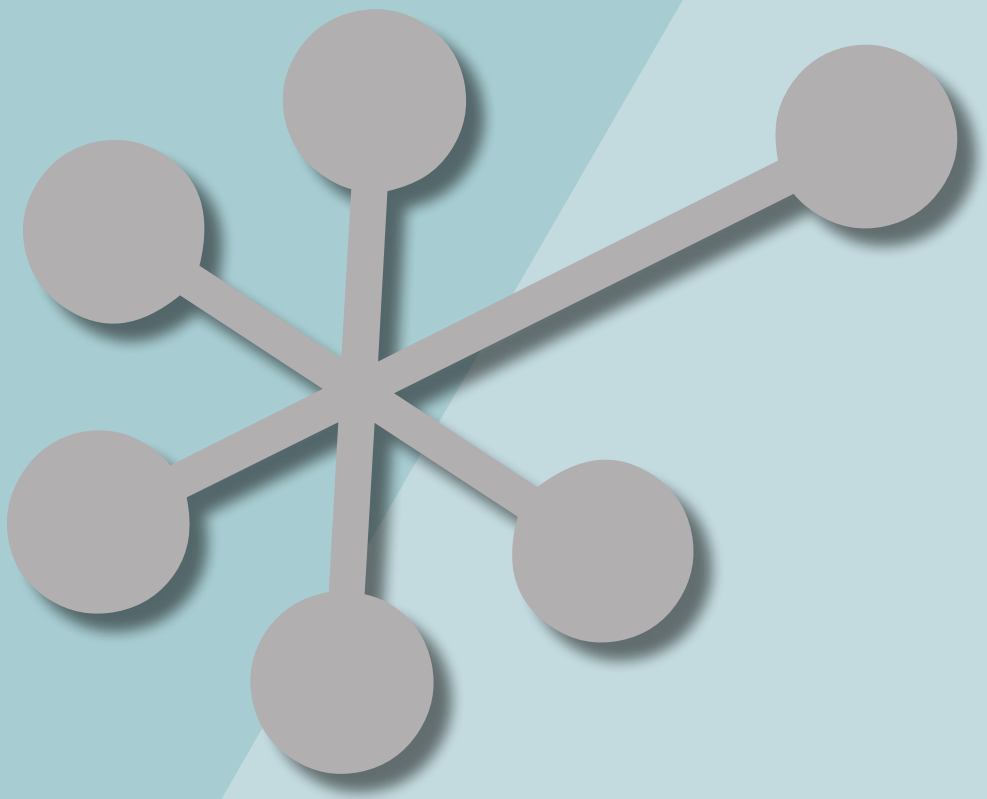
LIFE / FIT FOR REACH

Chemicals Risk Management Handbook for Formulators



Author

Antonia Reihlen, Baltic Environmental Forum - Latvia

Contributors

Dr. Jolita Kruopienė, Kaunas University of Technology

Edgaras Stunžėnas, Kaunas University of Technology

Juhan Ruut, OÜ Hendrikson & Ko

Heli Nõmmsalu, Baltic Environmental Forum - Estonia

CLP and REACH helpdesk Latvia

Paulina Porebska-Sektas, Lukasiewicz-Industrial Chemistry Institute

Anna Bankowska, Lukasiewicz-Industrial Chemistry Institute

The Project LIFE Fit for REACH-2, No. LIFE22-ENV-EE-LIFE-FitforREACH-2/101113947 is co-financed with the contribution of the LIFE Programme of the European Union.

The content of this report is the sole responsibility of the project LIFE Fit for REACH-2 and can in no way be taken to reflect the views of the EU.

Contents

1. Introduction

This document provides guidance to formulators on how to set up a new or improve an existing Chemicals Risk Management System (CRMS) in the company. It is intended for small and medium sized enterprises who are interested in improving their chemicals risk management performance.

The handbook presents a systematic and structured approach of a management system but is designed as a toolbox from which you can select individual elements for implementation. The handbook is developed and used in the framework of the LIFE FitforREACH project to guide the CRMS implementation. It is intended that implementation of individual elements or the entire CRMS is possible also without external help.

The guidance

- Provides an overall understanding of what elements are needed to ensure a good chemicals risk management and how they are interlinked (Chapter **2**),
- Explains the various elements in more detail and how they can be implemented at a formulator's site,
- Lists tools and further information sources to support the implementation of the CRM elements at the end of several chapters.

2. Overview of chemicals risk management

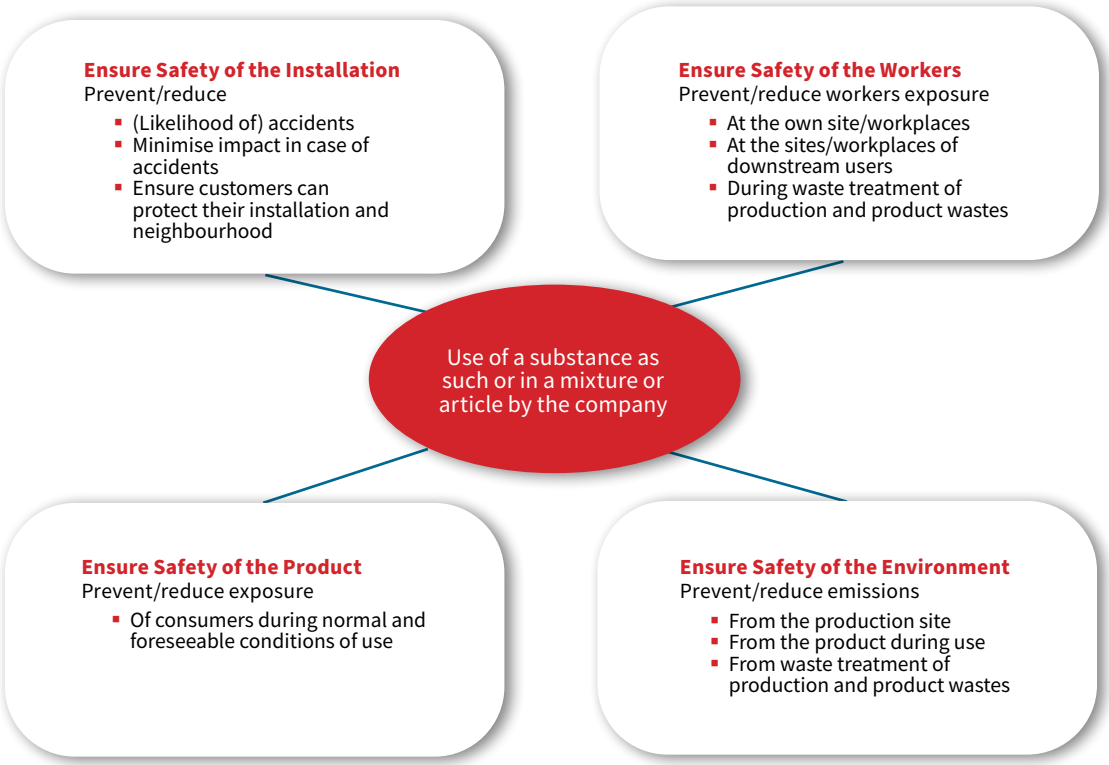
2.1. Aim of a chemicals risk management system

With the help of a chemicals risk management system (CRMS) harm to human health or the environment from a company's use of chemicals should be prevented or minimised, both inside the company but also along the chemicals' life cycle (in products).

Hazardous chemicals may cause risks to:

- Your facility and the facilities of your customers, where they are stored and handled (installation safety),
- Your workers and workers of your customers who handle the hazardous chemicals as well as workers in waste treatment installations,
- The environment into which your company and the companies downstream may emit hazardous chemicals with waste gas and wastewater, as well as from emissions during waste treatment, and
- Consumers who use the final product in which the chemicals are included.

Figure 1: Objectives and Subordinated Aims of Chemicals Risk Management

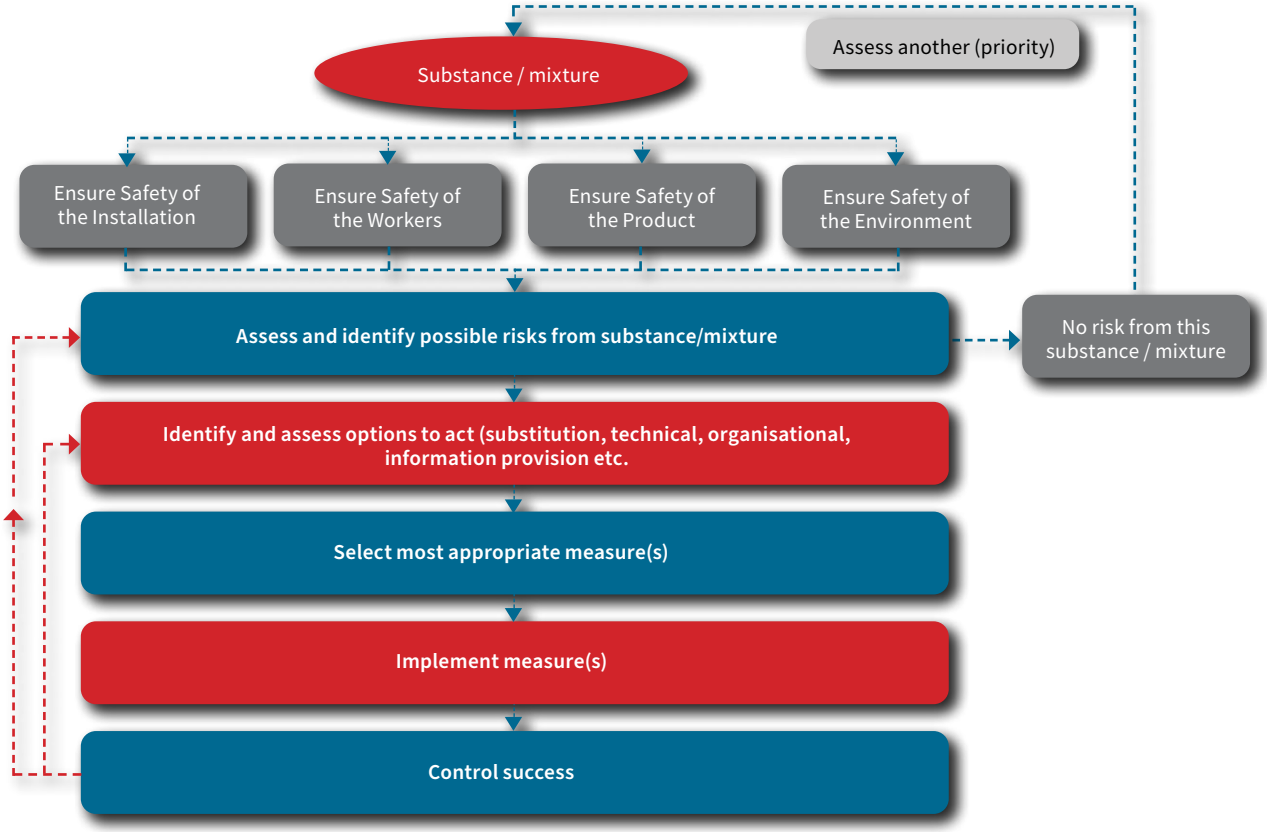


2.2. Main steps in chemicals risk management

To ensure the safety of the installation, workers, consumers, and the environment from chemicals, your CRMS needs to:

- **identify chemicals** and in particular chemicals of concern you use to make your mixtures and the potential risks resulting from their use,
- **set priorities** on which chemical(s) or use(s) to deal with (first) and to decide on the most efficient and effective means to change the situation,
- **implement** the respective measures and activities,
- **monitor** whether the measures are successful, **identify deficits** in the system hindering the achievement of the goals and **take corrective actions, or derive new priorities** if the goals are achieved and new challenges can be met.

Figure 2: Steps to achieve the aims of risk elimination or reduction



Depending on the perspective and its aim, the scope of the risk assessment and the corresponding options to act may differ.

In the optimal case, you assess all aims for the issue you explore to prevent reducing risks in one area but creating one in another. Your system should not only cover the impacts from your production site(s) but also those from the use of the product(s)

they are included in as well as the waste stage, which may start a second life (recycling, reuse). Advanced approaches also include risks from the production of the chemical itself and from the production of raw materials for their production.

2.3. Corporate chemicals risk management systems

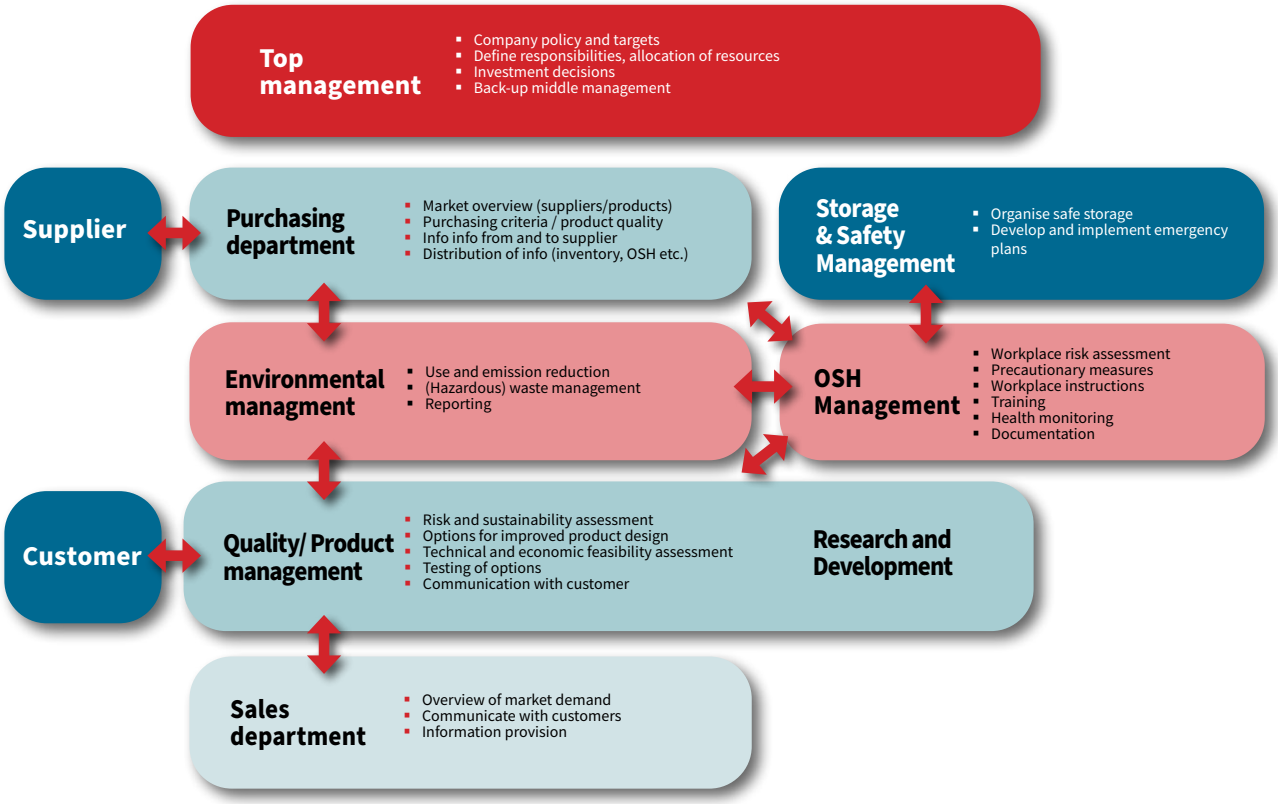
A chemicals risk management system (CRMS) is a structured and systematic approach of risk identification, prioritisation, implementation of risk reduction measures and controlling success.

The system approach ensures a continuous learning, an efficient use of resources and sustainable and consistent decision-making, which should secure your company's operation in general.

The CRMS concerns most of the internal processes and business units as well as the relations and communication with suppliers, customers, and the authorities. Each unit plays a distinct role. All concerned units need to communicate and cooperate to ensure information flows and best decisions are taken. If potential changes concern the composition (and performance) of your mixtures, you should also involve your customers. The following figure shows the departments and functions in a company and their potential roles and tasks in a CRMS.

Figure 3: Departments / functions and their roles in a chemicals risk management system

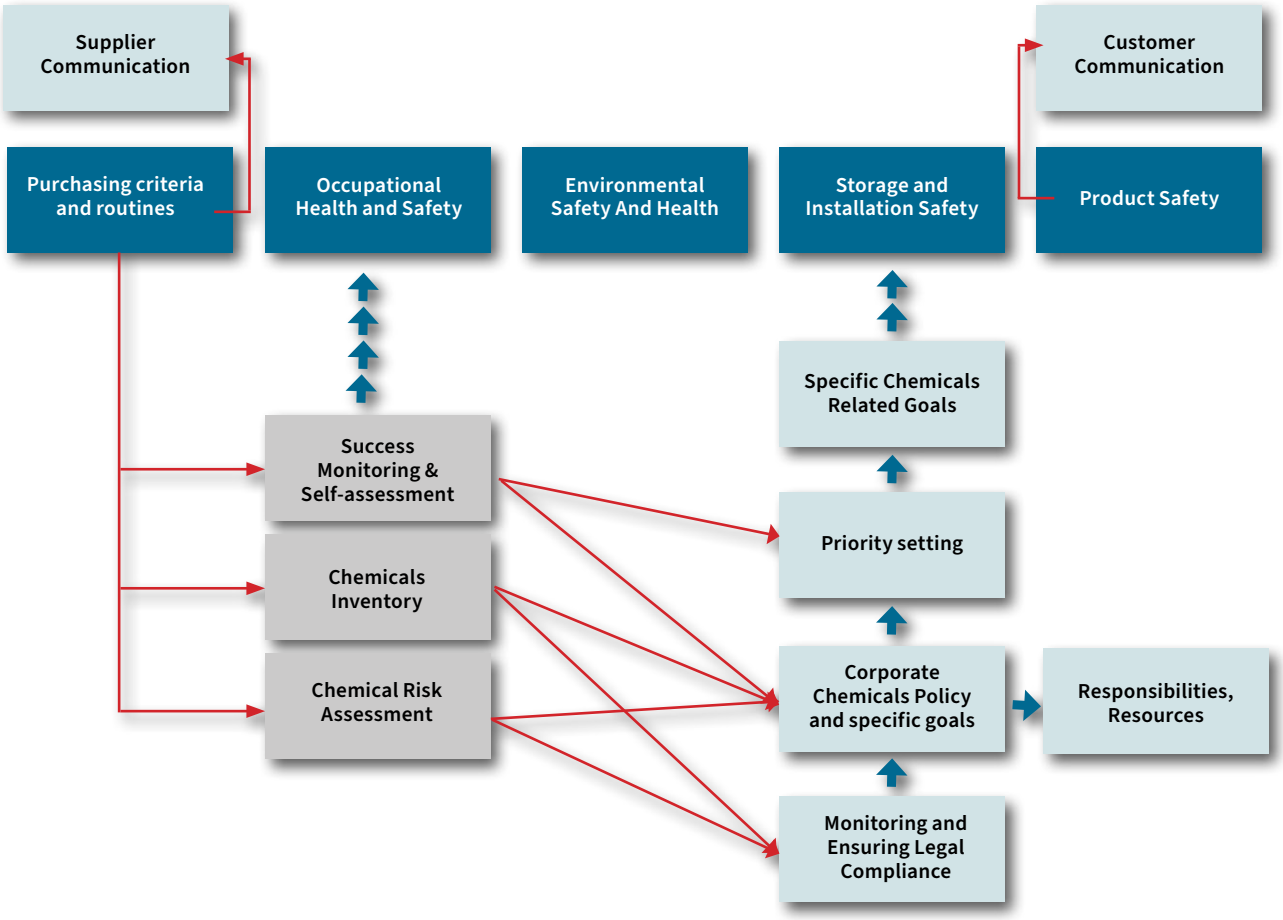
** OSH = Occupational Safety and Health*



2.4. Main elements of a chemicals risk management system

A CRMS consists of various elements, including a chemicals-policy (potentially as part of a larger (environmental) corporate policy), procedures for priority setting and decision making on chemicals, assigned responsibilities and resources for chemicals risk management tasks as well as a chemicals inventory and a system to monitor compliance with chemical requirements. It covers purchasing and supplier communication, storage and safety issues, occupational health and safety, environmental and waste issues as well as the product quality and customer communication. The following overview shows the various elements of CRM and how they are interlinked.

