# REACH Practical Guide on Exposure Assessment and Communication in the Supply Chains

## Part I: Introduction, Chemical Safety Assessment, Obligations of Downstream Users, Use of Existing Knowledge

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**Important note to the reader**

This document has been prepared by a VCI working group as part of the joint Cefic/VCI project to develop tools and guidances for industry – in respect of Chemical Safety Assessments, Chemical Safety Reports and Exposure Scenarios.

It is Part I of the REACH Practical Guide on Exposure Assessment and Communication in the Supply Chains. It describes the status of development as per Q1 2010. Many activities, both in industry working groups as within ECHA are still ongoing. The guide is therefore not to be regarded as complete, but as a status overview.

The Practical Guide comprises several parts. An overview is given in the preface of this Part I.

The structure and the contents of the REACH Practical Guide are described on the following web sites:

VCI: http://www.vci.de/default~cmd~shd~docnr~125022~lastDokNr~102474.htm

All related documents can be downloaded from this site. In addition you find here information on related issues and actual developments.

CEFIC: http://cefic.org/templates/shwPublications.asp?HID=750

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# 1 Preface

This practical guide gives an overview of REACH tasks related to the chemical safety assessment, chemical safety reports, exposure scenarios, exposure assessments, extended safety data sheets and the related obligations of downstream users.

It aims to support small and medium sized enterprises in particular which do not have their own experts to do this work. The guide is primarily written for “non-experts,” which so far have not been engaged intensively in these topics.

A glossary is available in chapter 12 in part II

Figure 1 gives an overview on the structure and the contents of this guide.

Part I of the Practical Guide gives an introduction into the main tasks. Part II explains more in detail the preparation of exposure scenarios as part of the chemical safety assessment by registrants and the communication of exposure scenarios in the supply chains. Part III is of interest especially for formulators receiving extended safety data sheets with (and without) exposure scenarios from their suppliers. They have to prepare own safety data sheets for their customers. Part IV gives an overview of approaches and tools for exposure estimation.

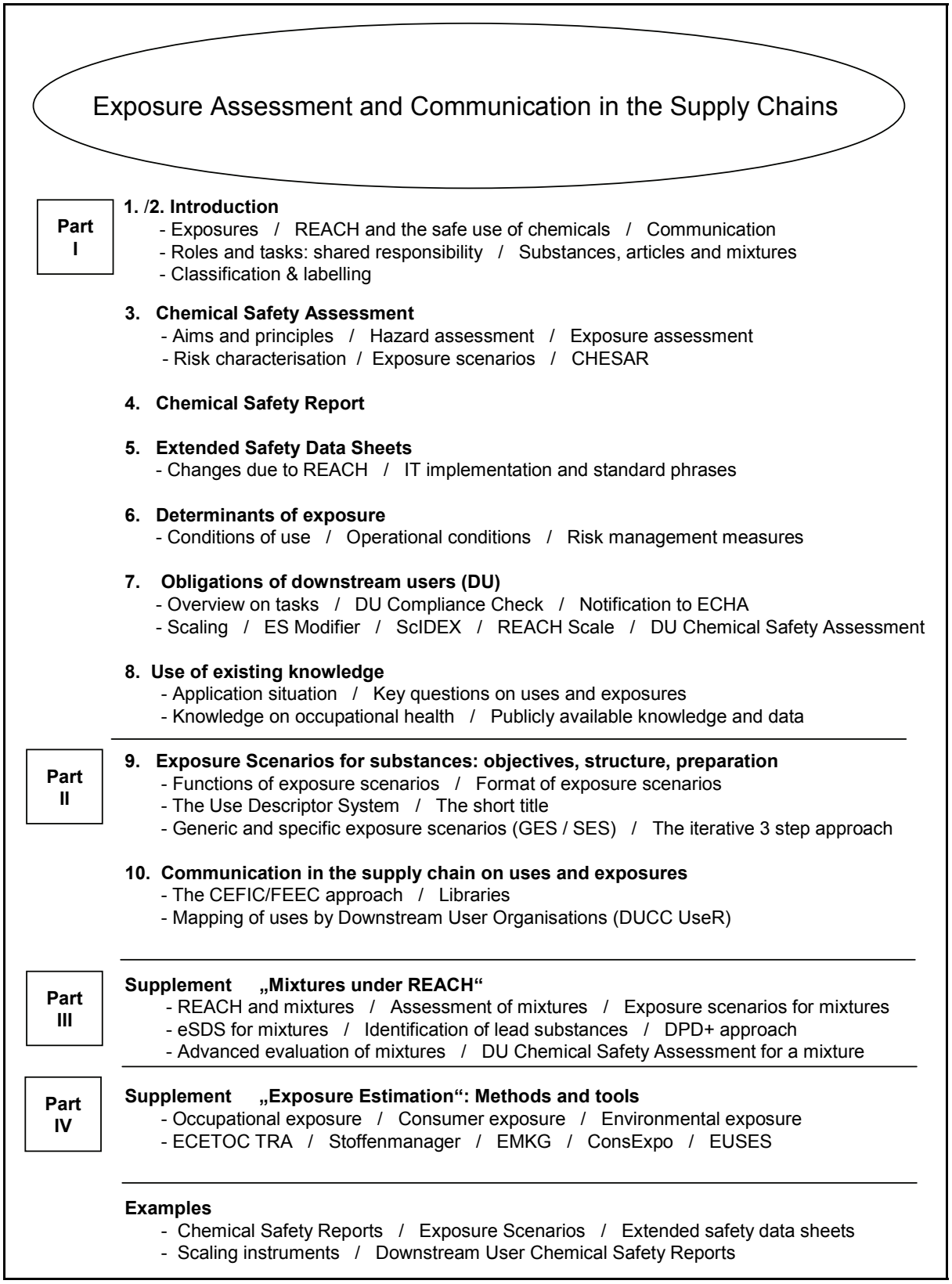


Figure 1 Structure and contents of the practical guide

# REACH Practical Guide on Exposure Assessment and Communication in the Supply Chains

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# 2 Introduction

## 2.1 Exposure

The use of chemicals – substances and mixtures ("preparations")[1] - and articles often leads to exposure: contact of humans and the environment with different substances on different ways.

This contact can be intended and happen consciously, e.g. with fragrances. Exposure can also occur unintentionally, e.g. by residual dyes on fibres.

For industrial safety and environmental and consumer protection, the question of where substances with hazardous characteristics ultimately occur, where exposures to the population and the environment can arise, with which duration and at what concentrations, is crucial. In this context, "Safe use of chemicals" means that exposures can be demonstrated to be so small that no harmful effects for humans and environment are to be expected or occur.

## 2.2 Exposures and related instruments under REACH

Safe use of chemicals is a central goal of REACH, the new European chemicals policy. This also means that all potential exposures must be assessed. Therefore within REACH the manufacturers and importers of chemicals and their customers have defined obligations which are the main targets of this practical guide.

Where the existing knowledge of process operational conditions and risk management can be tied to workplace, environmental and consumer protection, much of the information required for such assessment is already available. For efficiency, new tasks due to REACH should be linked to the efforts already been made for risk assessment of chemicals e.g. according to the Chemical Agents Directive 98/24/EC.

The safe use of chemicals is dependent on several preconditions:

- knowledge of the properties of the substances and mixtures used;
- knowledge of the conditions of use and the surroundings

[1] The term „preparation" is replaced in the CLP regulation by the term „mixture". In the practical guide we use the term "mixture".

- knowledge of any exposures while directly handling the substances and also of exposures which can result from the use of the substances
- development of appropriate risk management measures to prevent exposures, if hazardous substances are involved, and their communication to the users;
- implementation of the risk management measures by everyone who deals with the substances.

For the safety assessment of chemicals and the related communication in the supply chains a set of instruments is prescribed in REACH, which are related to each other:

- the chemical safety assessment (CSA);
- the chemical safety report (CSR);
- the exposure scenarios (ES);
- the safety data sheet (SDS).

**Chemical Safety Assessment**: The chemical safety assessment examines the conditions under which substances can be safely used. This requires an assessment of the substance properties and the uses which potentially lead to exposure.

A chemical safety assessment of a substance starts with the following steps (see also fig. 2 and chapter 3.1.4):

a) Human health hazard assessment;
b) Physicochemical hazard assessment;
c) Environmental hazard assessment;
d) Persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment.

If, as a result of carrying out steps 1 to 4, the registrant concludes that the substance meets the criteria for classification as dangerous (in accordance with Directive 67/548/EEC; from 1.12.2010 with CLP regulation) or is assessed to be a PBT or vPvB substance[2], then the chemical safety assessment must additionally include the steps 5 and 6: the exposure assessment and the risk characterisation.

[2] ”PBT” substances are persistent, bioaccumulative and toxic, “vPvB” substances are very persistent and very bioaccumulative (vPvB).

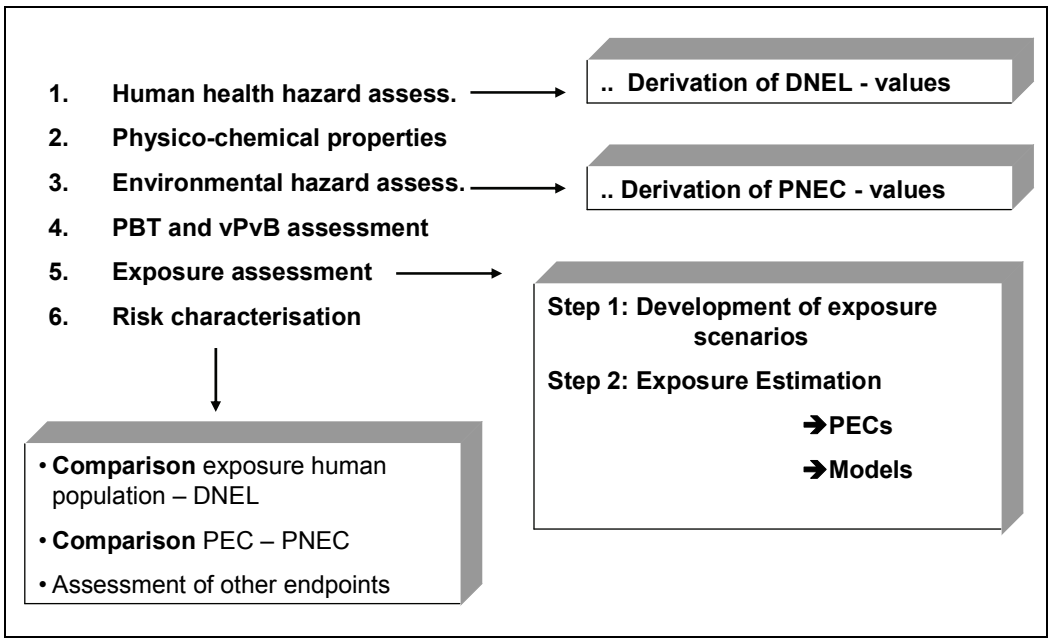


Figure 2 The main steps of a chemical safety assessment

In these steps it should be determined which risk management measures are necessary for adequate control of the risk resulting from handling the involved substance.

**Chemical Safety Report:** The chemical safety report documents, in writing, the results of the chemical safety assessment. (chemical safety reports – for acetonitrile, potassium tertiary butylate, HDDA and NaOH – have been prepared as examples for the practical guide and are available as separate documents (http://www.vci.de/default~cmd~shd~docnr~125022~lastDokNr~102474.htm)).

**Exposure Scenarios:** Exposure scenarios describe the conditions for the safe use of substances, in particular the conditions of use and the risk management measures. Exposure scenarios are compiled in the context of the chemical safety assessment, dependent on the individual case, in a multi-level procedure. They are documented in the chemical safety report. Exposure scenarios which refer to the uses by downstream users are communicated with the safety data sheet[3]. (Part II of the Practical Guide, Annexes A2.11, A2.14–A2.17 give examples of exposure scenarios. Further explanations to exposure scenarios are given in this part in chapter 3.2 and in Part II of the Practical Guide, in chapter 9).

[3] Through new information on substance properties and use conditions, exposure scenarios can change in the course of time. The manufacturer and/or importer decide, in the context of his registration, when an exposure scenario is, in his view, “final “and is to be documented and/or communicated as necessary.

**The Safety Data Sheet**: The safety data sheet is the central **communication instrument** for the supply chains for industrial and professional users. Under REACH it is extended with additional information and where relevant with Exposure Scenarios and called "extended safety data sheet" (eSDS). For safe use, the key results of the chemical safety assessment are transferred directly to the core safety data sheet (see chapter 5).

For the safe use of substances and mixtures, cooperation between manufacturer, importer and downstream users (formulators and further downstream users) can be of decisive importance – including in many cases the distributors. This is especially the case if not any actor of the supply chain has sufficient information. We deal with this topic in the following chapter and more in detail in Part II of the Practical Guide, chapter 10.

## 2.3 Improved communication in the supply chains

For substances and mixtures which are placed on the market in the European Union, REACH requires more and improved communication. The duties for suppliers to provide information to their customers were extended under REACH (REACH articles 32 and 33). There is also a new REACH requirement that downstream users of substances have information obligations with regard to their suppliers (REACH article 34).

Beyond the legally specified duties to supply information, the successful – and effective – implementation of REACH will also depend on the extent to which manufacturers, importers, distributors, formulators and users voluntarily exchange their information on substances and conditions of use. The preparation of the chemical safety assessment requires data, knowledge on the substance properties and conditions of use. By information exchange between substance manufacturers, formulators and users it can be guaranteed that the necessary knowledge is communicated in the supply chain.

Practical options of structured and standardized communication processes between manufacturers/importers and downstream user have been developed in different projects. (see Part II of the Practical Guide, chapter 10).

## 2.4 Roles and tasks: The principle of shared responsibility

Under REACH, companies are primarily responsible for the assessment and the safe use of chemicals. The tasks of the European and national authorities are limited to providing appropriate guidances and tools and to checking whether industry follows its obligations under REACH. The principle of shared responsibility in the supply chains leads to the following distribution of tasks (related to exposure assessment of substances and communication in the supply chains):

- The manufacturer and/or importer has to submit the registration of a substance. In the chemical safety assessment the manufacturer and/or importer decides under which conditions the substance can be used safely. He has to implement these conditions himself and to communicate these conditions for their safe use to the downstream users.
- Downstream users are obliged to examine own conditions of use of substances and mixtures to see whether they are considered within the scope of the exposure scenarios described. (see chapter 7).

  Uses that are not described in the SDS can be notified to the supplier so that they can be considered and included in the safety data sheet. Alternatively, the downstream user can prepare his own chemical safety assessment.

  As the DU is obliged to check that his uses are covered, he should familiarise himself with the principles and fundamental ideas of the chemical safety assessment. This will also facilitate the communication between downstream users and manufacturers regarding the conditions of use of substances in the supply chains. The understanding of each actor in the chain, as to exactly what his upstream suppliers have assessed and covered and/or not covered, is of central importance for the safe use of a product.

  Downstream users can be divided into five groups: Formulators, end users, users who repack or re-fill chemicals, importers with an Only Representative and re-importers. (For more detailed information, see chapter 7).
- Private consumers and distributors of chemicals are not considered as DU under REACH
- EU Importers of substances (on their own or in mixtures) and EU importers of articles (according to REACH Art. 7) can have registration obligations. But manufacturer, formulator or article producer established outside the EU can appoint an “only representative” established in the EU to fulfil the registration obligations of importers.

## 2.5 Substances, mixtures and articles under REACH

Most of the REACH obligations are related to substances – on their own, in mixtures or in articles. Only a few articles in REACH are related to mixtures as such.

- Registration, authorisation and restriction according to REACH Titles II, VII and VIII refer to substances (on their own, in mixtures or in articles[4]). Registration dossiers are prepared only for substances, not for mixtures. However, in the chemical safety

[4] Registration of substances in articles according to REACH Article 7.1 and Article 7.5 refers to substances which can be released from the article.

assessment of a substance its whole life cycle has to be evaluated. In many cases substances are used in mixtures during their life cycle, and, therefore, these uses have to be considered in the chemical safety assessment. The use of substances in mixtures often implies specific conditions of use (i.e. mixture-specific operational conditions and risk management measures.

Some of the REACH requirements on information in the supply chain (Title IV) and on downstream users (Title V) address mixtures directly.

- Suppliers of mixtures have to provide their customers with safety data sheets for dangerous mixtures according to REACH Art. 31.1.
- According to REACH Art. 31.2. actors of the supply chain can opt for developing a chemical safety assessment for a mixture instead of a chemical safety assessment for a substance. In this case the information in the safety data sheet for the mixture has to be consistent with the chemical safety report of the mixture.
- Exposure scenarios as defined in REACH Annex I can refer to substances or to mixtures. There is no formal obligation to any actor in the supply chain to elaborate an exposure scenario of a mixture. However the ECHA Guideline for Downstream Users describes the preparation of exposure scenarios for mixtures as one of several ways to include information from substances into the safety data sheets of mixtures (according to REACH Art. 31.7).
- A downstream user has to prepare a chemical safety report according to Annex XII if his uses are outside the conditions described in an exposure scenario or if his supplier advises against it (REACH Art. 37.4). This downstream user chemical safety report can refer to substances or to a mixture (as described in the ECHA Guidance for downstream users).
- According to REACH Art. 37.4 (c) downstream users need not to prepare their own chemical safety reports if they use a substance or a mixture in a total quantity of less than 1 tonne per year or if the substance is present in a mixture in a concentration lower than any of the concentrations set out in Article 14(2).

