risk to workers' safety and health at the place of work; (b) application of collective protection measures at the source of the risk, such as adequate ventilation and appropriate organizational measures; (c) where exposure cannot be prevented by other means, application of individual protection measures including personal protective equipment”
HMCS	Harmonised Mandatory Control System
HPV	High Production Volume chemicals
HSE	Health and Safety Executive (UK)
IARC	International Agency for Research on Cancer
IFA	Institute for Occupational Safety and Health of the German Social Accident Insurance (Germany, Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung)
ILO	International Labour Organisation
INRS	***National Research*** and Safety Institute (France, Institut National de Recherche et de Sécurité)
Internal influences	Influences from within the company
IOM	Institute of Occupational Medicine (UK)
IPCS	International Programme on Chemical Safety
ISTAS	Trade Union Institute for Work, Environment and Health (Spain, Instituto Sindical de Trabajo Ambiente y Salud)
IVAM	Interfaculty Environmental Science Department of the University of Amsterdam (Netherlands, Interfacultaire Vakgroep Milieukunde)
IVL	Swedish Environmental Research Institute

JRC	Joint Research Centre
KEMI	Swedish Chemicals Agency (Sweden, Kemikalieinspektionen)
KENK	Finland's Advisory Committee on Chemicals (Finland, Kemikaalineuvottelukunta)
KETU	Chemical products registry (Finland, Kemikaalien tuoterekisteri)
Major accident hazard	An occurrence of such as a major emission, fire, or explosion resulting from uncontrolled developments in the course of the operation of any establishment covered by Seveso II Directive, and leading to serious danger to human health and/or the environment, immediate or delayed, inside or outside the establishment, and involving one or more dangerous substances
Motivators	Something that "pulls" companies towards substitution, i.e. creates a desirable advantage for companies to substitute
Mutagens	A substance or other agent that changes the genetic material
NACE	European standard classification of productive economic activities
NGO	Non-Governmental Organisation
Occupational exposure limits	The limit of the time-weighted average of the concentration of a chemical agent in the air within the breathing zone of a worker in relation to a specified reference period (OELs)
OECD	Organisation for Economic Co-operation and Development
OSPAR	Convention for the Protection of the Marine Environment of the North-East Atlantic
PBB	Polybrominated Biphenyl
PCB	Polychlorinated Biphenyl
PIMEX	Picture Mix Exposure
PON system	Petroleum Operators Notice system
PPE	Personal Protective Equipment
PROC	Process category
Process industry	The industry where chemicals are used within the processes themselves to perform a specific function, such as within paper and pulp industry. This may or may not include chemical reactions but often require very specific chemical or molecular functionality
PVC	Polyvinyl chloride

R&D	Research and development
RCF	Refractory Ceramic Fibres
REACH	A European Community Regulation on chemicals and their safe use (EC 1907/2006), it deals with the Registration, Evaluation, Authorisation and Restriction of Chemical substances.
Risk	The possibility that something not wanted will happen.
Risk Assessment	Is a process of quantifying the probability of a harmful effect, chemical risk assessment is based on hazard information and exposure potential
RIVM	National Institute for Public Health and the Environment (Netherlands, Rijksinstituut voor Volksgezondheid en Milieu)
RoHS	Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2008
RSC	Royal Society of Chemistry (UK)
SAICM	Strategic Approach to International Chemicals Management
SEPA	Scottish Environment Protection Agency
SIDS	Screening Information Data Set
SME	Small and Medium Sized Enterprises
STOP-principle	Substitution, technical measures, operational measures, personal protection
Substitution	Replacing a chemical agent used with a less hazardous one; replacing a physical form of a chemical agent with one less hazardous (e.g. using pellets instead of powder); replacing a process used with a less risky one (e.g. lower temperature)
SUMER survey	Medical Surveillance of Workplace Risks (France, Surveillance Medicale des Risques Professionnels)
SVHC	Substances of Very High Concern
SYKE	Finnish Environment Institute (Finland, Suomen ympäristökeskus)
TRGS	Technical Rules for Hazardous Substances (Germany, Technische Regeln für Gefahrstoffe)
Tukes	Safety Technology Authority (Finland, Turvatekniikan keskus)
UBA	Federal Environment Agency (Germany, Umweltbundesamt)
UN	United Nations
UNEP	United Nations Environment Programme

UNIDO	United Nations Industrial Development Organisation
Value chain approach	Analysis based on the position of a company in the industry's value chain
Valvira	National Supervisory Authority for Welfare and Health (Finland, Sosiaali- ja terveysalan lupa- ja valvontavirasto)
VOC	Volatile Organic Compounds
VROM	Ministry of Housing, Spacial planning and the Environment (Netherlands, Ministerie van Volkshuisvesting, Ruimtelijke Ordening en Milieubeheer)
WEEE	Waste Electrical and Electronic Equipment
WFD	Water Framework Directive (Directive 2000/60/EC)
WHO	World Health Organisation
WM	Environmental Management Act (Netherlands, Wet milieubeheer)
WMS	The Environmentally Hazardous Substances Act (Netherlands, Wet milieugevaarlijke stoffen)
WVO	Pollution of Surface Waters Act (Netherlands, Wet verontreiniging oppervlaktewateren)
WWF	World Wildlife Fund

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Annex 1 Participants

Steering group

Angelidis Antonis, DG EMPL

Huici-Montagud Alicia, DG EMPL

Morris Alick, DG EMPL

Interviews

Ahonen Leena, Tukes

Alen Hannu, Ministry of Social Affairs and Health (Finland)

Amuko Omara, IUF - International Union of Food Workers

Annys Erwin, CEFIC

Antonsson Ann-Beth, IVL

Bailey Keith, Defra

Brændgaard Sofka Ane, Lego

Bugeja Josef, GWU - General Workers Union - Hospitality and Food

Calvez Olivier, Ministère du Travail, de la solidarité et de la fonction publique

Carter Martyn, BP

Castel Francoie, ENGINERERING SECTOR

Cherrie John, IOM - Institute of Occupational Medicine

de Bruijn Jack, ECHA

de las Heras Merino Mabel, CCOO

Elreedy Salma, French Agency for Environmental Health and Labour

Garland Emmanuel, Total

Geron Henri, Ministry of Labor

Guilleux Annabella, INRS, Institut National de Recherche et de Sécurité

Harris Tim, Health and Safety Executive

Hayward G R, ERMA European Resin manufactures association

Herdina Andreas, ECHA

Hollander Alber, TNO Kwaliteit van Leven

Isager Per, Danisco

Kapanen Mika, Norpe Oy

Karhu Elina, ECHA

Kortelainen Tarja, Palmia

Kruse Henrik, Danish Crown

Kuhl Klaus, Kooperationsstelle Hamburg

Kuiri Mikko, WWF

Kyrkkö Kirsi, Ministry of Social Affairs and Health (Finland)

Lechtenberg-Auffarth Eva, BAuA - Federal Institute for Occupational Safety and Health

Liesivuori Jyrki, Finnish Institute of Occupational Health

Lill Andreas, European federation of cleaning industries

Lissner Lothar, Kooperationsstelle Hamburg

Lyngbye Anne, Danisco

Machida Seiji, ILO

McAlinden John J, Health and Safety Executive

Meier Poul E., Poul E. Meier

Mongelard Patrice, Defra

Musu Tony, ETUI

Nazareth Joseph, ISS

Nouwen Johan, ECHA

Oljakka Merja, SOL

Orsila Reetta, Ministry of Social Affairs and Health (Finland)

Peltola Jukka, ECHA

Perenius Lena, CEFIC

Perez Miguel, Anglatex

Robert Sophie, French Agency for Environmental Health and Labour

Robin Foster, Health and Safety Executive

Romano Dolores, ISTAS

Ryland-Jones Philip, Defra

Saling Peter, BASF

Schneider Elke, OSHA

Schröder Volker, Verband TEGEWA e.V.

Smith Gill, Health and Safety Executive

Steele Christopher, Elkem Silicon Materials

Still Ian, EOSCA

Thiesen Jens, NKT Cables

Torma Trygve, Nera Networks AS

Unger Timo, Hyundai Europe

Vater Ursula, Fachzentrum für Produktsicherheit und Gefahrstoffe im Regierungspräsidium Kassel

Wibroe Lone , grontmij | carl bro

Workshop attendees

Annys Erwin, CEFIC - European Chemical Industry Council

Argiles Geoffrey, ANSES

Bender Herbert, BASF

Brenzel Steffen, Kooperationsstelle Hamburg IFE GmbH

Capon France, Nickel Institute

Fouquet Marie, Michelin

Hatscher Norbert, Steel Institute VDEh - Stahl-Zentrum

Heughebaert Linda, VLARIP - REACH & CLP Implementation Projects in Flanders

Hutoran Svetlana, BAuA - Federal Institute for Occupational Safety and Health

Kamps Klaus, Unifrax GmbH

Lanne Claire, IMA-Europe (European Industrial Minerals Association)

Lechtenberg-Auffarth Eva, BAuA - Federal Institute for Occupational Safety and Health

Mongelard Patrice, Defra

Musu Tony, ETUI

Niaudet Aurélie, ANSES

Petkova Martina, Goodyear Dunlop Tires Europe B.V.

Schaub Julian, BGA - the Federation of German Wholesale and Foreign Trade

Schneider Elke, OSHA - European Agency for Safety and Health at Work

Seitz Gilles, CGT- General Confederation of Labour (France)

Smith Gill, HSE - Health and Safety Executive

Vlandas Penelope, DG Environment

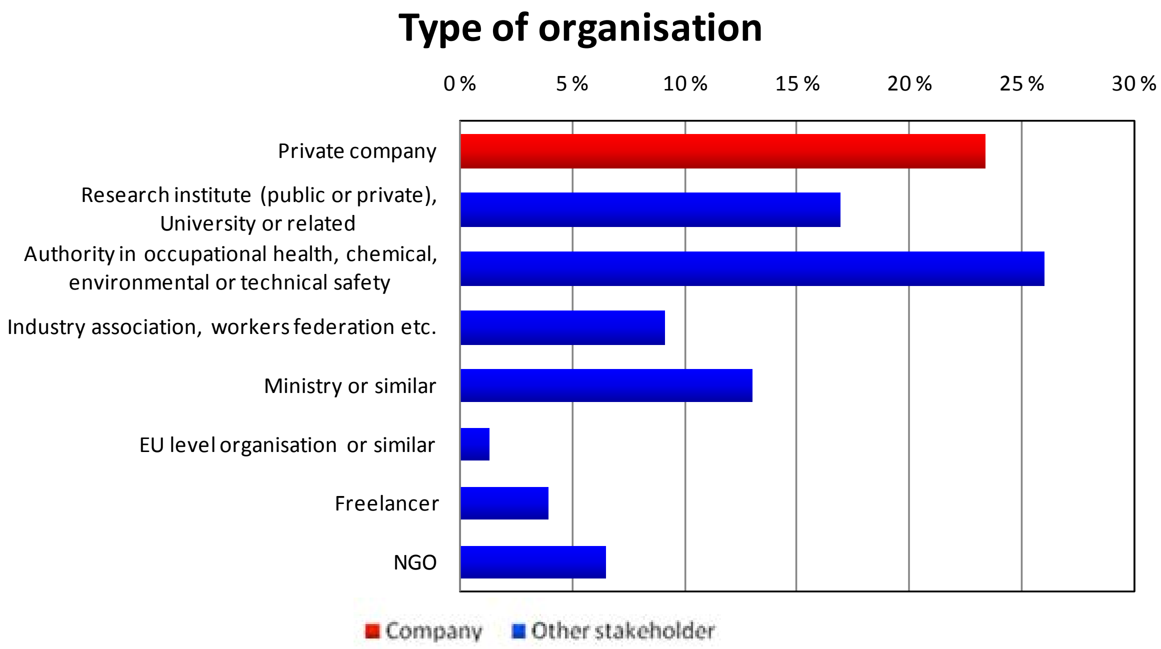
Weijnen John, PPG - SBU Architectural Coatings EMEA

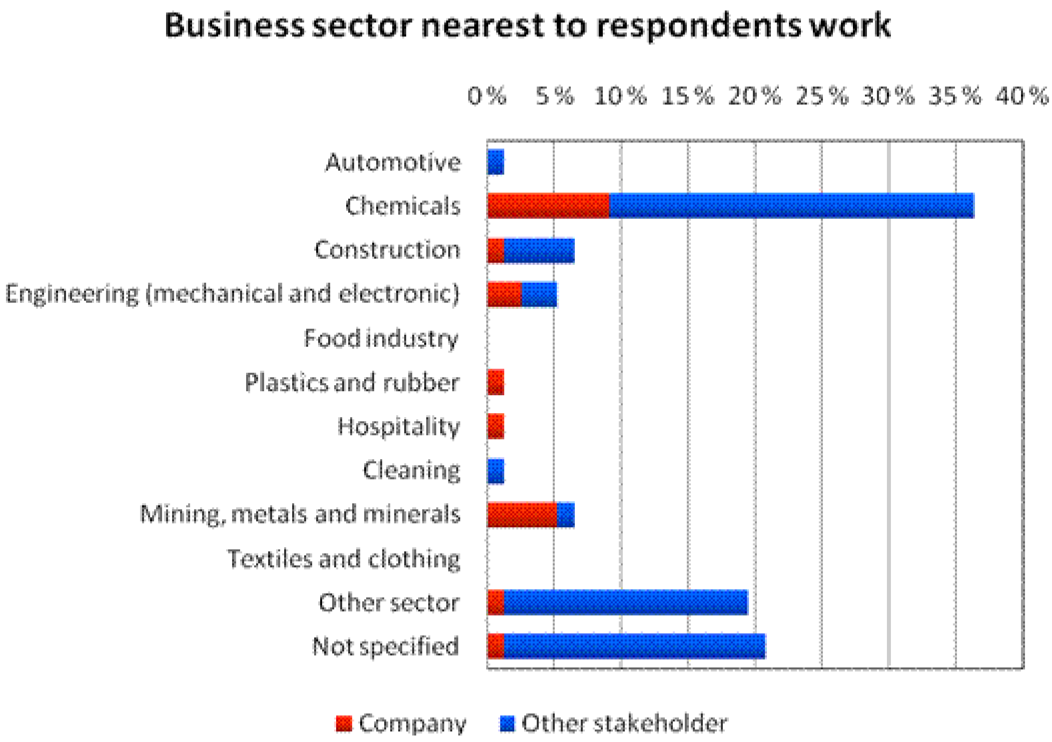
Zullo Lorenzo, ETRMA - European Tyre & Rubber Manufacturers Association