Figure 4: Overview of chemicals risk management system elements



It is essential that:

- You ensure that your company complies with any **legal requirements** on chemicals, as this a must for any economic operator,
- You have a **chemicals inventory** to monitor what chemicals you purchase and for what you use them and
- There is **trained staff** in your company to implement the legal information requirements on (hazardous) chemicals that you provide and assess potential risks from them, or that this is outsourced to a competent service provider.

In addition, it is very useful to **analyse your performance** in CRM to identify improvement options, opportunities for synergies, save resources and identify priorities for your policy.

Based on the above the company management can define or refine an overall **chemicals policy**, which is the framework within which specific chemicals-related goals can be defined. These goals may directly or indirectly relate to any one or all of the following: Safety of

- The Product,
- The Workers,
- Consumers and/or
- The Environment.

As a formulating company, you should be familiar with the basics of classification and labelling as well as hazard communication on chemicals via SDSs. You should have trained staff and in-house expertise on the basic chemicals language and communication formats. Therefore, this aspect of chemicals risk management is not discussed in-depth in this handbook.

3. Chemicals inventory

A chemicals inventory lists all chemicals used as input materials and contains relevant information for chemicals risk management in the company. It is the main data base on chemicals in a company.

3.1. Legal background

Chemicals inventories are not required under EU legislation. However, the Baltic States and Poland require companies to have a chemicals inventory and define what type of information should be contained as a minimum.

Table 1: Overview of legal requirements on inventories

Country	Legislation reference	Requirements
Estonia	Procedure for keeping records on the use of hazardous chemicals (Ohtlike kemikaalide arvestuse kord)	When keeping records, at least the following need to be included: ▸ Name of hazardous substance, CAS/EC[1] number and registration number acc. to REACH; ▸ Name or trade name of the hazardous mixture and list of hazardous ingredients incl. substance identification as in Section 3 of the Safety Data Sheet (SDS) of the mixture; ▸ Date of receiving and amount of the chemical; ▸ Use time and quantity of hazardous chemical; ▸ Time and quantity of transferring the hazardous chemical to waste management as waste
Latvia	Cabinet of Ministers Regulation No.795 Procedures for Registration of Chemical Substances and Mixtures and Their Database (MK noteikumi Nr. 795 Ķīmisko vielu un maisījumu uzskaites kārtība un datubāze)	According to these rules, the following information must be collected on manufactured and imported chemical substances and mixtures: ▸ **Substances:** Trade name, scientific name (IUPAC[2]), CAS/EC, field of application according to NACE[3] code system, Classification and Labelling (C&L), Manufactured amount [t/a]; Imported amount [t/a]; Adress of storages; SDS; country from which the substance is imported if the substance falls under the PIC[4] regulation; PRODCOM[5] code if relevant ▸ **Mixtures:** Trade name and composition, IUPAC name, CAS/EC of components, classification of substances, concentration, content of volatile organic compounds (VOC), product group; field of application according to NACE codes, PRODCOM code; amount of manufactured/imported mixture; addresses of storages; SDS of mixture; if a chemical substance included in Annex 1 to PIC Regulation is present in the composition, the country from which the mixture is imported shall be indicated

1 Chemicals Abstract Service, European Community
2 International Union of Pure and Applied Chemistry
3 Nomenclature statistique des activités économiques dans la Communauté européenne
4 Regulation on prior informed consent
5 PRODCOM is the classification system of the EU Commission to organise trade statistics.

Country	Legislation reference	Requirements
Lithuania	"Description of the accounting procedure for chemical substances and chemical mixtures", Order No. D1-360 of the Minister of the Environment of the Republic of Lithuania on July 2, 2008	Establishes procedures for the collection and storage of data and information on substances and mixtures by manufacturers, importers, downstream users and distributors. The inventory must contain at least: the name of the chemical substance; name of the chemical mixture; CAS number, registration number under REACH if granted; country of origin if imported; name of the supplier; amount of substance/ mixture that is purchased, produced, imported, supplied to the market, consumed, or exported.
Poland	Ustawa z dnia 26 czerwca 1974 r. Kodeks pracy. (Dz. U. 1974, nr 24, poz. 141) z późniejszymi zmianami	It is unacceptable to use a hazardous substance or a hazardous mixture without having an up-to-date list of these substances and mixtures and safety data sheets, as well as packaging protecting against their harmful effects, fire or explosion. (Article 221, § 2)
	Ustawa z dnia 25 lutego 2011 r. o substancjach chemicznych i ich mieszaninach (Dz. U. 2011, poz. 322) z późniejszymi zmianami	The manufacturer, importer and downstream user are obliged to establish, maintain and update on an ongoing basis a list of hazardous substances or hazardous mixtures produced, imported or used. (Article 25)

3.2. Advantages of a chemicals inventory

- You have all information on chemicals in one place, facilitating updating and data maintenance,
- You can document legal compliance using inventory data,
- You can quickly assess the impact of upcoming legislation on your operations,
- You can retrieve data making tailored requests on what is specifically needed,
- The inventory facilitates checking if all information is available and up to date,
- Setting up and maintaining a good chemicals inventory requires time; however, in the long run it saves a lot of resources.

3.3. What information a chemicals inventory should contain

A chemicals inventory should list **all substances and mixtures you use**. This includes substances and mixtures which:

- Are included in your products, i.e. the mixtures you produce,
- You use as processing agents, e.g. to clean or lubricate your machinery,
- You use e.g. for lab analysis, neutralisation of wastewater etc.

If you use mixtures as input materials, at least all ingredients indicated in the SDS, i.e. which are classified, should be listed separately but clearly linked to that mixture.

Nice to have

You may also purchase other types of goods, such as stationary for the offices. These goods have no immediate connection to your production but also contain chemicals. Therefore, you may include them in the CRM of your company and hence, in the inventory, potentially in a separate section. For non-chemical input materials, include any available information on the content of Substances of Very High Concern.

The following information types should be included in the inventory.

Table 2: Overview of minimum information that should be contained in a chemicals inventory (mandatory plus needed for risk management)

Type of information	Substance as such	Substance in mixture	Mixture as such	Why
Product/ Trade/ Scientific name	√	√	√	Identification of product
Unique substance identifier (e.g. CAS number or EC number)	√	√	-	Allows comparing with external sources via these numbers, ensures substances can be sorted and searched, compliance checking
Hazard statements (from SDS or other sources) - Codes	√	√	√	Core information for all risk management, e.g. risk assessment, prioritisation, compliance checking and documentation, answering customer requests etc.
Content of hazardous substances in mixtures	Not relevant	Not relevant	√	Links information on substances with the mixture / article they are contained in
Purchased amount per year	√	--	√	Input information for risk assessment and prioritisation, compliance checking and reporting, assessment of resource efficiency etc.
Concentration (ranges) in a mixture	--	√	--	Allows calculating annual use amounts (c.f. above) and compliance checking (e.g. restrictions with concentration thresholds)
Fate/Purpose: included in product xyz or processing aid, such as lubricant	√	--	√	Important information to monitor the flow of chemicals through the company. If substances/mixtures end up in products, the specific product(s) must be listed. This information can be used e.g. for compliance checking or identifying impacts of future regulation on the own products. For processing auxiliaries that do not end up in a product, e.g. cleaning agents or lubricants, it is useful to define terms / categories in the inventory to allow sorting and searching for these terms
Concentration in the final product	√	√	(√)	The concentration of a substance in a final product is important to check compliance of the produced mixture with restrictions as well as to analyse resource efficiency in the production
Date of SDS	√	--	√	Supports checking and ensuring that the most recent information on chemicals is available in the company
Supplier	√	--	√	Contact information is useful, so the supplier can be quickly contacted.

Additional information that is considered useful for chemicals risk management but is not as essential as the above is provided in the following table.

Table 3: Overview of additional, non-essential but useful information in a chemicals inventory

Type of information	Substance as such	Substance in mixture	Mixture	Why
Internal identifier	√	--	√	Allows linking the inventory to other internal data systems via the internal identifier if one is used
Stored amount: start of the year	√	--	√	Allows calculating the exact use amount in combination with the purchased amount. Useful to check applicability of SEVESO Directive
Stored amount: end of the year	√	--	√	
Location of SDS	√	--	√	Information for everyone on where the SDS is archived
Legal information	√	√	√	You may include legal requirements, such as restrictions or if a substance is an SVHC[6]
Quality of SDS	√	--	√	It may be useful to centralise this information, so it is accessible to all, e.g. for evaluating suppliers.
Supplier evaluation	√	--	√	Can be useful to centralise documentation of experience with suppliers centralised, e.g. for purchasers or product developers to assess sourcing options for new materials.

6 Substance of Very High Concern

3.4. Integration into existing routines

If you have a material management system to organise information on your input materials, check what information types and what functionalities that are discussed below it offers.

All relevant data types included	(Most) needed functionalities offered	Consequence
√	√	Expand existing system by adding all missing information and using existing functionalities
√	--	Expand existing system by adding missing information; build an excel file for exporting data to allow data analysis and functionalities not provided by the system
--	√	Assess if additional modules are available for your system that allow extending the information types in the database. If available, check if you want to buy it. Otherwise: build a separate chemicals inventory
No material management system in place		Assess existing software if purchasing one is an option. If not, build a separate chemicals inventory as described below.

If your material management system does not sufficiently support you in your work or you do not have any such system at all, assess at which scale you want to implement a chemicals inventory. If your company handles a high number of input materials and products it may be useful to choose a commercially available tool, as they can handle large data amounts.

3.5. Step-by-Step implementation

Based on the above sections, decide on the inventory tool that you want to use and the type of information to include in the chemicals inventory. If you do not use / expand an existing material management system, you may use the excel-template or apply the MS Access®-based inventory tools provided in the Section .

It is essential to define the responsibility and assign sufficient resources for setting up and maintaining the inventory. Do not split the responsibilities between departments and staff; however, it is useful to train several staff to operate the inventory. You could assign the responsibility for the inventory to the purchasing department, the chemicals or environmental manager or a technical department, for example. Staff should have knowledge about chemicals and the own products and be well connected to other units of the company to ensure information flows.

The process of filling the inventory is laborious and different information sources have to be used.

Listing substances and mixtures by (trade/product/scientific name)

A list of all purchases should be available in the purchasing department. Use it to include all substances and mixtures purchased during e.g. the last year. Use the trade or product name of the substances or mixtures for the initial list.

Including information about safety and about suppliers

Get the SDS of all listed substances and mixtures. In SDSs, the following can be found:

- Substances (as such or mixture components): CAS number and/or EC number
- Mixtures: substances in the mixture and concentration ranges,
  The concentration ranges may be rather broad, and it may be necessary to have more precise information about the content of individual substances, e.g. if their use is restricted in the mixtures you produce. In these cases, you should ask your supplier for more information (c.f. chapter 12.3 on supplier communication).
- H statements of substances identified in the SDS
  You may check the correctness of the H statements of your supplier by comparing them to information in public databases, in particular the classification and labelling inventory by ECHA.[7]
- Supplier name and contact address
- Date of the SDS
- Remarks on the SDS's quality

Adding purchased amounts

Get the purchased amounts of substances and mixtures from the purchasing department. Define the period of use as one calendar year or align the period with any relevant processes in the company.

Adding purpose of chemicals

The intended use of a chemical may have to be inquired from different departments in the company. Product recipes should include information on input materials that end up in the product. Be specific and enter the exact name of the product(s) a substance ends up in. This is important for later analyses of what products are or may be affected by legislation on a particular substance. Information on processing auxiliaries may be available from technical departments of quality officers.

7 Note that there may be different classifications for the same substance, which may have different reasons, including differences in impurities, physical form of the substances and the use of different testing results as the basis for classification. In case of inconsistencies, you should contact your supplier.

Including information on stored amounts

Get data on the stored amounts of chemicals from the staff responsible for storage and/or if the company has inventoried materials. It is useful to include information on stored amounts at the beginning and the end of the year for which the inventory is set up.

Adding additional information

Additional information, such as on legal requirements or from internal evaluations of suppliers, SDS etc. can be added when necessary. As the main information source will be staff inform all relevant people need to be informed to forward such information. Check what additional information is needed and for what!

3.6. Using the chemicals inventory

The main aim of the inventory is to provide structured and comprehensive data on chemicals to support answering specific questions and/or decision making. Hence, the use of the inventory involves the following steps:

- **Formulate the question to answer, e.g.**
  a. What SVHCs[8] are used ? This question could be asked to analyse the status quo and derive reduction targets for SVHCs in the future and for what are they used?
  b. What amount of chemicals classified as explosive are stored by the company? This question could be asked to review the safety measures of the storage place?
  c. Which amounts of solvents are used by the company? This question could be asked to identify if a threshold value for permitting is exceeded?
- **Identify what information can answer the question; in the above cases this would be:**
  a. List of SVHCs; amounts purchased as such and in mixtures; purpose/fate of substances,
  b. List of substances classified as explosive; and stored and purchased amounts,
  c. List of substances uses as solvent; destiny of solvents (product, processing aid); purchased amounts.

8 SVHCs are substances which have been included in the so-called Candidate List for Authorisation (candidate list) under the EU REACH regulation. They have very severe health or environmental effects, e.g.carcinogenicity, reprotoxicity, genotoxicity, are persistent, bioaccumulative and toxic or endocrine disruptors.

- **Retrieve information from the inventory**: This action depends on the type of inventory that is implemented. In the case of an excel-file, information could be sorted and extracted directly. If an access tool is used, a respective request can be used or developed. Commercially available tools are likely to have pre-defined data mining forms, which can be used.

The inventory can be used to demonstrate absence of certain chemicals to the authorities (compliance) or be used as a basis for declaring compliance with specific requirements to the customers.

3.7. Updating the chemicals inventory

The chemicals inventory is only useful if it contains complete and up-to-date information. In addition, there may be national requirements for updating the inventory. Therefore, it is essential that the following routines are implemented:

- Purchasers must ensure new products that they purchase are included into the inventory.
- If it is decided that a certain product is not produced anymore, the respective product manager must communicate that input materials which are solely used for this product are removed from the inventory or marked as “not in use anymore”.
- Purchasers or technical staff receiving updated SDSs should ensure that new / changed information is transferred to the inventory and the date of the SDS is updated.
- If the composition of a product is changed, the product manager is responsible to provide this information for changing the fate/purpose of respective input materials, including their concentration.
- Purchasers must update supplier information.
- If SDSs are quality checked, suppliers evaluated or any other assessments are made which may support decision making on what chemicals to buy and from which supplier, this information should be communicated by the assessors to those maintaining the chemicals inventory and included, e.g. as a “remark”.

You may sort the inventory according to the “date of the SDS” once per year and request updated versions for those, which are older than 3 years.

3.8. Tools and Links

- Chemicals inventory
- MS Access® inventory (will be linked later)
- Guidance on how to use ECHA’s registration database (will be linked later)

4. Company Policy and Goals

The corporate chemicals policy describes the guiding principles of using chemicals and managing potential risks from their use. Based on an analysis of the status quo, it sets areas for improvement and defines measurable goals and timelines for their achievement. The chemicals policy is the very basis of corporate risk management and gives orientation for priority setting and decision-making.

You can either develop a separate chemicals policy for your company or integrate it into the existing overall or environmental policy (e.g. according to the EU Environmental Management and Auditing Standard (EMAS) or the international ISO 14.000 standard on environmental management sytems). It should be supported and in the ideal case be developed with participation of the top management of the company. In the following, the main elements a chemicals policy should contain, are introduced.

4.1. Legal background

No legal requirements exist to have a chemicals policy at company level.

4.2. Advantages of having a chemicals policy

The chemicals policy helps to communicate the attitude of the company towards chemical safety internally and externally. It gives orientation for decision making and the derivation of specific goals. It allows all actors to better understand a company's action and priorities and to decide whether this fits to the own business practices.

4.3. Content of a company policy and examples of goals

4.3.1. Aims regarding the use of chemicals

The overall aim of your company should generally consist in providing products and services that are of high quality and do not cause harm to human health or the environment. Making a respective and company-specific statement at the beginning of your policy provides insight into your company's motivation to work on chemicals and thus frames all following statements and goals.

You could complement the statement of the company's overall aim with information on your main products / services and specify whether there are products or services to which the policy does not apply. Reasons for exempting parts of the business from the overall policy could be e.g. that:

- action needs have been deprioritised because all resources are focussed on more important aspects or
- the options for change are (currently) limited due to e.g. legal or technological conditions or
- economic reasons prevent changes for the time being.

Such exemptions are usually not necessary, as the overall aim is very general. If you do exempt business areas from the overall policy, provide reasons so your customers understand your decision.

4.3.2. Means of implementation

In the further sections of your policy, you should outline what the company is going to do to implement the overall goals. You could differentiate into the following aspects:

- Safe products
- Safe production
- Transparency and information
- Research and innovation
- Monitoring and reporting

4.3.2.1. Safe products

As a formulator, the **safety of your mixtures** should be a focal area for chemicals management. Intrinsic safety, i.e. the **absence/reduction of hazardous** (classified) **chemicals** in your mixtures should be a main goal, which can be quantified in different ways. In the (public) company policy you might specify in more general terms, which chemicals you aim to phase out e.g. SVHCs on the candidate list. Examples of quantified goals could be e.g.

- Currently, 25% of our mixtures contain at least one per- and polyfluorinated alkyl substance (PFAS). By 2030 we will have phased out the use of all PFAS, i.e. all mixtures will be PFAS free.
- Currently, 75% of all consumer mixtures contain skin sensitisers, mainly biocides to preserve the products. By 2025 we will have found non-hazardous alternatives, and all consumer mixtures will be free from skin sensitisers.
- By 2025 the company will reduce the use of SVHCs by 50% (by volume) in mixtures for professional / commercial use.
- Every year, the restricted substances list is reviewed and amended in the light of new scientific information about the substances we use (or then intend to phase out).

If the use of (some) hazardous chemicals cannot be avoided, the goal of the company could be to ensure safe use by providing mixtures in a form that prevents exposure and/or by providing good information and support for their safe use. This is normally only an option for professionally used mixtures. Examples of quantified goals are:

- By 2028, all solid mixtures will be provided in forms (pellets, containers with dispensers etc.) that prevent dust formation at the workplace.
- By 2025, we will review the use instructions of all mixtures for professional applications and provide specific, high-quality information on how they should best be handled and disposed of to minimise exposures.
- By 2028 we will provide safety gloves together with all products requiring skin protection during use.
- We will provide training for the professional use of all mixtures containing carcinogenic, mutagenic and/or reprotoxic substances (CMRs).

4.3.2.2. Safe production

In addition to ensuring safe products, preventing emissions from the own production facility could be included as a company goal. Safe production could mean to reduce the use of hazardous processing aids, reduce emissions to the workplace or the environment by organisational or technical means or to reduce worker and environmental exposures by technical means or personal protective equipment.