Classification and labelling is required for substances and for mixtures. The related timelines are described in chapter 2.6.

Part III of the practical guide deals in details with tasks and obligations of the different actors who handle mixtures. It includes a description of exposure scenarios for mixtures and downstream user chemical safety assessments for mixtures.

**Substances in articles and REACH**: Registration and information requirements related to substances in articles are defined in REACH Art. 7 (Registration and notification of substances in articles) and REACH Art. 33 (Duty to communicate information on substances in articles).

Registration of substances in articles according to REACH Art. 7.1 is required if the substance is present in quantities totalling over 1 tonne per year (per producer or importer) and if the substance is intended to be released under normal or reasonably foreseeable conditions of use. Such a registration is not required if the substance has already been registered for that use in articles (REACH Art. 7.6). Therefore, uses of articles with relevant exposure have to be considered in the chemical safety assessment by the manufacturer/ importer of the respective substance that has to cover the whole (relevant) life cycle of the substance.

In the practical guide tasks and obligations related to substances in articles are not further specified. Further information is given in the ECHA Guidance on substances in articles (http://guidance.echa.europa.eu/docs/guidance_document/articles_en.pdf). This guidance aims to assist article suppliers in deciding if they have to fulfil REACH requirements related to substances in their articles. (Chapter 7 describes how to decide whether a substance can be released from an article, chapter 8.8 deals with exposure estimation for substances in articles).

## 2.6 Classification and labelling of substances and mixtures

Several obligations in REACH refer to the results of classification and labelling of substances and mixtures. The Globally Harmonised System (GHS) for classification and labelling prepared by the United Nations is implemented in the EU in parallel to REACH as the CLP regulation (EC/1272/2008). Finally CLP replaces the classification and labelling provisions of the Dangerous Substance Directive (Dir 67/548/EEC) and the Dangerous Preparations Directive (DPD, Dir 1999/45/EC). In the transition period, both classification systems can be applied for several years in parallel. Apart from that downstream users can receive safety data sheets for the same substance from different suppliers which contain differing information on classification.

**Timeframe for substances:** Substances have to be classified according to CLP as of December 1st, 2010. From December 1st, 2010 until June 1st, 2015, results from application of both classification systems (CLP and Dir 67/548/EEC) have to be documented in the safety data sheets.

**Timeframe for mixtures:** Mixtures have to be classified according to CLP as of June 1st, 2015. Before that date, CLP classification of mixtures can be documented in the safety data sheets voluntarily.

Classification of mixtures according to the Dangerous Preparations Directive (Dir 1999/45/EC) has to be reported in the safety data sheets for mixtures until June 1st, 2015.

For many substances, classification according to CLP may change their current classification and labelling. As a consequence, it might become necessary to update the registration dossier. In order to avoid this additional workload, companies should check which changes

can be foreseen. In this case, classification in the registration dossier should be also applied according to the CLP classification before registration.

# 3 The chemical safety assessment

## 3.1 Aims and principles of the chemical safety assessment

Manufacturer and importer of substances with an annual production volume of 10 tonnes and more have to prepare a chemical safety assessment as part of registration. The results of the chemical safety assessment are documented in chemical safety report, which is submitted to the European Chemicals Agency[5] by the registrant.

In specific cases it can become necessary that downstream users themselves undertake a chemical safety assessment and document this in their own chemical safety report. This is the case if downstream users apply substances and mixtures under conditions which are not covered by the exposure scenarios of their suppliers (see chapter 7.5 and chapter 7.8).

The chemical safety assessment evaluates whether the intended uses of a substance are “safe“. Here “safe“ means that exposures of workers, the general population and the environment may only arise under such conditions that the risk is controlled, and no damage to humans and environment is expected.

In the risk assessment approach, which is the basis for REACH, the level of the risk results is a combination of both the substance’s intrinsic properties and the level of the exposure that can be expected.

A chemical safety assessment presupposes knowledge of the substance properties, the use or application situations and the resultant exposures. The concentrations and/or quantity specifications where no harm will arise can be derived from knowledge of the physico-chemical, toxicological and ecotoxicological properties of the substance. The limit values are those at which there is no significant risk of harmful effects. For human health these are called DNELs („Derived No-Effect Level“[6]). The limit values for the environment are called PNECs (“Predicted No-Effect Concentrations“)[7,8].

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5 Exception: see REACH article 14, 2.

6 DNELs are limit values derived based on scientific studies. In addition, the derivation includes the use of assessment factors.

7 PNECs are limit values derived based on scientific studies. In addition, the derivation includes the use of assessment factors.

Starting from the knowledge of the conditions of use, the resultant exposures can be assessed. This takes into account the kind, duration, frequency and level of the exposure. The basis of the exposure assessment can be measurements, expert estimates or model calculations. In all cases knowledge of the physicochemical substance properties is of high importance.

The exposure level when using the substances depends crucially on the conditions of use, the physicochemical properties of the substances and the applied risk management measures.

The principal purpose in the assessment of the arising exposures is to determine the conditions under which the substance can be handled safely – in the production and along the entire life cycle. These conditions are documented in writing – as "exposure scenarios" (see chapters 3.4.1 and 9 of this practical guide).

The following illustration shows a typical application situation of a mixture in the printing industry. The arising release (emissions) of the substances in water, soil and air depends crucially on the substance and mixture properties; the conditions of use (e.g. applied quantity); the implemented risk management measures; and the boundary conditions (e.g. with process wastewater connection to a sewage treatment plant), in which the substance is used (figure 3).

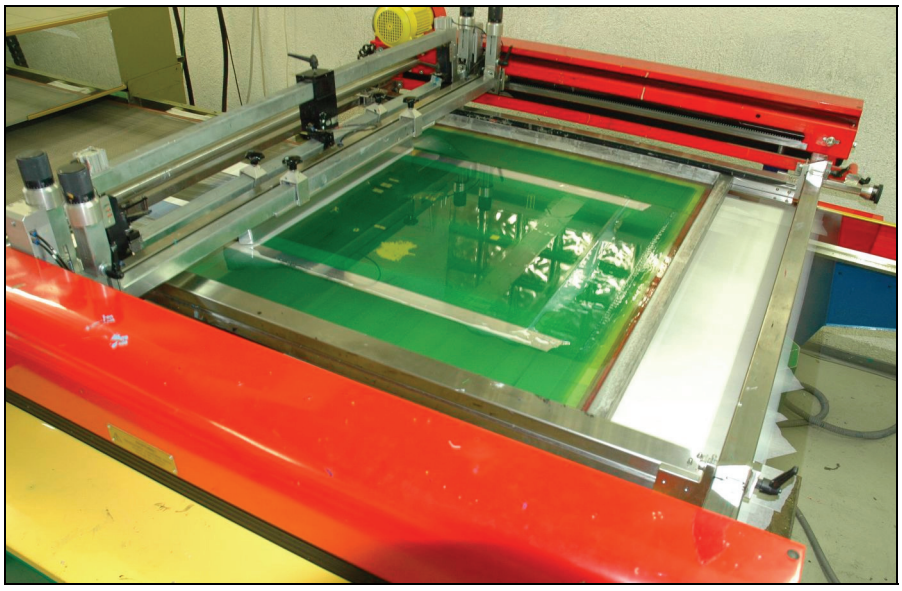

Figure 3 Use of a colouring substance mixture for the printing industry. Source: Thorn 2008.

[8] A special case is when there are substances with harmful effects for which no thresholds can be determined. Here in the assessment it is assumed that every exposure – no matter how small – can cause damage. In REACH for such "substances without effect thresholds" special assessment steps are foreseen (ECHA 2008a, part C and part R11).

Mixtures can differ in their properties considerably from the properties of the individual substances contained. The assessment of mixtures and/or of substances in mixtures can thus make additional assessment steps necessary in certain cases (see Part III).

In the final risk characterization the derived limit values are compared to the expected exposure. The use is safe if the ratio of expected exposure and derived limit values (PNECs or DNELs) is below 1.

In the chemical safety assessment, knowledge on the substance properties, the derived limit values and the arising and/or expected exposures is united in the step of the **risk characterisation** (see the following chapter and chapter 3.4.2).

## 3.2 The structure of the chemical safety assessment

A chemical safety assessment consists of the following **main steps**:

1. Assessment of harmful effects on human health
2. Assessment of harmful effects through physicochemical characteristics
3. Assessment of harmful effects on the environment
4. Assessment of the PBT and vPvB characteristics
5. Exposure assessment having two steps
   (a) Development of exposure scenarios
   (b) Exposure estimation;
6. Risk characterisation

If no indication of possible hazardous effects resulted for a substance, the chemical safety assessment is complete after performing steps 1–4.

If, during the chemical safety assessment a substance was identified which could be classified as dangerous (in accordance with Directive 67/548/EEC before 1/12/2010 and/or CLP Regulation as of 1/12/2010) or a substance is categorised as a PBT and/or vPvB- substance[9,10], then steps 5 and 6 of the chemical safety assessment are also necessary; namely the determination of the exposure and the risk characterisation.

[9] An assessment also includes whether the substance is poorly degradable (persistent) or can accumulate in organisms. Both are problematic substance properties, which are examined in specific assessment steps.

[10] PBT substances: Substances which are persistent, bioaccumulative and toxic / vPvB substances: Substances which are very persistent and very bioaccumulative.

The results of the chemical safety assessment are documented in the chemical safety report which is sent to ECHA. The essential information from the CSR is transferred to the extended safety data sheet[11].

## 3.3 Hazard assessment and PBT/vPvB assessment

The first three steps of the chemical safety assessment aim to assess harmful effects of the substance.

**Human Health Hazard Assessment:** The determination of harmful effects on human health has two goals:

- the classification and labelling of a substance in accordance with Directive 67/548/EEC and/or CLP Regulation;
- the derivation of the uppermost limit values/exposure levels for human exposure. These values are called DNELs (see above). Here the different effect end points (e.g. irritation, corrosiveness, acute and chronic toxicity) and the behaviour of the substance in humans (absorption, metabolism, distribution and elimination) are considered. DNELs have to be derived for the target populations and pathways relevant for exposure. According to REACH Annex 1 “a single DNEL may be sufficient if justified by the exposure scenario(s)”.

Therefore the human health hazard assessment consists of the following elements: evaluation of non-human information, evaluation of human information, classification and labelling, derivation of the limit values (DNELs).

**Physicochemical Assessment:** In the case of harmful effects from physicochemical properties (explosivity, flammability, oxidising potential) the goal of the assessment of these properties is to find out whether the substances are to be classified according to the Directive 67/548/EEC and/or CLP (this also includes the derivation of limit values for the explosion potential of substance/air mixtures).

For each physicochemical property the assessment consists of an examination as to what extent the substance can elicit this effect during the production and the identified uses. The appropriate classification and labelling developed in accordance with the criteria of Dir 67/548 EEC and/or CLP Regulation has to be presented and justified in the chemical safety report.

**Environmental Hazard Assessment:** The determination of the harmful effects on the environment has similar goals as the human health hazard assessment:

[11] Safety data sheets for substances and mixtures are required for users within and outside the EU. However only uses taking place in the EU have to assessed according to REACH.

- the classification and labelling of a substance in accordance with the Directive 67/548/ EEC and/or CLP Regulation;
- the derivation of limit values below which no harmful effects are expected for the environmental sphere concerned (including the compartment “activated sludge in sewage treatment plant”). These limit values are called PNECs (see above).

Many factors are considered here including:

- the fate and the behaviour of the substance in the environment (degradability, distribution, bioaccumulation (accumulation in the food chains));
- the harmful effects on the environmental compartments – water (with sediments), soil and air;
- possible effects on the microbiological activity of sewage treatment systems, on the food chain via accumulation (“secondary poisoning “);
- as well as effects on man via the environment.

If, for individual substances, the derivation of a PNEC and/or a DNEL value should not be possible, this is to be clearly indicated in the chemical safety report and justified (e.g. lack of data). The results of the determination of the harmful effects are then documented in the chemical safety report.

The environmental hazard assessment consists of the following three steps, which shall be clearly identified as such in the chemical safety report: evaluation of information, classification and labelling, derivation of PNEC values.

**The PBT and vPvB assessment** is the fourth step in the chemical safety assessment. It aims to assess whether a substance fulfils the criteria of REACH Annex XIII for persistent, bioaccumulative and toxic substances or for very persistent and very bioaccumulative substances. If this is the case, the potential emissions of the substance have to be described.

## 3.4 Exposure assessment and risk characterisation

### 3.4.1 Exposure assessment

The aim of the exposure assessment is a quantitative estimation of the dose and/or concentration of the substance to which humans and the environment are or may be exposed. This estimation should enable a comparison of the expected exposure level with the exposure-related limit values (DNELs and/or PNECs).

Only in the case a DNEL cannot be derived (e.g. DNELs may be difficult to be obtained for the endpoints skin and eye irritation/corrosion and skin sensitisation), a quantitative exposure assessment may not be useful. A qualitative risk characterisation has to be carried in such cases.

It should include all life cycle stages of a substance, which result from the production and the identified uses. The exposure assessment consists of two steps.

In the first step, exposure scenarios are developed which describe how substances can be used safely. Detailed information on exposure scenarios is given in Part II of the Practical Guide, chapter 9.

In the second step, the exposure is estimated.

For environmental exposure, this estimation steps consists of three elements:

- the estimation of the substance release ("emission estimation");
- the evaluation of the fate and the behaviour of the substance in the environment
- the estimation of the exposure level.

For exposure of workers and consumers exposure estimation focus on the release of the substances and the expected exposure levels.

To estimate the exposure, knowledge of the substance properties and uses together with existing measurement data (if necessary also of similar substances) should be used wherever possible (see also Part IV of the Practical Guide, "Exposure estimation").

For exposure estimation several models are used – related to exposure of workers, consumers and/or the environment. An overview of such models is given in table 1.

Table 1 Models used for exposure estimation. The models are described in Part IV of the Practical Guide, "Exposure estimation". The abbreviations are explained in the glossary (Part II of the Practical Guide, chapter 12).

| Tier | Workers | Consumers | Environment |
|---|---|---|---|
| 0 | | Algorithms for spreadsheet calculations | |
| 1 | ECETOC TRA<br>EMKG EA | ECETOC TRA | ECETOC TRA<br>EUSES 2.1<br>TGD spreadsheet calculator |
| higher | Stoffenmanager<br>RiskOfDerm | CONSEXPO | |
| other tools | SprayExpo | BAMA<br>E-FAST (CEM)<br>MCCEM | Focus<br>Charm |

Details on the models and how to use them are given in the supplement "Exposure estimation" (Part IV).

Users of these tools should keep in mind that most exposure estimation models are of a very conservative nature (i.e. in most cases the calculated exposures are much higher than the real exposures) and that they are validated to a limited extent and/or for some uses only. Application of higher tier models especially will, in many situations, require in-depth under-

standing of exposure estimation, and expertise in handling the tools to avoid highly inaccurate estimates.

### 3.4.2 Risk Characterisation

Risk characterisation is the last step in the chemical safety assessment. In this step the expected exposures for humans and environment are compared to the limit values (DNEL and/or PNEC values). In addition, a judgement is made regarding the probability and the severity of impacts from the physicochemical substance properties. The risk management measures described in the exposure scenarios have to be implemented.

For effects for which no quantitative limit value can be indicated, below which no effect is to be expected, a qualitative assessment is made as to whether adverse effects can be avoided by applying risk management measures according to exposure scenarios.

A chemical safety assessment is successfully completed, if it shows the safe use of the regarded substance. This means:

- During the production, and in identified uses of the substance throughout its entire life cycle, the risks are controlled. Limit values for the environment and humans (PNEC values and DNEL values) are not exceeded.
- For substances with hazardous physicochemical properties (flammable, oxidising, explosive) the probability and the severity of an event occurring due to these properties is so small that it can be disregarded, that is, for example, that danger is avoided by the use of explosion protection secured devices.
- For substances with PBT and/or vPvB properties the emissions and exposures are reduced as far as possible by risk reduction measures[12].

If the first risk characterisation shows that the limit values will be exceeded, an iteration of the assessment is required. The assessment has to be repeated assuming other conditions of use until a sufficient reduction in exposure can be proven (e.g. by proposing additional risk management measures). It may be necessary to use further information (e.g. from testing). Methods and tools for exposure assessment are described in Part IV.

[12] The actual implementation of the risk management measures included in the chemical safety assessment is of decisive importance, so that also in practice the application of the substances is safe.