Annex 2 Survey summary

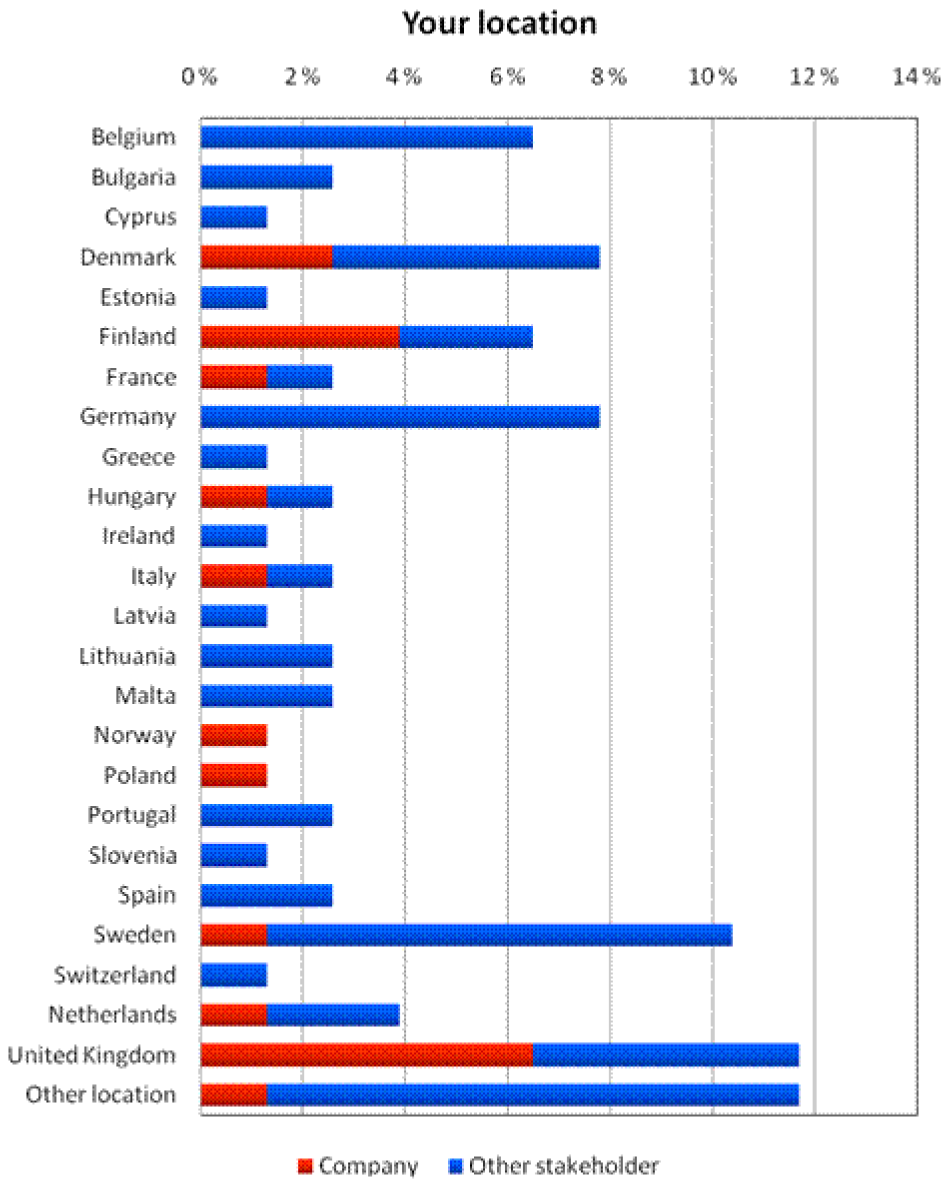
Background information

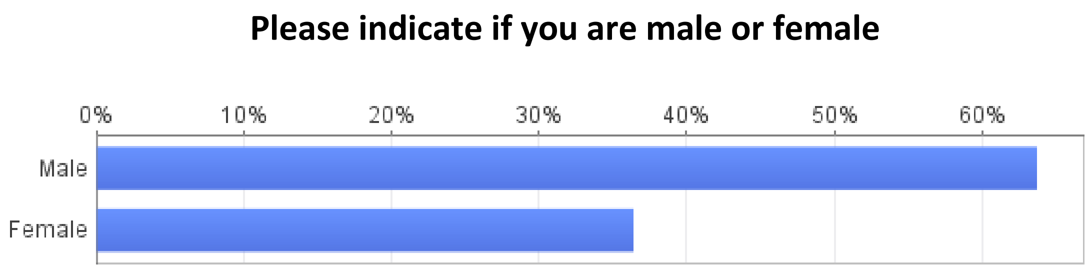
Total number of answers 77



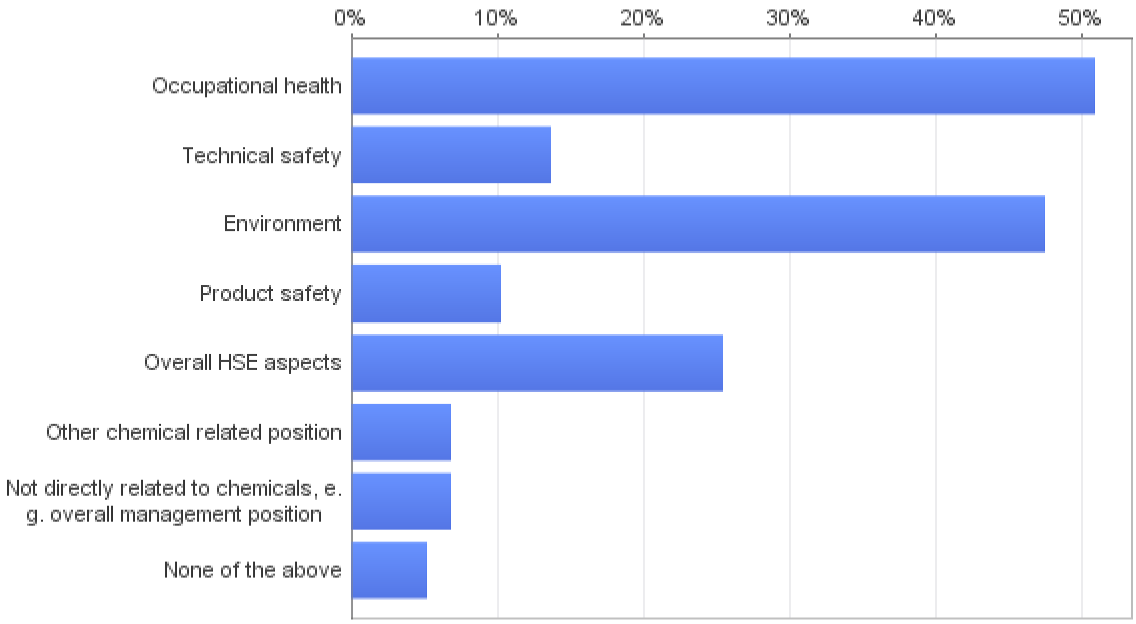


Not specified = mainly research or government related positions

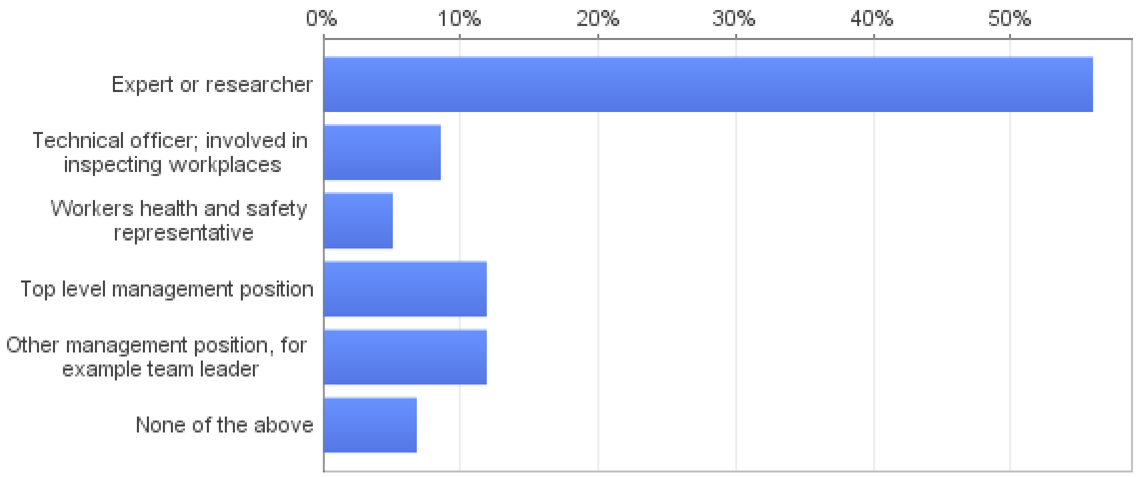

Your location
0%
2%
4%
6%
8%
10%
12%
14%
Belgium
Bulgaria
Cyprus
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Ireland
Italy
Latvia
Lithuania
Malta
Norway
Poland
Portugal
Slovenia
Spain
Sweden
Switzerland
Netherlands
United Kingdom
Other location
Company
Other stakeholder


Please indicate if you are male or female
0%
10%
20%
30%
40%
50%
60%
Male
Female

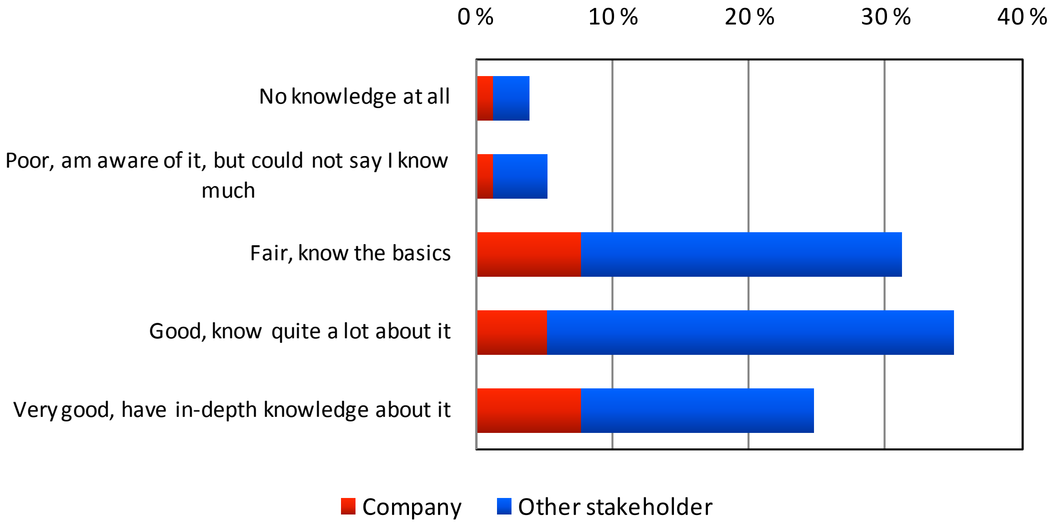
Select the perspective of your position in relation to use of hazardous chemicals. (You can select more than one) - Other stakeholders



Your role in your organization – other stakeholders



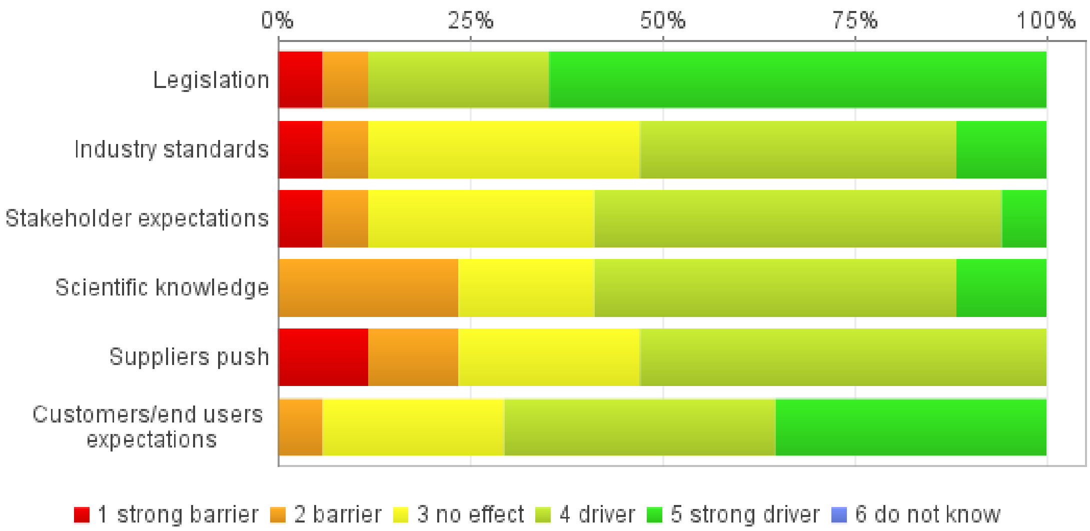
Level of knowledge about the principle of substitution of hazardous chemicals and its implementation?