Example of quantified goals are:

- By 2028, all our processing aids will be free of endocrine disrupting chemicals.
- By 2030, none of our processing aids is classified as CMR.
- By 2025, all production processes are contained, and dosing systems are fully automatized.
- By 2025, all workplaces will have been reviewed regarding minimizing by-stander exposures and eliminating (unnecessary) manual tasks.
- By 2028, all exhaust gases collected via local exhaust ventilation will be cleaned by absorption and recovery technologies or, where recovery is not possible, incineration.

4.3.2.3. Transparency and information

Providing information and being transparent about the use of chemicals is another important area of chemicals management, which could be included in the chemicals policy. Various aspects could be touched here, such as:

- We have internal procedures in place to reply to customer requests about chemicals. Any request is answered within one week.
- We provide information on all hazardous ingredients in consumer mixtures on the packaging to allow consumers to make informed decisions.
- We disclose the full composition of our mixtures to our customers; information may be kept confidential for a maximum of 10% (w/w) of the mixtures.
- We request all our suppliers to test and document compliance with legal restrictions as well as our company-specific restricted substances list.
- We provide full transparency about our business activities by publishing annual figures of production volumes by mixture type.
- We support consumer decision making by using eco-labels for all products that fulfil the eco-label criteria.

4.3.2.4. Research and innovation

If products or processes should be changed to reduce the impact of hazardous chemicals from a company, research and development activities are inevitable. Hence, goals for this business area may also be relevant for your company policy. Quantified goals could be, e.g.:

- We will spend 5% of our annual turnover on finding alternatives for SVHCs in our products.
- In any reformulation process of our products will include an assessment of whether the most hazardous component could be replaced with a less hazardous alternative.
- By 2030 the research and development (R&D) department will test and/or develop tools to assess the sustainability of mixtures and use it in their activities.
- The development of new products will exclude the use of endocrine disrupting chemicals.
- Our R&D department will involve in sector activities for the substitution of hazardous chemicals in our products.

4.3.2.5. Monitoring and reporting

Although not a goal in itself, monitoring and reporting about the implementation of a chemicals policy is also an essential part of it. This can be rather short and just specify how often the achievement of goals is monitored and how the company will report about it. It could be useful to define indicators of success or check how the implementation of goals can be measured and establish respective data collection routines.

4.4. Integration into existing routines

If a company (environmental) policy exists, integrate the chemicals policy into it. Develop the chemicals policy in parallel to the overall (environmental) policy to identify synergies and interlinks. This includes harmonising goal setting and monitoring timewise. Otherwise, develop the chemicals policy independently from other processes.

4.5. Step-by-step development of a company policy

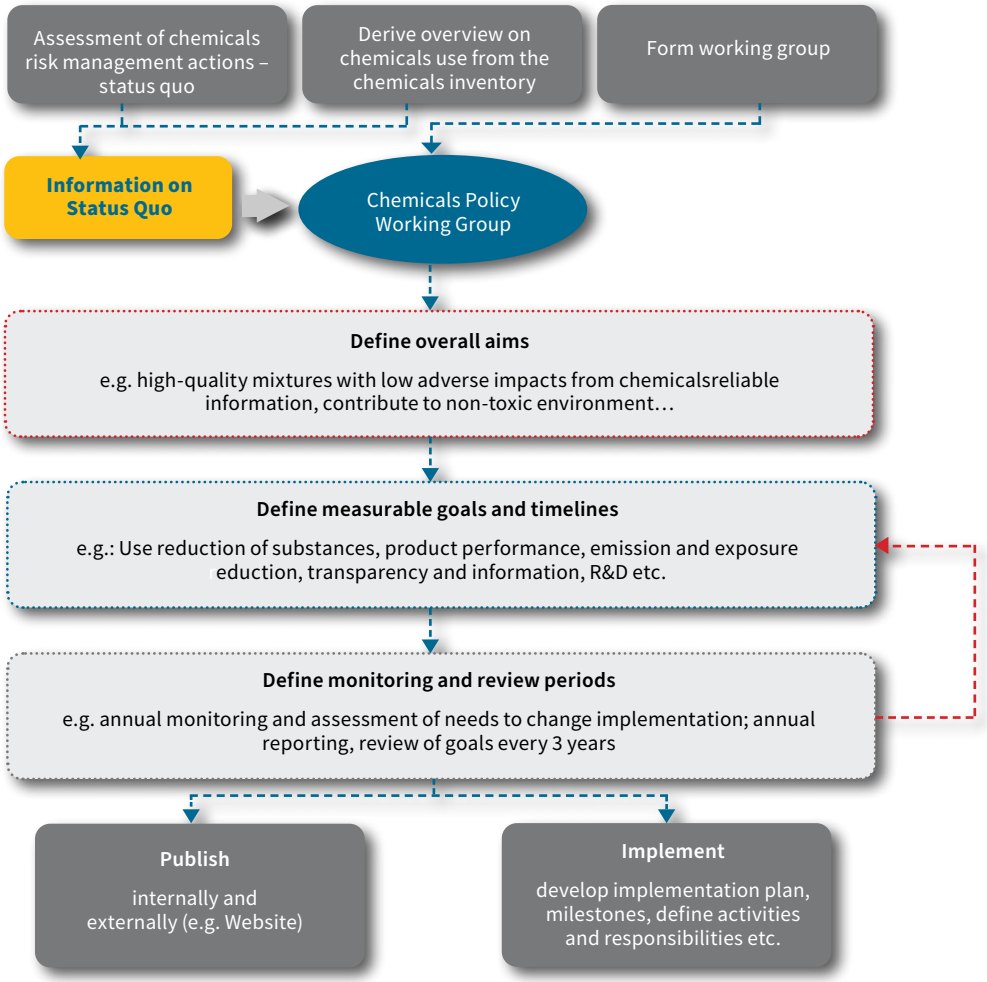
If no internal procedures exist, the following steps may support a structured and systematic process of developing a company policy:

Identify who in the company should be involved. The following list of people could be a good and comprehensive group:

- Representative of the (top) management, to ensure the resulting policy has full backing of the top management, is realistic and economically feasible,
- Legal advisor, to ensure information about (future) regulation is considered,
- Technical staff responsible for the production, to ensure a realistic perspective on options for change and limitations regarding equipment, processes design and potentially also space,
- Product / quality manager, to ensure product safety and potential limitations for change are considered in the goal setting,
- Staff responsible for environmental and occupational safety and health (OSH) management, to ensure that any existing challenges in environmental and worker protection are considered from the start and potential synergies are identified.
- Salesperson to ensure customer demands and “no-go’s” are well represented in the discussions.

Such a **cross-cutting working group** discussing the chemicals policy can be very fruitful and initiate improvement processes in many ways, including around communication, competences and information resulting in more efficient cooperation in the company.

Figure 5: Developing a chemicals policy



Base discussions about the chemicals policy on **knowledge about the status quo** of chemicals risk management and the use of (hazardous) chemicals in your company. Therefore, start with a self-assessment of all relevant business areas. A self-assessment questionnaire (c.f. Section) in combination with data from the chemicals inventory can already provide a good information basis.

The **self-assessment** should at least provide information on:

- What types of chemicals are used, e.g. list volumes of substances per classification, total volume of SVHCs, types of products containing hazardous chemicals (by type) etc.
- Overview of (which) legal requirements and future developments regarding chemicals, e.g. upcoming restrictions, regulatory priorities, and trends
- Purchasing criteria and routines, problems identified with suppliers and input materials
- OSH and environmental management: chemicals-related problems in the production, permitting, storage etc. If available, costs for waste treatment, emission abatement and workers protection
- Products: overview of the types of products and their content of hazardous chemicals
- Sales: sales statistics, including tends, overview of main markets and customers, their demands etc.

Base the development of specific goals on the overall policy and an evaluation of which business areas and activities is of highest priority and/or most relevant to address (first). If necessary, additional information may have to be collected on the current situation if the initial self-assessment is not sufficient for specific aspects. It may be useful to start the chemicals policy with only a few but quickly implementable goals to get started and to increase the level of ambition and the variety of goals over time. This way, you give the company time to learn and develop the system over time.

4.6. Tools and Links

- Self-assessment questionnaire on chemicals risk management
- The chemicals inventory (cf. Chapter **3**) can be used to compile statistical information about the use of chemicals in products
- The organisation bizNGO provides a Chemicals policy template, which similar elements but a slightly different structure for presenting the chemicals policy.

5. Responsibilities, Procedures, and Resource Allocation

Defined responsibilities ensure that it is clear who is responsible for which tasks in a CRM and that everyone understands the own role in the system. Procedures describe how certain tasks are performed, standardise processes and create transparency. Adequate resources need to be allocated so that the responsible staff has sufficient time to implement their tasks.

5.1. Legal background

There is no legal requirement to define responsibilities and procedures for CRM chemicals risk management (CRM) in companies. However, there are some requirements from EU and national legislation on the competences of staff working on specific CRM tasks including:

- The **employer** is responsible for implementing workplace risk assessments, the implementation of exposure reduction measures and ensuring health monitoring as well as training on the safe use of chemicals at workplaces. He may delegate the tasks but remains responsible in a legal sense (EU and national)
- There should be trained staff responsible for the **development of safety data sheets**, as this requires expertise in hazard identification and risk management

Examples of further, national legislation:

- Estonia: general competence required as stated in § 8-2 of Chemicals Act
- Latvia: specific education needed for risk assessments at workplaces / OSH work
- Staff should comply with the established competence requirements when working with so-called poisonous substances (acute toxic 1-3 cat.; CMR 1A and 1B, Systemic target organ toxicity (STOT) single or repeated exposure 1 cat.)
- Poland: no specific requirements

5.2. Advantages of defining responsibilities and procedures, and allocating resources

Advantages of assigned responsibilities are:

- Everyone knows who can be asked or made responsible in case of problems
- Staff feels more dedicated to the tasks
- Ensures that all tasks are implemented, and nothing is omitted "just" because nobody feels responsible.
- Should be linked to decision power, i.e. staff can act independently of the hierarchy. This increases work satisfaction and supports a lean management.

Advantages of using Procedures are:

- Routine processes and harmonised actions are implemented.
- (New) staff can be supported when starting handing over tasks.
- Updating of routines based on experiences ensures institutional learning.

Advantages of clearly allocated resources are:

- Tasks are done and not sacrificed for another; the overall workload is well controlled,
- Increases the predictability of workloads at the managerial level and gives guidance to staff on how much time they can spend on implementing their tasks,
- If resource spending is monitored, ensures better information is available on the efforts of risk management in the company.

5.3. What should be considered and defined

5.3.1. Responsibilities

The type of responsibilities and how they are attributed to staff is very individual to a company and there is not "standard approach" to this. One person could have more than one responsibility. However, giving several persons the responsibility for the same element or area of CRM will create uncertainty about the "who does what" and should be avoided.

To ensure all relevant activities are covered, assign at least the following responsibilities to specific persons:

- Overseeing the overall CRMS, including tasks like progress monitoring, initiating reviews of policy and goals, being contact person for all involved staff to discuss and assess challenges and new ideas,
- Setting up and maintaining a chemicals inventory,
- Ensuring legal compliance, e.g. assessing what chemicals-related requirements exist and that they are all implemented, documenting compliance, and monitoring legal changes and future regulatory developments and informing about it,
- (Chemicals- related) occupational health and safety tasks, including workplace risk assessment on chemical, implementation of chemicals-related precautionary measures, developing workplace instructions regarding the handling of chemicals etc.
- (Chemicals-related) environmental issues, including permitting and monitoring of emission limit values, wastewater treatment / discharge, treatment of air emissions, waste management,
- Ensuring chemicals-related purchasing criteria are implemented, information on chemicals (Safety Data Sheets (SDSs) and additional) is obtained and forwarded inside the company,
- Chemical safety of the products, eco-labelling and certification, consumer communication,
- Compilation of SDSs and additional information on hazards and risk management for downstream users, answering customer requests on chemicals, including on emergencies
- Storage of chemicals in and emergency plans/ measures if relevant (i.e. SEVESO installation)
- Chemicals risk / sustainability assessment of substances and mixtures along the life cycle.

5.3.2. Procedures

Chemicals-related operating procedures do not differ regarding their aim and structure from those related to other topics or activities. Therefore, no details are provided on this aspect, here.

Discuss the need for standard operating procedures in the company as it depends on the size of the enterprise, its management culture, the existence of quality management systems and handbooks and many other issues. To decide on the need of such procedure ask the following questions:

- Who would use the procedure and how often?
- Does such procedure help handing-over tasks and documenting knowledge for the future?
- For what other cases do such procedures exist?
- What experiences have been made with operating procedures (these should be considered in drafting new ones)?

It is generally useful to develop procedures for complex methods and processes.

5.3.3. Resource allocation

There are no standard solutions and information on how much time should be allocated to a particular CRM task. It is rather advisable to implement a system of documentation to monitor resource spending regularly, in particular in the first years of implementing a CRMS, in order to learn how much time should be allocated. It should be noted that there may be a learning curve for staff who receive new responsibilities and tasks. Professional training and appropriate (software) tools may reduce the time needed for task implementation.

5.4. Integration into existing systems

In the optimal case, you can attribute the responsibility for the CRMS (or elements thereof) to existing roles by extending the descriptions of responsibilities, tasks and increasing resources. The environmental manager could be made responsible for overseeing the chemicals management[9], a product manager could be responsible for assessing chemical risks from products etc. If no suitable role exists, you may have to create new ones, e.g. that of a CRM officer. Staff may need additional competences for the new tasks and should receive respective (professional) training. Ensure staff has clear guidelines on:

- What are their tasks,
- What they can decide and what must be decided further up in the hierarchy,
- Who they need to involve in their work,
- What outcome is expected by when and
- How much time they can dedicate to their tasks.

This information should be clearly communicated and documented in workplace instructions as well as in management handbooks, if existing.

5.5. Tools and links

There are no specific tools or guidance documents.

9 If an environmental management system exists, chemicals management should be integrated into the system. Hence, the environmental manager would „automatically“ be responsible for chemicals as part of the system.

6. Legislation and Compliance

Legal compliance with requirements on chemicals is essential for any company. A compliance monitoring system should therefore be established that ensures all requirements are known, implemented and compliance is documented. Additionally, the company should be informed about potential changes in requirements in future to ensure sufficient time to prepare for the implementation.

6.1. Legal background

There are no legal requirements on how a company should ensure compliance with legislation, but there may be requirements on documentation and reporting, such as for the chemicals inventory (c.f. Chapter **3**). This is specific to the legislation and the country you are located in and therefore, no guidance on documentation and reporting is provided here.

Chemicals-related requirements are scattered across legislation. Therefore, it is important to check legislation from different areas including chemicals, products, the installation, worker protection. A list of legislation that could be applicable to your company and your products is provided in the Overview of Legislation to help identifying potentially relevant legislation.

There are different types of requirements on chemicals, which are relevant to formulators[10]:

- **Hazard identification and communication on chemicals:** hazard communication via labels, SDSs – H statements, pictograms, P statements
- **Restrictions of the content of chemicals in products:** bans and/or concentration thresholds defined in REACH Annex XVII or product specific legislation, such as on detergents, biocides or pesticides
- **Authorisation:** prohibition of use e.g. via REACH Annex XIV, unless an authorisation exists
- **Storage:** various requirements based on and related to the storage of hazardous chemicals under the SEVESO Directive
- **Workplace risks:** OSH legislation defines requirements e.g. risk assessment, implementation of measures, Occupational Exposure Limit Values (OELs), health monitoring etc.
- **Environmental emissions:** e.g. limits on the emissions to air, water and soil in environmental permits
- **Waste:** various requirements regarding the classification, proper handling and disposal, documentation
- **Reporting:** to the authorities, e.g. on the use of chemicals, emissions etc.

10 There are additional requirements on substances in articles which are not included here, as they are not relevant for producers of mixtures.

6.2. Advantages

Advantages of a compliance monitoring system:

- You ensure the basis of any economic operation, i.e. that you follow the law.
- You ensure that up-to-date information (and documentation) of compliance is available and can be provided on request, e.g. to inspectors, which increases trust.
- Resources are used efficiently, as compliance checking becomes a routine.
- You get a comprehensive overview of all (future) requirements, which guides your decisions for innovation and investments and gives you time to plan how to choose the best solution to a future challenge rather than to implement emergency measures on short notice.

6.3. What a compliance monitoring system comprises

There should be one person who is responsible for the compliance monitoring system. This person may delegate tasks or ask for help from experts inside or outside the company (e.g. legal advisors or consultants). The system comprises:

- A list of all relevant legislation and the specific requirements applicable to the company
- A schedule for monitoring legislation
- A documentation system of compliance checking
- A reporting mechanism to the top management and/or to the public (e.g. as part of environmental or sustainability reporting).

6.4. Integration into existing routines

If you have an environmental management system, you should already have a compliance monitoring system in place. In this case, you only need to check if all chemicals-related requirements are identified and included in the system.

If you do not have a compliance monitoring system in place, you should set up the system step-by-step. In doing so, it is recommended you involve all people who have dealt with legal requirements “in general” and use their experience and expertise.

6.5. Step-by-Step building up a compliance monitoring system

Identify who should be responsible for the compliance monitoring system. Ensure the top management is involved in the decision and dedicates sufficient resources (cf. Chapter). This person should involve internal experts in the system set-up, such as environmental or product managers, purchasers and potentially also sales personnel. You may organise involvement via a working group or bilateral consultations.

6.5.1. Develop a list of relevant legislation

Check the **Overview of Legislation** and prepare an initial list of potentially relevant legislation. This list could be structured as shown in the following table. Two examples of legislation are included, of which the first is for sure applies to you, while this is not the case for the second, depending on your products and production volumes.

Table 4: Example of a List of applicable Legislation

Legislation	Classification and labelling regulation	Permitting laws[11]
Link	CLP Regulation	Industrial Emissions Directive
Hazard identification	Mixtures must be classified according to the rules of the regulation's annexes. Harmonised classification must be applied if existing in Annex VI	Reporting of products used as part of the permit application and potential renewals.
Communication	The classification must be communicated on the chemical labels and packages according to the rules specified in the regulation's Annexes.	Not applicable
Bans, restrictions or authorisations	Not applicable	No restriction, but the use of CMR solvents should be avoided (substitution requirement). Depending on the national legislation, it may be required to indicate in the permit application if the used substances (in mixtures) are restricted under other legislation or require authorisation
Use	Not applicable	General prohibition to contaminate the environment and potentially clean-up after ending the operation. Requirements on the operation of the installation defined in the permit depend on the national legislation
Emissions	Not applicable	Emission limit values and additional requirements defined in national legislation
Waste	Not applicable	Specific requirements defined in the permit, depending on national legislation
Certification needs (incl. downstream)	Not applicable	Normally not applicable; there may be certification schemes for by-products and/or products generated from waste
Reporting needs	If chemicals are imported their classification must be notified to the classification and labelling inventory	Emissions that are listed in the permits must be reported to the authorities. There may be feeds if limit values or emission loads are exceeded for substances or substance groups.

11 The Industrial Emissions Directive sets the permitting framework at the EU level. National legislation implements this framework. This is not specified here to keep the guidance applicable to all countries.

Legislation	Classification and labelling regulation	Permitting laws[11]
Other requirements	Specific requirements e.g. for very small packages or child-safe packages	Not applicable
Related documents	Guidance documents on classification and labelling of the ECHA and nationally	Environmental permit, measurement protocols in air and water, waste documentation
Responsible contact in the company	Product quality management; dedicated staff [name] qualified for classification	Environmental manager
Responsible contact in the authorities	National help desk; Market surveillance inspectorate [include details if known]	Permitting authority [specify relevant person, if known]
Issues for compliance checking	New harmonised classifications, new hazard classes (EDCs, PBT/vPvB and PMTs/vPvMs)	Assess new input materials and whether they have implications on compliance with the requirements
Update frequency	Regular updates to include new harmonised classifications; communication via the ECHA newsletter!	According to permit and depending on national legislation; update in case of changes to the installation
Last check	01.01.2024	01.05.2023
Next check	Regularly check ECHA newsletter	01.05.2026

You can implement such register of (chemicals-related) requirements from different legislation as an excel-file or as fact sheets per legislation (e.g. one table per legislation). The best option would be to establish a database of requirements that are accessible to all staff and allows them to include compliance information from their area of responsibility. The form of the register depends on the preferences and possibilities of your company.