## 3.5 CHESAR – the ECHA IT tool for chemical safety assessment and reporting

A new IT tool for the chemical safety assessment and for the reporting of its results is developed by ECHA: CHESAR ("**CHE**mical **S**afety **A**ssessment and **R**eporting"). This tool intends to support the registrant to perform a chemical safety assessment and to prepare the chemical safety report. The main tasks are:

- Support the user to use existing data on the intrinsic properties
- Support Exposure Scenario building based on Tier 1 exposure estimates
- Allow to report Exposure Scenarios built with other exposure assessments tools or based on measured data
- Support the building of ES from existing structures (ES templates) available in libraries (see Part II of the Practical Guide, chapters 9.2 and 10).
- Provide some flexibility in the structure of information sent to customers based on what is documented in the CSR
- Report the results in the requested formats (chemical safety report, exposure scenario annexed to extended safety data sheets)

The following figure shows the structure of CHESAR.

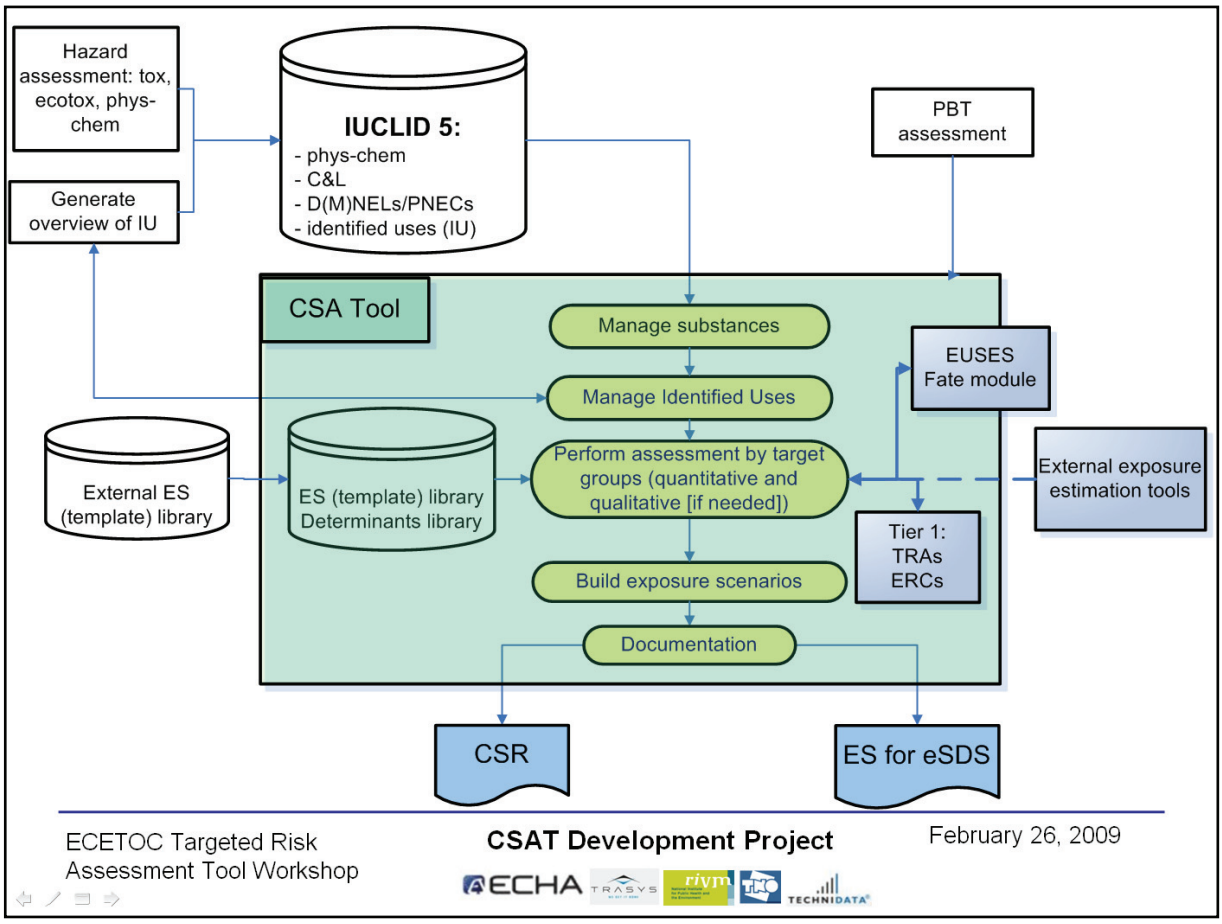


Figure 4 Structure and main elements of the ECHA tool for chemical safety assessment and reporting ("CHESAR"). Source: ECETOC TRA Workshop February 2009.

CHESAR will automatically generate the chemical safety report and the exposure scenarios for a substance. For this it is required to provide the tool with the following information generated outside:

- Data on substance properties and hazard assessment of the substance (imported as a IUCLID 5[13] file);
- Results of the PBT / vPvB assessment;
- Mapping of uses and conditions of use (overview of which uses are typical for a specific sector of industry, see Part II, chapter 9.3.1 of the Practical Guide);
- Exposure scenarios (describing conditions of safe use of substances, see Part II, chapter 9 of the Practical Guide);

[13] IUCLID is the International Uniform Chemical Information Database. More information on http://www.iuclid.eu/

- Exposure estimation tools (used by the registrant within the chemical safety assessment; such tools are described in Part IV of the Practical Guide);
- Standard phrases for risk management measures and operational conditions.

CHESAR includes a use description module. This module provides a standard life-cycle tree structure to map the uses of substances. In addition, CHESAR will have a functionality to report the identified uses and the related exposure scenarios after the assessments have been finalised and the exposure scenarios have been build (ECHA Guidance on information requirements and chemical safety assessment, Part R.12, Use Descriptor System, chapter R.12.5 (version 2, May 2010)).

For the assessment of exposures of workers and of consumers, the related modules of ECETOC TRA version 2 are implemented in CHESAR. For the assessment of exposures of the environment, a new dedicated release module and the EUSES module are used (for details on the exposure estimation tools EUSES, ECETOC TRA and ConsExpos see supplement “Exposure estimation”).

CHESAR is developed as an IUCLID plug-in. The initial version of this tool has been released by ECHA,12th of May 2010[14] and updates with extended functionalities are scheduled.

## 4 The chemical safety report

The chemical safety report is the written documentation of the chemical safety assessment. The format of the chemical safety report is specified in annex I of REACH, section 7. The chemical safety report is arranged in two parts.

In part A an overview is given of the risk management measures which are necessary for the safe use of the substance. In addition two declarations follow this summary. The first declaration confirms that the risk management measures for the manufacturer and/or importer are used by them. The second declaration states that the exposure scenarios for the identified uses, which were compiled in the chemical safety report, are communicated to distributors and downstream users with the safety data sheets.

In part B the information compiled in the chemical safety assessment is documented – along with the results of the assessment of this information. Thus the structure reflects the

[14] Details on CHESAR has been given in a presentation from Andreas Ahrens October 2009, see http://www.bohs.org/resources/res.aspx/Resource/filename/1576/Session_1___Exposure_Scenarios_in_the_Chemical_Safety_Report_and_CSA_Tool___A_Ahrens.pdf

individual steps of the chemical safety assessment and the information presented here (table 2).

Table 2 The individual chapters in the chemical safety report. Source: REACH annex I, chapter 7.

| | |
|---|---|
| **Part A** | |
| **1.** | **Summary of risk management measures** |
| **2.** | **Declaration that risk management measures are implemented** |
| **3.** | **Declaration that risk management measures are communicated** |
| **Part B** | |
| **1.** | **Identity of the substance and physical and chemical properties** |
| **2.** | **Manufacture and uses** |
| 2.1. | Manufacture |
| 2.2. | Identified uses |
| 2.3. | Uses advised against |
| **3.** | **Classification and labelling** |
| **4.** | **Environmental fate properties** |
| 4.1. | Degradation |
| 4.2. | Environmental distribution |
| 4.3. | Bioaccumulation |
| 4.4. | Secondary Poisoning |
| **5.** | **Human health hazard assessment** |
| 5.1. | Toxicokinetics (absorption, metabolism, distribution and elimination) |
| 5.2. | Acute toxicity |
| 5.3. | Irritation |
| 5.4. | Corrosiveness |
| 5.5. | Sensitisation |
| 5.6. | Repeated dose toxicity |
| 5.7. | Mutagenicity |
| 5.8. | Carcinogenicity |
| 5.9. | Toxicity for reproduction |
| 5.10. | Other effects |
| 5.11. | Derivation of DNEL(s) |
| **6.** | **Human health hazard assessment of physicochemical properties** |
| 6.1. | Explosivity |
| 6.2. | Flammability |
| 6.3. | Oxidising potential |
| **7.** | **Environmental hazard assessment** |
| 7.1. | Aquatic Compartment (including sediment) |
| 7.2. | Terrestrial Compartment |

| | |
|---|---|
| 7.3. | Atmospheric Compartment |
| 7.4. | Microbiological Activity in Sewage Treatment Systems |
| **8.** | **PBT and vPvB assessment** |
| **9.** | **Exposure assessment** |
| 9.1. | [Title of Exposure Scenario 1] |
| 9.1.1. | Exposure Scenario |
| 9.1.2. | Exposure Estimation |
| **10.** | Risk Characterisation |
| 10.1. | [Title of Exposure Scenario 1] |
| 10.1.1. | Human Health |
| 10.1.1.1. | Workers |
| 10.1.1.2. | Consumers |
| 10.1.1.3. | Indirect exposure to humans via the environment |
| 10.1.2. | Environment |
| 10.1.2.1. | Aquatic Compartment (incl. Sediment) |
| 10.1.2.2. | Terrestrial Compartment |
| 10.1.2.3. | Atmospheric Compartment |
| 10.1.2.4. | Microbiological Activity in Sewage Treatment Systems |
| 10.2. | [Title of Exposure Scenario 2] (further exposure scenarios, if applicable) |
| 10.x. | Overall exposure (combined for all relevant emission/release sources |
| 10.x.1 | Human health (combined for all emission routes) |
| 10.x.2 | Environment (combined for all emission sources) |

A document template for the compilation of a chemical safety report was prepared by the European Chemicals Agency (“CSR Template “; see http://reach.jrc.it/formats_en.htm).

**Example chemical safety report**: In the substance volume of this practical guide you will find the chemical safety reports for acetonitrile, potassium tertiary butylate, HDDA (hexanedioldiacrylate) and NaOH solid / caustic soda solution. They were provided using the document template format specified above.

Using the template lead to some simplification:

- In chapter 9, *Determination of the exposure*, a tabular compilation of the exposures considered was presented at the beginning;
- In chapter 10, *Risk characterisation*, the subchapters were summarized and the presentation was streamlined overall.

These simplifications facilitate the preparation of the chemical safety report and increase its clarity.

# 5 Extended safety data sheets

Safety data sheet are the central communication instrument for substances and mixtures in the supply chains. In many cases they have to be generated using specific IT software systems. In the following two chapters changes in the content of safety data sheets due to REACH are described and possibilities how to handle these changes. In addition, Part III of the Practical Guide gives specific information on extended safety data sheets for mixtures, including a chapter on IT support to generate these safety data sheets (Part III, chapters 6 and 9).

## 5.1 Changes in the safety data sheet through REACH

With REACH the previous safety data sheet Directive 91/155/EEC has been replaced. REACH Article 31 and Annex II defines the requirements on safety data sheets. Structure and contents equal the recommendations of UN-GHS for the safety data sheet. Under REACH the safety data sheet still remains the main information document for the supply chain – related to individual substances and mixtures in industrial and commercial uses. It is also possible to prepare safety data sheets for groups of substances. The safety data sheet contains not only data for the direct customer, as before, but also information for all downstream users in the chain up to disposal and/or the use of the substance or the mixture in an article (for articles however no safety data sheet is necessary.

REACH Annex II describes the structure of the safety data sheet. The Commission Regulation (EU) No 453/2010 amending REACH states that this REACH Annex II will be replaced by Annex I of the amending regulation No 453/2010 with effect from 1 December 2010[15].

Content wise, in several chapters of the safety data sheet there are additions due to REACH that are important for the assessment of individual substances and mixtures (see table 3).

[15] The present version of Annex II – Safety data sheet – has been published by the European Union 31.05.2010: ( see http://eur-lex.europa.eu/JOHtml.do?uri=OJ%3AL%3A2010%3A133%3ASOM%3AEN%3AHTML).

Table 3 The extended safety data sheet in accordance with REACH (latest version due to the Commision Regulation (EU) No 453/2010), published 31. May 2010): Changes of contents in relation to the specifications of the safety data sheet Directive 91/155/EEC.

| Section | Heading | New Information |
|---|---|---|
| 1 | Identification of the substance/mixture and of the company/undertaking | |
| 1.1 | Product identifier | Registration number[16] |
| 1.2 | Relevant identified uses of the substance or mixture and uses advised against | identified uses |
| 1.3 | Details of the supplier of the safety data sheet | e-mail address |
| *Attention:* Chapter 2 and chapter 3 from the safety data sheet are going to be interchanged which means statements on possible/potential dangers are made in chapter 2 under REACH, statements concerning the composition/ingredients are made in chapter 3 | | |
| 2 | Hazards identification | |
| 3 | Composition/information on ingredients | Information on PBT and vPvB-substances.<br>Registration numbers[16] for dangerous substances above threshold. |
| 8 | Exposure controls/personal protection | DNEL- and PNEC-values<br>Summary of RMM concerning work place and environment |
| 11 | Toxicological information | In the case of substances which need registration: summary of information provided according to annex VII–XI REACH |
| 12 | Ecological Information | (if CSR is required)<br>Results from the **PBT** assessment |
| 13 | Disposal considerations | (if CSR is required)<br>Information concerning waste management and recycling to limit and control the exposure of humans and environment |
| 15 | Regulatory information | Statement, whether a chemical safety assessment was made |
| | | Statements on authorisations and restrictions |
| 16 | Other information | Recommended restrictions of uses |
| Annex 1 | **Exposure scenario** | |
| Additions to existing information because of an improved database are to be expected, especially in the following sections: | | |
| 9 | Physical and chemical properties | |
| 11 | Toxicological information | |
| 12 | Ecological Information | |

Summing up, it is to be expected that the extended safety data sheets will ultimately contain substantially more extensive information on substances and mixtures than previously.

[16] It is possible to give the registration number without the last four digits – see Annex II.

## 5.2 IT-implementation of safety data sheets and the European Standard phrases catalogue (EuPhraC)

Text modules or so called standard phrases allow a technical solution to generate eSDS in different languages with ensured recognition of all uses. This is especially useful for cases where thousands of safety data sheets have to be produced by companies.

A working group of the BDI drew up a standard phrases catalogue for EC safety data sheets and has been keeping it up to date since 1999. This BDI Standard phrases catalogue is available on the website of the BDI REACH Helpdesk[17] and has become the European Standard Phrases Catalogue (EUPHRAC) since 2009 with an EU-wide project group at BusinessEurope now keeping it up to date. The catalogue was recently adapted to REACH requirements and to the Globally Harmonized System for Classification and Labelling (GHS). Since then, the current practical experiences and the respective new legislation are continuously taken into account.

**Examples of such standard phrases** from the EUPHRAC (available on the web site of the Federation of German Industries BDI (http://reach.bdi.info/378.htm) are:

- Vapours/aerosols must be exhausted directly at the point of origin. (section 07, subsection “Technical measures” resp. “Measures to prevent aerosol and dust generation”)
- Use a closed dosage system (section 07);
- Ensure the proper conditions of sealings and connection threads. (chapter 07, subchapter “Specific requirements or handling rules”);
- Unsuitable container/equipment material: alloy, containing copper (chapter 07, combination of two standard phrase codes).

Thus standard phrases are a valuable tool in order to prepare the (extended) safety data sheets necessary under the provisions of REACH. Since safety data sheets have to be provided in the language of the destination country, standard phrases must be translated in a formal manner into different languages. This avoids the cost of an individual translation in each case and ensures a good understanding of the respective content; both of which are of fundamental interest for the companies involved. Harmonised and quality checked phrases ensure recognition by all users.

[17] The catalogue is available free of charge from BDI in German and English (http://reach.bdi.info/378.htm). In addition, it is commercially available with a further 30 languages. .

The main part of the catalogue of the standard phrases covers sentences generally usable within all industrial and professional areas. However, in addition the catalogue is open to include sector-specific communities/associations or initiatives.

Individual results of the chemical safety assessment will also be transferred to the extended safety data sheet. The EUPHRAC also offers standard phrases for this, e.g. for the results of the PBT and vPvB assessment.

Before REACH, in the safety data sheets the standard phrases only covered contents with emphasis on technical and personal protective measures at the workplace. Data on environmental protection and consumer protection-related measures were rare. The updated extensions made for REACH and CLP now also cover environmental and consumer protection, the structure and data of the exposure scenarios in the annex and additional structuring data.

The application of the catalogue is recommended for software suppliers and manufacturers who established their own tools for the elaboration of safety data sheets.