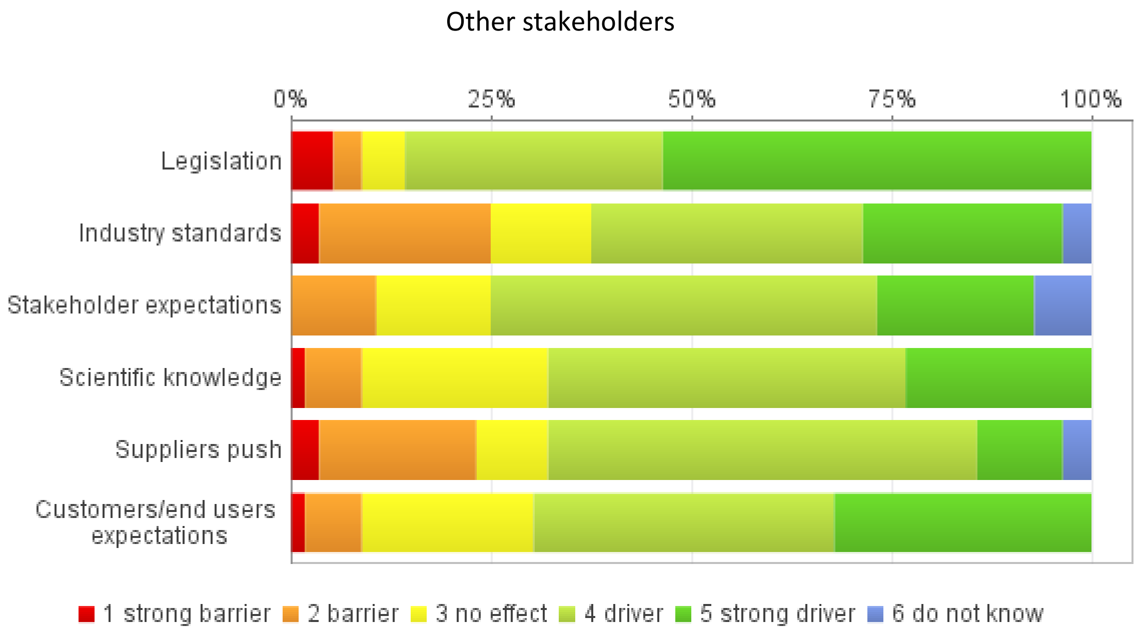


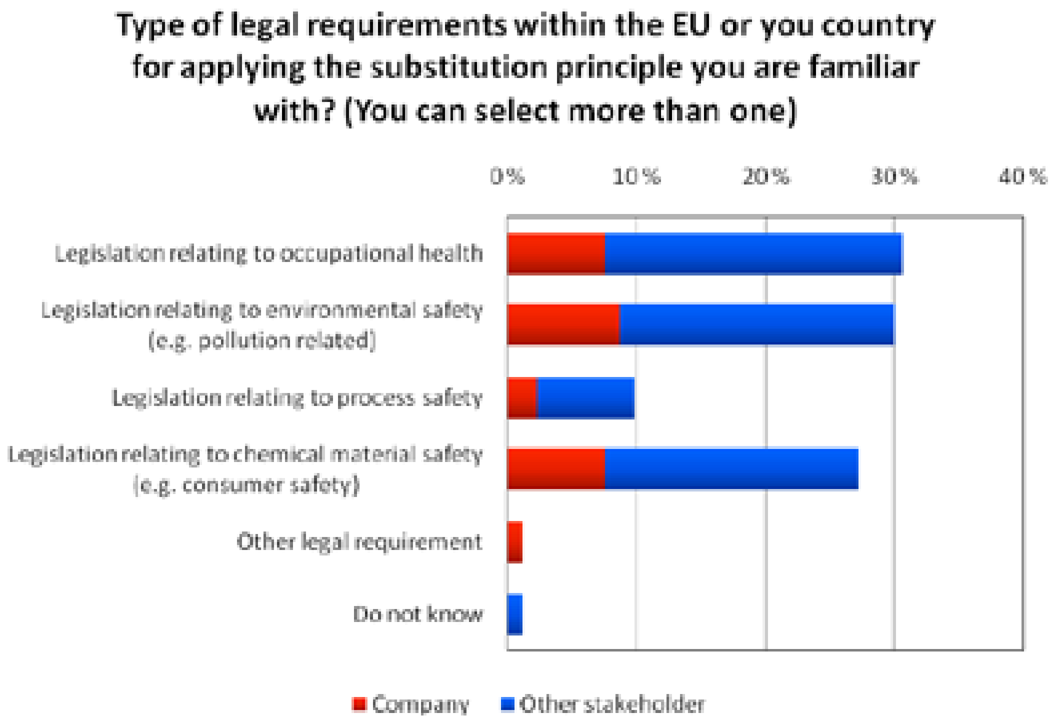
Substitution at policy and societal level

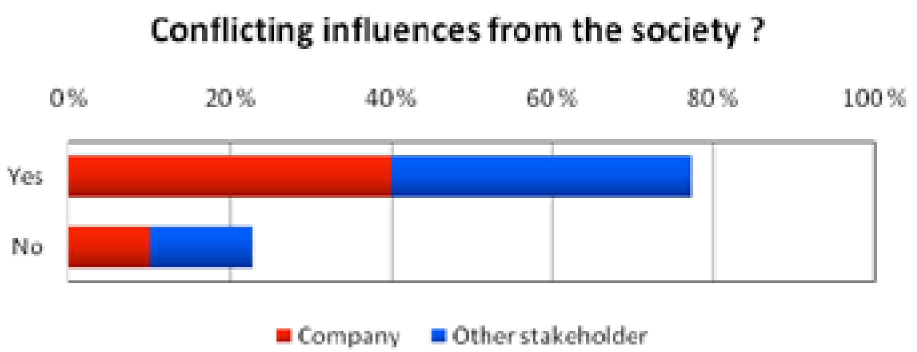
In your opinion, how do the following external aspects influence the use of substitution as a risk management measure in companies?

Company

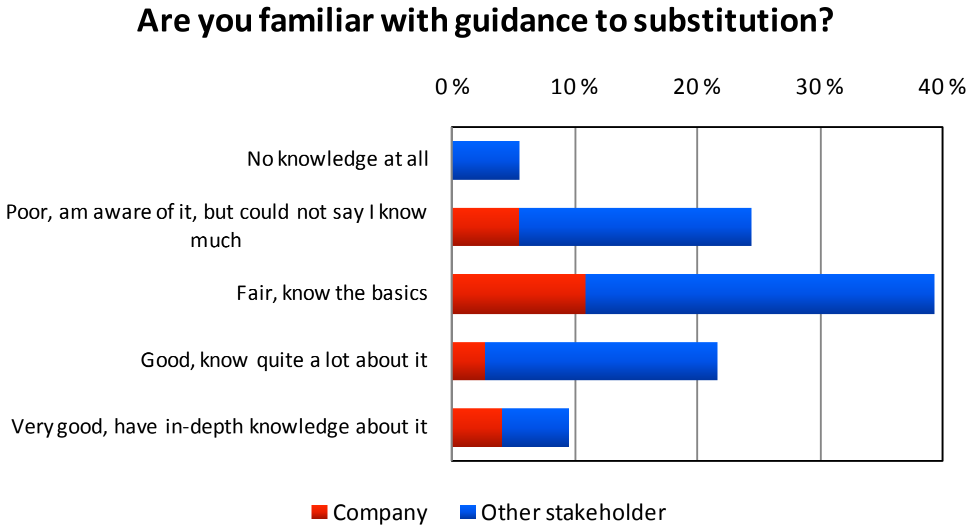


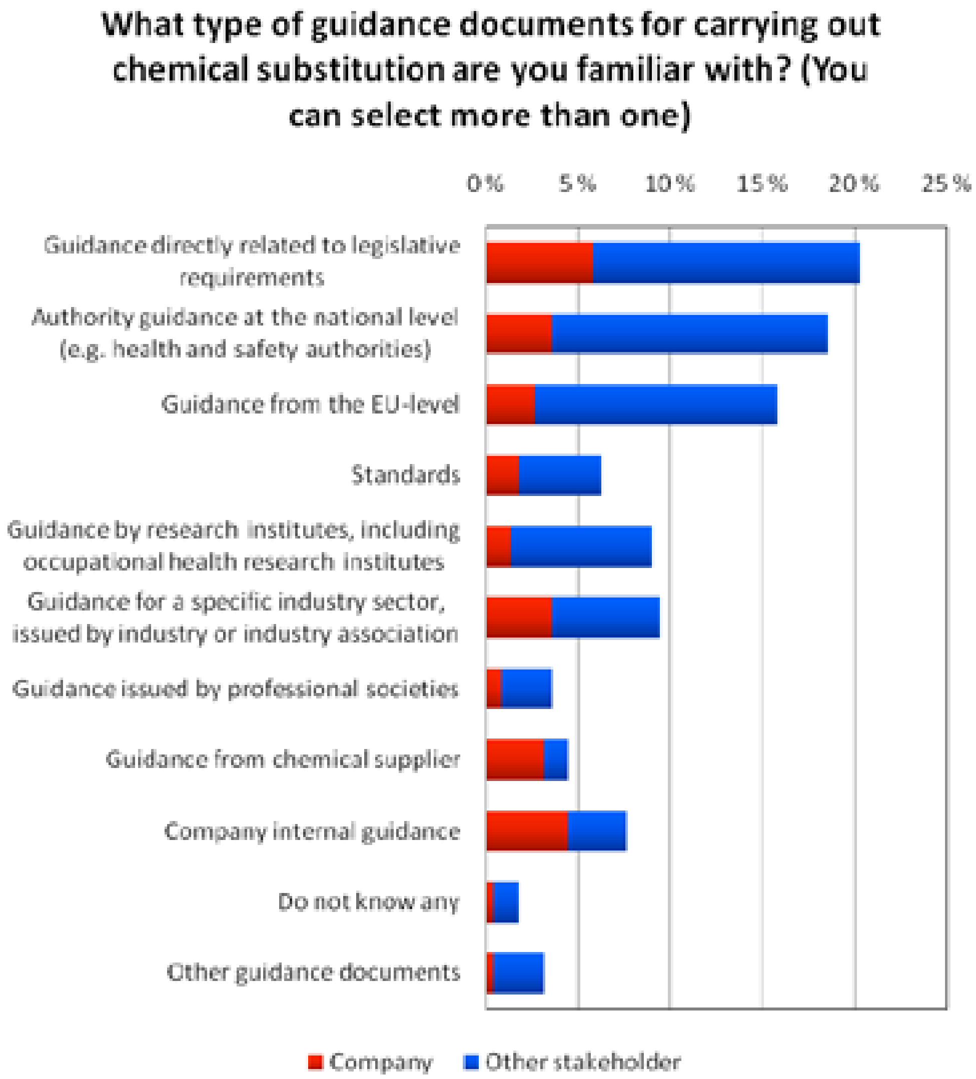

Other stakeholders
0%
25%
50%
75%
100%
Legislation
Industry standards
Stakeholder expectations
Scientific knowledge
Suppliers push
Customers/end users expectations
1 strong barrier
2 barrier
3 no effect
4 driver
5 strong driver
6 do not know

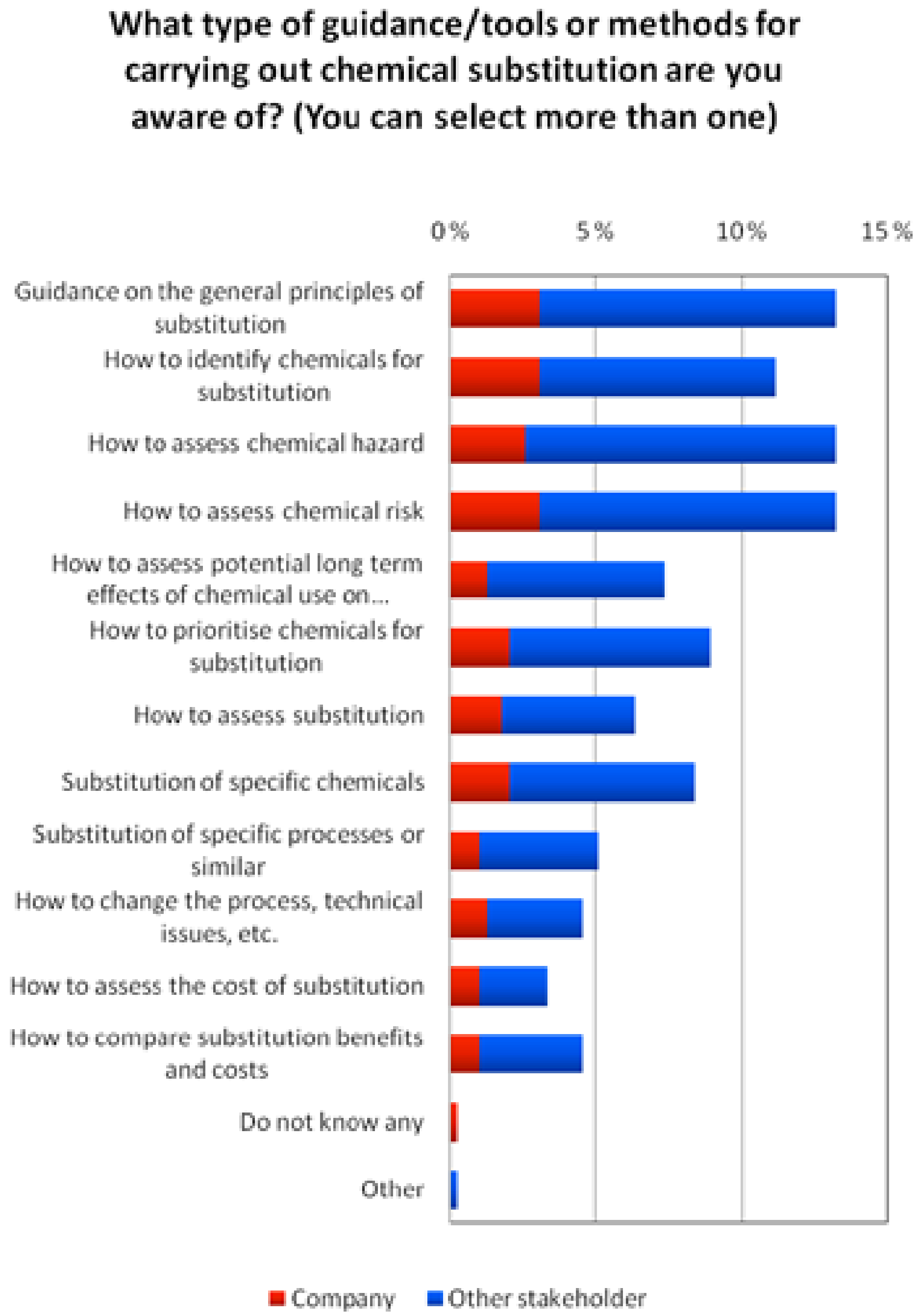

Type of legal requirements within the EU or you country for applying the substitution principle you are familiar with? (You can select more than one)
0%
10%
20%
30%
40%
Legislation relating to occupational health
Legislation relating to environmental safety (e.g. pollution related)
Legislation relating to process safety
Legislation relating to chemical material safety (e.g. consumer safety)
Other legal requirement
Do not know
Company
Other stakeholder