Ensure that all departments in the company know of the applicable legislation. When a monitoring system is newly introduced, it is useful to discuss the existing obligations and to agree on the actual compliance checking procedure at least once.

6.5.2. Monitoring schedule

Based on the last lines of the list of requirements “Issues for compliance checking” and “Update frequency” you can prepare a monitoring schedule. It is useful to separate the monitoring schedule into two parts:

Part 1 defines groups of legislation that need to be checked with the same frequency. This could be the following groups: Legislation where compliance is to be checked:

- every half a year (e.g. 01.02 and 01.07 of each year)
- based on newsletters (e.g. newsletter of the European Chemicals Agency (ECHA) with updates on harmonised classification, SVHC identification, biocide approvals etc.)
- once a year (legislation with infrequent updates)
- at specific dates (e.g. permits which have a certain duration)
- upon announcement from service providers, which are contracted to alert about legal changes (e.g. on legislation that applies in export markets)

Note that the trigger for checking compliance with legal requirements as part of the monitoring system is the legislation itself, e.g. when substances are regularly added to lists, like the REACH candidate list or Annex VI of the CLP regulation.

Another type of trigger are your or your suppliers activities, e.g. when new raw materials are purchased. Here, it is the responsibility of the purchaser to know which legislation applies and to check if new materials are compliant, or to inform the relevant people of the changes.

Part 2 of the monitoring schedule could look like / be a calendar and mark the dates when a legislation check should be performed. The dates could then be linked to the groups defined in the first part of the monitoring schedule.

The actual checking of compliance may involve different steps and checks. Check restrictions or bans using the chemicals inventory. Check compliance with emission limit values according to the needs, e.g. continuous measurements of waste gas or wastewater emissions. As this requires expertise, the actual checking can/should be delegated to the relevant staff.

Another option, which ensures that “blind spots” are avoided is to regularly ask an external organisation to check the implementation of legal requirements (audit). For example, it is not promising to have the same staff checking the classification of mixtures that actually does it, as their main job. Therefore, asking e.g. consultancy services to check the classification can be more effective in finding mistakes.

6.5.3. Documentation system

The aim of the documentation system is to document internally but also for inspectors:

- That the compliance check for (certain) legislation (with regard to chemicals) has been performed;
- What the results of the compliance check are, specifying where the company

- Is well within the limits of compliance
  → no action is needed,
- Is compliant but could do better to ensure this is the case also in future (including because new legislation is upcoming)
  → options to act to improve the regulatory situation in the future could be discussed in the company,
- Is non-compliant and must implement measures
  → Action to ensure compliance (again) must be taken immediately! The monitorer must inform the top management and the persons responsible for the non-compliance. It is useful to document what action is taken, who is responsible and when compliance should be achieved (not in the monitoring schedule). Another specific compliance check should be done after that action to ensure and document compliance.

- That the company is aware of its obligations and has a system in place to ensure these are implemented. This is particularly helpful during inspections and increases trust between company and authority.

6.5.4. Reporting to the top management

As compliance is essential for any business activity, the top management should be informed in any case of non-compliance, so a decision can be taken on how to act.

It depends on the management style and preferences of the top management how often and in which form information on legal compliance should be reported. Upcoming requirements that might affect the company's ongoing business and/or its policy should be communicated clearly, so this can be considered in strategic decisions.

For example: the Toy Safety Directive is currently (2024) under revision, and it is likely that the generic ban of substances of concern in Toys will be extended from CMRs to EDCs. If you provide mixtures to the toys supply chain, it is essential that you review your raw materials and ensure that no such substances are contained in them. If you do use such substances, the company management must take decisions on how they should be phased out.

6.5.5. Non-EU legislation

If you export to non-EU countries, the legislation of the importing country must be followed, i.e. it is essential that you know what requirements apply to the product. The identification of applicable legislation and the communication of requirements is part of the compliance monitoring system.

6.6. Beyond compliance

While legal compliance is the very basis for placing any product on the market, you may be more pro-active with an ambitious chemicals policy and thereby increase trust in the company's performance, including by investors.

Advantages

- **Being a frontrunner** - strengthen your brand by taking responsibility and preventing potential risks for humans and the environment.
- **Being prepared for stricter regulation** – it may be a competitive advantage to foresee future developments and adapt your processes accordingly. Less human and financial resources will be needed to redesign your products (in a short time) when new requirements are decided.
- **Ensuring advanced chemical safety** – the use of less hazardous chemicals is an overall policy goal in the EU and contributes to reduced toxic risks for humans and the environment.
- **Staying attractive for investors** - investors have long term strategies and aim to reduce any business risks, of which the use of (very) hazardous substances is one. Avoiding potential chemicals-related liability claims is a core criterion for an increasing number of investors.

Avoiding double standards

Going beyond legal compliance also means to avoid double standards. "Double Standard" means that the same product is manufactured in different (chemical) qualities for markets with different requirements. This usually means that countries with less stringent requirements get more hazardous products. This business practice is unethical and inconsistent with the aims to reduce (overall) toxic risks. Apart from the uneven level of protection having just one "quality" of a product can also be more efficient in the long run and considering all costs, instead of only the raw material prices.

Examples

- Apply stricter concentration limits for chemicals than allowed in legislation.
- Apply restrictions not only to one chemical but also to members of "its group", i.e. chemicals which are structurally similar (groups) and are likely to have similar hazards.
- Avoid the use of chemicals which are not (yet) regulated but of which there is sufficient evidence that they are hazardous to human health and/or the environment.

- Restrict the use of chemicals in products for which legislation requires compliance with migration limits; this would ensure that no emission would occur rather than one that is limited to the migration rate.

6.7. Tools and Links

- List of relevant legislation and overview of main requirements
- ECHA database on legal requirement per substanc (EUCLEF)

7. Purchasing

Considering chemicals in purchasing is essential to ensure only those chemicals pass the company's "entry gate" that comply with the company policy and that all information necessary for the safe handling of the chemical is available.

Covering chemicals explicitly via purchasing criteria is an important step to ensure that all input materials, including articles, are checked regarding their chemicals content. Additionally, purchasers can ensure that appropriate and complete information is provided with all chemicals used as input materials. This requires certain awareness and expertise of the staff in the purchasing department. The work of the purchasing department is particularly important when new input materials are introduced.

7.1. Legal background

There are no legal requirements to integrate chemicals-related criteria into purchasing routines.

7.2. Advantages of chemicals-related criteria in purchasing routines

- Purchasers initially screen compliance and conformity with the company policy of all input materials and ensure no raw materials are purchased that would endanger achieving the company goals.
- Products which do not correspond to the company policy can be excluded from purchasing with low effort and without involving additional resources in the company.
- The availability of information for safe handling of chemicals is checked and information is distributed to the relevant departments, e.g. OSH or environmental managers as well as storage personnel and staff responsible for other chemicals-related tasks.

- The purchasing department gets a good overview of input materials on the market and their content of unwanted chemicals; if no alternatives are available, information can be forwarded to the top management for decision making on exemptions from the chemicals policy and goals.

7.3. Principles and aspects of purchasing criteria

The purchasing criteria should be based on the company policy and its goals. If the company policy aims to phase out the use of SVHCs in input materials, reflect this in the purchasing criteria, e.g.: “No SVHCs are indicated in Section 3 of safety data sheets (SDSs) of mixtures or section 2 of the SDS of substances.

If a target is to reduce the amount of SVHCs in input materials, establish a process to monitor the amounts of SVHCs in input materials, including criteria for exemptions, i.e. when SVHC use is acceptable. This could include guidance on which processes are highly dependent on certain input materials (product quality) or where substitution might require changes of processes (high investment need). Low hanging fruit could be harvested first, and the more challenging options be postponed for later. Or purchasing criteria could be derived considering the size of impact from a changed choice of raw materials.

Certain chemicals, like PFAS may be of very high priority in the company policy and should be hence reflected in the purchasing criteria!

Consider information on customer demands regarding the use of specific substances in purchasing, as this might be essential for keeping business relationships.

Define indicators to monitor the change in purchasing and/or content of specific chemicals in your products due to considering chemicals-related criteria to assess progress and improvement needs.

Document challenges in purchasing due to chemicals-related criteria and procedures to learn how routines and criteria should be designed to be implementable.

Purchasers may have to differentiate between

- Chemicals the company incorporates in its products, where changes need to be discussed with the customers and
- Chemicals used as processing aids, where only internal communication is needed, and
- General products for the company (e.g. office equipment), where chemicals can also play a role.

The company policy may differentiate between these types of input materials, as the impacts along the lifecycle of chemicals differ.

Purchasers need to be competent in identifying hazardous chemicals in the documentation of input materials (SDS, label etc.) and communicating on them with suppliers. They should cooperate with other departments to ensure that requirements towards the purchased input materials for the own product are included early in the purchasing process.

7.4. Integration into existing routines

If purchasing routines and criteria already exist, integrate chemicals-related criteria and routines to assess reived information into the system. Use the bullet points in the following section to amend or build up your chemicals – specific purchasing routine.

7.5. Step-by-step implementation

- Assess how purchasing is currently organised. Identify key responsible staff and discuss the intended changes to consider chemicals-related criteria in purchasing.
- Analyse the company policy and translate the goals and targets into purchasing criteria, i.e. requirements a product must fulfil.
- Consider developing a restricted substances list for your company that is provided to suppliers so they are aware of chemicals that should not be contained in their products.
- Check potentially available standard text to ask (potential) suppliers to provide information on chemicals in the products they offer so they are provided on a routine basis.
- Assess existing (standard) supply contracts and identify options to require all suppliers to provide products that comply with your company's demands on chemicals and transparency.
- Discuss if and how suppliers should prove compliance of their products; include such requirements in standard supply contracts.
- Assess existing operating procedures for purchasing processes and integrate steps to:
  - Check that chemicals related criteria are fulfilled,
  - Assess if proof of compliance is provided by the suppliers if relevant,
  - Control documentation provided with chemicals for completeness, correctness and currency,
  - Document the above steps, e.g. in the supplier evaluation section of the chemicals inventory (cf. Chapter 3).
- Define criteria for monitoring the implementation of the purchasing procedures and criteria and identify indicators to measure success; integrate data collection processes for measuring indicators in the purchasing routine.
- Assess competences of purchasing staff to conduct the purchasing process regarding chemicals; develop either staff training plans to close competence gaps or identify options for delegating tasks to staff in other departments.
- Define responsibilities for implementing chemicals-related purchasing procedures and integrate management handbook (if existing).

- Define reporting routines and schedules of purchasing department to the top management.
- Ensure material management systems and/or the chemicals inventory are fit to integrate (new) data from purchasing and support reporting and progress monitoring.

7.6. Tools and Links

- Procurement guide
- How to effectively build and implement a chemical purchasing policy - Eurofins Scientific

8. Storage and installation safety

Chemicals need to be properly stored to prevent accidents caused by or involving chemicals. This ensures that no damage occurs to the installation, workers, and the close neighbourhood as well as the environment.

The proper design of storage places is crucial to ensure not only that safety risks are prevented and minimised but also to ensure the availability and accessibility of raw materials, so production processes are not interrupted by shortages. As storage place is expensive, storage times of raw materials should be minimised by ordering materials “just in time”.

8.1. Legal background

EU legislation does not define any specific legal requirements on how chemicals should be stored. A proper storage place should be in the interest of any company to prevent accidents, safety risks and disturbances to the production process in general.

The EU Seveso Directive (respectively the national legislation transposing the directive) defines requirements to “establishments” that store significant amounts of chemicals that could either cause or aggravate accidents or incidents in an installation. It differentiates between facilities that store relevant amounts (lower-tier) and high amounts (upper-tier) of chemicals. To identify if an establishment is covered and to which tier it belongs, the amounts of the chemicals classified with certain hazard classes (and) that are listed in the Annex of the Directive present in the establishment must be compared to threshold values.

Establishments covered by the Directive mostly are from the sectors power generation, supply and distribution, fuel storage, chemicals production and wholesale and retail sale.

Measures of installations under the scope of the Seveso Directive:

- Inform the competent authority of which chemicals are present in the establishment,
- Assess accident and incident risks and develop an accident prevention policy, including measures for prevention, preparedness, and responses to accident,
- Implement measures to minimise risks of accidents and incidents in the installation as part of the safety management system,
- Develop emergency plans for the (potentially various types of) accidents and incidents, including communication to the authorities and neighbourhood,
- Provide information in case of accidents.

Upper-tier establishments have to provide a so called “safety report” and make internal emergency plans in addition to the above.

Note: Legislation on transport of dangerous goods and workers protection, including the ATEX[12]-Directive, c.f. Overview of Legislation, also apply to storage places.

8.2. Advantages

Implementation of any requirements under the Seveso Directive are not only a compliance issue but contribute to limiting risks to the installation and hence, limiting financial risks of the company. The same applies to a proper design and maintenance of all storage places in the company.

If chemicals are not properly stored, they may ignite or explode, lead to the corrosion of chemical containers resulting in leaks, or they may emit gases that could cause fire or intoxication. Hence, identifying and implementing proper storage conditions can prevent or at least minimize the risk of aggravation of accidents and incidents.

8.3. Integration into existing routines

The process of ensuring safe storage of chemicals could be implemented in the risk assessment and management of workers protection, as safety is an essential part of this, and the storage place is also a workplace. However, it may be more reasonable and better manageable to implement a separate process for managing the storage places.

If the Seveso Directive is applicable, establish a separate work process and routine for this.

12 Explosive atmospheres

8.4. Step-by-step

Storage places may be very different in companies, depending on the size, the location, whether they are centralized or decentralized in the company etc. Therefore, some general principles for the design of storage places are given here.

- Assign a person who is responsible for safe storage in the company. The person should receive training on safe storage, have access to all relevant information and sufficient time to implement the task. The person should receive all deliveries of chemicals and decide on how they are stored.
- Always ensure all containers are closed, i.e. not vapours can be emitted.
- Assess potential risks from the storage of chemicals by
  - Identifying the potential harm of chemicals (i.e. check hazardous properties, in particular related to storage),
    Check Section 2, 5, 7 and 10 of the Safety Data Sheet (SDS) with information on the hazards, fire-fighting measures, handling and storage recommendations and reactivity, which all are relevant for storage.
    Contact your supplier if you do not understand the information or if it is inconsistent.
  - Assess what chemicals should not be stored together in Section 7 and 10 of the SDS.
    Never store oxidising chemicals together with flammable liquids, and separate bases and acids.
    In this assessment, take a broader perspective on the raw materials in the storage place, as they may increase the chances of fires (e.g. wood or paper) or may react with chemicals (even if not hazardous). Additionally, check the containers in which chemicals are stored; they may be affected by chemicals stored in close neighbourhood and hence give rise to leaking of chemicals.
  - Identify potential ignition sources in the vicinity of storage places and avoid them, if possible. This could be open flames or electrical equipment operated close or in the storage place.
  - Assessing what type of measures could prevent harm, in particular identifying appropriate types of containers or which chemicals should not be stored in close vicinity. Ensure that the measures and tools to fight fires are compatible with all chemicals stored in the storage place. If this is not possible, provide instructions what measure to use for what chemicals, and consider another separation of chemicals according to the fire-fighting method.
  - Based on the risk assessment, design measures to eliminate and control these risks. In this, the hierarchy of measures should be implemented:
    - Eliminate risks, e.g. by reducing the amount of chemicals stored in general or disposing of chemicals that are not used (anymore).

  - Substitution: if possible, chemicals posing safety risks should be substituted.
  - Technical measures: Engineering controls to reduce storage risks could include: ventilation of storage places and spill management systems to prevent that chemicals enter and contaminate other storage areas.
  - Organisational measures: Separate incompatible chemicals in the storage place as well as ignition sources, separate workers from storage places. Separation could consist of e.g. creating a distance between chemicals and/or establishing barriers between chemicals (rooms, buildings etc.).
  - Administrative measures: this includes training of workers on accident prevention and fire-fighting measures, ensure proper labelling of chemicals, ensure the paths in the storage places are free from obstacles, forklifts can shunt within the storage place or restricting the number of people that can access the storage place.
  - Personal protective equipment: ensure protective gear is available to implement measures in case of an accidents.
- Consider reorganisation of storage places to reduce safety risks for the installation and workers; frequently decentralised storage places are good to increase options to separate incompatible chemicals and reduce the amounts of chemicals stored in one place. Consider how many workers might be a at risk in the case of an accident/fire.
- Review the storage management: It is essential that the assessment of risks and the related measures to ensure safe storage are regularly reviewed. The frequency depends on the frequency of changes to the stored chemicals but, in any case, includes regular repetition of safety training of workers and an assessment of whether the different measures are effective (i.e. is the labelling still readable, are containers intact, is the storage place in order etc.)

8.5. Providing information on safe storage to customers

As a supplier of chemicals, you are responsible for providing information about the safe storage to your customers via the SDS, including in the sections on chemical hazards, firefighting measures, incompatibilities and storage conditions. Ensure your staff compiling the SDSs is competent in developing this information based on the chemicals' hazardous properties and how it is used.

8.6. Tools and Links

The most important information tool to organise safe storage is the supplier's SDS. In addition, the following guidance documents provide useful information on safe storage.

- Guidance on safe storage for SMEs by Safe Work Australia for SMEs
- Chemical storage guidance note on incompatible chemicals
- Guidance on safe storage by HSE UK
- Guidance document(s) on implementation of the SEVESO requirements at EU level

9. Occupational safety and health (OSH)

Employers must protect their workers from any harm, including from chemical risks. Legal obligations exist to carry out and document several tasks aimed to identify and manage (chemical) risks.

Ensuring occupational safety and health in companies is a complex task and requires several competences. It is recommended to appoint an OSH manager in the company, who ensures all legal requirements are properly implemented effectively and efficiently.

As for other management processes, OSH management consists of

- Analysis of the situation (risk assessment),
- Identification of the goals or targets and how to achieve them (identification of needs and options to reduce risks)
- Assessment of implementation options (evaluation of risk management measures),
- Actual implementation and a monitoring step to control success.

In the further sections of this chapter, the principles of workplace risk assessments, the hierarchy of risk management measures and training of workers are described with regard to chemicals to give some orientation on these aspects. For the implementation, more detailed guidance should be used.

9.1. Legal background

The minimum requirements on workers safety and health in general are defined in an EU framework directive and several daughter directives address chemical agents in particular (cf. Overview of Legislation). These minimum requirements must be transposed to national legislation.

Regarding chemicals, employers must:

- Assess risks from chemical agents at all workplaces; the assessment must be reviewed in case the use of chemicals or the activities at a workplace change.
- The risk assessment may involve measuring concentrations of hazardous substances in workplace air, where national or European Occupational Exposure Limit Values (OELs) exist.
- If risks are identified at the workplace, the employer must implement measures to eliminate or minimize these risks, respecting the hierarchy of measures (cf. below).

- If chemicals are used at the workplace, which are carcinogenic, mutagenic or reprotoxic (CMR), the employer must assess if these substances can be substituted and document the results of this assessment. If substitution is possible, it must be implemented.
- Workers' health must be monitored if exposure to CMRs occurs at the workplace.
- Workers have to be regularly trained on chemical risks, first aid measures and activities in case of incidents and accidents related to chemicals have to be known.
- All the necessary information at workplaces has to be provided, in particular on chemical hazards and preventive measures, so that workers can protect themselves from exposures.