On the website mentioned, the BusinessEurope project group makes additional modules available, e.g. for the new “Globally Harmonized System for Classification and Labelling “(GHS) and for exposure scenarios as an annex to the extended safety data sheet. In addition there are blank forms for REACH conforming safety data sheets (with consideration of CLP regulation) in German and English. It is in progress yet to change the EuPhraC catalogue from Excel to a database structure which will offer an IT solution too for the European phrases authorisation workflow. Every European interested party will have in future the chance to make proposals for new phrases. The new catalogue will be available ca. end of 2nd Q 2010 on www.euphrac.eu.

Furthermore, at the Federal Institute for Occupational Safety and Health (BAuA), “Bekanntmachung 220” is available for downloading[18]. This proclamation replaced the previous “technical rule for hazardous substances 220” (TRGS 220) and is a technical recommendation for the elaboration of REACH conforming safety data sheets.

**Practical tip:** The standard phrases of the European Standard Phrases Catalogue (EuPhraC) make it possible to provide extended safety data sheets and exposure scenarios, as annexes of the safety data sheet, in a uniform way. The new contents necessary for REACH are also illustrated here. The catalogue provided by the BusinessEurope project group can be used for different formats. The blank form provided for an extended safety data sheet enables the use of the Use Descriptor System.

[18] http://www.baua.de/nn_16700/de/Themen-von-A-Z/Gefahrstoffe/TRGS/pdf/Bekanntmachung-220.pdf

In the standard phrases for risk management measures contained in the EUPHRAC, the existing inventory of the CEFIC Risk Management Library was also considered. In addition, further measures were included, e.g. instructions and organizational measures. These are not (yet) contained in the CEFIC RMM Library.

## 6 Determinants of exposure

Operational conditions of the use of substances and mixtures differ widely between industries. Which exposures arise, and how high these are in individual cases, can be traced back to the interactions of a set of determining parameters. These parameters are called "determinants of exposure"[19],[20].They can be arranged in the following way:

- **Physicochemical substance properties** e.g. vapour pressure, water solubility, release behaviour (e.g. migration potential (this is the potential of a substance to move e.g. from a textile to the skin, or from a plastic matrix to the surrounding indoor-air)); particle size and shape (fibres, spherical particles), dustiness (flakes, granules, fine or coarse powder).
- **Determinants of the activities, procedures and processes**, in which the substances are handled. This includes the conditions of use and the risk management measures. Thus, the exposure level will be substantially higher with open brush-painting of a coating than in the case of a closed system; dust formation must be expected in grinding; in a spraying cabin the possibility of aerosol formation will have to be considered. In addition, indirect exposures can result from these uses.
- **Properties of the articles**, which contain the substances to be evaluated during service life, e.g. the surface-to-weight relationship of the article. In the case of volatile substances this relationship plays a role as to what quantity of the substance is released from the article.
- **Characteristics of the surroundings** in which a substance is used (e.g. room sizes) or into which the substance is released (e.g. the volume of the river, into which the wastewater of a local sewage treatment plant is introduced) or by which the substance

[19] In the ECHA guidance on information requirements and the chemical safety assessment, a stronger distinction is made in part A. Determining parameters of substance "release" and determining parameters for the "exposure" are distinguished. Here in the practical guide we speak of exposure-determining parameters for the sake of simplicity. This also includes parameters that determine the substance release.

[20] In the case of high concentrations of dust, even substances which are not classified as dangerous can cause health problems.

is taken up e.g. the average body weight of an adult (in exposure models assumed to be 70 kg for men and 60 kg for women[21]).

These determinants vary from use to use in the degree of interaction and to the degree in which they affect the exposure. A list of the "key parameters" which are important for the exposure assessment has been provided. This is based on existing experiences with exposure assessments, in completely different industries, in the context of the REACH implementation projects. They are shown in annex A2.7 in Part II of the Practical Guide. In the different sections of the exposure scenarios only those exposure-determining parameters which are of importance for the respective use are described.

**Practical tip**: You will see the exposure-determining key parameters again and again in the context of the REACH tasks. They are used for REACH in many places:

- The registrant makes his chemical safety assessments on the basis of these parameters.
- Downstream users will be asked about some of these parameters by registrants and/or manufacturers´ associations, since the manufacturers often do not know them. This is particularly valid for branch-specific typical operational conditions of use.
- Downstream users can use these parameters in order to inform manufacturers about their uses – to ensure that they will be included as identified uses by the manufacturer in his registration.
- When downstream users examine whether their uses are covered in the safety data sheet of the supplier, they must compare the values of the exposure-determining parameters.

As part of the preparation for REACH we recommend that you prepare an overview of the exposure-determining parameters which are relevant for your substances and mixtures. For this we provide references to possible priority setting in chapters 8.2 and 8.2.4.

## 6.1 The conditions of use

Some of the determinants of exposure can be influenced or controlled by the user of the substances, others can not.

Usually neither the respective substance properties nor the characteristics of the surroundings can be influenced (e.g. the average body weight of an adult, which one assumes in the

[21] The values can be different in different assessment tools. You will find more information on such default values in Part IV of the practical guide on exposure estimation.

chemical safety assessment or the quantity of receiving stream water into which the substances are released).

In contrast the characteristics of the processes and the products, e.g. the type of process, the operational conditions or the applied risk management measures can clearly be influenced. If the chemical safety assessment for the examined uses results in an excessively high exposure, one can try to reduce the predicted exposure level to a safe level by changing the process and product properties. These characteristics of the processes and products can be generally called conditions of use.

REACH differentiates between two kinds of changeable determinants of exposure:

- operational conditions (of use) ("OCs") and
- risk management measures ("RMMs").

Operational conditions and risk management measures together form the conditions of use of a substance.

Borderlines between operational conditions and risk management measures often overlap. Operational conditions and risk management measures can decisively affect the real exposures[22].

**Operational conditions** are all actions, use of instruments, or parameters, which occur during the production or the use of a substance (as such, or in a mixture) and which have an effect on the exposure of humans and/or environment.

**Risk management measures** are all actions, use of equipment, or parameters, during the production or the use of a substance (as such, or in a mixture) to be introduced with the goal to prevent, to control or to reduce the exposure of humans and/or environment.

This topic is discussed in greater detail in the following two subchapters (chapter 6.2 and 6.3)

In many cases the usual practice of the use conditions will already have lead to sufficient control of the risk in handling hazardous substances. In such cases this may be all that is required to be documented in the chemical safety assessment. It is a requirement that the appropriate risk management measures, as well as further conditions of use, must be communicated to downstream users in the extended safety data sheet.

[22] **Note**: A clear allocation of a measure or an condition of use to the group "operational conditions" or "risk management measures" is not always possible from a technical aspect. Operational conditions which are given for a safe use, e.g. limiting the processing temperature or the processing duration, are to be regarded at the same time as risk management measures. However there is – related to the exposure – a general difference between operational conditions and risk management measures, which was already presented in the text. The operational conditions can have an influence on the exposure (e.g. an increase of the order quantity), this is however not the goal of these parameters. In distinction to this, risk management measures are used deliberately in order to decrease exposures.

Detailed information for the consideration of technical conditions of use and for the consideration of risk management measures is given in part R.13 of the ECHA guidance.

## 6.2 Operational conditions

The operational conditions of use which are important for the exposure assessment include:

- the duration and the frequency of the use (e.g. in an 8-hour-operation, or only 15 minutes; e.g. daily or only once a month);
- the physical form of the substance or the mixture in which it is used (e.g. as a dust forming solid or as dust free granulates; as a liquid, which can form an aerosol, or included into a matrix),
- properties of the product in which the substance is used (e.g. the concentration of the substance in a mixture or in an article);
- if necessary, properties of the article which contains the substance (e.g. the ratio between surface and volume of the article).
- the quantity of the substance or the associated mixture, which is used per activity;
- physico-chemical parameters which mark the use (e.g. the operational temperature, the pH value of the process fleet, the supply of mechanical energy during the process).

Information on the “local“ conditions of use existing in practice, together with the common risk management measures, is usually available from the downstream users of substances or mixtures – but not necessarily from the manufacturers and/or importers, who need these data for the chemical safety assessment.

## 6.3 Risk management measures

Risk management measures – and compliance with them or measures that offer an equivalent level of control – are of central importance for the safe use of substances. They are not new under REACH but are already prescribed in other pieces of legislation. (e.g. EC Chemicals Agents Directive (CAD) and the IPPC Directive (Integrated Pollution Prevention and Control)). However, the starting point of the consideration of risk management measures for the chemical safety assessment under REACH should be the existing documented guidance and recommendations:

- in the documents on the best available techniques (BREF documents) for the different industries
- and guidance of national authorities (e.g. the technical rules for hazardous substances of the German Federal Institution for Occupational Safety and Health (BAuA) and of the BAuA developed “Easy-to-use workplace control scheme for hazardous substances”

(EMKG), which builds on the British system COSHH Essentials (see also chapter 8.3 (Part I), Annex III (Part III) and chapter 1.2.4.2 (Part IV) of the practical guide).

The chemical safety assessment may show that additional risk management measures are necessary in order to control the risk associated with the use of the substance or mixture.

In this case, manufacturers and/or importers have to implement appropriate measures for their own uses, and communicate via the e-SDS to the downstream users the appropriate measures applicable to their uses. The DU will examine whether his use(s) is/are covered by the ES. If so, it is necessary to implement the necessary RMM. In these cases the downstream user may perform scaling, based on guidance given in the exposure scenario, the determinants of exposure provided, in order to check whether his use is covered by the received ES and demonstrate control of risk even if some conditions of use are deviating from the description in the exposure scenario (see chapter 7.2 and chapter 7.8).

If this should not be the case (and no exemptions apply), the downstream user has the obligation to take care that this use will be covered. This may e.g. be done by communicating this use to the supplier (for inclusion in the suppliers registration as identified use) or by performing an own downstream user chemical safety report (for details on the downstream user compliance check see chapter 7).

**Note:** The result of a chemical safety assessment may be that less RMM are required as already applied. Nevertheless existing e.g. national regulations may require stricter RMM which are already implemented because these regulations consider the entirety of the impact on the workplace and/or in the environment.

The arising exposures can be substantially reduced by risk management measures. Which specific risk management measures are implemented may differ from user to user. In the risk management measures distinction is made between

- instructions;
- product-related measures;
- organisational measures;
- technical measures;
- personal protection measures.

When considering different options for minimizing the risk, process and/or product-related measures, generally have priority over additive emission reducing measures at the end of the process. Technical measures, wherever they are practicable for the use under consideration, usually have priority before the use of personal protection. In the ECHA guidance for the development of exposure scenarios (ECHA 2008, part D, chapter D.4.5.3, P. 30-31) for the collection and recommendation of risk management measures, eight

helpful guidance questions are given, which also consider the hierarchy of measures given above:

- Which uses of the substance should be avoided? Here the manufacturer/importer should make a clear statement in the context of the registration that such uses are not supported. They are then not covered by the exposure scenario.
- How can the exposure potential be reduced at the product level with respect to a dangerous substance in a mixture or product? Possibilities are e.g. change of the physical condition of a product (minimal dust formation); decrease of the concentrations of a product in a mixture; design of the packaging (e.g. selection of child resistant closures) among other things.
- Can the exposure be prevented or avoided by strict containment?
- Can the exposure be reduced by a limitation of the time and/or frequency of handling the substance?
- Can emissions be reduced by process related technical measures, e.g. an increase of the degree of absorption of a dyestuff (e.g. to increase in the proportion of the substance that during a dyeing process remains on the treated material (and thus does not end up in the process wastewater)).
- Can the exposure at the workplace be reduced by technical measures, e.g. local exhaust ventilation
- Can air and water emissions be reduced by local or overall operational measures e.g. pre-treatment as part of the process or local waste water treatment?
- In which situations can a reduction of the exposure be achieved only by personal preventive measures?

In addition there should be a consideration of any instructions and organizational measures which would enable exposures to be reduced.

In the selection of the recommended risk management measures, the manufacturer and/or importer should ensure that the measures will provide adequate control of risk and that they are practicable for implementation in the respective industry.

Detailed descriptions of the inclusion of risk management measures are given in chapter R.10 of the ECHA guidance for chemical safety assessment. CEFIC has collected descriptions of risk management measures in a so-called “library of risk management measures” (see chapter 10.6 of the Practical Guide).

Strictly controlled conditions for intermediates for which reduced registration is being sought (according to REACH Art. 18.4) are an important specific case of risk management measures. CEFIC published a guidance on confirmation of strictly controlled conditions (http://www.cefic.be/Files/Publications/Demonstrating-SCC-for-intermediates.pdf).

Also ECHA publishes a guidance on intermediates (http://guidance.echa.europa.eu/docs/guidance_document/intermediates_en.pdf). In this document registration requirements are described for non-insolated intermediates, on-site isolated intermediates and transported isolated intermediates.

**Practical tip:** In practice many risk management measures are already in place in the industry for certain uses. Critical examination of the effectiveness of the already common measures should usually demonstrate that any possible risk is already sufficiently reduced. In this case usual and safe practice can be continued by the user.

**Example – textile finishing:**

Within the development of broadly composed exposure scenarios for textile finishing it was first assumed that there was no need for special risk reduction measures, which go beyond the general measures of good practice in handling of chemicals already established in this use sector. In some cases, however, it was found to be necessary to carry out additional measures to decrease the discharges to wastewater.

In textile finishing different emission reduction measures are used for this:

- organisational measures;
- process-integrated/upstream measures and
- end-of-pipe measures.

Each of these measures can reduce the release of chemicals into the wastewater. In the exposure scenario developed for textile finishing, different possibilities were described for emission reduction and shown in a separate table. If they are applied, a larger quantity of the mixture can be used in the process, without the expected concentration in the environment reaching critical values (the value of the PEC/PNEC ratio calculated for the receiving stream[23] remains under 1).

Examples of typical emission reduction measures, and their effectiveness, are presented below in table 4. The reduction factor specified in the third column can be inserted directly into the formulas for the calculation of the predicted environmental concentration (PEC)

[23] Receiving stream: waters into which the wastewater is discharged (after treatment in a local sewage treatment plant or, with direct discharges, directly (if necessary after an operational treatment)).

Table 4 Typical emission reduction measures in textile finishing, the associated effectiveness, and the resultant increases of the permissible daily quantity used.

| Measure | Effectiveness | Reduction factor | Quantity required Orange 703-R |
|---|---|---|---|
| Retention of remainder fleets in the KKV dyeing | 50% | 0.5 | 240 kg/d |
| Decolourisation of the remainder fleets and the washing water of the KKV dyeing e.g. by oxidative or reductive procedures | 95% | 0.95 | 2400 kg/d |

# 7 Downstream users and the implementation of REACH

## 7.1 Who is a "downstream user" under REACH?

Downstream users handle substances (as such or in mixtures) in the context of their industrial or commercial activities, but do not manufacture or import substances. Downstream users can be divided into five groups:

- Formulators (if they are not themselves manufacturers/importers of the substance): They manufacture mixtures from substances (which in part are then used by following formulators as raw materials)[24].
- End users, who use substances or mixtures in industrial or professional applications, without the substance or the mixture being passed on to another actor. Under end users there can be further differentiation between industrial users, manufacturers of articles and professional users. The professional users also include craftsmen and workshops, by and/or in which substances and mixtures are used.
- Users who repack substances and/or mixtures from one container into another (without exposure to substances) and/or re-fill ("re-filler") (exposure can occur here!), but perform no further actions with the substances and/or mixtures.

[24] In practice, in the same legal entity, different life cycle steps of a substance can take place. Many companies manufacture and/or import substances and then use these substances in their own company, or manufacture mixtures from them. These manufacturers of mixtures, which are at the same time manufacturers or importers of these substances, are generally called formulators. According to the definitions given in REACH, they are not downstream users. However, they are manufacturers and/or importers of the respective substances! Only formulators who do not manufacture and/or import the substances are considered as downstream users under REACH.

- Re-importers (who can prove that the substances imported by them into the European Union were originally manufactured in the European Union and are already registered). The essential obligation of the re-importer lies in the documentation that his substances are the same substances as those already registered in the European Union.
- Importers, for whom an Only Representative took over the obligations of registration.

Private consumers are not downstream users under REACH.

Distributors of chemicals are not downstream users in the sense of REACH art. 3.13. However, they have obligations under REACH, particularly in the passing on of the relevant information in accordance with REACH articles 31 and 32 (see chapter 2.4 of the practical guide).

## 7.2 Tasks of downstream users in overview

Nine tasks can apply to downstream users under REACH. The first three of these concern everyone; the following six are specific for individual subgroups of downstream users.

- Task 1: Downstream users have to identify their specific roles and obligations.
- Task 2: Downstream users have to inform their suppliers if they have new information on hazardous properties, also relating to classification and labelling.
- Task 3: Downstream users have to inform their suppliers if they have information that the risk management measures communicated in the exposure scenarios are inappropriate.
- Task 4: Formulators[25], end users and refillers must identify appropriate measures and apply these, in order to control the risks of their own activities with the substances and/or mixtures, as communicated in the safety data sheets and in any further information.
- Task 5: Formulators, end users and refillers must examine whether their uses agree with the exposure scenarios which they received from their supplier and with any discrepancy, take further measures (communication to the suppliers and/or carrying out their own chemical safety assessment, see chapter 7.3).
- Task 6: Formulators and refillers must place sufficient information at the disposal of their customers, also distributors, in order to ensure a safe use of the chemicals[26].