Conflicting influences from the society ?
0%
20%
40%
60%
80%
100%
Yes
No
Company
Other stakeholder

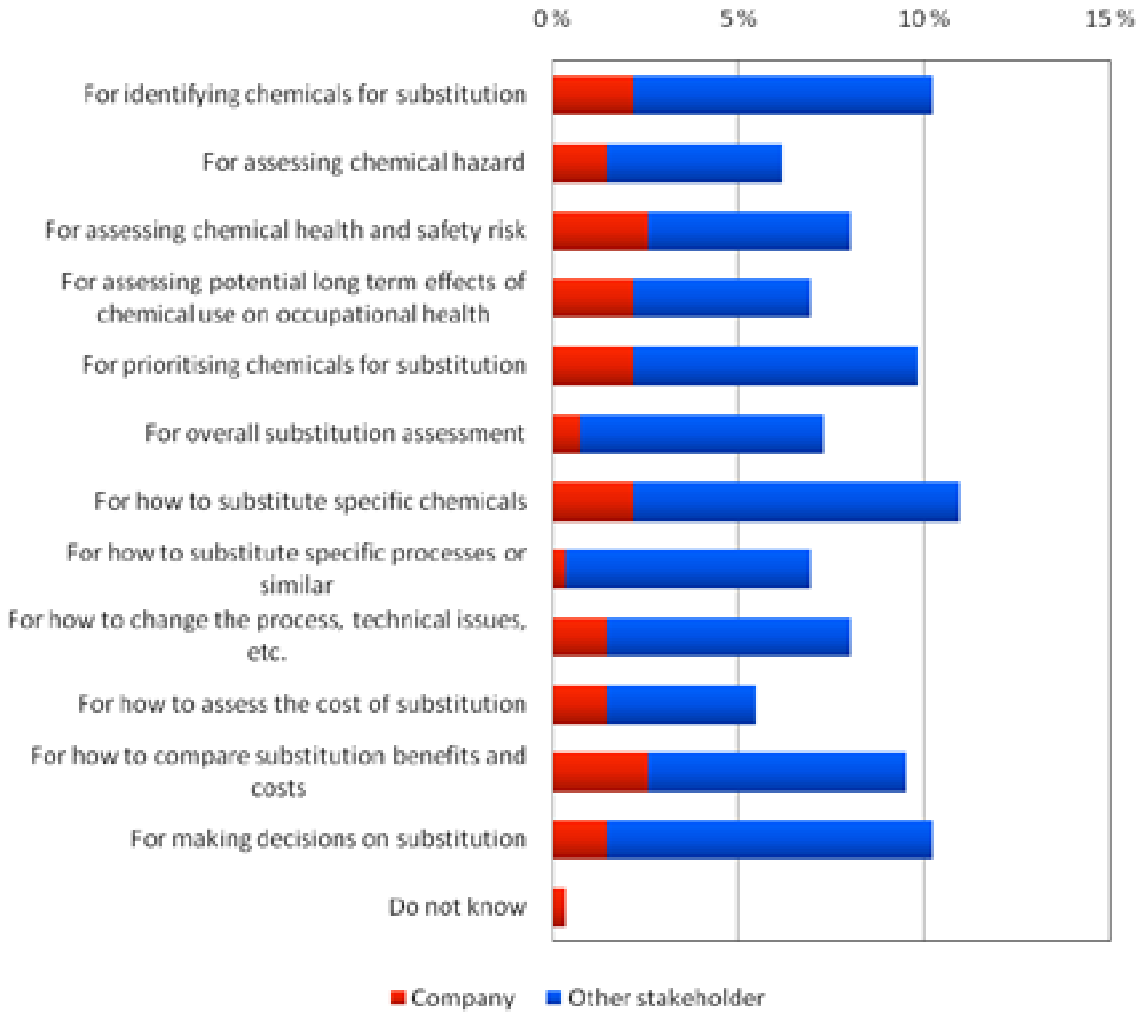
Guidance to substitution



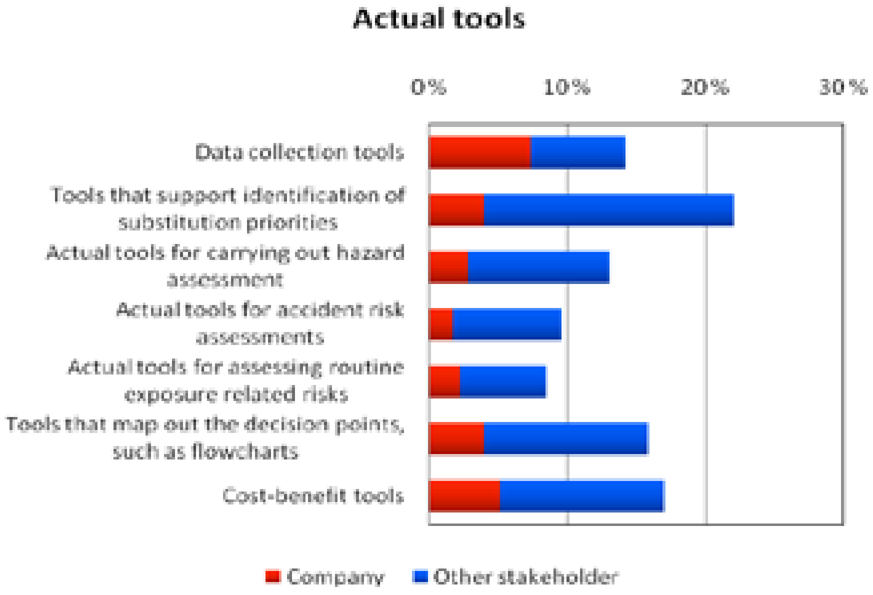


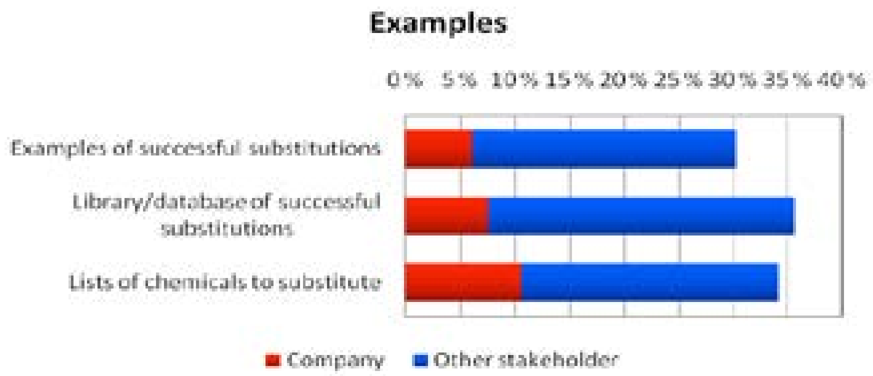

What type of guidance/tools or methods for carrying out chemical substitution are you aware of? (You can select more than one)
0 %
5 %
10 %
15 %
Guidance on the general principles of substitution
How to identify chemicals for substitution
How to assess chemical hazard
How to assess chemical risk
How to assess potential long term effects of chemical use on...
How to prioritise chemicals for substitution
How to assess substitution
Substitution of specific chemicals
Substitution of specific processes or similar
How to change the process, technical issues, etc.
How to assess the cost of substitution
How to compare substitution benefits and costs
Do not know any
Other
Company
Other stakeholder

Which subjects are the ones where you see there is the most pressing need for guidance? (Choose a maximum of 5)



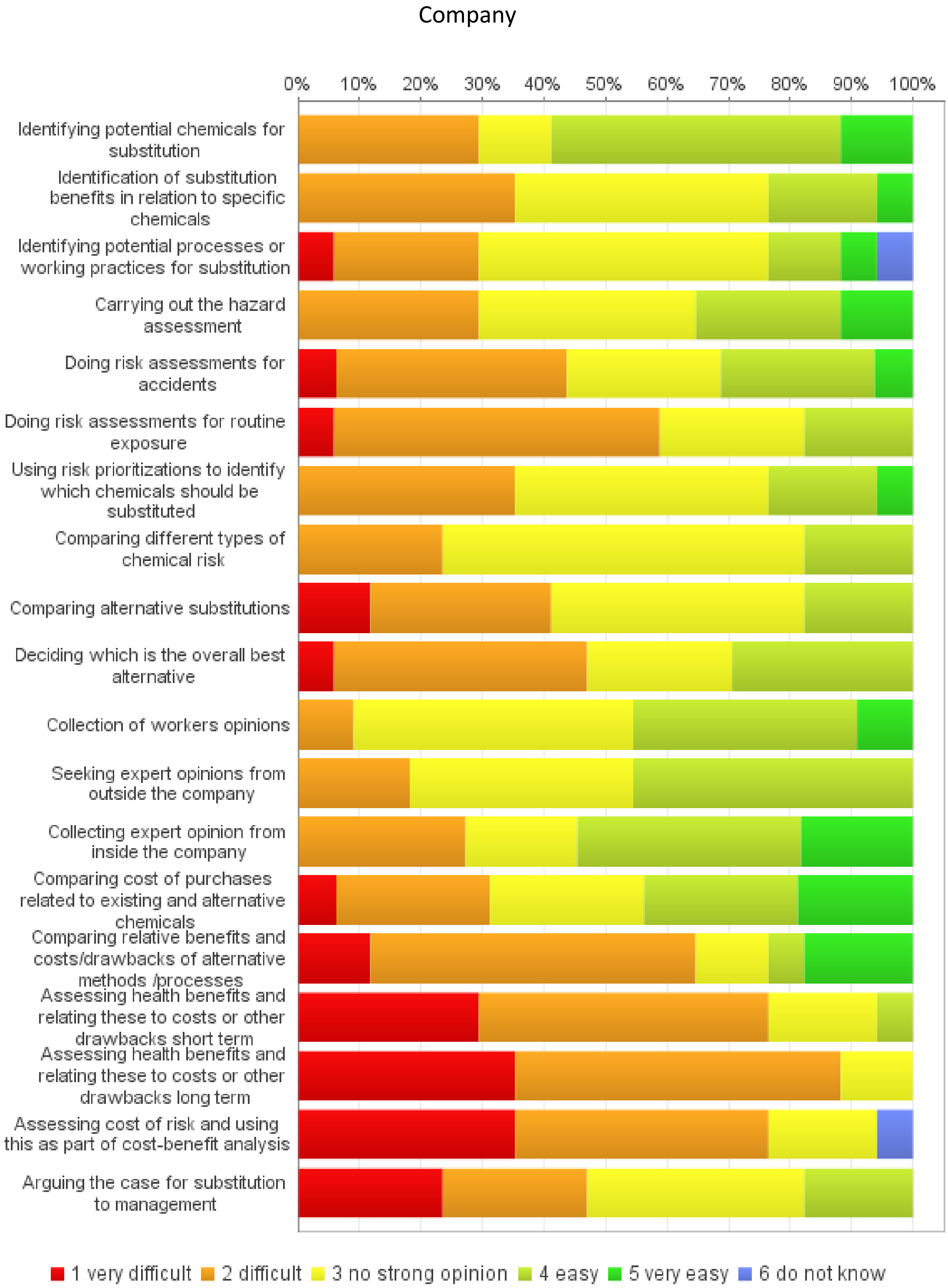
Type of tools, guidance or processes to be developed