It should be noted that the term "chemical agents" not only includes chemicals that are intentionally used at workplaces but also chemicals that may be formed during the work process, such as welding fumes.

9.2. Advantages

Advantages of a proper OSH management are manifold: Workers are more confident about their work and able to act responsibly resulting in less accidents and incidents, less severe consequences if something happens and not least, healthier workers resulting in a low number of work-related sick leaves. As workers are an important factor for successful production, it is not only an ethical but also an economic interest to ensure risks (from chemicals) are prevented.

9.3. Risk assessment at workplaces

The risk assessment at workplaces is a crucial step as it reveals if and to what extent a worker is at risk from chemicals at the workplace. It is the information basis upon which risk management measures are identified.

The aim of risk assessment at workplaces is to identify risks from chemical agents and to prevent harm to workers. The risk assessment consists of several steps:

- Definition / description of the workplace
  It is useful to clearly define the location of the workplace and the activities carried out at that workplace and thereby define the coverage of the risk assessment. If a worker is active at three places, there should be three risk assessments, as they are related to the workplace rather than a worker. It is possible that several activities are carried out at one workplace; each of them should be briefly described with a focus on the potential sources of exposure to chemicals.

- Identification of all chemical agents at the workplace and their quantities
  All chemicals used and/or potentially formed at a workplace should be listed to get a full overview of what chemical agents a worker is exposed to. The chemicals inventory may be used as an information source as well as the workers themselves.
- Assessment of hazards
  The hazards of all relevant chemicals at one workplace should be identified, either from the SDSs. In the case of substances that are generated at the workplace, such as welding fumes, information should be researched in the literature or from discussions with suppliers. All chemicals which are not hazardous can be ignored in the further assessment.
- Chemicals should then be sorted according to the exposure pathways: there may be substances (in mixtures) that are hazardous via skin contact or via inhalation or both. Chemicals which are hazardous exclusively via oral exposure can also be ignored in the further assessment.
- Assessment of potential exposures
  The next step of the assessment is an estimation or measurement of exposure levels.
  - **Dermal contact**: usually the duration of contact and the potentially exposed area of the skin are identified (considering the use of personal protective equipment). A semi-quantitative assessment of exposure is performed, resulting in conclusions on whether (more) measures are needed for better skin protection.
  - **Inhalation**: There are two options to identify exposure levels via inhalation: measurements or modelling workplace air concentrations of the relevant substances. Measurements may be the best option to demonstrate compliance with OELs and must be carried out in a situation that is representative for the workplace. Exposure models for workplace air are particularly helpful if many different substances are used. There are different models available which derive air concentrations based on the room volume, air exchange rate, temperature, substance properties and estimations of the amounts emitted from the process(es) at the workplace.
- Conclusion on risk: the effect thresholds (OELs or derived no effect levels (DNELs))[13] are compared with the modelled or measured exposure level.
  - **Dermal risks**: Frequently the risk assessment is not quantified, because quantitative effect thresholds are missing or because it is rather obvious that dermal risks exist at a workplace or not and what preventive measures are needed.
  - **Inhalation risks**: To identify risks, the exposure levels are compared to the effect thresholds; long term and acute exposures must be differentiated. If the quotient of exposure and effect threshold exceeds the value of 1, the worker is at risk.

13 OELs and DNELs should be included in the safety data sheet or can be retrieved e.g. from ECHA's website. More information on this can be obtained from guidance documents on OSH.

The scope of the assessment are all chemical agents[14] at one workplace. If several substances with the same effect are used at one workplace, the combined effects are considered in the risk assessment (mixture effects e.g. from solvents). The SDS, the chemicals inventory, the workplace itself and the worker are the main information sources.

The risk assessment should be documented and kept available for potential inspections. It should be reviewed if the conditions at the workplace change, i.e. if new chemicals are used (change of hazard and exposure), if the classification of a chemical changes (change of hazard) and/or if the way a process is conducted changes (change of emitted amounts and exposure potentials).

9.4. Risk management measures at the workplace

Any activity that reduces workers' health and safety risks are risk reduction / management measures. The effect and effectiveness of measures depend on the conditions at the workplace, the use of equipment and the chemicals themselves.

OSH legislation requires employers to follow the so-called "hierarchy of measures" when they reduce risks to workers. This hierarchy starts with the most far-reaching risk management approach that is closest to the source of the risk and ends with the measures that are closest to the worker and the farthest away from the source of risk.

The hierarchy of measures is also called the "STOP principle", with STOP being an acronym consisting of the first letter of all four measures:

- Substitution,
- Technical measures,
- Organisational measures,
- Personal protective equipment.

The STOP principle ensures that the measures close to the source are selected rather than those (only) preventing exposure. The former usually are also more protective and less burdensome for the worker to implement. The measures are explained in more detail in the following sub-sections.

9.4.1. Substitution

Substitution is the replacement of hazardous chemicals with less hazardous alternatives, which could be other chemicals, changes in the design of processes or the product itself, the use of different materials etc.

14 Chemical agents are all substances and mixtures used at a workplace and also substances formed during the activities at the workplace, e.g. welding fumes

Substitution eliminates the hazard and therefore, it addresses the risk at the source (no hazard – no risk) and has impacts along the entire lifecycle (no emissions, no exposures). Substitution should start from the question of how the functionality of the product can be achieved if the substance of concern is substituted, rather than on how a chemical can be replaced. This widens the view for different types of alternatives.

It is important that alternatives are carefully evaluated to avoid regrettable substitution, where the replacement chemical is equally hazardous or even more hazardous than the original chemical. Frequently, alternatives are less well studied, and less data are available on their hazards, which creates uncertainty and makes it difficult to compare alternatives.

The main steps of substitution are:

- Definition of the functionality to be achieved,
- Definition of core requirements for the product or the service for which the chemical is used and that must be achieved also after the substitution (quality, economic, etc.),
- Identification of potential alternatives, including non – chemical ones
- Assessment of alternatives regarding chemical risks, sustainability and the (quality) requirements,
- Selection of the most promising alternatives for testing; documentation of decision,
- Testing alternatives,
- Evaluation of product/process with a view to the core requirements,
- Decision making.

Some legislation includes substitution requirements, such as OSH legislation (assessment of substitution of CMRs, or the Industrial Emissions Directive (VOCs classified as carcinogens)). Additional information on substitution processes and basic guidance is provided in Chapter 14.6.

9.4.2. Technical controls

Technical controls aim to prevent human or environmental exposure to hazardous substances. They include any measure involving technical equipment that eliminates or reduces emissions from a process. Technical measures may but not necessarily increase resource efficiency at the same time (reduction of “losses”).

Examples of technical measures that reduce workers exposure are:

- Automatic dosage systems feeding chemicals into processes or enclosure / housing in of processes: prevent emissions from the process to the workplace air and prevent direct contact of the worker with any chemicals used

- Automation of manual processes, e.g. change of manual parts cleaning to cleaning in immersion baths or industrial cleaning equipment. This reduces possibilities of skin contact and air emissions of chemicals during the cleaning process
- Local exhaust ventilation: emissions from the process are removed from the workplace and hence, worker exposure is reduced. This measure does not affect dermal risks
- General ventilation: this control is the weakest but still leads to a removal of substances from workplace air via an increased air exchange rate.

Technical controls are usually specific to a process because the technical equipment has to physically fit to the production equipment and the operational conditions.

Technical measures may have different efficacies for different chemicals and their adequacy for a specific substance should be checked with the supplier. Installing an exhaust ventilation only makes sense if the used substances are volatile at operating conditions, or if aerosols are formed during the process, for example. The way, a local exhaust ventilation is installed in relation to a process determines the effectiveness of exposure reduction to a very significant extent.

If a local exhaust ventilation is installed, the emissions from the workplace are eventually released to the ambient air. In the design of measures, it should be ensured that risks are not shifted from workers to the environment, i.e. the installation of a waste gas treatment device to protect the environment may be necessary (cf. Chapter).

There are no specific tools available on technical risk management measures.

9.4.3. Organisational measures

Organisational measures include any measure that concerns the design of a process and the organisation of a workplace, both regarding the location, tools and (number of) workers active at one workplace. Examples of organisation measures are:

- changing the sequence of processing steps, which may eliminate the need for using chemicals or reducing the use amounts
- reducing the number of workers “near” a workplace where chemicals are used; for example, the lacquering booth should not be located next to the break room or bathrooms, as many workers will “walk by” without a direct relation to the work, and be potentially exposed to vapours of lacquer or solvent emissions (reducing “by-stander” exposure)
- reducing the cleaning frequencies by organising product orders: if a product

is supplied in different colours, changing the sequence from bright to dark colours or producing larger batches of the same colour (and storing the products) would reduce the need to clean the painting equipment and hence reduce the frequency of workers having to conduct this (manual) task

- reducing the working time of exposed workers by involving more workers for shorter time periods (reduces the overall exposure of one worker); this measure only reduces the individual exposures, which may be legitimate to prevent acute effects, but it does not reduce the overall exposure potential of workers
- improving logistics and avoid long storage of (wet) materials, thereby minimising the need to use preservatives or fungicides to protect materials from moulding or a deterioration of their quality
- optimising the workplace design to reduce safety risks and ensure a smooth work process.

There are no specific tools on organisational measures. Frequently, the workers themselves have a good understanding of potential organisational measures that would improve the work organisation and lead to a reduction of health and safety risks.

9.4.4. Personal protective equipment

The use of personal protective equipment (PPE) can provide (additional) protection to workers. It reduces exposure by "enclosing the worker" and leaving the chemicals "outside". Examples of personal protective equipment are gloves, overalls, goggles, face masks and filters, and safety shoes.

Select PPE with care to ensure it is effective against the chemical(s) in question. The suppliers' SDSs should include recommendations on the types of PPE that can be used for their product. If several chemicals are used, the selection of PPE may become more complex and require more expertise.

As PPE are uncomfortable to wear, they should be used only if no other protective measures can be applied. SDSs may include information on what equipment to select, but this must be checked, in particular when more than one chemical is used.

9.4.5. Information and Training

Informing workers of chemical risks and ways to protect themselves and regular training on handling hazardous chemicals is an essential element of successful OSH management. It ensures that workers can work safely and are able to react in case of incidents or accidents.

At the workplace

Give workers direct access to understandable information on the hazards and the safe handling of all chemicals they use. Provide workplace instructions or “safety cards” in addition to SDSs. Workplace instructions summarize how to perform the tasks at a particular workplace and should include all relevant information on the used chemicals. All chemical containers must be clearly labelled according to the classification and labelling regulation.

The appropriate handling of chemicals may require additional efforts from the workers, the use of PPE may be uncomfortable. Although training should convince workers of the importance and benefits of implementing the recommendations on safe handling of chemicals, it is useful to “check” the implementation and sanction workers, who do not follow the instruction.

Training

A regular and general training on chemicals and chemical risks, including on understanding the classification and labelling of chemicals and using SDSs should be performed for all workers handling chemicals. In addition, workers with very risky workplaces or who handle very hazardous chemicals should receive regular training on the best practice of managing chemical risks at their workplace. A REACH restriction requires workers handling isocyanates to participate in a respective safety training.

Training and participation in trainings should be documented and a training plan be developed, implemented and kept up to date to ensure regular trainings take place and no worker is untrained.

9.5. Integration into existing routines

OSH management is a well-defined area of chemicals risk management. The assessment of workplace risks benefits from a chemicals inventory (as all information is compiled in one place and available). Do not view implementation of risk management measures separately from other chemicals risk management processes and tasks, because the decision on a measure may involve more aspects than just workers safety and health. Therefore, the person responsible for OSH should be well connected to other relevant departments but may act independently on some issues.

9.6. Step-by-step

The implementation of an OSH management within a CRMS could consist of the following main steps:

- Appoint a person responsible for OSH
- Inform workers of the implementation of an OSH management and ask for their involvement in risk assessments and discussions about potential improvement options at workplaces[15]
- Identify training needs, develop training plans and implement trainings
- Take inventory of workplaces, potentially developing priorities for which workplaces a risk assessment is needed most (in case of limited resources)
- Conduct workplace risk assessments at all workplaces and conclude on action needs; especially when CMRs are used
- Identify and evaluate risk reduction measures, consult the affected workers and consider the STOP principle; consult with other departments on priorities and limitations for risk management as well as longer-term objectives in the use of chemicals (company policy)
- Decide on and implement risk reduction measures
- Develop specific training for workplaces with specific risks and consider the results of the risk assessments
- Implement any needed health monitoring
- Assess risks after measures are implemented to control success
- Develop work plan for the further work including routine tasks, reviews of risk assessments, trainings as well as “projects” to reduce specific risks at workplaces.

9.7. Tools and Links

15 While the identification of risks triggers an obligation to eliminate or minimise the risk it is of course also possible to improve workplace conditions (regarding the use of and exposure to chemicals) also if there is no immediate risks but to improve the overall workplace organisation and workers satisfaction

9.7.1. Workplace risk assessment

- Easy to use workplace control scheme (assessment wheels can be obtained in English but control sheets are only in German, to be checked)
- COSHH[16] essentials (English) COSHH essentials: online control banding tool for chemical agents; slightly complicated to use
- OSHA (checklist page 20)
- Lists of national OELs
  - Estonia: Regulation of Government No. 105 of 20.03.2001, including occupational exposure limit values of chemical danger factors"
  - Latvia: Minister Cabinet rules for normal work day exposure and short time exposure https://likumi.lv/ta/en/en/id/157382-labour-protection-requirements-when-coming-in-contact-with-chemical-substances-at-workplaces
  - Lithuania: Hygiene norm HN 23:2011 "Occupational exposure limits for chemicals. General requirements for measurement and impact assessment". Approved by Order No. 7 of September 1, 2011 of the Minister of Health of the Republic of Lithuania and the Minister of Social Security and Labor of the Republic of Lithuania. V-824/A1-389. Available at: https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.405920/asr
  - Poland:
    - Rozporządzenie Ministra Rodziny, Pracy i Polityki Społecznej z dnia 12 czerwca 2018 r. w sprawie najwyższych dopuszczalnych stężeń i natężeń czynników szkodliwych dla zdrowia w środowisku pracy (Dz. U. poz. 1286, 2018);
    - Rozporządzenie Ministra Rodziny, Pracy i Polityki Społecznej z dnia 9 stycznia 2020 r. zmieniające rozporządzenie w sprawie najwyższych dopuszczalnych stężeń i natężeń czynników szkodliwych dla zdrowia w środowisku pracy (Dz.U. poz. 61, 2020);
    - Rozporządzenie Ministra Rozwoju, Pracy i Technologii z dnia 18 lutego 2021 r. zmieniające rozporządzenie w sprawie najwyższych dopuszczalnych stężeń i natężeń czynników szkodliwych dla zdrowia w środowisku pracy (Dz. U. poz. 325, 2021);
    - Rozporządzenie Ministra Rodziny i Polityki Społecznej z dnia 18 sierpnia 2023 r. zmieniające rozporządzenie w sprawie najwyższych

16 To implement the Control of Substances Hazardous to Health Regulation in the UK

dopuszczalnych stężeń i natężeń czynników szkodliwych dla zdrowia w środowisku pracy (Dz. U. poz. 1661, 2023).

- Models for workplace air exposure
  - ConsExpo software he exposure to chemical substances from everyday consumer products;
  - ChemSTEER to estimate workplace exposures and environmental releases for chemicals manufactured and used;
- Training package on OSH risk assessment by ILO

9.7.2. Risk management measures

Substitution

- SubSport plus portal – general information on substitution, case studies
- Various materials and tools to support substitution by the OECD
- Alternatives to PFAS (database)
- ChemSec Market place
- Kemi guidance on substitution

PPE

- nce and materials on the use of gloves by the UK HSE

Informing workers

- International chemical safety cards by the International Labour Organisation (ILO)
- Training package for work improvement in SMEs by ILO
- Good example of chemical hazard card for information provision
- Template for chemical hazard cards

10. Environmental emissions and waste

Input chemicals can be integrated into a company's products, may react in the process (e.g. 2-component glues or cross-linkers) or may be emitted via waste gas, wastewater, or as waste.

Managing environmental emissions is not only relevant to protect the environment from hazardous substances but may also lead to efficiency gains or cost reductions, for example if fees for water discharges or waste disposal can be saved.

The current approaches to control emissions to the air and water focus on "traditional" pollutants, such as nitrogen oxides (NOx), sulfur oxides (SOx) or certain heavy metals (air) as well as the biological oxygen demand (BOD), and sum parameters, such as the total amount of halogenated compounds (AOX). Individual hazardous substances are only regulated if there are specific requirements in installation permits or local requirements or discharge fees have been imposed.

From the perspective of a "non-toxic environment", persistent chemicals are of highest concern, e.g. PBT/vPvB and PMT/vPvM[17], such as the group of per- and polyfluorinated chemicals. This is because they are neither degraded nor destroyed in the environment and hence exist for a long time. They may accumulate in the environment and concentrations build up over time and eventually reach levels that cause damage to the environment. Another group of priority chemicals environmental endocrine disrupters (EDCs env)[18]. The reduction of emissions of these chemicals should be the highest priority.

The content of hazardous chemicals may contribute to waste being classified as hazardous waste. This triggers additional legal requirements (and costs) for the waste disposals. According to the EU waste hierarchy, hazardous wastes should be prevented and reduced.

The basis of managing chemical emissions is a good knowledge of the flow of chemicals through the company and its processes. The starting point for this is the chemicals inventory with information on the input amounts of chemicals and their uses in products or processes. As (the emissions) of all (relevant) substances cannot be measured to identify emissions, material flow analyses may involve estimates and assumptions based on knowledge of the intended use of chemicals, the design of the processes in which it is used and the properties of the substances.

This section deals with the emissions at site. Emissions from products are discussed in Chapter .

17 Substances with these properties have to be identified in the safety data sheet. They may also have a classification with the H-statements EUH440, EUH441, EUH450 or EUH451

18 These should be indicated via an EUH 430 or EUH 431

10.1. Legal background

Requirements on the emission of hazardous substances to water and air are normally defined in environmental permits. There are certain criteria and conditions defining which types and sizes of installations need to have a permit.

Requirements of a permit may include:

- Emission limit values (ELVs) for waste air, with an obligation to demonstrate compliance either by continuous measurements or with representative measurements of the air emissions,
- ELVs for the wastewater, with obligations to demonstrate compliance either by continuous or representative measurements,
- Reporting obligations about annual emitted amounts to water and air for specific substances.

Depending on the type of your production and where it is located (e.g. in ecologically sensitive areas), specific requirements may be defined in the environmental permit. Even if you do not have a permit, out of responsibility for the environment and good practice considerations, you should consider reducing or eliminating emissions of hazardous substances to the environment.

All companies that generate (hazardous) waste must classify and label it and ensure that it is safely and appropriately disposed of. If waste is classified as hazardous, only specific installations may process it and the disposal process must be documented according to EU legislation. The requirements are transposed to national legislation, i.e. specific requirements may exist.

10.2. Advantages

Analysing chemical flows through the company to identify relevant emissions of hazardous substances to air, water and waste and to optimise products and process with the aim of minimising emissions has several advantages:

- Working on environmental emissions starts with an analysis of the flow of chemicals in the company. This analysis can identify inefficient resource uses and unnecessary losses of chemicals; if consequences are implemented, savings are possible due to
  - more efficient resource use (smaller amounts can be purchased),
  - reduction of (hazardous) wastes resulting in lower disposal costs or
  - the reduction of fees for wastewater discharges.
- Reducing the emission of hazardous substances is a contribution to an improved regional environment and supports wellbeing of the neighbourhood. It increases trust in the company and contributes to a good reputation.