[25] As already described above, this task is valid for formulators, end users or refillers, who do not manufacture and/or import these substances as downstream users, but rely on a manufacturer/an importer or a supplier in the European Union.

[26] The bases for this are the safety data sheets, the information contained in them due to article 32 and if necessary the chemical safety reports which they have carried out themselves.

- Task 7: Manufacturers of articles must provide sufficient information for safe handling to their customers and supply them with information on substances of very high concern (substances on the “candidate list” within the authorisation procedure) in articles, if they contain these substances in concentrations of more than 0.1 weight percentage. On demand, this information is also to be communicated to private consumers (Art. 33 REACH).
- Task 8: With substances which are subject to an authorisation, it is to be examined by all users wherever their uses are authorized. If this is not the case, the users must request an authorisation if they want to use the substance further.
- Task 9: With substances which are subject to a restriction, it is to be examined by all users wherever their uses are forbidden due to an existing restriction.

Beyond that, re-importers of substances have the task of documenting that the substances imported by them are identical to substances already registered in the European Union. (Distributors, which are no downstream users under REACH, have the following specific task: they must pass on the relevant information (safety data sheets, exposure scenarios, information in accordance with article 32) to their customers. They have to give (new) information regarding hazardous properties of the substances (irrespective of uses) to their suppliers. In addition, they have to pass on any other information that might call into question the appropriateness of the risk management measures identified in a safety data sheet supplied to them (only for identified uses)).

**Note:** The ECHA guidance for downstream users provides assistance with **all** tasks. (In table 5, an overview is given in the guidance document (ECHA 2008d, chapter 2.5.5, P. 25) regarding the tasks’ allocation to the respective advanced chapters). In chapters 3 and 4 of the ECHA guidance for downstream users recommendations are also given, how downstream users can prepare well for REACH and what is to be done, when a downstream user receives “new information“.

In the REACH practical guide we focus on the task of the downstream users, which is most important for the exposure assessment: the examination of whether their own uses were assessed by their supplier to be safe or not. Otherwise, the user must take his own steps to determine safe use if he wishes to continue the use. Chapters 7.2 – 7.6 describe in detail the downstream user compliance check and the different options for the downstream user.

Beyond that, REACH also grants downstream users the right to participate in the effective implementation of REACH by targeted communication of their knowledge. Downstream

users can support[27] manufacturers and importers in their tasks of registration, by informing them about the typical use conditions for the substances in their industries – with the goal that these uses be considered as identified uses in the chemical safety assessment and are covered by the exposure scenarios. We will go into that more closely in Part II of the Practical Guide, Chapter 9.

## 7.3 The task "Examination of the conditions of use by the DU"

Under REACH the substance manufacturer/importer communicates to the downstream user by means of one or more exposure scenarios, under which conditions of use the substances supplied by him can be used safely[28].

It is then always the task of the downstream user to assess whether the descriptions of safe use contained in the exposure scenarios received cover the conditions under which he actually uses the substance (or mixture) and, if applicable, the conditions applied by his customers.

Each downstream user must consider the safe use conditions included within the relevant exposure scenario(s) and ensure that the measures he is applying offer the same or an equivalent level of control. This implies that the DU examines whether the indicated safe use conditions are actually in place in his company. (If the downstream user has information that might call into question the appropriateness of the risk management measures communicated to him for the identified uses, he shall communicate this to his supplier (see REACH Art. 34b)).

The core task "examination of the own conditions of use" consists of two steps for a specific substance or mixture:

- Step 1: The evaluation of the main body of the extended safety data sheet (a task existing already before REACH);
- Step 2: The examination whether the operational conditions and the risk management measures for his use are in line with the information in the exposure scenario, and initiation of further steps, if this is not the case.

Figure 5 illustrates the situation for a downstream user of a substance or of a mixture who receives an extended safety data sheet.

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[27] This concerns a voluntary possibility, it is not legally prescribed.

[28] The registrant considers here the amount of substance brought by him into the supply chain. In most cases he cannot judge the total exposure for the total quantity of the substances applied.

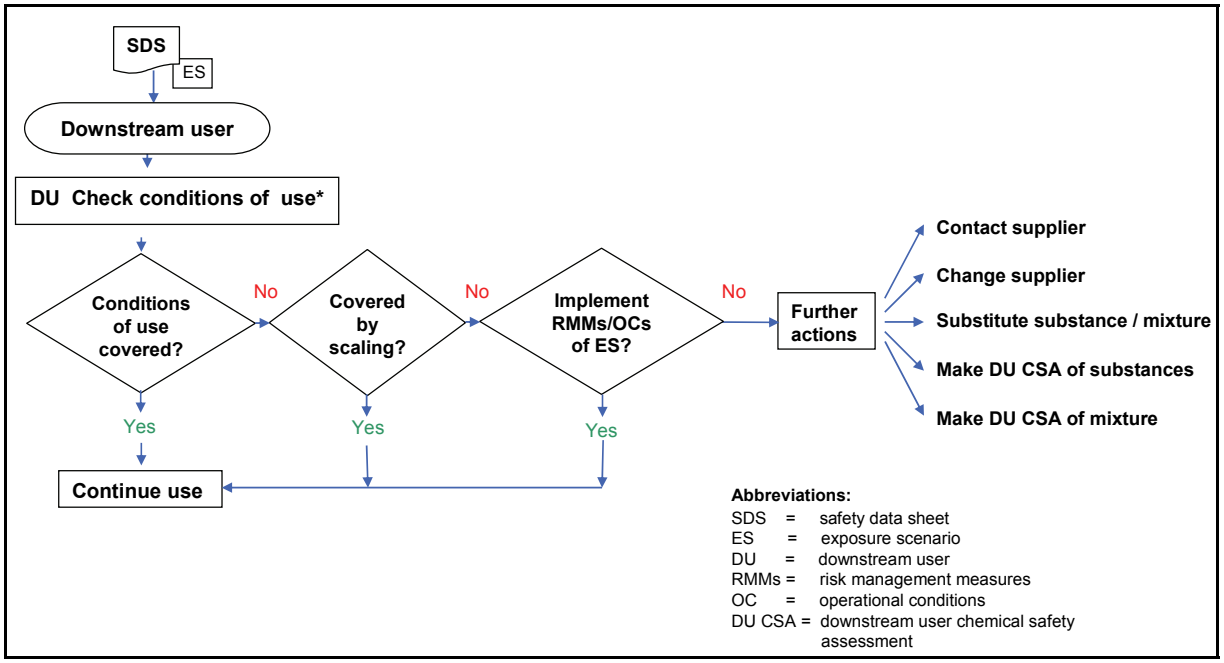



Figure 5 Main tasks for a downstream when receiving an extended safety data sheet. “Further actions” are options which can be chosen from the downstream user as alternatives or in parallel.
*) “use” includes own uses and identified uses of customers, if applicable (e.g. in case of formulators).

At first, the downstream user checks whether the conditions under which he uses the substance or the mixture are described as a safe use in the exposure scenario. If this is the case, he can continue his use.

It might be that he uses the substance in a way which differs from the description in the exposure scenario. Such deviations do not mean automatically that a use is not covered. In the exposure scenario guidance can be given to asses whether such differences still lead to a safe use. Application of such guidance is called “Scaling”.

If it is not possible for the downstream user to become compliant with the exposure scenario even by scaling, his use is not covered by the exposure scenario. However, it might be that he applies (another) exposure scenario and implements in this way the conditions of use described in the exposure scenario which he received (or even a more stringent exposure scenario). In this case he can continue his use, too (REACH Art. 37.4d).

If the use is not covered by the exposure scenario and the conditions of use are not implemented, the downstream user has a number of options.

- Decide to adapt his conditions of use to the ones included in the exposure scenario.
- Communicate the use to the supplier and ask him to provide an exposure scenario which corresponds to his conditions of use.

- Prepare his own chemical safety assessment and develop an exposure scenario for his use (and the related uses of his customers, respectively) and – if necessary – communicate it to his customers;
- Decide to change to another supplier who covers his use in the extended safety data sheet.

The downstream user has 12 months time to examine his own use, to communicate with the supplier (if necessary) and to implement the recommended risk management measures – or to make his own chemical safety assessment and – if necessary – to communicate his exposure scenario to his customers.

Generally, the downstream user also has to inform the ECHA within 6 months about any use of a substance (on its own or in a mixture) outside the conditions described in the exposure scenario which has been communicated to him by his supplier (REACH art. 38). The obligations for downstream users to report information to ECHA are described in more detail in chapter 7.6.

These periods start when the downstream user receives the safety data sheet with the substance registration number and the exposure scenario from his supplier (Art. 39, 2 REACH)).

**Exemptions from the obligation to prepare a downstream user chemical safety report, despite having a deviating use?**

In several cases the downstream user does not need to prepare his own chemical safety report (Art. 37,4 a-f[29]). This is valid in particular,

- if, for the substance or mixture, the communication of a safety data sheet is not prescribed;
- if a safety data sheet is supplied, but it contains no exposure scenario;
- if the downstream user implements or recommends an exposure scenario which includes as a minimum the conditions described in the exposure scenario communicated to him in the safety data sheet;
- if the downstream user uses the substance or the mixture in a total quantity of less than 1 tonne per year;
- if the substance is present in a mixture in a concentration lower than any of the concentrations set out in REACH art. 14(2).

**Note:** Even if no exposure scenario is contained in the safety data sheet as an annex, the downstream user must still consider the specifications given in chapters 1-16 of the safety data sheet for safe use.

[29] In article 37.4(f) a further reason is described: the use for research and development (see REACH art. 37 (4f)).

In the following chapter details are given how to do the downstream user compliance check.

## 7.4 How to perform the downstream user compliance check?

The compliance check of the downstream user means to compare conditions of his uses (and of his customers, if applicable), which are relevant for the exposure situation, to the conditions described in the exposure scenario submitted to him by his supplier. (If the supplier has submitted several exposure scenarios for different uses, the downstream user first selects the exposure scenario which is relevant for his own use).

Especially for the downstream user compliance check, existing experience of the downstream user with risk assessment requirements from other pieces of legislation can be used, e.g. from the Chemical Agents Directive 98/24/EC.

This compliance check starts when a downstream user receives a SDS with an exposure scenario attached or integrated.

Information given in the exposure scenario which are relevant for the safe use have to be compared with the situation of the downstream user. If there are deviations, it has to be assessed whether they may cause higher exposures than expected under the conditions of use described in the exposure scenario.

The following figure 6 illustrates the working steps (from ECHA Guidance for downstream users, 2008). It consists of two steps.

- A first screening, referring to the short title of the exposure scenario and the description of the activities which are covered by the exposure scenario. This information is given in chapter 1 and 2 of the exposure scenario.
- An assessment whether his individual conditions of use are covered by the operational conditions and the risk management measures described in the following sections of the exposure scenario which are relevant for his use.

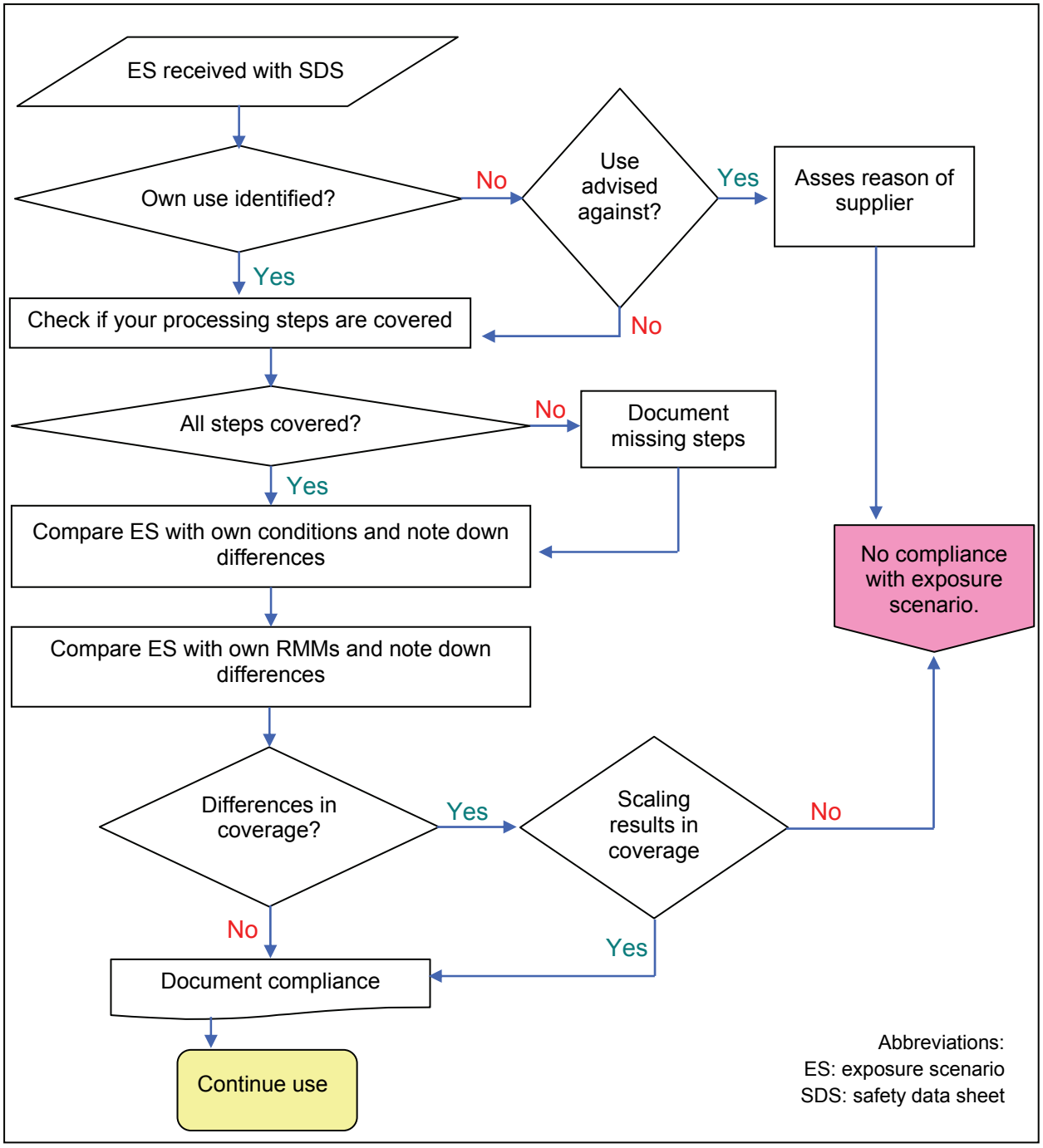



Figure 6 Workflow on checking compliance with the exposure scenario. Source: based on ECHA Guidance for downstream users, fig. 5.4, p. 48 (with minor modifications). In the case of "no compliance with exposure scenario" the downstream user has several options. They are illustrated in Figure 5 and described in chapter 7.3.

**Step 1: Check title section of the exposure scenario**

The downstream user compares his uses (and the uses of his customers, if applicable) with the short title and the description given in section 1 of the exposure scenario (see Part II of the Practical Guide, chapter 9.2, which describes the standard format of exposure scenarios). If the short title of the exposure scenario fits with the uses of the downstream user and his customers, this is a first hint that his processes and activities are covered by the description given in the exposure scenario.

Deviations from the use description in the title section do not trigger automatically legal obligations for the downstream user, if he complies with the conditions of use as described in the other sections of the exposure scenario.

As an example, it can be that the deviations are caused by a missing process categories. (In this case it should be checked whether the supplier has given a more generic process category – which might cover the more specific process category of the downstream user. A list of process categories which are covered by more generic process categories has been elaborated and is given in Annex A1.2).

These deviations should be documented internally and considered in the following part.

Accordance with the information in the title section does not automatically mean that the operational conditions and the risk management measures of the downstream user are in line with the specifications given in the exposure scenario. Therefore in the second step a direct comparison of the relevant conditions of use is necessary.

**Step 2: Check operational conditions and risk management measures**

Here the downstream user compares operational conditions and risk management measures described in the ES with his use. For the documentation of this analysis, a helpful format is provided in the ECHA Guidance for downstream users (ECHA 2008). The structure of this format is presented in a slightly modified form in table 5. The complete table is given in Annex I.1.

Table 5 Format to support and document downstream user compliance check. Source: ECHA Guidance for downstream users, 2008, Table A.4, p. 140ff. It refers to the structure of the ES with 9 sections. The table shows only a part of the format. The whole format is given in Annex I.1.

| Item | Information in ES | Present situation | Conclusion | Action need |
|---|---|---|---|---|
| Short title of exposure scenario | | | No immediate need for action, as deviations from the use description does not trigger legal obligations, if you comply with the conditions of use indicated. | |
| Description of activities/processes covered | | | | |
| Processing steps at own site not explicitly covered (not mentioned in Section 2 of the exposure scenario) | | | | |
| Considerations on exposures from missing activities and whether or not they are covered by the other activities or require more detailed assessment | | | | |
| (Maximum) duration of use event | | | | |
| (Maximum) frequency of use/event | | | | |
| ……. | | | | |

The comparison should cover all types of risk management measures described in the exposure scenario, including instructions given there.