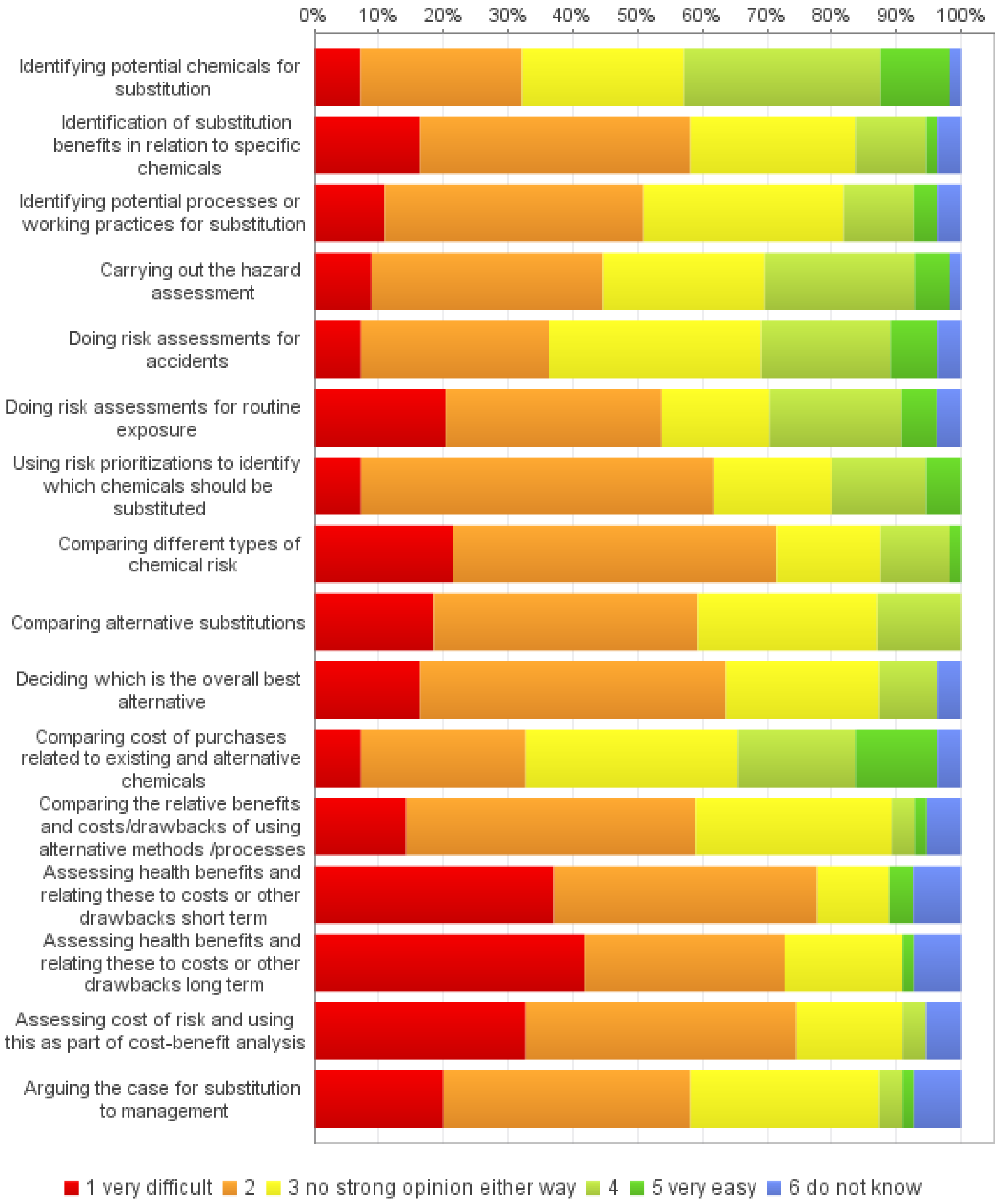


Substitution at a practical level: Current state of play

What do you think is overall difficult and what is easy for companies in relation to substitution?



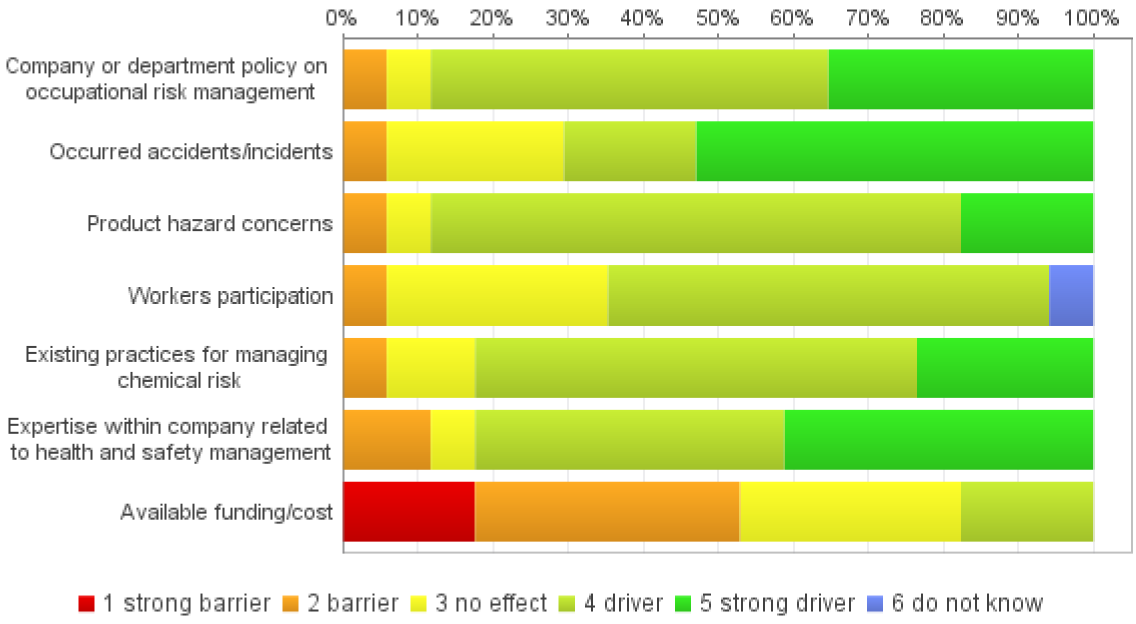
Other stakeholders



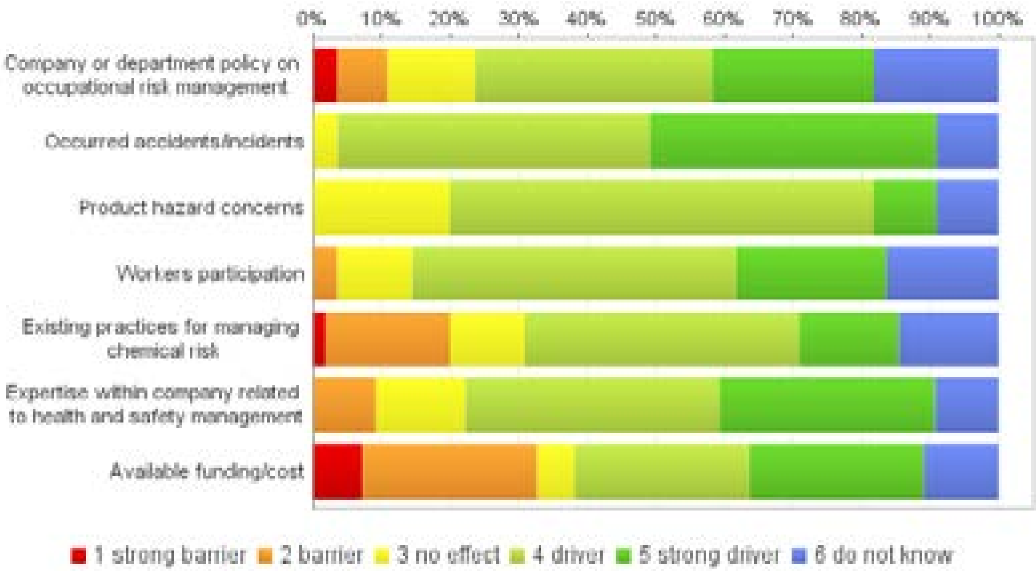
Substitution at a practical level: Decisions

In your opinion, how do the following internal aspects, i.e. acting inside the company, influence the use of substitution as a risk management measure in companies?

Company

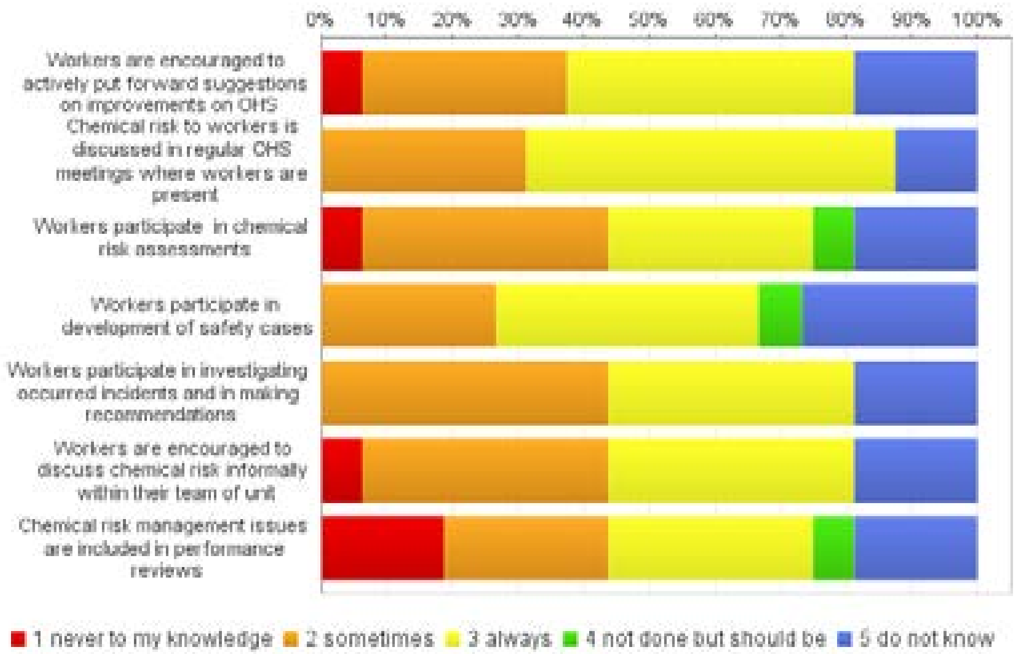


Other stakeholders

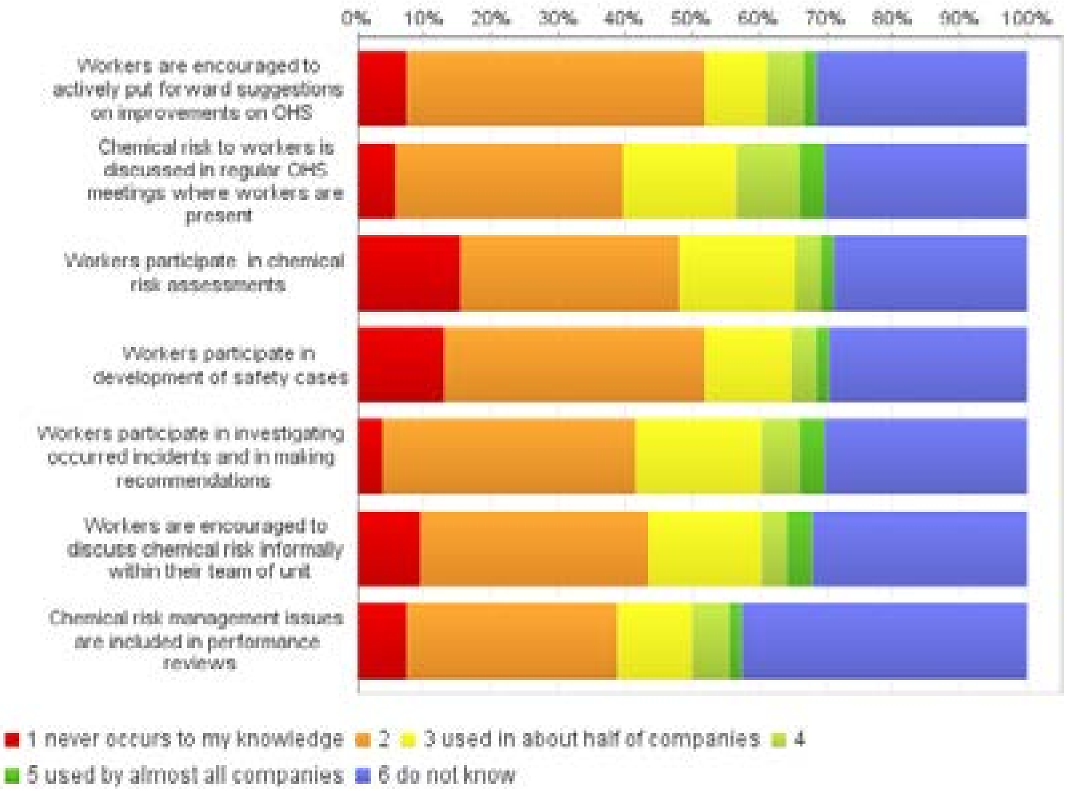


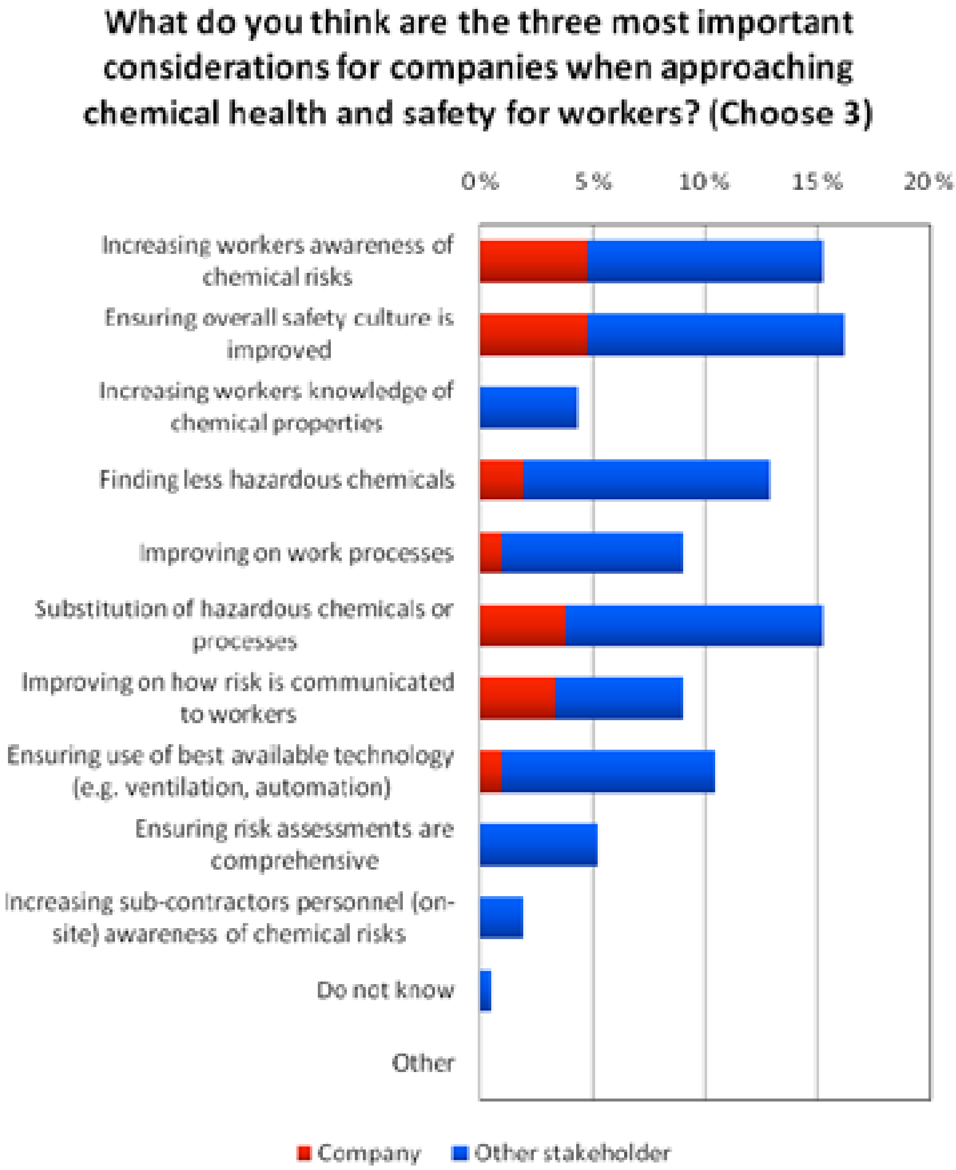
How are workers included in chemical risk management and/or substitution processes in practice?