- If emissions are reduced (significantly) below legal limits, accidental incompliance is less likely, and inspectors tend to be more inclined to be cooperative in solving issues with the company.
- Knowing company processes well is a value as such, as e.g. chemical flow analyses can also be used for other purposes, such as technical process organisation, emergency planning, OSH risk assessment and risk management etc.

10.3. Assessment of the flow of chemicals in the company – mass balancing

The analysis of the flow of chemicals is a core tool to identify potentials for resource savings and/or emission reduction. Such mass balances can be useful for companies of all sizes. Their complexity depends on the use of a chemical. In formulation processes, the mass balance is comparatively simple, as chemicals are mostly dosed, mixed and package, with main emission sources being the filling, cleaning, and packaging processes.

The following description guides an initial analysis, which may have to be refined or complemented with measurements or more thorough estimates. It is explained for just one specific chemical to demonstrate the principles.

Identification of use amounts

Use the chemicals inventory to identify which amount of the chemical is purchased and what it is used for in the company. Use the SDS or chemical databases to identify the water solubility and the boiling point of the chemical.

Identification of the workplaces where the chemical is used

Find out, at which workplaces and in which processes the chemical is used. Look at the process design and discuss with technical staff and workers to understand how the use actually takes place. Based on this information, develop a flow chart that illustrates the chemical's flow through the company. Note down if there are sources for emissions to air, water or waste at each of the workplaces and/or if the substance is incorporated into the product.

Quantify flows

Think how the substance may behave during processing and estimate the shares of the used chemical which is integrated into the product, reacts or is emitted to air, the water and the waste for each of the process steps.

You may use measurements of workplace air, waste gas or wastewater as well as knowledge on the composition of wastes to complement and check your estimations. Involve technical experts and ask them for their estimates to further consolidate your mass balance.

Examples of considerations:

- Solid substances may emit to the workplace air as dusts, but this dust may settle rather than being transferred to ambient air. Dusts settling on the floor are disposed of as waste.
- Solvents with a low boiling point will emit to the workplace air. The amounts eventually emitted to ambient air depend on any waste gas treatment and how efficient it is.
- If a process is water based, substances may be emitted with the wastewater, especially when they are water soluble and are washed off. Also here, the existence of wastewater treatment and its efficacy to remove/degrade the substance determine the emitted amounts.

Make a simple mass balance for each relevant processing step and include quantities of the chemical in the process flowchart: Set the input amount at the first processing step to 100% and define the amounts ending up in product, air, water and waste, ensuring that their sum equals 100%. The input amount to the next processing step would be lower than the first, as the emissions must be subtracted. At the end, you should have a flow chart with quantified (estimated/measured) amounts of all inputs and emissions, including to products and wastes, of the chemicals.

Analyse the mass balance

When you have finished the mass balance, discuss it with colleagues and check what it means in terms of resource efficiency and potentials to reduce emissions.

Options to increase resource efficiency and potential measures to implement them, e.g. automatic dosage systems, process redesign to eliminate the use of certain chemicals or lowering operating temperature would benefit both the environment and the company's finances. Hence, they could be a priority to implement and easiest to convince the company management.

If there are processes giving rise to large environmental emissions without abatement technologies, you should start identifying options for emission reduction, starting with substitution, and ending with technical options that may allow the internal reuse or recycling of the chemical use. The options to reduce emissions are like those described in Chapter on OSH. Therefore, they are only briefly described here.

10.4. Emission reduction measures

10.4.1. Substitution

As described in Chapter , substitution is the risk management option that addresses risks at the source and therefore may solve several problems at the same time, such as workplace risks, environmental risks and the occurrence of hazardous wastes. Also, in the context of environmental risk reduction, substitution should start from asking what function a product or chemical fulfils to identify all options for risk reduction, including those based on different materials or technologies.

10.4.2. Technical controls

Technical controls to reduce environmental emissions normally consist of two steps:

- technologies to capture emissions from a process and
- technologies to prevent the emission to the environment by either enabling recycling and reuse of the chemical or by destroying the chemical and/or disposing them as waste.

Capturing water emissions is “naturally” implemented for waters, as it is used in a process in a targeted way, lead through piping and kept in containers, not least to keep workplaces and the installation dry.

Capturing air emissions may be implemented to protect workers and/or to avoid losses of chemicals to the air. Devices and equipment range from closed processes with directly attached exhaust extraction via local exhaust ventilation to the general ventilation of a production hall.

The so-captured emissions to water and air can either be processed to recover a potential chemical substance or be subjected to treatment technologies that destroy the unwanted chemicals. An example of the former are absorbers, which accumulate solvents from waste air, which are then recovered when the absorber is regenerated. An example of the latter are wastewater treatment plants, which degrade organic substances or remove pollutants with the sewage sludge, which is eventually disposed of as waste.

Technical measures may have different efficacies for different chemicals and their adequacy for a specific substance should be checked with the equipment supplier.

10.4.3. Organisational measures

Organisational measures that are relevant to environmental emissions mainly include changes in process designs that lead to changes in the use of chemicals, either a reduction of amounts or, in the context of a substitution, to the use of different chemicals with less harmful properties. Examples are: changing the sequence of processing steps, reducing the cleaning frequencies of paint pistols by better planning of colour changes or improving logistics to avoid long storage of (wet) materials to avoid the need to use biocides.

10.5. Integration into existing routines

Reducing environmental emissions is a core goal of environmental management systems. Hence, if an environmental management system exists, the steps of analysing chemical flows and identifying risk / emission reduction measures should be integrated into the routines and procedures of this system. The environmental manager should either be tasked with the specific assessment of chemicals emissions or at least be closely involved in this work.

If no environmental management system and similar procedures exists, the person working on emission reduction should closely cooperate with the technical staff to derive the mass balances (estimates) and discuss emission reduction options.

In any case a person responsible for the waste management should exist in the company. This person should be involved in any discussions and analyses of emissions to waste. This may lead to reconsidering established waste classifications, e.g. if the content of certain hazardous chemicals had not been known before. You may consider providing additional information on the composition of wastes to ensure safe waste processing.

10.6. Step-by-step

The main procedures of working on emission reduction are described in the above chapters. A possible sequence of implementing these steps is the following:

- Identify priority chemicals for the mass balance; priorities could be derived based on the company policy, identified problems with emissions (permits, fees, wastes) or specific hazards
- Identify use amounts and substance properties
- Develop a mass flow scheme with all (processing steps) and products the chemical is used in
- Identify emission pathways for all steps in the company

- Quantify emissions; the entire input amount should be allocated either to the product, wastes, waste air or wastewater
- Identify problem areas, e.g. large amounts of chemicals ending up in waste, risks of exceeding limit values etc.
- Discuss action needs with colleagues and the management
- Identify risk reduction / emission reduction options and evaluate which one is the most appropriate regarding risk reduction and costs
- Implement the measure and monitor success
- Start with the next priority substance.

10.7. Tools and Links

10.7.1. Identification of environmental emissions / challenges

- Guidance on mass balancing (will be provided later)
- Free tool to develop mass balances of substances STAN (rather high-level)

10.7.2. Substitution

- SubSport plus portal – general information on substitution, case studies
- Various materials and tools to support substitution by the OECD
- Alternatives to PFAS (database)
- ChemStec Marketplace

10.7.3. Technical controls

As technical measures to abate environmental emissions (of hazardous substances) are very specific, no generally applicable guidance or tools exists. The Best Available Technology Reference Documents for the chemical industry might be a starting point, however.

11. Product safety and consumer risks

Companies must ensure that their products are safe for consumers to use, i.e. if mixtures are used for what they are intended, no risks should occur. Additionally, also environmental safety should be considered, and a holistic view be taken on the impacts of the own product.

It is obvious that products should neither harm their users nor the environment, but it is not so obvious what that means in practice and how formulators can ensure that this condition is fulfilled. This may include considerations about wider environmental impacts, such as on climate change.

11.1. Legal background

REACH Annex XVII prohibits the use of certain substances in mixtures above specified concentration limits that are available to the public, namely CMRs of the category 1A or 1B. Further restrictions are contained in that Annex for specific substances. New restrictions may be included in the future.

There are additional requirements for specific mixtures available to consumers, such as detergents or cosmetics, which are briefly introduced in the Overview of Legislation.

The EU General Product Safety Directive, which is transposed into national legislation (c.f. Overview of Legislation), specifies that products on the market should not cause any harm to consumers under normal and foreseeable conditions of use. The scope of that Directive includes all products that are intended for the consumer use or may reasonably be assumed to be used by a consumer. Hence, all mixtures which are freely available on the market, including in DIY stores, fall under this legislation.

The legislation does not prescribe or provide any specific methodology for the risk assessment; however, compliance with product-specific standards is regarded as one means to ensuring safety.

11.2. Advantages

Assessing legal compliance thoroughly and including further considerations about product safety in the evaluation procedures can help:

- Preventing liability claims and potential damage to the brand name, as potential risks are identified and can be managed
- Better understanding not only of the benefits of the own product but also its potential drawbacks and hence, identifying improvement potentials
- Supporting the development of green claims and/or the application for ecolabels as well as identifying aspects that could also be used for marketing purposes.

11.3. Assessing product safety

11.3.1. Compliance check

Start the product safety assessments with a thorough compliance check and assess requirements from all applicable legislation (cf. Chapter). As a minimum, answer the following questions:

- Are there any restricted substances contained in the mixture above the allowed concentration limits?
- Is the classification of the mixture correct?
- Does the product label conform with all requirements?
- Has the mixture been notified to the authorities (cf. section)
- Does the product conform to existing standards, e.g. under the construction products regulation?

11.3.2. Consumer risk assessment

As a general rule, consumer mixtures should not contain CMRs or other hazardous substances at all. However, this may not always be possible.

The use of consumer mixtures should be safe without any risk management measures because you cannot assume or ensure that consumers wear gloves or goggles, for example. If the use of hazardous (classified) substances cannot be avoided, those with the lowest hazard should be used.

No specific rules or guidelines for the safety assessment of consumer mixtures exist. Perform at least a qualitative assessment by considering the mixture's classification, how it is normally used, and which exposures could occur. You may have to investigate this more deeply if the hazards and exposure routes of substances indicate potential risks at a qualitative level.

In the qualitative assessment, anticipate the normal use of the mixture and identify all potential consumer exposures. Check if dermal contact is possible and which areas of the skin may be exposed for how long. Consider if spills may reach the eye. Assess if substances in the mixture be inhaled via aerosols, vapours or as dusts. Check ingestion possibilities, e.g. dishwashing agents remaining on dishes.

To identify a risk, compare the exposure levels with the effect thresholds quantitatively (cf. Chapter on risk assessment). If the mixture contains a considerably hazardous substance and the user is most likely significantly exposed, you may immediately conclude the risk is unacceptable and seek for substitution.

A description of risk assessment principles, including for consumer risks as well as for the evaluation of the overall impacts of a product, such as a chemical mixture, is provided in Chapter . Links to tools are provided in that section for the risk assessment as screening or expert level.

11.3.3. Risk reduction measures for products

As for the management of occupational or environmental risks, substitution is the most far-reaching and effective measure of risk reduction if alternatives are available that are less harmful. Hence, if there are concerns that a mixture could cause consumer risks, this should be the first measure to check.

There are not too many additional measures that can be implemented for consumer mixtures, because neither technical measures nor the use of personal protective equipment should be a condition for safe use by consumers. Therefore, mostly the exposure potential of the mixture could be reduced by changing the form of mixture and how it is used. One example is washing agents for textiles: Instead of providing them as powders, alternatives with lower exposure potential are liquids (no dusting but risk of spills to the skin) or pre-packaged portions of the washing powder, which is contained in a packaging that dissolves in the washing machine (no dusting, no direct contact with the skin). Similar approaches consist in the change from spray to foam applications or to design packaging in a way that dosing or pouring is less prone to give rise to skin exposure.

11.4. Integration into existing routines

Product safety aspects related to chemicals may be allocated to several departments or responsibilities. For mixtures, it seems most appropriately allocated to the department for the design of products and/or for quality control procedures. However, the overall responsibility may also be allocated at the environmental manager, if one exists, or the sales department.

The two parts of ensuring product safety – risk assessment and implementation of risk management measures – may also be divided between departments and staff with the relevant expertise.

The risk assessment should become an integral part of any new product development to ensure that mixtures are safe from the start. If no such assessments have been performed up to now, a plan should be developed for a successive assessment of all mixtures, starting with those containing the most hazardous substances.

11.5. Step-by-step

Implement the following steps if no systematic work on product safety has been performed, yet:

- Identify staff who could implement a product safety assessment in terms of competences and resources; if competences are lacking, identify options for training a person to perform at least a qualitative risk assessment of products
- Prioritise mixtures for risk assessment based on their classification and/or content of hazardous substances
- Define how broad the product safety assessment should be performed: as a (legal) minimum it must be assessed that the mixture does not cause any harm to the user during normal and foreseeable use. Extensions of this scope could be to
  - Include environmental safety
  - Assess product safety along the entire lifecycle, e.g. up and down the supply chain and regarding the waste treatment
  - Assess the sustainability of a mixture, i.e. including non-toxic environmental impacts such as on climate change or resource use
- Carry out and document the assessment of one or several mixtures and identify if there is an action need. The assessment may start with a screening / qualitative approach and be refined if the results are ambiguous or considered as too rough for decision making.
- Interpret the results
  - If there is no action need, document and proceed to the next mixture
  - If there is an action need: inform the relevant staff of the assessment results and identify options to reduce risks. Monitor implementation and assess results.

11.6. Tools and Links

Expert tools for the assessment of consumer risks from mixtures are:

- ConsExpo
- ECECTOC TRA consumer tool (Download necessary)
- Database on restrictions under REACH (Annex XVII)

12. Communication

Ensuring chemical safety is based on good communication and high-quality information being passed along the supply chain, to the users of products as well as to authorities. Information on hazards and risk related to (the use) of a mixture is an integral part of the product itself and should therefore not be neglected.

The main requirements to communicate about chemicals should be known to you, as they are the very basis of your business. Therefore, no detailed guidance on classification, labelling and packaging as well as the compilation of SDSs is provided.

Chemicals risk management relies on good communication within the company but also up and down the supply chain. This does not only concern the legally required communication but also all efforts implemented in addition to that to facilitate safe use, substitution and/or compliance of downstream users.

Communicators in companies should be trained and know about chemicals and chemical risks. Information providers should be aware of the needs for information from their customers, information receivers should ensure the information suppliers know why they need what information and not ask for any information that is not needed. Standardised communication, e.g. exchanging compliance declarations is not sufficient in many cases.

12.1. Legal background

The CLP regulation is one of the core pieces of legislation applicable to mixtures and should hence be the basis of your work.

The requirements for communicating about chemicals - substances and mixtures - in form of an SDS are defined in the REACH regulation: An SDS must be provided for all classified substances and mixtures and for all mixtures on request of the customer, which contain substances posing health hazards above 0.1%. The SDS must be compiled in accordance with REACH Annex II and provided in the language of the Member State, where it is placed on the market.

In addition to the SDS, classified substances and mixtures must be labelled, indicating the main hazards and protective measures to take at the workplace, for the environment and potentially also for uses further downstream and for waste disposal. Also, the design of packages and what information must be provided on it is defined in legislation. Both provisions are included in the Regulation on Classification and Labelling of Chemicals.

Another legal communication obligation is the notification to the poison information centres (PCN), which is standardised and concerns data on the composition and hazards of a mixture.

According to REACH, the use of authorised substances must be notified within 3 months after starting the use to the European Chemicals Agency. More information on how to submit a notification is provided on ECHA's website.

Further national communication obligations may exist, e.g. on whether SVHCs are used, and in which amounts (cf. Overview of Legislation).

12.2. Advantages

- Compliance with the legal communication requirements ensures future operation of the business.
- Having trained staff able to communicate with suppliers ensures all necessary information for CRM is available and that a trustful relationship can be built up and maintained to suppliers. This can be a good basis for improving chemical safety, including to find alternatives, and replacing unwanted chemicals.
- A competent contact person that customers can turn to and get information from is the basis for a good business relationship. It helps securing markets, building trust and implementing changes as needed.
- Good communication with authorities can help being informed about upcoming legislation, identifying options to improve operations at site and implementing a cooperative rather than a confrontative relationship.

12.3. Communication with different target groups

12.3.1. Suppliers

You should have just one contact person for your suppliers and vice versa, you should ask for a stable contact person on the side of your suppliers. If either one lacks information or background further staff may be involved internally.

The person communicating with the suppliers should be competent and explain the background of any requests to ensure the answer is useful for the company and the supplier knows that the efforts he will make to answer it serves a purpose.

You may want to document experience with supplier contacts (e.g. in a supplier database or as a note in the chemicals inventory). For example, note down if a supplier provides current SDSs only after you asked him 3 times or if the supplier's contact person is not competent. This information supports decision making on (future) business relationships.

There are different reasons why communication with suppliers may be necessary:

- You have questions or needs regarding the compliance of supplied information, e.g. an updated SDS is needed; in this case the supplier is legally required to provide information and if he does not do so, you should consider changing the supplier.
- You may need additional information about a product that is already used, e.g. regarding the purity of a substance or the composition of a supplied mixture; the supplier is not required to answer but should do so in order to build trust and keep you as a customer.
- You want to phase out a substance or mixture of that supplier and you want to discuss if he offers alternatives that are less harmful and with a similar function; in this case, the supplier should answer in order to keep you as a customer; you watch if there are any attempts to convince you to keep using the original product and what is your assessment of such behaviour.
- You need a new input material and contact a supplier to get information and potentially also samples for testing the product in your production. You may build on existing relations if you already know the supplier or establish new ones. In either case, suppliers should be open and take time to communicate with you.
- You want to make a supply contract for a longer time and potentially include conditions about the purity of substances or the content of hazardous chemicals in any mixtures you intend to purchase. Such contracts could also include requirements to show such conditions regarding purity or content are fulfilled, e.g. by chemical analyses.

The information provided by the supplier should be checked, especially if the supplier is new and you do not have experiences with the quality of information he provides. Hence, check the quality of SDSs you receive and look for information in alternative sources, such as ECHA's database on registered substances or from other suppliers. The staff compiling your own SDSs will be competent to do that. The quality of the (legally required) information is a good indicator for the trustworthiness of the supplier and the quality of the product alike.

If you request substances of a particular purity or define lists of substances which must not be contained in the mixtures you purchase from a supplier, you may consider making a few random chemical analyses to test if the products are compliant or not.

12.3.2. Customers (businesses)

When considering how you communicate with your customers, you need to change perspective but can use your own experience from communicating with your suppliers. What approaches of your suppliers do you like? What services do you expect and where have you been disappointed in the reaction of your suppliers. This gives you a lot of information on how you should set up your communication to your customers.

- Make communication with customers about the chemical safety of your products a high priority and consider providing respective information as integral part of your products.
- Provide up-to-date, high-quality and compliant SDSs; ensure any changes in input materials or are reflected in the SDS of your product.
- Ensure you have a competent person in charge of taking customer requests, who can either directly respond or coordinate the necessary actions within the company to generate the needed information.
- Establish a good relationship with your customers (and their contact person) – it is the basis for trust and cooperation, including in product development when substances need to be substituted, and will support you in maintaining your markets.
- Don't ignore your customers' information needs and do not make differences for those who purchase only small amounts; all of them need to get your complete product to ensure safe handling and use!