Not all of the items listed may be relevant for each exposure scenario and additional exposure drivers may be of relevance which have not been listed here. Information should be filled in only for differences!

Examples for qualitative and quantitative deviations are given in the following table 6.

Table 6 Check of compliance with an exposure scenario: examples for quantitative and qualitative differences.

| Type of information | Description in exposure scenario | Practice of downstream user | Comment |
|---|---|---|---|
| Risk management measure (RMM) | Half mask, protection factor 10 | Half mask, protection factor 25 | Quantitative difference, RMM covered |
| | Local exhaust ventilation, efficiency 90% | Local exhaust ventilation, efficiency 95% | Quantitative difference, RMM covered |
| | Chemical resistant protective gloves (EN 374), e.g. nitrile rubber (NBR) – 0,4 mm coating thickness, break through time 480 min. | Not yet | Qualitative difference. RMM should be implemented by the downstream user |
| | Safety glasses with side-shields | Not yet | Qualitative difference. RMM should be implemented by the downstream user |
| Process/type of application | Brushing (manual application) | Spraying (industrial application) | Qualitative difference. Exposure routes and related measures are different. Check operational conditions and risk management measures to decide whether application is covered by the exposure scenario. |
| | Ambient temperature | Elevated temperature, 60°C | Qualitative difference. Effect on exposure has to be assessed, use not covered by ES. |
| | Duration of activity: < 4 hours | Duration of activity: 8 hours. | Qualitative difference. Effect on exposure has to be assessed, use not covered by ES. |
| | Maximum amount used per day: 250 kg | Max. amount used per day: 200 kg | Quantitative difference, condition of use covered. |

Some of the deviations shown in table 6 are qualitative deviations, e.g. brushing by manual application instead of spraying. These qualitative deviations can effect different exposure routes. Based on the results of the comparison, the downstream user performs an assessment of all deviations and their influence on the exposure level.

- If quantitative deviations lead to lower exposures, the use of the downstream user is covered by the ES. (e.g. the amount used is lower / the volume of the receiving water is higher / the process temperature is lower than given in the ES).
- Quantitative deviations could lead to higher exposures (e.g. the amount used is higher / the volume of the receiving water is lower / the process temperature is higher than given in the ES). If the exposure scenario contains scaling guidance related to these parameters, the downstream user can check whether his conditions of use are still representing a safe use. If no scaling guidance is given, the use of the downstream user is not covered by the exposure scenarios.

- Qualitative deviations indicate that other types of exposure could occur. Brushing by manual application for example could cause dermal contact which is not addressed in an exposure scenario related to industrial spray applications. Application of mixtures at elevated temperatures can lead to higher concentrations of substances at the working place than application at room temperature. Therefore such situations need a specific exposure assessment and risk characterisation, if it is not evident from the details of the exposure scenario that the downstream users relevant conditions and measures are covered. If they are not described in the exposure scenario, the related use of the downstream user is not covered by the exposure scenario. Different from quantitative deviations, qualitative deviations can not be covered by scaling. In some of these cases still a scenario that is at least as stringent as that received from the supplier may be documented.

In the final conclusion, the effects of all deviations on the exposure situation have to be assessed together.

- If the assessment shows that his conditions of use are covered, the downstream user can continue his use[30].
- If there are differences between individual conditions of use and the description in the exposure scenario, the downstream user can use scaling guidance given in the exposure scenario to show that his individual conditions of use are covered, too. Also in this case he can continue his use.

**Scaling:** Generally the downstream user should comply with the conditions of use indicated in the exposure scenario of his supplier which are related to his use. However, it could be that he uses another combination of risk management measures and operational conditions – and achieves the same (or a higher level) of safety.

Not each difference between the description of the conditions of use in the exposure scenario and the own practice of the downstream user means that his use is not covered. Within the exposure scenario guidance can be given how to assess deviations from the conditions of use described in the exposure scenario, e.g. higher amounts of a substance used per day. This guidance can be a simple equation or a reference to a specific tool for this assessment. The use of simple mathematics to asses own conditions of use is called “Scaling”. (ECHA Guidance on information requirements and chemical safety assessment, 2008, Chapter G, Extending the safety data sheet, p.18). Scaling allows the registrant to

[30] If all conditions of use and risk management measures are implemented, but nevertheless limit values are exceeded, this should be communicated to the supplier – with the obligation for both sides to clarify why the use described in the exposure scenario as being safe, is in practice not safe. One reason can be that the registrant has made assumptions for exposure modelling which do not fit to the real conditions of use.

broaden the range of conditions of use which is covered by his exposure scenario. Scaling is described in detail in chapter 7.7[31].

**Implementing conditions of use or stricter conditions (REACH Art. 37.4c):** It can be that downstream users have conditions of use (relevant for the exposure situation) which show clearly qualitative deviations from the conditions of use described in the exposure scenario and which are also not covered by scaling guidance in the exposure scenario.

In this case this use is not covered by the exposure scenario.

However the downstream user is not required to make his own chemical safety assessment if he can show that he implements – another – exposure scenario which includes as a minimum the conditions of use described in the exposure scenario communicated to him in the safety data sheet. This is also the case if the downstream user implements a more stringent exposure scenario. According to REACH Article 37.4d in this case a downstream user does not need not to prepare his own chemical safety report and he can continue his use. (As an example: it can be that the downstream user implements a more generic exposure scenario which defines stricter conditions than the specific exposure scenario submitted by the supplier).

If the conditions of use relevant for the exposure situation of the downstream user are not covered by the exposure scenario and scaling can not show coverage either, the use of the downstream user is not covered by the exposure scenario. Consequences are described in chapter 7.5.

**Additional note: measured data and the downstream user compliance check**

As said above, if the use of a downstream user differ from the description in the relevant exposure scenario and minimum implementation can not be demonstrated by scaling, the use is not covered.

This is the case even if the downstream user can provide results from measurements of substances at the workplace and/or in the environment which indicate that the use is safe (ECHA Guidance for Downstream Users, 2008, chapter 5.4, note i, p.54). Safe use means that measured exposure levels are below the Derived No Effect Levels (DNELs) or below the Predicted No Effect Concentrations (PNECs) communicated in the safety data sheet.

[31] The possibilities of scaling specific parameters have to be carefully assessed in the chemical safety assessment of the registrant. In many cases, relationships between determinants of exposure and exposure are not linear or linearity is restricted to a certain range. The applicability of scaling for a specific use has to be checked individually as part of the CSA of the registrant. Only on this base can recommendations for scaling be communicated to the downstream users in the ES.

Such data are an indication that, “as a minimum”, the conditions of use of the exposure scenario have been implemented (REACH Art.37.4(d)). However, this has to be demonstrated by the downstream user by performing a downstream user chemical safety assessment for his use (ECHA Guidance for Downstream Users, 2008, chapter 5.4, note i, p.54).

Within this assessment actual measurements can be used for demonstration of safe use (if they are based on a suitable protocol and have a good quality standard). In this case the downstream user has to make a notification of this use to ECHA (if the downstream user wants to continue his use and he decided to perform his own chemical safety assessment. Other options for him are described in chapter 7.3, see figure 6 and in the following chapter 7.5).

## 7.5 Consequences of the examination and courses of action

If his own use is not covered and no exemption applies, the downstream users has in principal a variety of options which we have already described above (chapter 7.3, figure 6).

- He can modify his conditions of use and implement the operational conditions and risk management measures given in the exposure scenario which he has received.
- If this is not possible for him, he can decide to implement another exposure scenario which is at least as strict as the exposure scenario which he received with the safety data sheet.
- If both options are not applicable, the downstream user can request his supplier to include his use in the safety data sheet (in accordance with article 37 (2) and (3)). If the supplier follows this request, he will send a safety data sheet to the downstream user with a revised exposure scenario that covers his uses.

**Note:** The procedure for making the decision of whether one’s own use is covered or not is explained in chapter 6 of the ECHA guidance for downstream users. In chapter 8 of the ECHA guidance assistance is given on how to communicate one’s own use to the supplier as an identified use (ECHA 2008d), CEFIC developed a specific approach to support the communication of uses in the supply chain. This approach is described in chapter 10.3.

Practical tip: If the downstream user makes a formal request to his supplier to include his use into the safety data sheet, the supplier has to extend his chemical safety assessment within a period of one month, according to REACH Art. 37.3. It is unlikely that this can be done in this short time. As a consequence the supplier would have to stop selling the substance to this customer.

If a downstream user informally contacts his suppliers because his use is not covered, the supplier can consider this use in his extended safety data sheet without starting the time period of 1 month.

It could be that the supplier, for environmental and health protection reasons, advises against the use or that the user for reasons of know-how protection would not like to communicate his special use to the supplier. In these cases the downstream user has the following options:

- He can independently prepare a chemical safety assessment to determine, under which conditions his use is safe. In this case a notification of the respective use to the European Chemicals Agency is then also necessary. (Chapter 7.8 describes the downstream user chemical safety assessment in more detail).
- He can change to a supplier of the same substance who covers his use in his exposure scenario.
- In rare cases he can stop the further use of the substance and/or the mixture by switching to another product, for which the intended uses of the downstream users are safe.

**Note:** Before the downstream user considers taking complex measures, the problem should be discussed with the supplier. Here in the evaluation of the environmental exposure it is of particular importance, on which data basis the PNEC values were determined. If only few data are available on the toxicity of a substance, high safety factors are used in the determination of the PNEC values. This means that in such a case a substance that is actually not particularly critical gets a very low PNEC value. The exposure can then be higher even when only small quantities are used. In such a case the downstream user should examine, with which safety factors the PNEC values specified in the safety data sheet were determined. Ideally this information is noted in the safety data sheet. If this is not the case, the formulator may be asked about it.

If the PNEC values were determined under application of very high safety factors, it should be the goal of communication with the manufacturer/formulator to examine options for a new determination of the PNEC values on the basis of additional data (usually by further ecotoxicological studies, in particular studies of long-term effects on aquatic organisms). This can lead to a lowering of the PNEC values and thus to an increase of the maximum permissible quantity applied.

## 7.6 Information obligations in accordance with Article 38 REACH

If a downstream user has to prepare a chemical safety report because his use is outside the conditions described in an exposure scenario communicated to him in a safety data sheet or his supplier advises against this use, he is obliged to report information to the European Chemicals Agency (article 38 REACH).

This information can be short and must contain the following points:

- his own identity and contact details;
- the registration number of the substance which it concerns (it can be mentioned in the safety data sheet);
- the identity of the substance (according to the specifications in the safety data sheet);
- the identity of his supplier (also named in the safety data sheet);
- short general specifications on the uses and on the conditions of use (operational conditions and risk management measures).

The downstream user has six months to prepare this notification and to send it to ECHA from when he received the safety data sheet with the substance registration number and the exposure scenario from his supplier (art. 39 (2) REACH).

If the downstream user is of the opinion that, for the assessment of the use, additional substance data are necessary, which can only be obtained by vertebrate animal testing, he has also to communicate a proposal for such studies to the Agency.

In two further cases, an obligation to report to ECHA also exists:

- if the data specified above change and the downstream user has to update them or
- if the downstream user classifies the substance or the mixture differently than the supplier.

In general, downstream users only have to inform ECHA (about uses not covered by the exposure scenario supplied to them) if they use the substance on its own or in a mixture in quantities of 1 tonne per year or more in this particular use (REACH art. 38 (5)).

There is one exception from this rule. If the downstream user does not prepare a chemical safety report for such a use (relying on REACH article 37 (4c)), he has to report the information mentioned above to ECHA.

## 7.7 Scaling

### 7.7.1 Introduction

Within the same industry, the uses for the same substance can differ widely between companies. Neither the manufacturer of an individual substance nor the formulator, who places the mixture containing this substance onto the market, can be expected to know the full range of all details of uses/use conditions and to evaluate them regarding the emission situations arising.

Thus, the manufacturer and/or formulator can communicate in his exposure scenarios the safe conditions of use on the basis of standard assumptions for all identified uses.

For the downstream user, other conditions of use (e.g. a different daily quantity required) and other risk management measures will be present in individual cases. If the essential key parameters of the exposure estimation are known, the downstream user can vary and adapt these to his actual circumstances. Using simple calculation steps, he can then examine whether the expected exposures under his special conditions of use are in the safe range or not. This procedure is called Scaling.

By the use of scaling tools, the supplier of the exposure scenario has the possibility to broaden the field of conditions of use which are covered in his exposure scenario.

**Note**: Scaling is only possible if the supplier has specified relevant scaling rules or assessment instruments in his exposure scenario. This indicates that the applicability and the limitations of scaling for the identified uses have been assessed by the supplier and have been documented in the chemical safety report of the substance. If the registrant specifies assessment instruments, he should deliver the input parameters which have been used for the exposure assessment and risk characterization.

Scaling rules may vary considerably in complexity: they may consist in simple linear relationships ("if half of the amount of substance is used, the exposure time can be twice as long") or may make necessary electronic tools.

**Note:** In the following example there is a linear relationship between determinants of exposure and the resulting exposure. This is not always the case. It can be necessary to consider additional parameters, e.g. different emission situations, impacts on the sewage treatment plant and others. Therefore scaling is not an easy task. During the chemical safety assessment the scaling options have to be checked by the registrant in detail.

***An example:*** If the use quantity is the double amount under otherwise identical basic conditions and the amount of substance released with the wastewater is also doubled, then – in first approximation according to the usual generally recognized models – a doubling of the substance concentration in the associated receiving stream is also to be expected[32]. This means: The downstream user finds the indication in the exposure scenario of a mixture where a maximum of 120 kg of mixture/day can be used, if the receiving water body after the sewage treatment plant has a water volume of 200,000 $m^3$/day. Since the sewage treatment plant, into which this wastewater is fed, emits into a large river with a water volume of 2 million cubic meters per day, he could apply up to 1,200 kg of the mixture/day. (In this

[32] The statement on the direct proportionality between quantity used and concentration in the receiving stream is valid only if the speed of all degradation processes is independent of the concentration of the substance ("processes of the first order "). In practice this is assumed to be the case.

example it has to be checked that there is no limitation of the use due to any impacts of the substance on the sewage treatment plant).

For the downstream user, several options to scale exist. He can apply the scaling rules provided in or with the exposure scenario, or he can use IT-tools specified by his supplier to adapt the conditions of use. If the downstream user can prove by these means that his conditions respect "as a minimum" the conditions described in the exposure scenario, his conditions of use are covered by the exposure scenario and his compliance check has been successfully finished. (ECHA Guidance for downstream users, 2008, chapter 5.4, note i, p. 53).

Scaling can broaden the range of applications which are covered by an exposure scenario. Several tools exist or are being developed which aim to support scaling.

### 7.7.2 Scaling tools

In the following subchapters, different tools are described which support scaling:

- The ES modifier. This tool can be used by registrants, formulators and experienced downstream users (chapter 7.7.2.1).
- Tools related to process categories and exposure modifying factors of exposure estimation instruments such as ECETOC TRA version 2. They aim to support registrants and experienced downstream users such as formulators (chapter 7.7.2.2).
- Tools related to a specific end use of a substance or mixture. They aim to support end users who have no experience with exposure estimation tools (chapter 7.7.2.3 ).

#### 7.7.2.1 ES Modifier

*Aim and scope of the ES Modifier*

The "ES modifier" has been developed by Danish and Dutch consultancy companies on the initiative of the Confederation of Danish Industries, who is the owner of the tool and with support by the Danish EPA. The software (prototype 3.0, May 2010) can be downloaded for free at http://es-modifier.dhigroup.com/. A final, not Excel®-based version is announced to be available at the end of 2010.

The aim is providing the downstream user with a tool to check and modify the REACH Exposure Scenarios (ESs) received from their suppliers. According to the ES Modifier, a downstream user is within the boundaries of an ES if all Risk Characterisation Ratios (RCR) for a single substance (as such or used in a mixture) are below 1, i.e. if exposure is lower than the respective hazard-based DNEL or PNEC.

According to the tool developers, the ES modifier is intended for use by downstream users with little experience in risk assessment, but with basic knowledge in chemistry and toxicology. Formulators who receive several ESs for the substances used in a mixture may

use the ES modifier to check and adjust the ESs for their own use and the uses of their customers.

The tool covers both human (occupational exposure and consumers) and environmental exposures and works mainly with information obtained from the REACH compliant safety data sheets of the suppliers.