Company

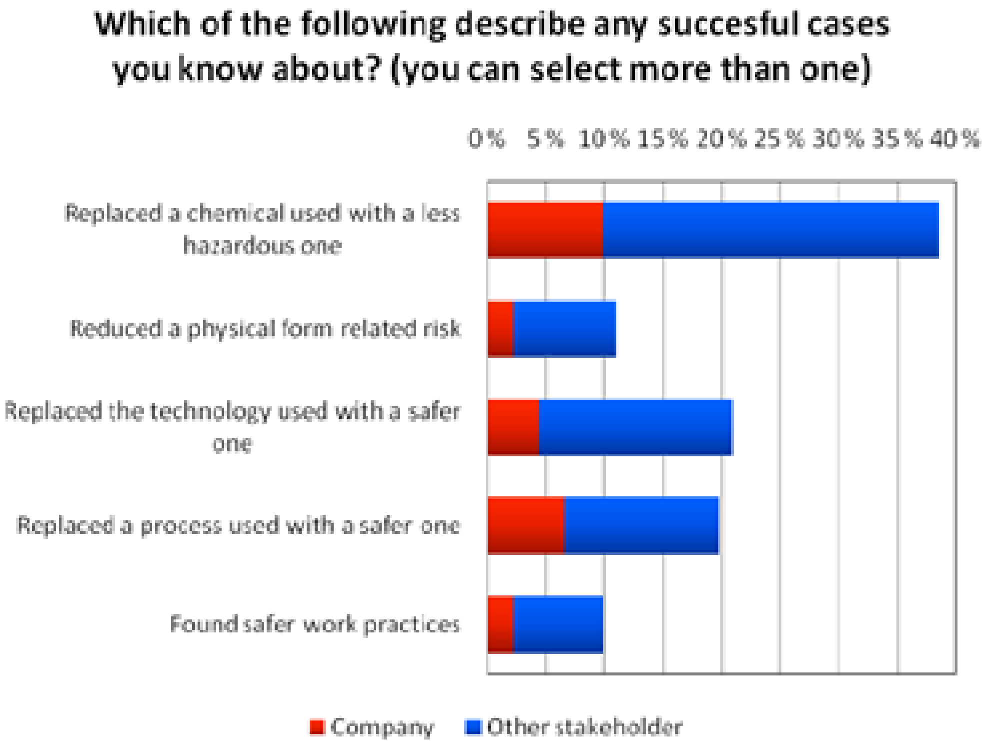


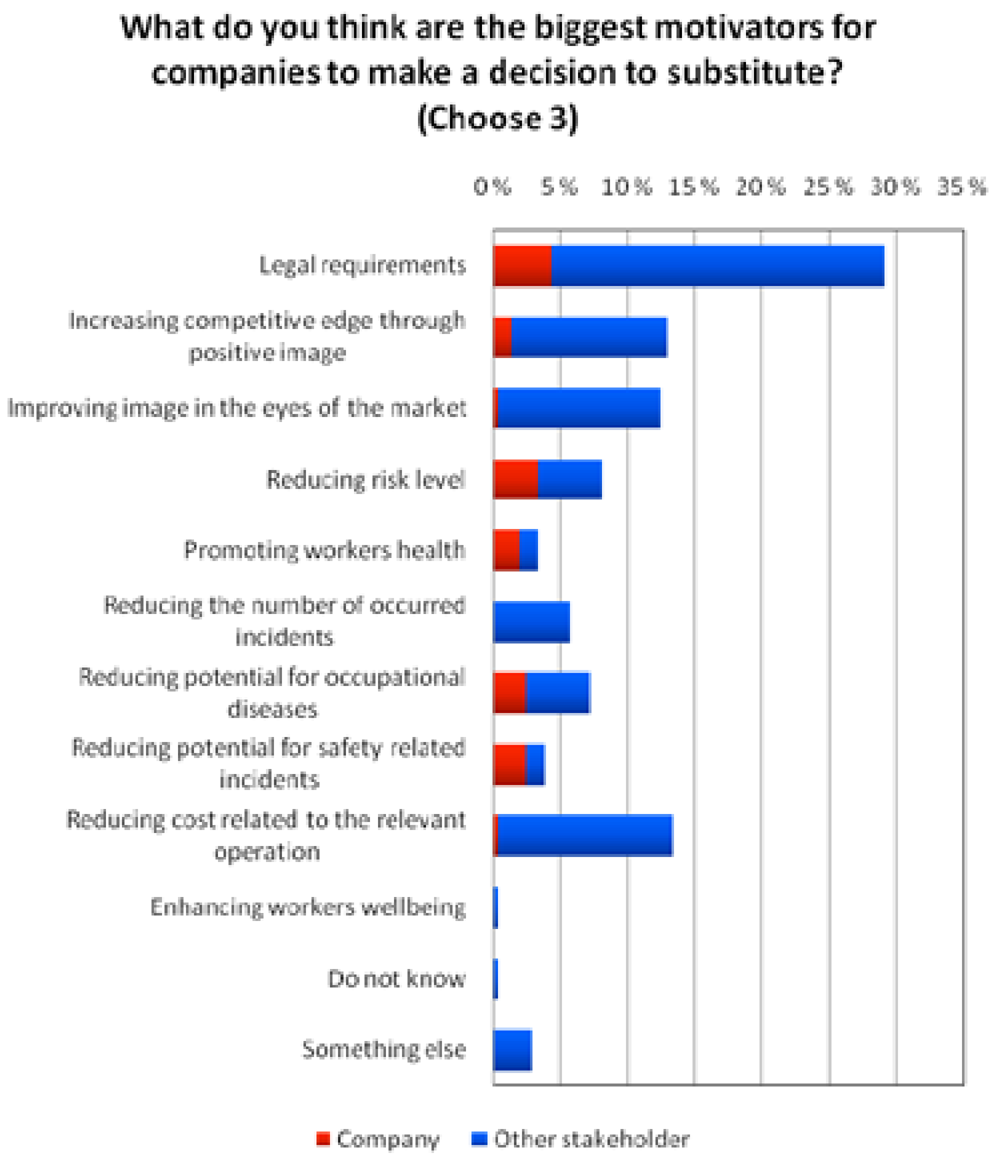
Other stakeholders

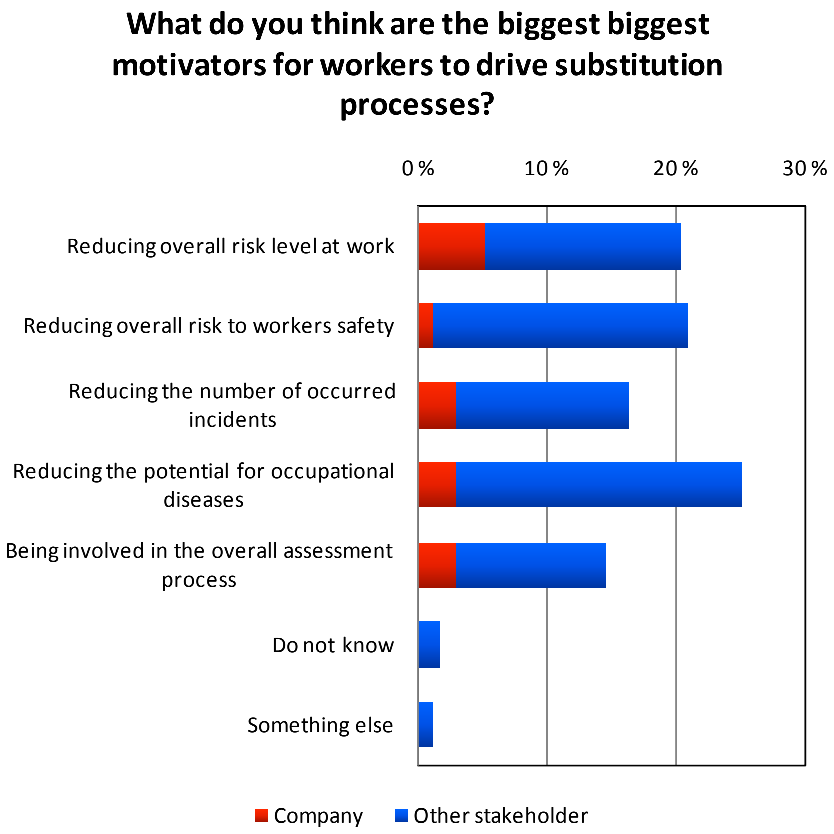



What do you think are the three most important considerations for companies when approaching chemical health and safety for workers? (Choose 3)
0%
5%
10%
15%
20%
Increasing workers awareness of chemical risks
Ensuring overall safety culture is improved
Increasing workers knowledge of chemical properties
Finding less hazardous chemicals
Improving on work processes
Substitution of hazardous chemicals or processes
Improving on how risk is communicated to workers
Ensuring use of best available technology (e.g. ventilation, automation)
Ensuring risk assessments are comprehensive
Increasing sub-contractors personnel (on-site) awareness of chemical risks
Do not know
Other
Company
Other stakeholder

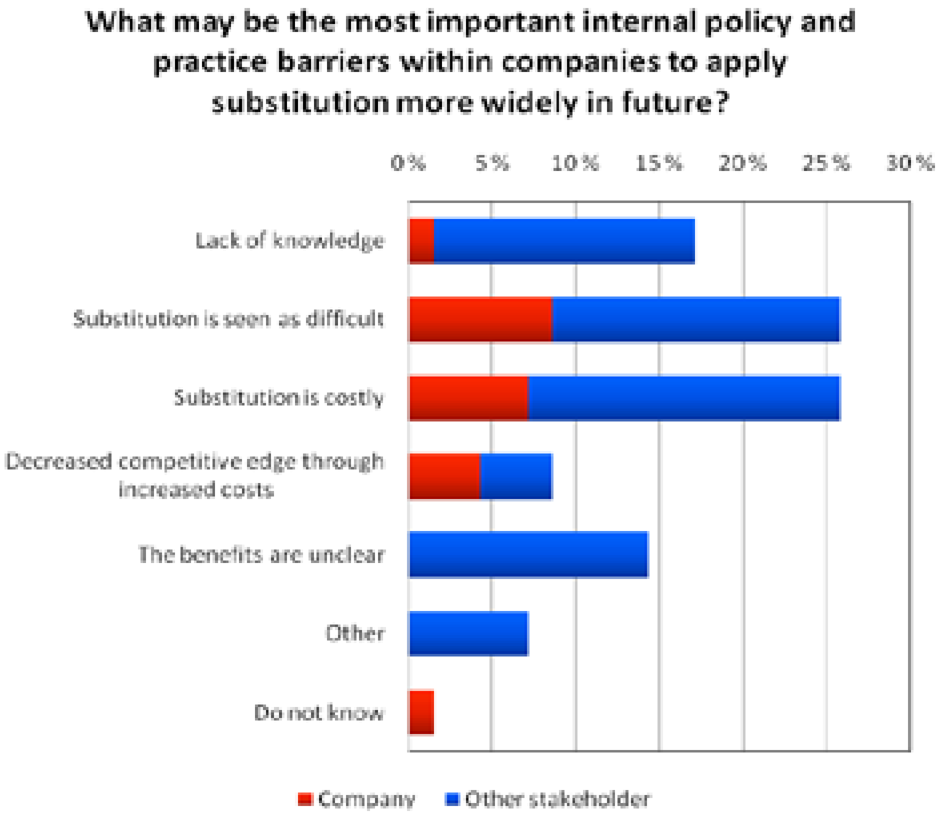
Substitution at a practical level: Experience