Customers may request you to document compliance with certain legal requirements. Make sure you answer to these requests and provide that documentation, after having checked that the conditions are implemented. This could be the case if you supply your mixtures for use in contact with food or if you supply the electronics sector, where RoHS compliance may be relevant.

Some sectors, like the automotive industry already have or may implement in the future, tools to communicate about chemicals in products. The automotive industry operates the so-called International Material Data System (IMDS) and requires all suppliers to report the composition of their products to this system via their supply contracts. Here, the communication is very standardised but supply contracts and discussions on e.g. substitution may still be necessary and important.

12.3.3. Consumers

If you produce mixtures for consumer use, a different type of communication is needed than for commercial customers. Usually, there is no direct contact with the consumers and the communication is 'one-way', i.e. you should provide all information that is useful and necessary to ensure consumers use your product safely and in the intended way.

While it is legally defined what chemical safety information must be provided on chemical labels and on packaging, no requirements exist for the provision of additional information on chemical mixtures for consumer use, i.e. no SDS is needed. The use of eco-labels may be an option for additional communication that supports the marketing of your product and guides consumer decision making.

12.3.4. Authorities

Communication with authorities is almost entirely related to compliance with chemicals and product legislation (c.f. section). Communication instruments like digital reporting tools, surveys or other forms of communication, such as e-mails or letters may be used.

One important example is the poison centre notification (PCN). In accordance with the provisions of Annex VIII to the CLP Regulation, importers and downstream users placing on the market mixtures classified as hazardous on the basis of their health or physical effects shall provide information to the appointed bodies[19] in all the Member States where the mixture is placed on the market. This obligation may also take effect, when product identifiers (for example re-branders and re-labellers) are changed and/or the mixture is supplied in other Member States, not (yet) included in the formulator's or importer's notification.
The notification is provided using a specific format. A Unique Formular Identifier is assigned to the mixture (UFI) and just be placed on the product label. This number links the specific product/mixture to the notified information (including toxicological data). Including the UFI number in the SDS is voluntary and recommended.
The notification dossier is prepared using the IUCLID format, an internationally harmonised data format for chemicals, and should be submitted online via the ECHA Submission Portal. This requirement is binding from 1st of January 2025 for all mixtures falling within the scope of Annex VIII of the CLP Regulation.

In addition, authorities may also be information providers, e.g. if legal requirements are not fully clear. According to REACH, all Member States must have a helpdesk to answer questions on the implementation of that legislation, for example. Authorities provide information on legal developments on their websites, send out newsletters or offer information events to companies to get information about current and potential future requirements.

19 Usually, but not always, the appointed body is the poison information center itself.

Another opportunity of communication with authorities are public consultations on legislation, either at national or at EU level. Here, authorities ask for information about the use of substances or substances groups to target legislation and assess potential impacts of their regulatory actions. It is advisable to provide information to these consultations to ensure the own sector and products are well reflected.

12.4. Environmental claims and eco-labelling

There are three types of eco-labels that can be used to highlight environmental benefits of mixtures: Third-party certified eco-labels, self-declared sustainability claims and verified environmental labels.

Examples of **third-party certified ecolabels** are the EU ecolabel, the Nordic Swan and the German Blue Angel. They guide consumers' purchasing decisions by differentiating products with an increased environmental performance from those with an average or low performance. The organisation awarding an ecolabel defines the criteria labelled products must fulfil and sets up a system to verify applications. The criteria are publicly available and concern different aspects, including chemicals. Products that fulfil the criteria may apply the logo of the eco-label on their packaging.

Self-declared environmental claims are statements about environmental and/or health impacts of the product, which are based on information and assessments of the company. The underlying argumentation and data should be correct and made accessible for anyone to verify the claim. If such information is not published, the claim is much less credible. Additionally, such claims should not be misleading. For example, "Bisphenol A (BPA) free" is used suggesting no BPA-related hazards are relevant for the product; however, if another, similarly hazardous bisphenol has replaced BPA, the statement is misleading. Such claims should follow the requirements of the "Green Claims Directive".

Environmental product declarations provide detailed information about the environmental impacts of a product following the ISO standard 14025:2006. They must be based on a life-cycle assessment. Usually, such product declarations are not used too much for the communication with consumers but are rather part of the business-to-business communication.

Environmental claims in general and regardless of their form should be reliable, relevant, and clear, and be accompanied by transparent and accessible information and arguments.

12.5. Chemical analyses and testing

Laboratory analyses can be a good approach to check supplier information in case of doubt and/or to get additional information on chemicals in the raw materials purchased. It may also be needed or useful to generate information on the own product to check compliance or to provide proof of compliance to customers.

Depending on the scope of the analysis and its purpose, different analytical techniques and methods are used, for example, chromatography, or spectrometry to identify and quantify the content of substances.

Testing facilities

If you have a laboratory in the company, you may conduct the respective tests in-house. Most companies will sub-contract laboratories which offer a wide range of services and tests. When you select a laboratory, ensure it works according to good laboratory practice so the results will be widely accepted. Lists of accredited laboratories may be available from the national or regional accreditation bodies. At the EU level the NANDO will be a good contact.

Why to analyse or test in a laboratory

Testing may be legally required, triggered by customer requests, or implemented as one element of quality control. While scope and frequency for legally required assessments are defined, any additional, voluntary work is defined by the company based on the needs. It may be sufficient to do just spot tests, e.g. to test one product. Reasons to analyse or test input material or the own product may include:

- quantification of substances in input materials, e.g. to check information from suppliers
- identification of potential contaminations with unwanted substances in input materials
- assessing certain performance parameters of chemicals/ products,
- classification of physical-chemicals properties
- documentation of compliance for customers, e.g. absence of (a list of) restricted substances to underpin a declaration of conformity
- defining the share of volatile organic compounds in a product.

Planning chemical analyses

Start with defining the purpose and scope of any measurement and carefully select the parameters which would answer open questions. Analyses for compliance purposes are normally very clear in this regard. Experienced laboratories can provide competent support. Consider how often a measurement is needed, i.e. tests for classification have to be performed only once, whereas analysis for quality control purposes should be undertaken regularly.

12.6. Integration into existing routines

Communication with suppliers is normally part of the purchasing department's work while communication with customers is usually part of the marketing department and communication with the authorities is integrated into the legal department. Although specific questions about chemical safety might require the support of the staff working with the technical processes or on product quality etc., it is useful to have dedicated people who are trained in communication and knowledgeable of the basics of the products that are purchased or sold.

If an environmental management system already exists, procedures, guidance and rules for working with suppliers and customers may already exist and could be amended to include any additional issues that stem from working on chemical safety.

12.7. Step-by-step

- Assess the implementation of legal requirements on communication and ensure your company provides good, up-to-date SDSs for all products that require one.
- Identify current routines, responsibilities and experiences of communicating with suppliers, customers, consumers and authorities.
- Evaluate past communication with the staff having implemented the communication:
  - Are there any internal guidelines? Are they implemented? Is that useful and what has proven not to work well?
  - What are main learnings from communicating with suppliers? Is information obtained? What can be learned from suppliers about do's and don'ts in customer communication?
  - What are the main learnings from communicating with customers? What questions are being asked? Is any feedback obtained on the provided information? How efficient is the provision of information to customers?

- How does cooperation work within the company to support the communicators in the purchasing and in the sales department?

- Identify improvement options for communication up and down the supply chain and implement them.

You may consider including communication goals into the company's chemicals policy to increase the importance of safety information and ensure sufficient resources are made available, especially for the compilation of good SDSs.

12.8. Tools and Links

Communication with suppliers

- Template and building blocks for supply contracts – conditions regarding purity / restricted substances
- Checklist Safety Data Sheets

Communication with customers

- Template for a Declaration of Compliance
- Some more information on the compilation of Safety Data Sheets is provided in Section

Guidance on Poison Centre Notifications

- Guidance on harmonised information relating to emergency health response – Annex VIII to CLP
- PCN: a practical guide
- UFI Generator
- UFI Generator application: User Guide

Communication with consumers

- Ekodizaina Kompetences Centrs (2019). Use of environmental claims: best practice guide. https://www.fitreach.eu/sites/default/files/editor/publications%20ENG/Use%20of%20environmental%20claims.pdf. Accessed 20 December 2021.

Testing and analyses

- OECD resources on Good Laboratory Practice (GLP), accessed 18 October 2022
  available at: https://www.oecd.org/chemicalsafety/testing/good-laboratory-practiceglp.htm
- Database of accredited bodies for testing the safety of toys in the EU, accessed 18 October 2022, available at: EUROPA - European Commission - Growth - Regulatory policy - NANDO

Eco-Labelling

- Link list to most common Eco-labels (will be provided later)
- Guidance on product declarations (will be provided later)

13. Closing the management cycle – performance measurement and revising goals

To maintain the process of continuous improvement in chemicals risk management the step of monitoring progress, comparing the results to the goals, analysing potential deficits and defining new or revised goals is essential.

The aim of CRM is a continuous reduction of chemical risks to all subjects of protection. Risk reduction can be achieved by reducing the use of hazardous chemicals (substitution, increased efficiency), reducing emissions and exposures via technical or organisational measures, the (re-) design of products, or the use of PPE. All these activities may be implemented as part of the CRM.

13.1. Legal background

As there is no legal requirement to implement a CRMS, no requirement to monitor its implementation exist either. However, for example the implementation of the corporate sustainability reporting directive benefits from data generated in the CRM review to assess the implementation of goals. Similarly, any obligations related to environmental emissions, worker protection or waste may be supported by information generated in a review of the implementation of the goals.

13.2. Advantages

A structured review of if and how well the goals of the chemicals policy are achieved allows to analyse (the efficiency of) internal processes or any hindrances to achieving risk reduction. It can be used to document efforts in chemical safety to external stakeholders, but also to motivate the own staff to continue their efforts.

If combined with e.g. economic figures, a structured assessment of progress may be useful to identify what changes have resulted in better market access or improved business relations along the supply chain. Positive trends can then be enhanced in a targeted manner, for negative trends an analysis of how to better implement risk reduction may be needed to align safety with economic needs.

13.3. Principles of progress monitoring

The data collection and analysis of progress monitoring largely depends on the company policy, the specific targets defined for its implementation and the related indicators of success (cf. Chapter). These should be defined in the monitoring plan and be collected according to the monitoring schedule.

If it turns out that some data cannot be obtained, the related indicator might have to be changed and implemented in the next phase of chemicals risk management.

The method of data collection may have to be defined in the monitoring plan as well to ensure data are comparable over time. One example could be the calculation of the amounts of substances used, where the stocks at the beginning and end of the year could be considered, depending on whether they are stable or fluctuating a lot.

13.4. Integration into existing routines

The person responsible for implementing the CRM activities should also be in charge of the progress monitoring. If an environmental management system exists, the indicators and data collection could be integrated into the existing ones.

The chemicals inventory, the purchasing and the sales department as well as the technical staff in charge of environmental and OSH may be important sources of information. They should therefore be informed of any data collection, so they have sufficient time to provide it.

13.5. Step-by-step

- Inform all relevant persons of the start of the review process
- Collect data to monitor progress towards the chemicals risk management goals of the company.
- Compile a draft report, which describes for all chemicals risk management goals:
  - Situation at the beginning and problem definition
  - Overall goal and specific targets
  - What activities were implemented
  - Result and indicator of success
  - If the goal was not achieved, analysis of reasons and recommendations on what could be improved
- Discuss the report with the relevant persons in the company, including the top management
- Decide on revised and/or new goals to start a new risk management cycle.

13.6. Tools and Links

- Self-assessment questionnaire

14. CRM methods and tools

14.1. Classification of Chemicals

The classification of chemicals ensures that all actors along the supply chain understand what types of adverse effects a chemical could cause. The classification is harmonised at global level.

The classification of mixtures is part of the core business of your company. This handbook only provides some framework and guiding information on this topic, as competence gaps should be filled by professional training rather than this handbook.

14.1.1. Legal background

All substances and mixtures placed on the EU market must be classified according to the rules set out by the EU classification and labelling regulation. Additionally, substance manufacturers and importers must notify the classification to ECHA's classification and labelling inventory (CLI). Mixtures do not have to be notified.

You should receive all relevant information on the hazards of substances or mixtures you purchase from your suppliers in the form of an SDS. The CLI is a good source of information to check that information. You are required to use at least the suppliers' SDSs to derive your classification of the mixture (and compile your own SDS).

The classification of (substances and) mixtures requires chemicals expertise. In the Baltic States and Poland no specific legal requirements on the staff's expertise exist. The task of classification may be outsourced to external service providers; however, the responsibility of the correct classification remains with the placer on the market.

14.1.2. Integration into existing routines

The classification of mixtures (and related compilation of SDSs) can either be attached to the "product quality" or at an overarching department, which classifies all mixtures in the company. As this work is part of the core business, it is assumed no changes are needed in the frame of the chemicals risk management system.

14.1.3. Step-by-step

- Check the national requirements for classification and labelling of mixtures.
- Assess if all requirements are in place and if staff is sufficiently trained to either do the classification or check the correctness of any external services classifying the mixtures.
- Develop routines to ensure that any new (hazard) information on substances is reflected in all relevant mixture classifications.

14.2. Safety data sheets and Hazard communication

The safety data sheet is the main communication tool and information source on chemicals in the supply chain and for risk management. Its quality is therefore of high importance.

The SDS structures hazard and risk information on chemicals, so that all users can find the data they need for their particular purpose. Therefore, it is very important that SDSs are of good quality, compliant and concise.

As not all SDSs are well prepared, and information may not be always reliable, it is advisable to at least cross-check important information and ask the supplier if there is unclear or contradictory information.

14.2.1. Legal background

According to REACH Art. 31, you must automatically provide an SDS with any mixture that is classified as hazardous and on request if it contains substances that are hazardous to human health in concentrations exceeding 0.1%. The format of an SDS is described in REACH Annex II. The SDS must be in national language.

You should consider the information from the exposure scenarios of substances and mixtures that you receive from your suppliers for your mixtures. REACH does not fully define what this means in practice and how the information should be forwarded and provided for your mixture: it could be an exposure scenario for the mixture or just the integration of information into the main chapters of the SDSs.

The EU industry associations have developed some formats and tools for some industry sectors/mixtures, but not for all.

14.2.2. Advantages

In addition to being legally compliant, if you compile high-quality, concise, and useful SDSs, your customers will trust more in your company and the safety of your products. In addition, you will get less frequent requests from the customers if you do it right from the beginning.

14.2.3. Use of the SDSs of suppliers

Here are just some guiding questions to help you make best use of your suppliers' SDSs:

- Is the SDS of your supplier up-to-date, and correct?
  You may make random checks or inquire more when you see inconsistencies or are in doubt. Compare the exposure scenario with the information in the main body, for example.
- Is the SDS information used for the classification of the mixture?
  Ensure the most recent version is available to the classifiers (in case of changes in hazard). Coordinate with the chemicals inventory.
- Are all exposure scenarios (ESs) considered in the SDS for your mixture?
  Check with the existing SDSs if any of the ESs contradict the advice you give on safe handling and use of chemicals
- Ensure that the suppliers' SDSs are available at all your workplaces and that any relevant information is available also in short form to the workers
- Consider storing SDSs at a central location, so that everyone who needs information can access them easily.

14.2.4. Some tricky issues

Identified uses

The SDS from your supplier should include the "identified uses" in the first section. An identified use is a use of the substance for which the supplier has made a chemical safety assessment as part of their registration and found out that no risk occurs from the substance under the condition described in the main body of the SDS or the attached exposure scenario. These uses can be considered as "allowed", whereas uses which are not covered by the list of identified uses are generally "not allowed".

Consequently, it is essential that you always check that your use of a substance is listed in Section 1 of the SDS of your supplier. If this is not the case, you have several options:

- Notify your supplier of your use and ask him to include it in his chemical safety assessment to make it an identified use, i.e. list it in Section 1 of the SDS. A supplier may or may not implement your request – this will depend on his "service mentality", the available resources for the assessment, the volume of chemicals he sees at risk if the use is not covered (the number of uses having asked for the use to be identified) and, not least, whether the use is actually safe.
- Find a supplier of the same substance who identifies your use in the SDS. The likelihood of finding an alternative supplier depends on the specificity of your use.

- Substitute the substance and use one for which the use is identified – this option will only be relevant if substitution is very easy and/or if substitution was anyway planned.
- Make a so-called downstream user chemical safety assessment and assess potential risks from your use of the substance and the uses of the downstream users. If there are no risks, you can continue using the substance for that use. You must then describe the conditions of use underlying your chemical safety assessment as obligatory conditions to your customers (if relevant) and attach your downstream user CSA to the SDS.

Registration numbers

All substances that are registered under REACH receive a registration number. However, not all substances that you may purchase are necessarily registered, and therefore, not all substances will have such number in the SDS.

All substances produced or imported in amounts below 1 t/a do not have to be registered under REACH; therefore, no registration number exists. There is also no requirement to register polymers as well as some other substances, which are covered under other legislation.

If there is a registration number of a substance you use, you must copy it to your SDS and list it alongside the CAS number if the substance has to be identified in your mixture (i.e. it contribute to the classification).

Authorisation numbers and conditions

If you use SVHCs that require authorisation in your mixture, which you should avoid wherever possible, you are only allowed to do that if an authorisation has been granted for your use and your customers' uses. If your supplier has applied for authorisation, he will include an authorisation number in his SDS for this substance and include specific and strict conditions of use in the SDS and related information.

It is essential that you copy this information to your SDS. The authorisation number allows authorities to check if the use of an SVHC is allowed (authorised). The authorisation is granted only under specific conditions, which should ensure emission and exposure minimisation for humans and the environment. These conditions may concern your own handling and use of the substance but also that of your customers. Hence, it is important that you communicate these conditions with your safety data sheet.

14.2.5. Integration into existing routines

The compilation of safety data sheets may be attached to the “product quality” or at an overarching department, which compiles the SDSs of all mixtures of the company. As this work is part of the core business, it is assumed no changes are needed in the frame of the chemicals risk management system and it is well integrated into the system.

14.2.6. Step-by-step

- Check if the requirements for SDSs are correctly implemented.
- Assess if staff is sufficiently trained to either compile SDSs or check the correctness of any external services making SDSs your company.
- Develop routines to ensure that any new (hazard) information on substances is reflected in all relevant SDSs.
- Ensure there is a good communication between the staff classifying mixtures and developing SDSs, if not done by the same people anyway.

14.2.7. Tools and Links

- SDS guidance for formulators (will be provided later)
- SDS guidance by ECHA

14.3. Assessment of Chemicals

Chemicals risk assessment is the core action to identify in what way the use of a chemical is problematic. It is the basis to decide on the urgency of action and identify effective and efficient options to act.

At EU level, a standardised methodology exists, which is described in guidance documents for implementing chemicals legislation. According to this methodology,

> a substance causes a **risk**
> if the **exposure** to that substance **exceeds** the
> **threshold** above which adverse effects are expected.

$$\frac{\textit{Exposure}}{\textit{Hazard}} = \frac{\textit{Exposure level}}{\textit{(Eco-)toxicological threshold above which adverse effects are expected to occur}} = \frac{\textit{Concentration / dose}}{\textit{DNEL* / PNEC**}} > 1 = \textit{Risk}$$

* Derived no effect level = threshold for human health
** Predicted no effect concentration = threshold for the environment

This is expressed with the following equation:

The effect thresholds are:

- Derived no effect level (DNEL) = dose above which an adverse human health effect is expected
- Predicted no effect concentration (PNEC) = concentration above which an adverse effect is expected for the environment

These values are specific for one substance and may be provided in the SDS of the substance or the mixture it is contained in. They may also be available from ECHA's database on registered substances.
Please note that this information is not normally available for substances, which are manufactured or imported below 10 t/a per manufacturer/importer. This is due to the lack of a requirement to derive these values for substances in lower volumes. If DNELs/ PNECs are missing, analogue values from other legislation, such as workers protection in the EU (OELs) or reference values from the US, Canada etc. may be researched and used. If no values are available, a quantitative risk assessment is not possible.