*Description of the ES Modifier*

The ES modifier is Excel®-based and includes the following exposure estimation models:

- for workers ECETOC TRA (all routes), Stoffenmanager and EMKG-EXPO TOOL (inhalation exposure only), RiskOfDerm (dermal exposure only)
- for consumers ECETOC TRA and EUSES (all routes)
- for the environment EUSES

It requires input at various stages:

- selection of the life cycle stage (manufacture, formulation, end use, or service life). For end use and service life, the user group also has to be chosen: industrial, professional or consumers;
- the use descriptors for the uses under consideration according to ECHA (ECHA Guidance on information requirements and chemical safety assessment, 2010, Part R12,): sector of use, and categories for product-, process-, and article description;
- intrinsic substance data: physicochemical property data (e.g. log Kow, vapour pressure, water solubility, biodegradability), PEC regional, water, PEC regional, soil and hazard data (DNELs and PNECs);
- if used in a mixture: composition of the mixture;
- depending on the exposure estimation tool selected more use data may be required .

Risk characterisation ratios for the human exposure pathways (inhalation, dermal and oral exposure) and for all environmental compartments (water, air, soil, sewage treatment plant) are graphically shown as bars, which switch from green to red, when the RCR of 1 is exceeded. In addition, the latest version of the ES Modifier (prototype 3.0, May 2010) contains a module to establish an exposure scenario.

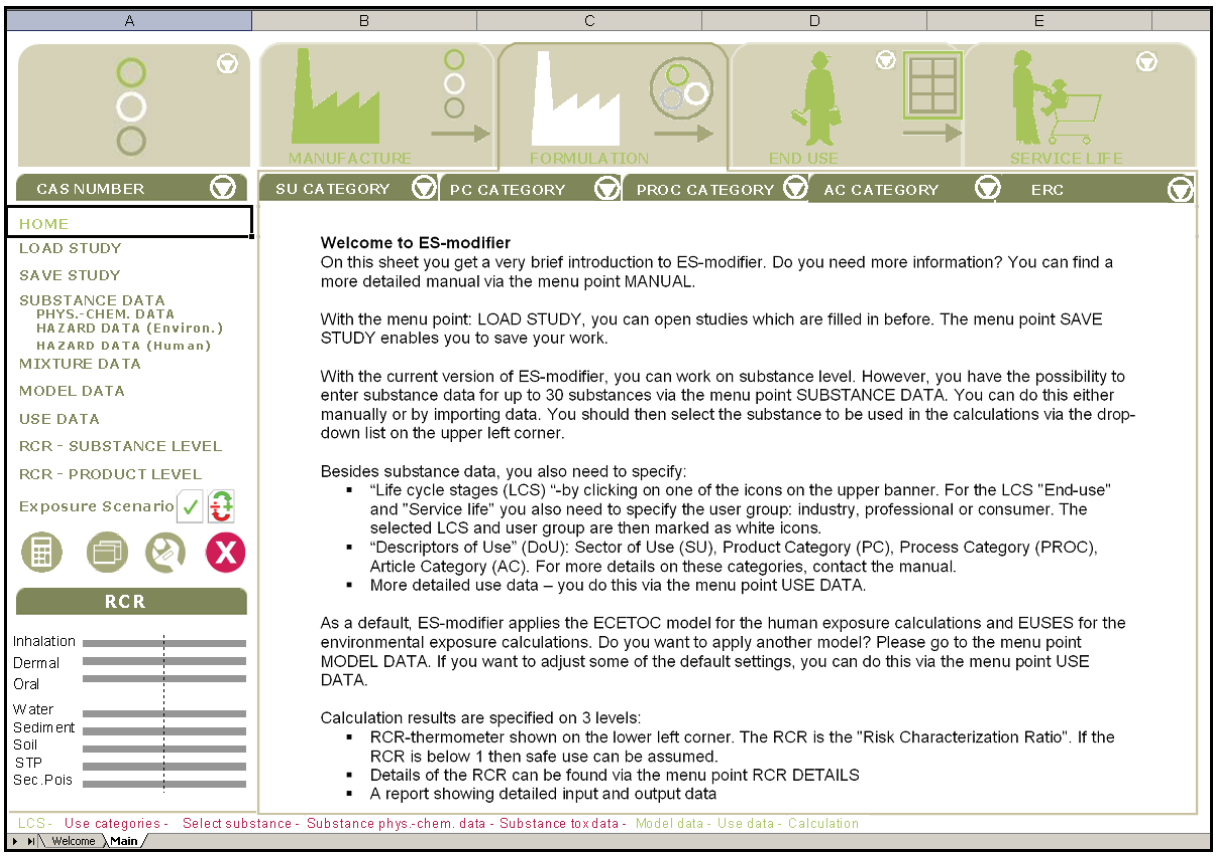



Figure 7 Structure of the ES Modifier.

*Mixtures and the ES modifier*

Following the REACH philosophy, the main output of the ES modifier is risk characterisation ratios (RCRs) for individual substances, either as such or contained in a mixture. The mixture then acts as a dilution of the substance under consideration.

Beyond this, dealing with mixtures is supported in the ES modifier by an extra module, which is basically an electronic implementation of the DPD+ method (see Part III of the practical guide, chapter 7.2). It requires the composition of a mixture and the classification (R phrases) for all substances as input. The module, by calculating the Lead Substance Indicators (LSI), determines the lead substances according to DPD+ and highlights these substances in a table. Also, substances with LSI having at least 10% of the lead substance's LSI are indicated by a different colour ("sub lead substances"). RCRs for the lead substance and all sub lead substances are summed up per exposure pathway to assess possible additive effects.

*Experiences and outlook*

The ES modifier tool integrates all current exposure assessment models. It allows to modify all relevant input parameters and, hence, recalculation of the risk characterisation ratios of

the individual substances in a mixture. With this, the user can investigate which of the model parameters are decisive for the risk characterisation outcome. This allows a downstream user to adapt various model parameters to his specific use situation and to compare the outcome from different exposure estimation models.

As practically every detail of the assessment is open to changes, guidance is needed to inform the user what type of change in scenarios and models is still covered by scaling and what is to be seen as a new exposure scenario. Guidance should also be available to describe the boundaries and limitations of the tool.

Application of the ES modifier requires knowledge on exposure estimation in principle and on the exposure estimation models contained. Therefore, the target user of the ES modifier may be seen in larger companies from the industrial formulation sector with experienced product safety people at hand.

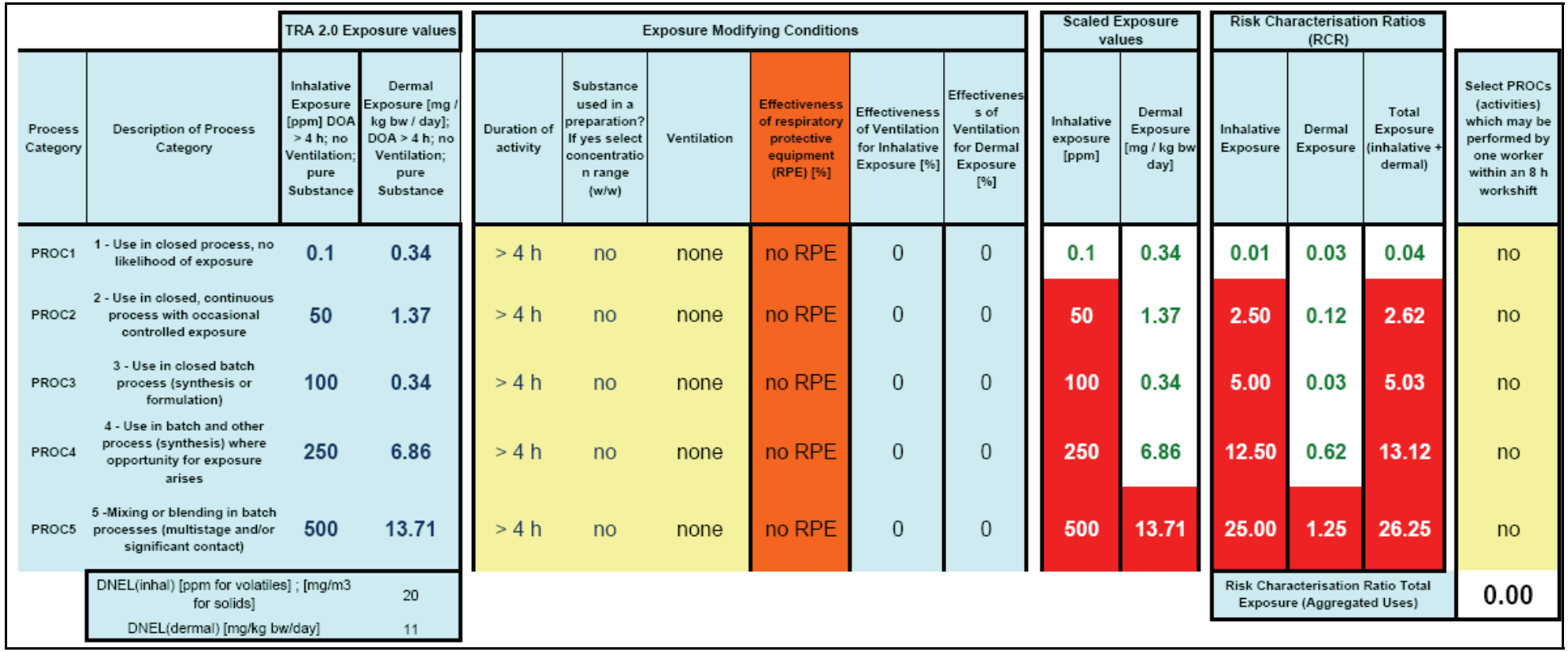
Required input may be largely retrieved from REACH-compliant safety data sheets, but provision of all required information for a mixture with several substances may be substantial work if done by hand.

#### 7.7.2.2 ScIDeEx: Scaling tools related to process categories and exposure modifying factors

In ECETOC TRA version 2 several exposure modifying factors (EMF) can be altered by the user. This functionality allows the scaling of determinants of exposure inside the tool. RiskOfDerm also offers some degrees of freedom which could be used by downstream users for scaling. A scaling tool based on RiskOfDerm is presented in chapter 7.7.2.3. .

Using ECETOC TRA and RiskOfDerm requires some level of experience. Therefore, user friendly tools were developed by members of the Practical Guide project group, which make scaling an easy task for downstream users. The tool “ScIDeEx” (Scaling of Inhalative and Dermal Exposure) is being developed by Merck for the purpose of scaling of worker exposure assessments based on ECETOC TRA 2. It supports scaling of inhalative and dermal exposures by downstream users.

The following figure 8 shows an example of the structure of the tool (development stage):



| | | TRA 2.0 Exposure values | | Exposure Modifying Conditions | | | | | | Scaled Exposure values | | Risk Characterisation Ratios (RCR) | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Process Category | Description of Process Category | Inhalative Exposure [ppm] DOA > 4 h; no Ventilation; pure Substance | Dermal Exposure [mg / kg bw / day]; DOA > 4 h; no Ventilation; pure Substance | Duration of activity | Substance used in a preparation? If yes select concentration range (w/w) | Ventilation | Effectiveness of respiratory protective equipment (RPE) [%] | Effectiveness of Ventilation for Inhalative Exposure [%] | Effectiveness of Ventilation for Dermal Exposure [%] | Inhalative exposure [ppm] | Dermal Exposure [mg / kg bw day] | Inhalative Exposure | Dermal Exposure | Total Exposure (inhalative + dermal) | Select PROCs (activities) which may be performed by one worker within an 8 h workshift |
| PROC1 | 1 - Use in closed process, no likelihood of exposure | 0.1 | 0.34 | > 4 h | no | none | no RPE | 0 | 0 | 0.1 | 0.34 | 0.01 | 0.03 | 0.04 | no |
| PROC2 | 2 - Use in closed, continuous process with occasional controlled exposure | 50 | 1.37 | > 4 h | no | none | no RPE | 0 | 0 | 50 | 1.37 | 2.50 | 0.12 | 2.62 | no |
| PROC3 | 3 - Use in closed batch process (synthesis or formulation) | 100 | 0.34 | > 4 h | no | none | no RPE | 0 | 0 | 100 | 0.34 | 5.00 | 0.03 | 5.03 | no |
| PROC4 | 4 - Use in batch and other process (synthesis) where opportunity for exposure arises | 250 | 6.86 | > 4 h | no | none | no RPE | 0 | 0 | 250 | 6.86 | 12.50 | 0.62 | 13.12 | no |
| PROC5 | 5 -Mixing or blending in batch processes (multistage and/or significant contact) | 500 | 13.71 | > 4 h | no | none | no RPE | 0 | 0 | 500 | 13.71 | 25.00 | 1.25 | 26.25 | no |
| | DNEL(inhal) [ppm for volatiles] ; [mg/m3 for solids] | | 20 | | | | | | | | | Risk Characterisation Ratio Total Exposure (Aggregated Uses) | | | 0.00 |
| | DNEL(dermal) [mg/kg bw/day] | | 11 | | | | | | | | | | | | |

Figure 8 ScIDeEx (Scaling of inhalative and dermal exposure): an Excel-based tool based on ECETOC TRA version 2. It has to be emphasised that the shown spreadsheet is substance specific.

The user can adapt three exposure modifying factors to his specific situation, i.e.

- the duration of activity;
- the concentration of the substance in a mixture;
- the type of ventilation.

These parameters have a linear influence on the exposure values, i.e. the worst case exposure values are simply multiplied by a factor. Exemplarily, the exposure modifying factors related to the duration of activity are presented below

Table 7 Modification of exposure due to the duration of activity (DOA).

| Duration of activity (DOA) | Exposure modifying factor (EMF) |
|---|---|
| > 4 h | None (1) |
| 1–4 h | 0.6 |
| 15 min.–1 h | 0.2 |
| < 15 min. | 0.1 |

ScIDeEX can be used to calculate the overall exposure if several activities are carried out by the same worker. In this case, the exposures for the single process categories are combined to the overall exposure. It is possible to calculate each individual combination of processes in the tool.

Exposure scenario suppliers can include in the exposure scenario a link to a web site where the substance specific ScIDeEx tool is available.

Figure 8 gives an idea how a substance specific ScIDeEx tool could look like. However, exposure scenario suppliers need a generic version which can be used to generate the substance specific spreadsheet. The generic version will work as follows:

- all PROCs are covered;
- non-relevant PROCs are simply removed by deleting the respective lines;
- the user fills in worst case data generated with TRA 2;
- non-relevant PROCs are simply removed by deleting the respective lines;
- the user secures the template and saves it as a substance specific version.

This substance specific version can then be made available to downstream users.

#### 7.7.2.3 REACH Scale: Scaling tools related to one specific use

Assessment tools such as ECETOC TRA or ES modifier allow users to change any of the parameters used as input values for the exposure assessment. They offer registrants, as well as formulators, large flexibility in modifying the exposure scenarios.

The use of these instruments requires a good understanding of the methods of exposure assessment and risk characterisation as well as the underlying assumptions of the calculations (which should be documented in a transparent manner). For the majority of end-users of substances and mixtures, these instruments are too complicated to be used in practice.

Registrants and downstream users who are supplying exposure scenarios to their customers have the possibility of describing tailor-made scaling rules in their exposure scenarios. REACH does not prescribe a way to do this nor does it give a specific format.

In many cases, the downstream user can influence only a limited set of parameters which directly determines the exposure situation (e.g. the amount used per day, the efficiency of a local exhaust ventilation, the volume of the receiving water body). Other parameters cannot be influenced by the downstream user, e.g. physicochemical properties of the substances or specific properties of the mixtures (e.g. concentration of substances).

Scaling by end-users of chemical products is supported if it is focused on the parameters which can be influenced by the user himself. For this purpose, the tool “REACH Scale” has been developed. It aims to support downstream users in scaling. It offers registrants and formulators a structure to give customer-specific scaling information within exposure scenarios.

REACH Scale is an Excel-based calculation tool. REACH Scale imports the risk characterisation ratio which resulted from exposure assessment for a specific use (which has been made within the chemical safety assessment of the registrant) or a related output value. This value is the key parameter for REACH Scale.

A related output parameter could be the amount of product which can be used by the downstream user without exceeding a critical concentration (risk characterisation ratio > 1).

In the next step, REACH Scale offers the possibility of modifying the parameters according to the specific situation of the final downstream user, e.g. the volume of the receiving water body. After entering the specific conditions of his application, the user can immediately see whether his use is covered by the exposure scenario or not.

REACH Scale does not show all parameters of the underlying exposure assessment. If advanced downstream users want to see this calculation, the registrant can provide a reference to a site where it is publicly available.

Which parameters can be influenced by the downstream users depends on the conditions of use and the resulting exposures Therefore, details of the structure of REACH Scale vary from application to application. The basic principles of REACH Scale remain the same:

- importing of the key parameter from a detailed exposure assessment and
- use-specific focus on a limited set of parameters for scaling.

Three examples for REACH Scale are given.

*REACH Scale Environment*

REACH Scale Environment refers to exposure assessment for the aquatic environment. A key parameter for downstream users is the maximum amount of a chemical product which can be used per day. The following figure 9 shows the Excel table which supports scaling by end-users who are not familiar with complete exposure assessment tools.