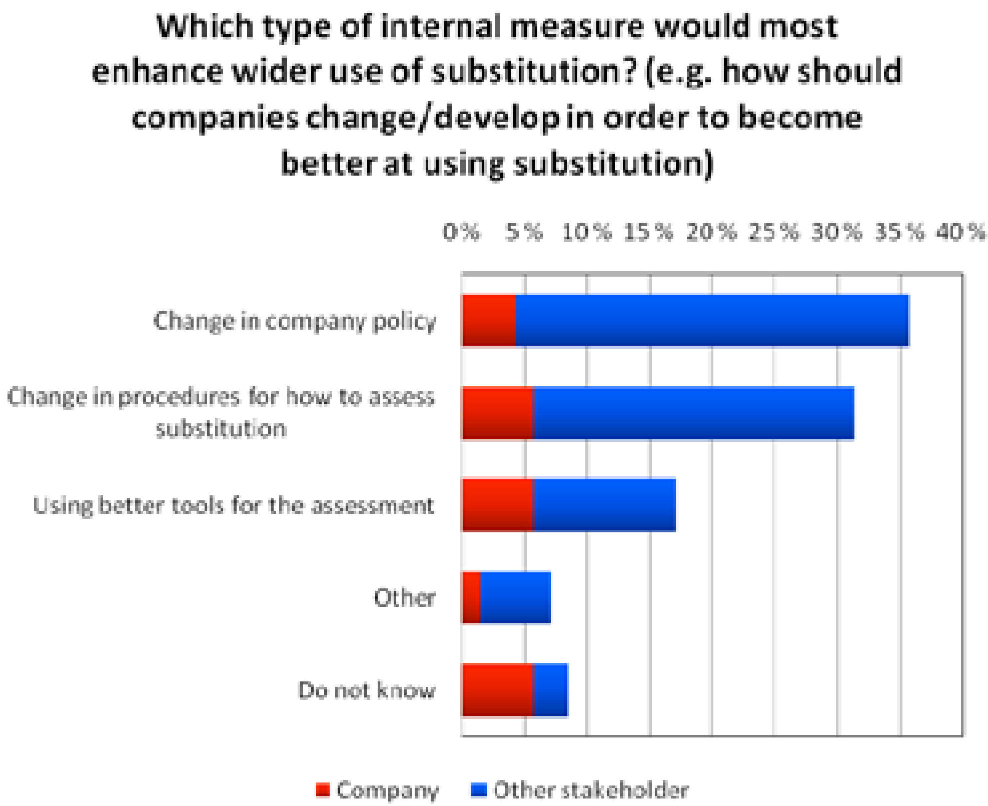



What do you think are the biggest motivators for companies to make a decision to substitute? (Choose 3)
0 %
5 %
10 %
15 %
20 %
25 %
30 %
35 %
Legal requirements
Increasing competitive edge through positive image
Improving image in the eyes of the market
Reducing risk level
Promoting workers health
Reducing the number of occurred incidents
Reducing potential for occupational diseases
Reducing potential for safety related incidents
Reducing cost related to the relevant operation
Enhancing workers wellbeing
Do not know
Something else
Company
Other stakeholder

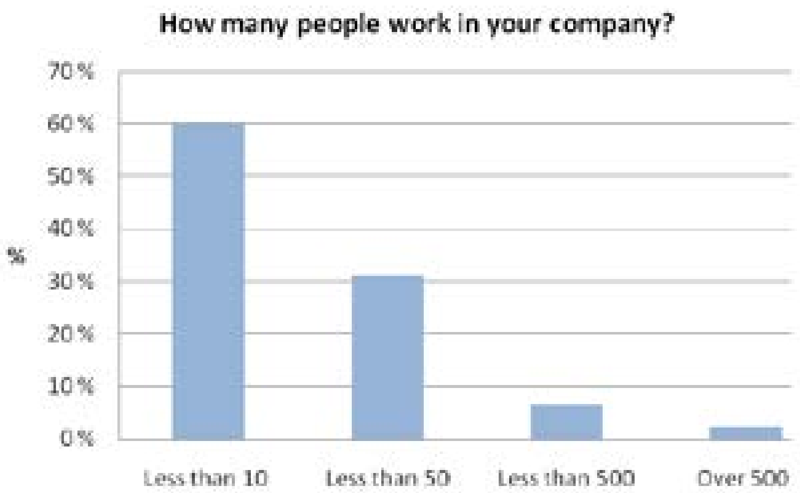

What do you think are the biggest biggest motivators for workers to drive substitution processes?
0 %
10 %
20 %
30 %
Reducing overall risk level at work
Reducing overall risk to workers safety
Reducing the number of occurred incidents
Reducing the potential for occupational diseases
Being involved in the overall assessment process
Do not know
Something else
Company
Other stakeholder

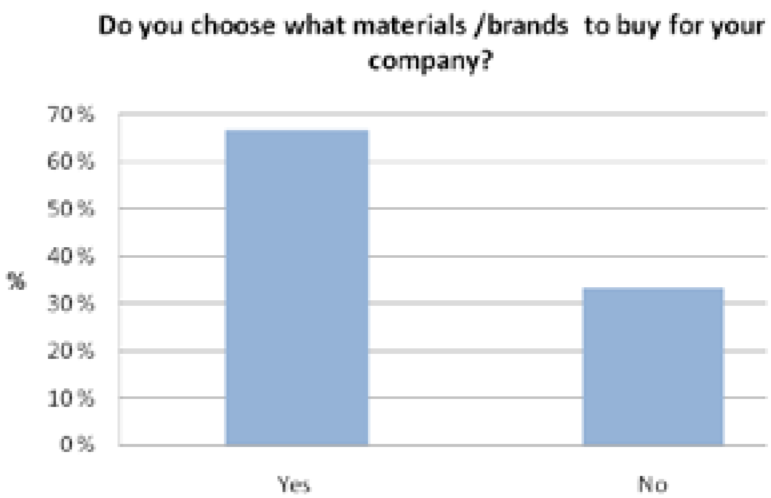
Substitution at a practical level: Future

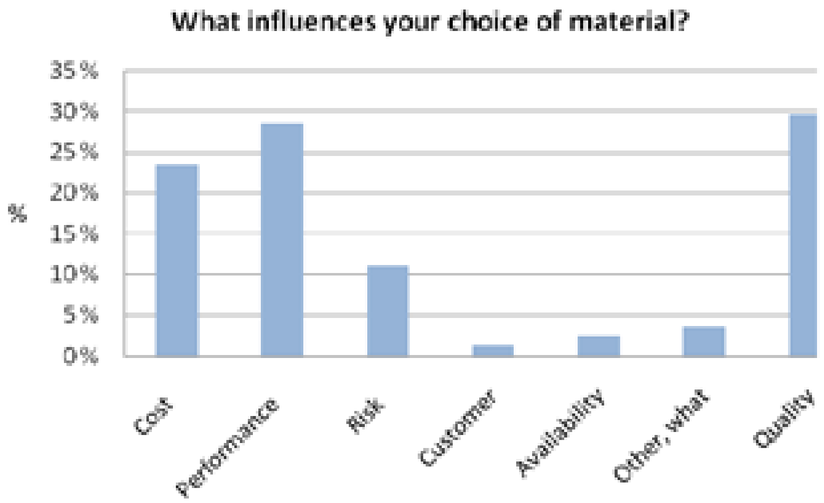


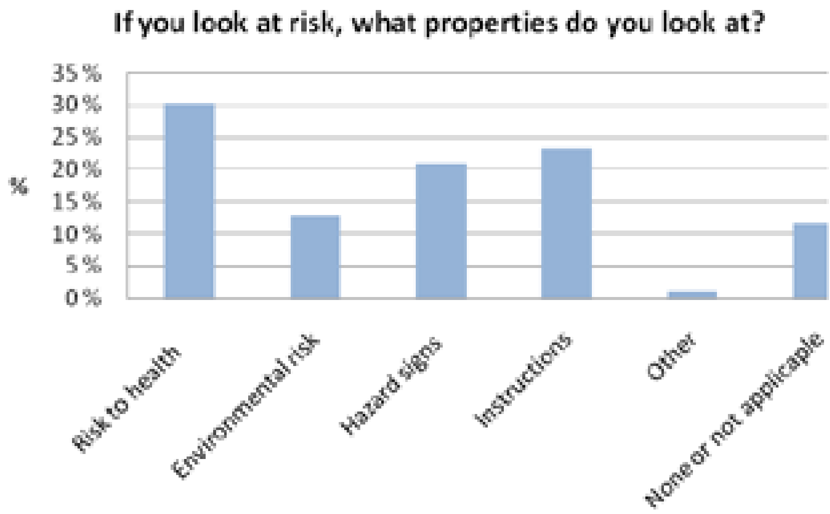


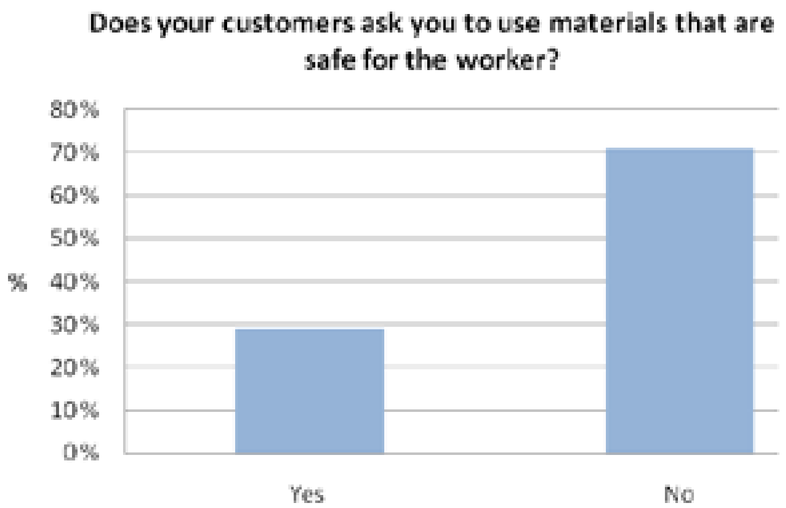
Annex 3 Construction survey summary

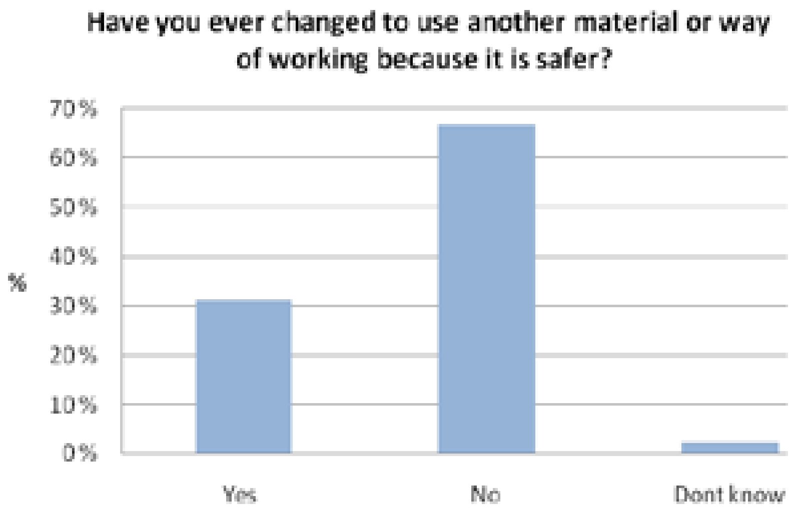


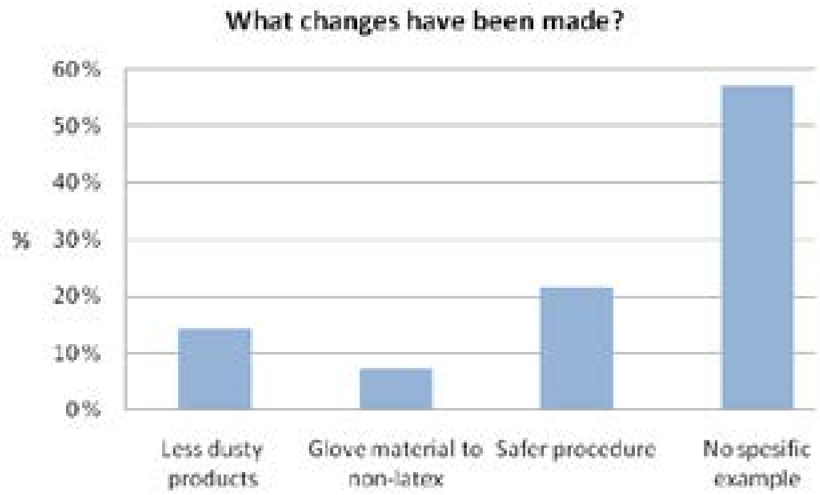



What influences your choice of material?
35 %
30 %
25 %
20 %
15 %
10 %
5 %
0 %
%
Cost
Performance
Risk
Customer
Availability
Other, what
Quality

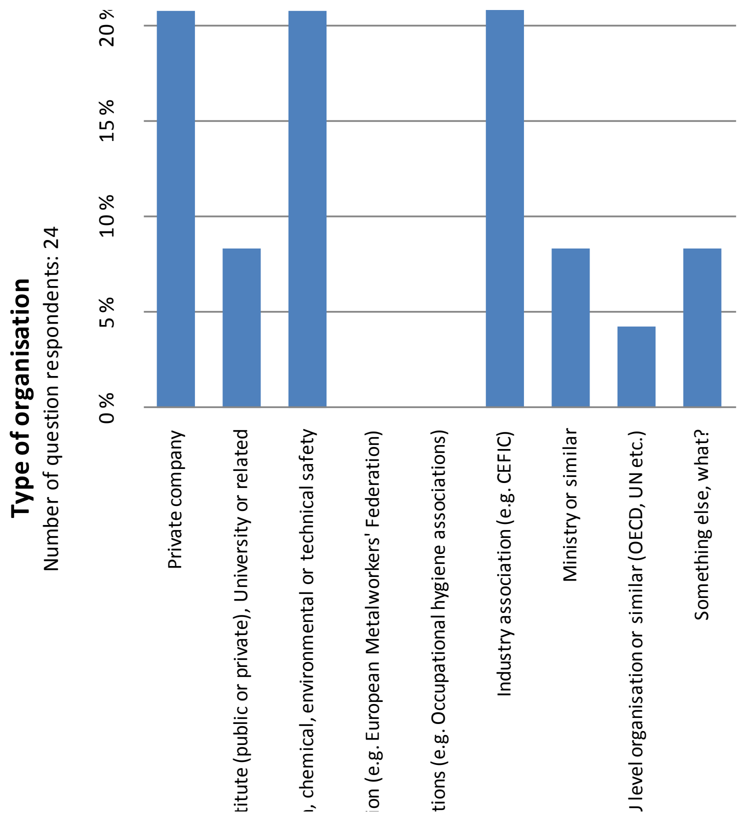

If you look at risk, what properties do you look at?
35 %
30 %
25 %
20 %
15 %
10 %
5 %
0 %
%
Risk to health
Environmental risk
Hazard signs
Instructions
Other
None or not applicable