DNELs and PNECs need to be selected in accordance with the assessed exposure

pathway: if risk from inhalation is assessed, the DNEL for inhalation must be used. DNELs and PNECs may not be available for all exposure pathways.

14.3.1. Generic risk approach – substances of very high concern

Substances of very high concern (SVHC) can cause very serious, irreversible effects and some of them do not have an effect threshold, i.e. no dose or concentration can be determined below which there is no effect. This may be the case for mutagens and carcinogens as well as endocrine disrupting chemicals. Additionally, for some SVHCs exposure cannot be controlled; because of their persistence they accumulate in the environment and the food chain and may eventually reach concentrations, where adverse effects occur. This is the case for PBTs/vPvB and PMTs/vPvMs. For both types of chemicals – non-threshold substances and persistent substances - no quantitative risk assessment can be performed. Instead, as a default, emissions of these substances should be minimised as much as possible.

Any of the SVHCs, also the non-persistent threshold substances, cause concern due to the severe environmental and health effects they may cause. As the concept of "zero emission" is unrealistic – all uses of chemicals cause some emissions – for these chemicals the EU set the goal of an eventual phase-out and replacement with safer alternatives, as soon as possible and whenever feasible.

As for any chemical, the use is associated with emissions and any emission/exposure of SVHCs is of concern due to the severe environmental and health effects they may cause, in the regulatory context a detailed exposure assessment is not required. Instead, the generic risk assessment allows to conclude on an existing risk for uses of SVHCs, at least in consumer products.

14.3.2. Quantified risk assessment

For all substances that are not persistent and do have an effect threshold, risk assessment can be performed in general, as the comparison of DNEL/PNEC with an exposure level is mathematically possible. Depending on its purpose a chemical risk assessment can have different scopes, for example:

- The workplace risk assessment aims to identify if workers are at risk from all chemical agents that are present at one specific workplace.
- An assessment to meet the requirements of the General Product Safety Directive (respectively its national implementation) checks if consumers, during normal and foreseeable use of a product, are at risk from the contained chemicals.
- The chemical safety assessment under REACH covers all lifecycle stages

and aims to identify any potential risk to consumers, workers and the environment.

- A sustainability assessment not only considers all chemical risks of a substance but also evaluates its other environmental, as well as social and economic impacts.

In your company, conducting workplace risk assessments is a legal requirement and needed to find out if precautionary measures are needed to protect your workers (Chapter).

If your mixtures are used by consumers, you should also assess whether the use is safe for them during normal and foreseeable conditions (Chapter). Depending on the ambitions of your CRMS and the progress monitoring, you may also want to conduct sustainability assessments of our products (c.f. next two chapters), especially if you plan to assess alternatives in substitution processes.

14.3.3. Assessment of chemical risks along the life cycle

If you plan to substitute a substance in your mixture, it is important that you compare different alternatives and make a holistic risk assessment for the entire lifecycle and all subjects of protection (workers, consumers, and the environment).

If your alternatives are also chemicals (drop-in solution or 1:1 substitution), the conditions of use along the lifecycle may be:

a) very similar if the replacement chemical does not change the main characteristics of the product and how it is processed,
b) or may differ significantly, e.g. if a solvent based paint is re-designed to become a water-based paint, where both the application and the curing / drying process of the paint may have to be significantly changed after substitution.

In the former case (hardly any changes in further processing), it is sufficient to compare the hazards and the mobility (vapour pressure, water solubility, dustiness etc.) of the substances to identify which alternative is better than another.

In the second case (changed application and processing), an assessment of the conditions of use is needed to characterise and compare the exposure and risk levels from the use of your mixture. This requires assessing risks at your production site but also for all following lifecycle stages. As you are unlikely to know the specific conditions of use at your customers' site(s) and further downstream, you may use tools and default assumptions for the exposure assessment. We recommend the tool "ECETOC TRA" for an initial risk assessment.

Tools

- Chesar – ECHA's tool to conduct a chemical safety assessment according to REACH; it is designed for individual substances but not mixtures
- ECETOC TRA – The Excel-based tool allows calculating chemical risks and was designed for use by the registrants under REACH

14.3.4. Sustainability assessment of chemicals

Chemical safety is an important part of the concept of sustainable chemicals. In addition, elements of the further pillars of sustainability – environment, economy, society are considered. The assessment of sustainability can further inform substitution decisions to complement information on toxic risks. This makes the assessment more holistic but also more complex and challenging to perform. Several efforts are made at EU level to develop methodologies and approaches, such as the "Safe and Sustainable by Design (SSbD)". However, even if the methodology evolves, the data to assess chemicals are frequently missing.

Environmental impacts are commonly evaluated by a Life Cycle Assessment (LCA). Computer software programs help to derive environmental impacts according to defined impact categories such as climate change, acidification, ozone depletion, land depletion or loss of biodiversity as well as toxicity. As the LCA method differs from chemical risk assessments, the results on (eco-)toxicity of either method may not correspond.

The quality of the LCA depends on the quality of the input information, the so-called life cycle inventory (LCI). Collecting own LCI data is the most accurate, but very resource intensive. Thus, secondary LCI data, available in LCI databases, is often used in practice. There is a number of LCI databases, coming from scientific or industry research. Even though these databases contain thousands of datasets, a variety of chemical substances is huge, and therefore only a part of substances are covered by ready datasets in the databases.

LCAs traditionally do not very well reflect the toxicity of chemicals. This can be compensated by using a more precise tool, the model "Usetox". This model derives assessment factors for toxicity, which can be applied in the LCA.

Tools

- ChemSelect: Screening tool on the sustainability of chemicals
- Webpage with links to LCA software
- Usetox provides assessment factors for LCA; it is specifically designed to assess toxicity and ecotoxicity of chemicals

14.4. Priority setting

When you use many different substances in your processes, you should prioritise with which substances to start improvement actions on chemical risks.

Prioritisation may consider different criteria, which are specific to your company policy. Obviously, compliance with legislation is the highest priority and not discussed here any further. We suggest a two-step process, in which first the chemical substances in their uses are assessed and prioritised based on hazard and (qualitative) risk considerations. The second step consists of a screening of risk management options and their economic implications. The result of that step might modify the initial priority.

14.4.1. Hazard

Obviously, the more hazardous a substance is, the more urgently it should be avoided. Hence, hazard is a strong prioritisation criterion for identifying action needs on input substances. Apart from ranking chemicals according to their hazards, you should consider your company's chemicals policy: if there is a target to reduce the use of EDCs, then these types of hazards should receive the highest priority for action.

14.4.2. Exposure

Additionally, you may consider the concentration of a hazardous substance in the mixture as prioritisation criterion, as the concentration may change the urgency with which action is required, especially for human health hazards.

Further exposure-based criteria could relate to

- The amounts of a substance that you use in your processes.
- The user group, where any exposure of vulnerable groups, such as children, would increase the priority for action.
- The type of use, where those uses with high exposure potential would increase the priority for action
- For chemicals produced exclusively for professional use, you may consider if workers protection exists and might reduce the priority for action.

14.4.3. Options to act

Different options to reduce the risk for the identified priorities should be identified and briefly described. Substitution is the most far-reaching option, and the availability of safer alternatives should always be assessed. This would include evaluating drop-in solutions as well as changes of processes and materials, which might require different manufacturing equipment etc.

If alternatives or other "easy" risk management measures are available, a substitution action could quickly be implemented, which might increase the priority to act. If alternatives to the use of a substance are not easily available, costly or lead to the reduction of product performance, the action need remains but other cases may be prioritised, where solutions exist, and action is quickly possible.

14.4.4. Economy

The economic consequences of a potential action are of course also of high relevance. To identify these, any changes in costs, product performance and possible reactions to the change in the supply chain should be assessed. This criterion can only be assessed based on the options for risk management. It could also be an argument pro action if customers have requested a change.

14.5. Deciding on an option to act

In principle, there are three different types of action one could take to reduce the risk from the use of a chemical. The following table lists the actions and provides pros and cons for each of them. It does not consider the technical feasibility or any case-specific factors that may influence decision making.

Table 5: Overview of options to act and their consequences pros and cons

Option to act	Pro	Con	Comment
Redesign product, i.e either use another material, or eliminate the (need for a) product part or material	• Substance can be avoided • Proof of compliance possible based on inventory • Clear communication possible, good marketing opportunity • Need for future action prevented • Opportunity to innovate and change several aspects	• Might significantly change product appearance and performance, potentially resulting in loss of clients • High resource input for a new design phase	• Mainly applicable regarding the physical form of a product; other redesign is substitution
Stop marketing / production	• Can be implemented immediately No investments needed	• Loss of income and clients	• Relevant option for products that 'do not sell anyway' and/ or where several aspects are identified as critical
Substitute with (less harmful) chemical(s)	• Substance can be avoided • Proof of compliance possible based on inventory • Clear communication possible, good marketing opportunity • Need for future action prevented	• Substitution may require substantial human and financial resources, and time • Unclear if quality of product can be maintained • May result in uncertainties due to new suppliers, warranty etc.	• Benefit depends on the alternative • Regrettable substitution to be avoid

14.6. Substitution

"Substitution means the replacement or reduction of hazardous substances in products and processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organisational measures" (Lohse 2003).

According to this definition, substitution results in the elimination or reduction of hazards and a related elimination or reduction in exposure and risk. There can be several types of substitution (ECHA 2019), which are explained in *Table 6*.

Table 6: Types of substitution

Types of substitution	Examples
1. Elimination of a chemical (no replacement)	A fragrance ingredient in a mixture is eliminated as it has no function other than providing a pleasant smell during the product use.
2. Drop-in substitution (1 to 1) of a chemical (one chemical is replaced by another without additional changes)	A cadmium containing yellow pigment in a mixture is replaced by an organic yellow pigment which is not considered hazardous.
3a. Changed product or process design by implementing chemical alternative	In polymer pellets the phthalate plasticizer DEHP is replaced by the plasticizer DINCH. The entire polymer needs to be reformulated (by re-adjusting the concentrations of most other components) to achieve the desired function.
3b. Changed product or process design by implementing non-chemical solution	This option is not relevant for formulators
3c. Changed product or process design by implementing new technology.	This option is normally not relevant for formulators

The following steps are part of a "standard" substitution process. Substitution starts from an identified problem and ends with the implementation of the most promising substitution option as well as a check of success.

- Definition of the scope of substitution
- Identification of alternatives
- Assessment of alternatives and selection of the most promising ones
- Testing alternatives in real production
- Implementation of the solution and checking of success and improvement options.

14.6.1. Definition of the scope of the substitution process

As a formulator, you are the provider of your customers and must ensure they receive the quality or functionality of the product you are currently supplying them with. Your task consists of replacing a problematic component of the mixture and ensure the overall function of the mixture is maintained, or better, improved.

Substitution may consist of using a drop-in alternative, replacing one chemical by another, or may involve a larger reformulation of the mixture. The substitution trigger may be regulation (e.g. a substance is prohibited), your own priorities (e.g. company policy targets the phase out of certain substances) or customer requests to avoid certain substances.

It is useful to identify the available resources for the substitution at the beginning of the process, e.g. how much time, human resources and expertise, and finances are available.

Defining the scope of substitution also involves the identification of criteria to evaluate alternatives. These criteria may concern the quality/performance of the product, the "acceptable hazardousness" of the alternative, the scale of reformulation that is acceptable, possible costs, the use of different equipment, customer requirements etc. These criteria are a good support for later decision making and help keeping focus on the essential aspects of the substitution.

14.6.2. Identification of alternatives

Start defining the functionality of the product and identify all possible options that could lead to the elimination of the chemical of concern. These options may also include technical options, e.g. if a processing aid should be phased out, or using different materials (e.g. discuss with the customer to change from one type of polymer to another).

There are various options as to where to look and whom to ask for possible alternatives:

- inside your company, as the purchasing department, the sales department or the technical officers may have good advice about products or suppliers to contact
- suppliers, especially if they offer alternatives; however, note that the alternatives may belong to a similar or the same (chemical) group and may, although not yet being regulated or in the focus of product designers, have the same or similar hazards, i.e. would be a regrettable substitute
- research alternative chemicals on the internet using search engines, screening scientific literature, contacting industry associations, governmental authorities, universities, or other experts who may consult on safer chemicals and product design.

It may also be possible to team up with customers or even competitors to find common and good solutions.

As a result of your research, you should identify at least one alternative that meets your quality criteria. If you identify more than one, you may consider them in step 3 and compare their advantages and disadvantages.

14.6.3. Assess, compare, and select alternatives

As a minimum condition, all alternatives should be compliant with regulatory requirements of your target markets and should neither be banned or restricted in any legislation.

For the remaining alternatives the assessment should cover a hazard and risk assessment, an assessment of technical feasibility and an assessment of economic viability. Furthermore, additional environmental impacts may be assessed (cf. chapter sustainability assessment). Also, communicate with your customer to ensure the reformulated product is acceptable to him.

Hazard assessment

Compare and benchmark hazards based on the EU classification as a first step. The more severe the hazards are, the less suitable is the alternative from an (eco-) toxicological point of view. If no classification is available, you may find test results for at least some endpoints in ECHA's database or other scientific sources that you may use to compare hazards. You may want to make a ranking list according to hazards. Ensure that you are aware of the information availability and what you do not know (and might become a bad surprise in the future).

Exposure assessment

If the alternative you select is a drop-in solution, i.e. you replace one chemical by another chemical with only minor changes to the overall mixture, the conditions of use and emission situation from the mixture is most likely the same for the original mixture and the alternative one. In this case, you can just compare the mobility parameters – volatility, water solubility – of the substances to identify whether a significant change in risk would occur. In most cases the change in hazard will be the dominating factor.

If the alternative results in a larger change of the mixture composition, the assessment of whether the substitution is useful or not is more complex, as all substances (the concentration of which) are changed need to be considered, and potentially also any changing conditions of use both at the formulation stage but also further down the lifecycle of the substance.

Assessment tools

There are several tools available to assess alternatives but mostly they concern a ranking of hazards. A more complex but still simple assessment, which also includes some aspects of sustainability, is possible using the ChemSelect tool provided by the German Environment Agency, which is available in several languages.

If you want to make a more sophisticated and elaborated assessment of the exposure and potential risk, you may want to try out the expert tool USEtox model. This can be linked to but does not include life cycle assessments.

Several alternative assessment tools of different levels of ambition and sophistication are made available on the OECDs webpage about a substitution toolbox.

Regrettable substitution – the replacement of a problematic substances by another, similarly hazardous one - can be prevented by a thorough assessment of potential alternatives regarding their toxicity and risk, as well as wider environmental impacts.

Technical and economic assessment

If alternatives are identified as appropriate from a hazard and risk perspective, their technical suitability and appropriateness must be tested. This shuld be done first at laboratory scale to get a first understanding of suitability and in a second step, for the promising candidates, at technical scale. The technical assessment should also contain a step of getting feedback from the customers.

This could include:

- Lab tests to identify if the quality and performance criteria of the mixture are met if the alternative is used.
- Testing if equipment works fine with the new mixture composition, including in the processes of the customers or in the articles they produced
- The purity of a substance may be analysed.

The economic assessment may include an analysis of

- Investment costs if e.g. new machinery is needed
- Price of the alternative(s)
- Savings that may be realised due to less waste or the avoidance of personal protective equipment that was needed before the substitution
- Changes in the market due to the changed product design, including opportunities to apply for eco-labels
- Training costs
- Options to increase mixture prices to regain investments.

There may be various aspects that have to be considered and many of them can only be estimated rather than precisely calculated. However, asking these questions will complement the former considerations and may indicate potential challenges in the implementation or limitations for certain alternatives.

After this assessment, there may be further alternatives that are deselected from your list on the grounds that they are not feasible from an economic or technical perspective.

14.6.4. Testing potential alternatives in real production

The last step of testing involves the use of the alternative at scale during the normal production. Any challenges related to the processing in the installation or the product quality that could not be observed in lab-scale reformulation will emerge during full-scale production processes. The customers should be involved in this technical testing to ensure the further processing is not affected by the change in mixture composition.

The testing may require specific attention by the technical staff, as the manufacturing parameters have to be changed due to the (partly different) properties of the alternative(s). Ensure good documentation and record keeping of your testing so that details on the tests are available at later stages in the process.

Apply the quality criteria defined in the first step to evaluate whether an alternative fulfils all relevant requirements. You may want to conduct chemical analyses to ensure the mixture does not contain any unwanted impurities or reaction products.

After completing the above steps, you should be able to take a good decision on which alternative to choose.

14.6.5. Implementation and checking of success

The last step in the substitution process is the use of the selected alternative in your full-scale manufacturing process. It is likely that you will be able to improve manufacturing efficiency over time as you work with the new material.

When introducing the new/changed product to your customers, be ready to take (critical) feedback and further improve or change the composition of the mixture.

Abbreviations

Abbreviations	
AOX	Sum of halogenated compounds
BOD	Biological Oxygen Demand
BPA	Bisphenol A
C&L	Classification and Labelling
CAS	Chemical Abstract Service
CCLI	Classification and Labelling Inventory
CMR	Carcinogenic, Mutagenic and Reprotoxic
CRM	Chemicals Risk Management
CRMS	Chemicals Risk Management System
DNELs	Derive No Effect Levels
EC	European Commission / European Community
ED	Endocrine Disrupting
EDC	Endocrine Disrupting Chemical
EMAS	Eco-Management and Auditing Scheme
Env	environmental
ES	Exposure Scenario
EU	European Union
Hh	human health
ILO	International Labour Organization
IMDS	International Material Data management System
ISO	International Standardisation Organisation
IUPAC	International Union of Pure and Applied Chemistry
LCA	Life Cycle Assessment
LCI	Life Cycle Inventory
NACE	Nomenclature statistique des activités économiques dans la Communauté européenne (Statistical nomenclature of economic activities in the European Community)
NOx	Nitrogen oxides
OECD	Organisation for Economic Cooperation and Development

Abbreviations	
OELs	Occupational Exposure Limit Values
OSH	Occupational Safety and Health
PBT	Persistent, Bioaccumulative and Toxic
PCN	Poison Center Notification
PFAS	Per and Polyfluorinated Alkyl Substances
PIC	Prior Informed Consent
PMT	Persistent, Mobile and Toxic
PNEC	Predicted No Effect Concentration
PPE	Personal Protective Equipment
PRODCOM	PRODuction of COMmodities – statistical nomenclature
R&D	Research and Development
REACH	Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals
SDS	Safety Data Sheet
SOx	Sulfuric oxides
SSbD	Safe and Sustainable by Design
STOP	Substitution, Technical measures, Organisational measures, Personal protective equipment
STOT	Systemic Target Organ Toxicity
SVHC	Substance of Very High Concern
VOC	Volatile Organic Compound
vPvB	Very Persistent and very Bioaccumulative
vPvM	Very Persistent and very Mobile
W/w	weight per cent

The Project LIFE Fit for REACH-2, No. LIFE22-ENV-EE-LIFE-FitforREACH-2/101113947 is co-financed with the

Co-funded by the European Union

Ministry of Environment Republic of Lithuania

ENVIRONMENTAL INVESTMENT CENTRE

Ministry of Environmental Protection and Regional Development Republic of Latvia

Narodowy Fundusz Ochrony Środowiska i Gospodarki Wodnej

contribution of the LIFE Programme of the European Union.

The content of this report is the sole responsibility of the project LIFE Fit for REACH-2 and can in no way be taken to reflect the views of the EU.