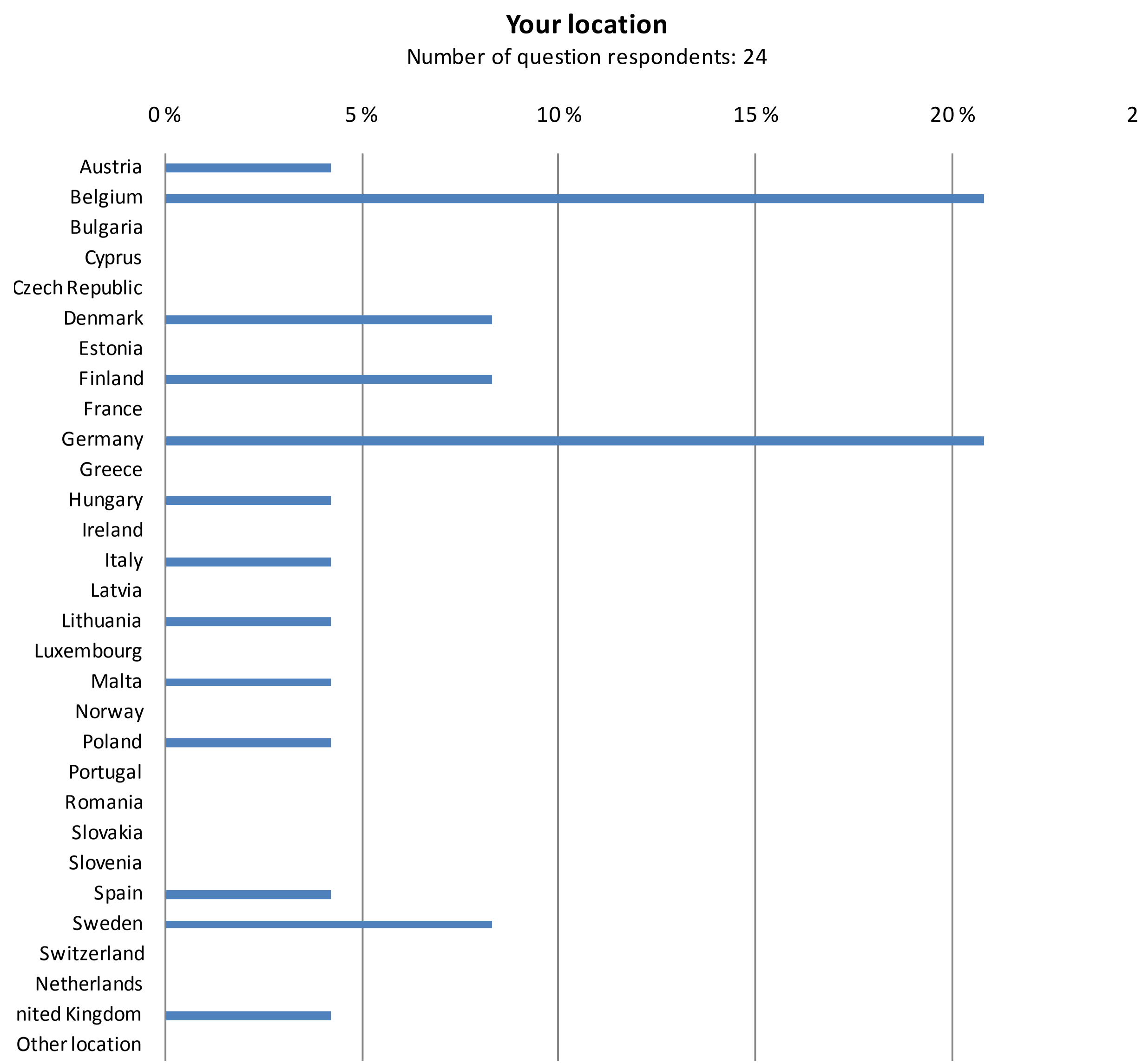

Does your customers ask you to use materials that are safe for the worker?
80 %
70 %
60 %
50 %
40 %
30 %
20 %
10 %
0 %
%
Yes
No


Have you ever changed to use another material or way of working because it is safer?
70%
60%
50%
40%
30%
20%
10%
0%
%
Yes
No
Dont know


What changes have been made?
60%
50%
40%
30%
20%
10%
0%
%
Less dusty products
Glove material to non-latex
Safer procedure
No spesific example

Annex 4 Summary of the validation survey

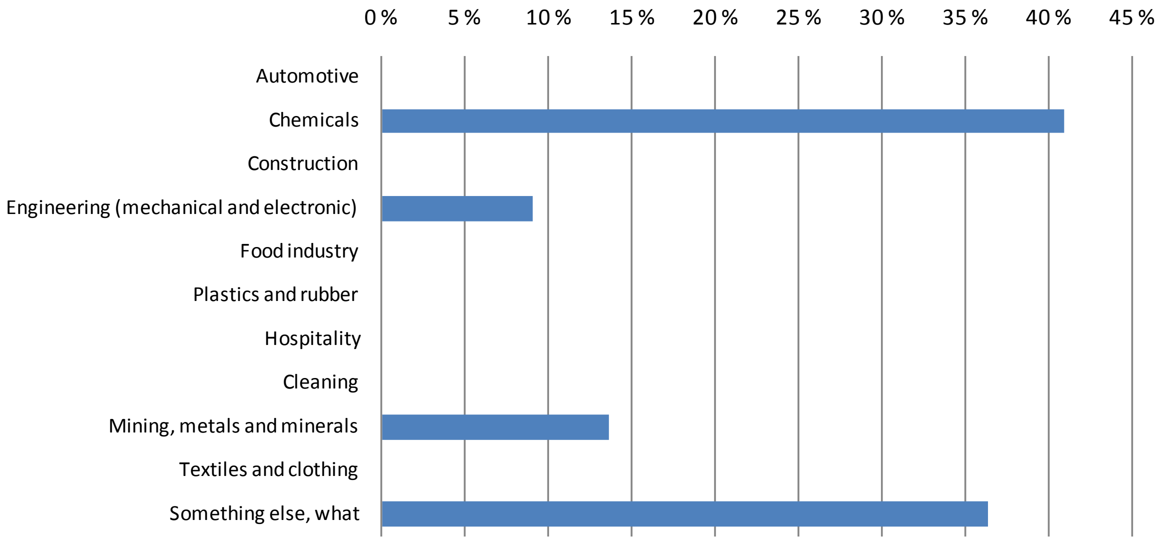




Your location
Number of question respondents: 24
0 %
5 %
10 %
15 %
20 %
2
Austria
Belgium
Bulgaria
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Ireland
Italy
Latvia
Lithuania
Luxembourg
Malta
Norway
Poland
Portugal
Romania
Slovakia
Slovenia
Spain
Sweden
Switzerland
Netherlands
nited Kingdom
Other location

Select the business sector that is nearest to your work, if applicable

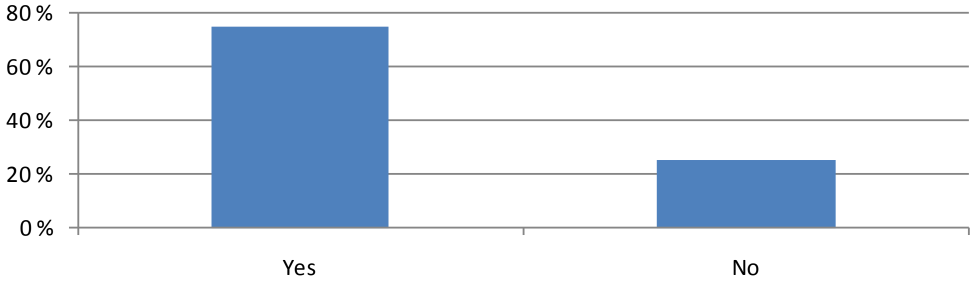
Number of question respondents: 22



PRACTICALITY

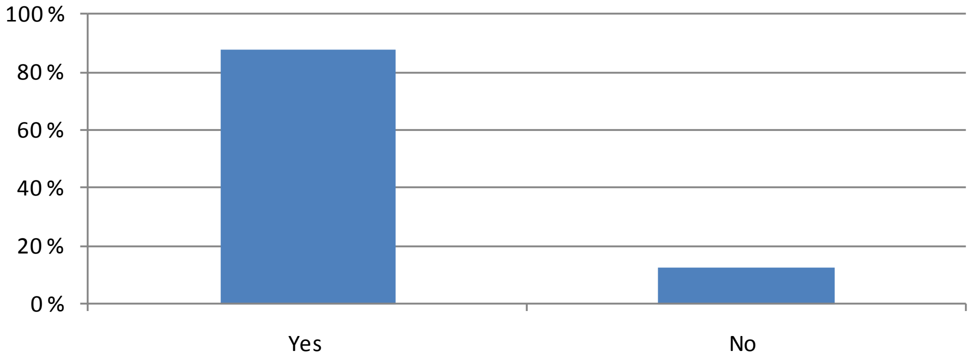
Do you find the guidance practical and easy to understand?

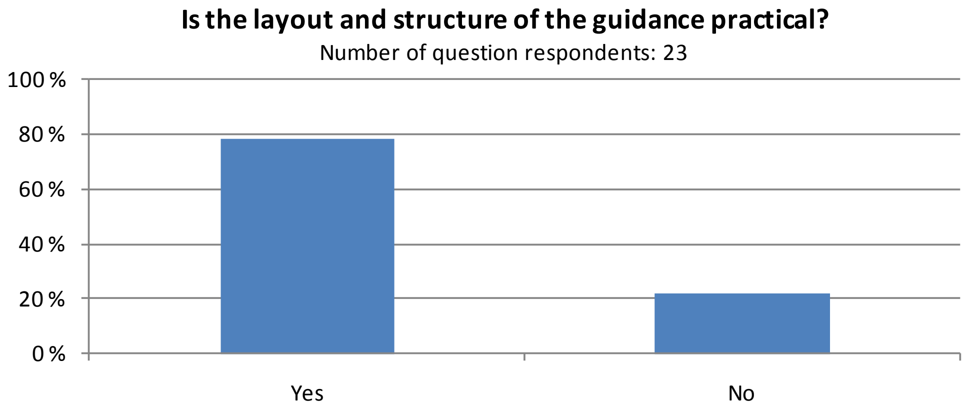
Number of question respondents: 24



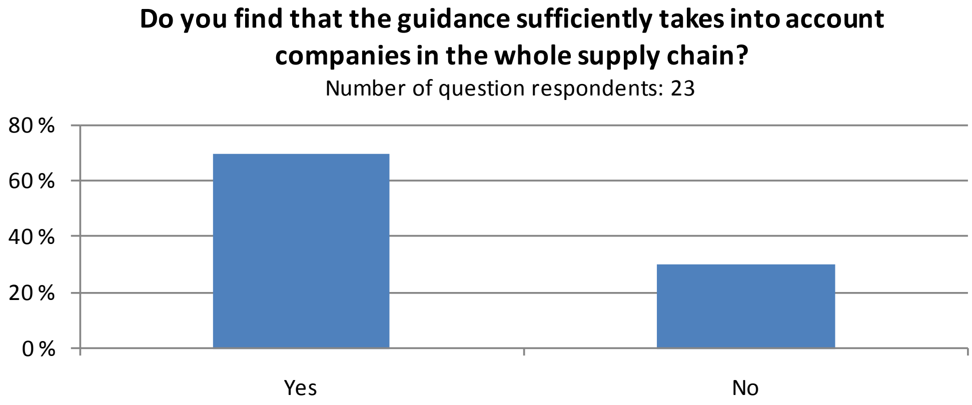
Was the text easy to understand?

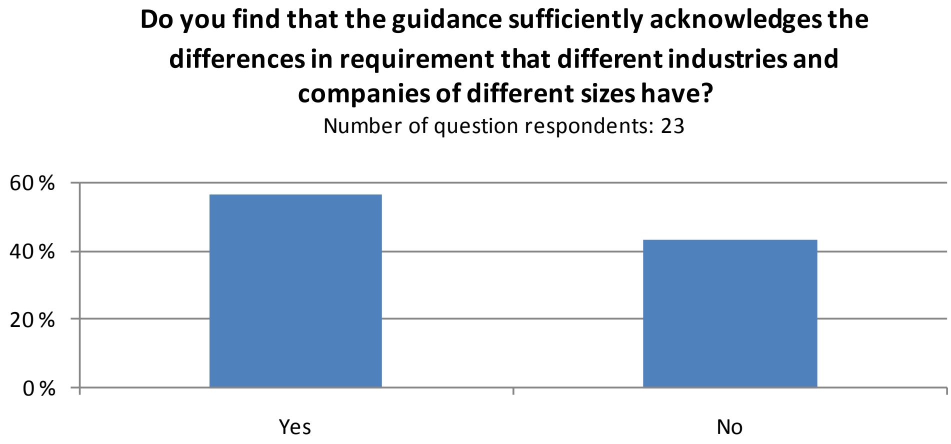
Number of question respondents: 24





APPLICABILITY





European Commission

Minimising chemical risk to workers' health and safety through substitution

Luxembourg: Publications Office of the European Union

2012 — 313 pp. — 21× 27.9 cm

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doi:10.2767/77360

This report presents the results of a study on the practical implementation of substitution of hazardous chemicals, as an occupational health and safety risk management measure, in workplaces across the EU. Funded by DG Employment, Social Affairs and Inclusion, the publication examines if there is a need for an EU-wide common guidance on substitution, with results indicating that such a document would be welcome. It recognises that various approaches to substitution – as well as challenges to these approaches – exist, and therefore the bulk of the report focuses on developing a common approach to substitution and presenting it as a guidance document. This publication is available in electronic format in English.

KE-30-12-758-EN-N

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Publications Office

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