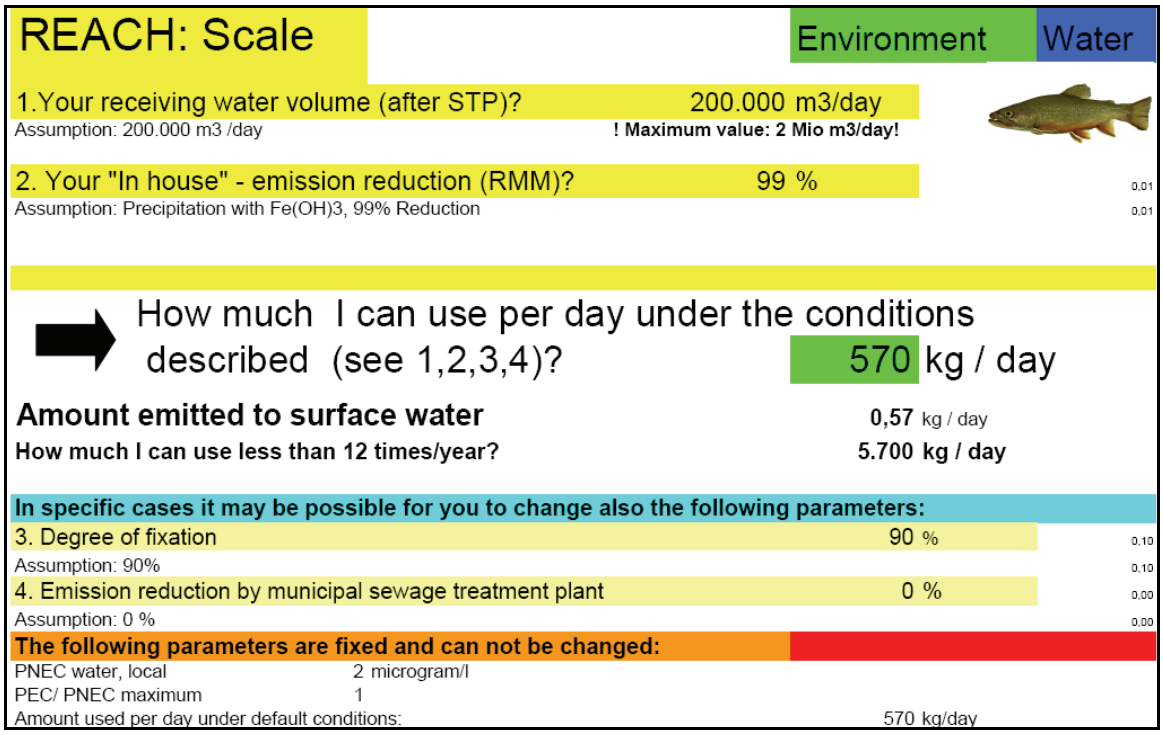



Figure 9 REACH Scale Environment

In the underlying exposure assessment using EUSES, the maximum amount which is allowed to be used per day has been calculated to 570 kg/day (this reference value is given as background information in the last line of the work sheet). If required, the complete exposure assessment performed by the supplier can be seen (reference is given in REACH Scale, e.g. http://reach-guide.oeko.info/L_REACH_environment_water.xls).

Two determinants of exposure can be modified by the downstream user:

- volume of the receiving water body (a default value of 200,000.00 $m^3$/day has been chosen for the standard calculation);
- efficiency of the emission reduction measures applied by the downstream user (a default value of 99% has been chosen for the standard calculation).

Both parameters can be scaled by inserting the real values of the application of the downstream user. In specific cases, the following parameters can also be changed:

- amount of the substance which stays on the material (degree of fixation);
- emission reduction by municipal sewage treatment plant.

Moreover, direct modifications are possible for these parameters.

Using REACH Scale, the downstream user can directly calculate the maximum amount of the product he can use under his specific conditions.

Within the ES, reference is made to a publicly available web site to ensure access to REACH Scale (e.g. http://reach-guide.oeko.info/L_REACH_Scale_Env_August_2009.xls).

Limits of scaling for a specific product have to be indicated in REACH Scale. Beyond these substance-specific limitations general limits are introduced. For the dilution of the emission in the receiving water volume, a maximum value of 1.000 is set. In addition to the maximum amount used per day it is indicated how much of the substance will be emitted to the surface water according to the calculation.

*REACH Scale Dermal*

This Excel-based tool has been developed for scaling **systemic dermal exposure at the workplace**. It is not meant to be used for local skin effects such as irritation, corrosion or skin sensitisation and should only be used for exposure scenarios where dermal exposure is dominant compared to inhalation exposure, i.e. where it accounts for more than 90% of total exposure. The tool is based on the rules used by the exposure estimation tools ECETOC TRA and RiskOfDerm and should be used only for scaling when the underlying exposure estimation has been done with these tools. The parameters which are available for modification are

- the concentration of the substance in the mixture;
- the duration of exposure;
- and the efficacy of the personal protection measures applied.

A linear relationship between these parameters and the exposure intensity is assumed in the tool. The following figure 10 shows the Excel table, which represents the tool.

| Dermal Exposure Scaling Tool | | v. 1.0 (October 2009) |
|---|---|---|
| Instructions: | ***For registrants***<br>*- Only use this tool for systemic exposure, i.e. NOT for local effects (irritation, corrisive effects or skin sensitisation)*<br>*- Only use this tool if dermal exposure accounts for more than 90% of total exposure*<br>*- Only use this tool, when the dermal exposure estimation is based on calculations with ECETOC TRA or RiskOfDerm*<br>*- Please fill in the details (green fields) in the yellow section*<br>***For downstream user***<br>*- Please fill in the green fields in the blue section*<br>***General notes***<br>*- Green fields allow data input by the user, shaded green fields are optional*<br>*- Orange fields are automatically calculated by the tool and are **excempt from user input***<br>*- Comments on the parameters are in column C in italics* | |
| Substance Name | Test | |
| CAS No. | 000-00-0 | |
| Date: | 27.07.2010 | |
| | | |
| ***Exposure estimate and risk characterisation by registrant:*** | | |
| Exposure estimated by registrant for: | Spray application, indoors | |
| Exposure estimation tool used | ECETOC TRA | |
| Concentration used in estimate | 100 | *If a specific concentration has been used, enter the value here; note that RISKOFDERM calculator estimates exposure to the neat substance or formulated product and that ECETOC TRA does not consider the concentration of the substance even if a concentration range is entered in the input module.*<br>***-> Enter 100 if one of these tools has been without manual adjustment to a specific concentration*** |
| Duration [h] | 8 | *If a specific duration has been used in the calculation of exposure (e.g. in RISKOFDERM calculator), enter the value here; ECETOC TRA assumes full-shift (8 hours) by default* |
| Appropriate personal protective equipment (PPE) assumed? | Yes | *Only enter "Yes" if a reduction of exposure due to PPE has been considered in the calculation* |
| Efficiency [%] | 90 | *Only enter a value if "Yes" has been selected for PPE* |
| | ENTER VALUE ABOVE | |
| Dermal exposure [mg/kg x d] | 100 | |
| RCR | 0,2 | |
| | | |
| ***Scaling by downstream user*** | | |
| Own use description: | Spray application, indoors | |
| Concentration in preparation for own use [%] | 100 | *Enter concentration of the substance in the product in %* |
| Duration for own use [hours] | 8 | *Enter duration in hours* |
| Appropriate personal protective equipment (PPE) used in own use? | Yes | *Please enter if appropriate PPE are implemented even if the registrant already included PPE in the calculation* |
| Efficiency [%] | 1 | *Enter efficiency for PPE (which may deviate or not from the one given by the registrant) if "Yes" has been* |
| | ENTER VALUE ABOVE | |
| | | |
| ***Results of scaling procedure*** | | |
| Revised dermal exposure estimate [mg/kg x d] | 990 | |
| Revised RCR | 1,98 | **safe use NOT demonstrated** |

Figure 10 REACH Scale Dermal Exposure

The registrant who intends to provide scaling rules to his customers by REACH Scale Dermal would fill in the green fields in the yellow section and protect it from modification. After reception of the worksheet the downstream user will be able to adjust the data in the blue sector to see whether the resulting risk characterisation ratio is still below 1.

Also, for inhalative exposures a similar REACH Scale instrument can be developed.

### 7.7.3 Limits of scaling

As already said above, by the use of scaling tools, the supplier of the exposure scenario has the possibility to broaden the field of conditions of use which are covered in his exposure scenario. However scaling is only possible if the supplier has specified relevant scaling rules or assessment instruments in his exposure scenario. This indicates that the applicability and the limitations of scaling for the identified uses have been assessed by the supplier and have been documented in the chemical safety report of the substance. If the registrant specifies assessment instruments, he should deliver the input parameters which have been used for the exposure assessment and risk characterization.

Scaling can only be applied to determinants of exposure for which **quantitative** deviations exist from the descriptions given in the exposure scenario. In case of RMMs, the key information is the effectiveness. The type of the measure can deviate from the measure

described in the exposure scenario, but it may only have the same effect or may be more efficient. If deviating types of RMMs are used, a comparison of their efficiency is possible if they are related to the same exposure route and the same field of protection.

In the ECHA Guidance for downstream users three situations are described in which scaling is definitely not possible (ECHA Guidance for downstream users, 2008, chapter 5.2.5, p. 47):

- different routes of exposure would result from the adjustment of an exposure determinant;
- different target groups would be involved; and/or
- the duration of exposure and the frequency of exposure are significantly changed, resulting in a different type of exposure (e.g. from acute to chronic exposure).

In all these cases the conditions of use of the downstream user would not be covered by the exposure scenario of the supplier.

## 7.8 Downstream User Chemical Safety Assessment for a substance

REACH distinguishes between two kinds of chemical safety assessments (CSA) for substances:

- CSA made by the registrants as part of the registration;
- CSA made by downstream users for uses which are not covered by the exposure scenarios of the suppliers. These chemical safety assessments are called “Downstream user chemical safety assessments” (Downstream user (DU) CSA).

These types of CSA differ in their scope and in their contents:

- The CSA of a registrant aims to describe conditions of safe use for all identified uses which are supported by the registrant. This CSA includes the complete assessment of the hazardous properties of the substance. For a dangerous substance and for PBT/vPvB-substances, the CSA contains the exposure assessment and the risk characterisation.
- The downstream user CSA concentrates on a specific use which has not been covered yet by the assessment of the supplier. For this use he performs the exposure assessment and the risk characterisation. The downstream user usually does not have to re-assess the hazardous properties of the substances and the assessment of the PBT / vPvB properties. He can use the information on hazardous properties directly from the safety data sheet. This shall be stated in his CSR. Therefore in most cases, the downstream user CSA will be much shorter than the CSA of the registrant referring to the same substance. (If the downstream user considers the hazard and the PBT / vPvB assessment reported in the safety data sheet supplied to him as inappropriate,

then he shall carry out the relevant assessments as appropriate to him (in accordance with sections 1–4 of Annex I).

- If the downstream user has different information on the hazards, he has to inform his supplier (and ECHA) and take this information into account for his own safety data sheet.

The following figure 11 shows the relationship between the CSA of the registrant and the downstream user CSA.

An example for a downstream user CSA (on inhalation exposure to sodium hydroxide contained in a consumer product – oven cleaner) is provided as a case study of the Practical Guide (http://cefic.org/templates/shwPublications.asp?HID=750).

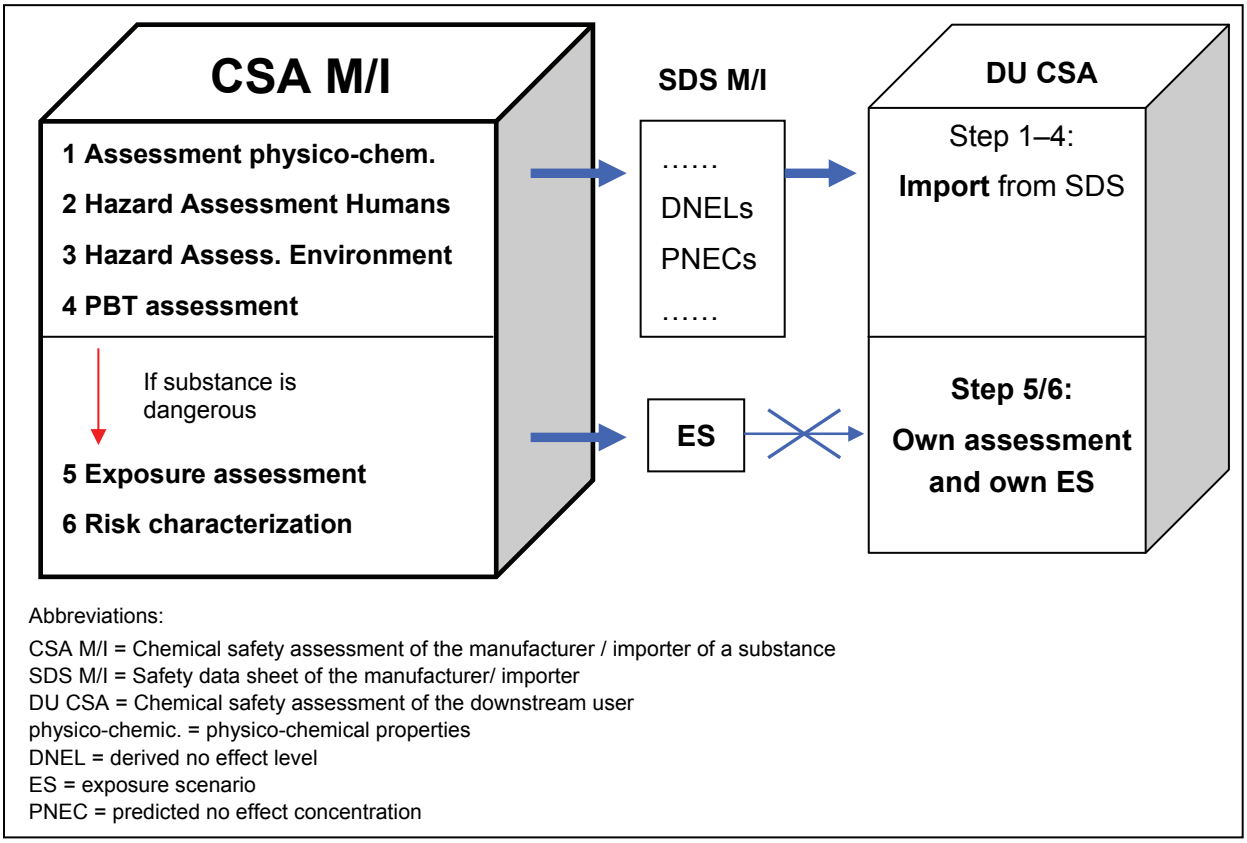



Figure 11 Relationship between the chemical safety assessment of a registrant (CSA M/I) and the chemical safety assessment of a downstream user (DU CSA). For his own assessment the downstream user can use relevant information from the extended safety data sheets which he has received.

The downstream user CSA is structured according to REACH Annex I and XII. The downstream user takes Part B, section 9 and 10 of the format described in REACH Annex I (section 7, structure of the CSR) to document the exposure scenario he has developed and

the results of the risk characterisation for his use. If necessary, he can in addition use further sections of the format described in Annex I.

The downstream user declares in Part A of his CSR that the risk management measures outlined in the relevant exposure scenarios are implemented by him for his own uses and that the risk management measures outlined in the identified uses (in the supply chain) are communicated down the supply chain.

The downstream user has one year starting from the reception of a SDS with a registration number and an ES to perform the chemical safety assessment. He documents the results in his downstream user CSR and keeps the report updated. He does not send the report to ECHA, but has to notify his use to ECHA according to Art. 38[33].

In specific cases it might be necessary that the downstream user also has to perform a hazard assessment. This can be required if, additional data on substance properties are necessary (e.g. long-term toxicity for inhalative exposures) for the assessment of his use, which have not been part of the CSA of the registrant.

When the use of several substances in a mixture is not covered by exposure scenarios of the supplier, the downstream user may have to carry out chemical safety assessments for each of these substances. In this case he has the possibility to do a chemical safety assessment for the mixture as a whole. This is described in Part III of this practical guide, chapter 10.

# 8 The use of existing knowledge and of specifications from other regulations

## 8.1 Introduction

The inclusion of existing knowledge and of specifications of existing regulations is very important

- for the development of exposure scenarios and
- in examining whether the actually occurring conditions of use and the risk management measures in exposure scenarios are covered by the measures already taken.

In many cases, new measurements (or new modelling) as well as new measures for risk reduction can be avoided. The use of existing data also guarantees that the experiences in safe handling of substances, already acquired, are used for REACH. This also includes the

[33] REACH Art. 39 defines the time lines for these notifications to ECHA. The downstream user has to inform ECHA about his use within half a year after receiving a registration number from his supplier in the SDS. If the information which has been reported change, the downstream user shall update this information to ECHA (REACH Art. 38.3).

knowledge about appropriate risk management measures and the conditions for their implementation.

Annex VI step 1 requires that registrants have to collect all available information on exposure, uses and RMM for his registration. This existing information should be used to avoid further animal tests, but as well for the CSR.

Existing knowledge and specifications for control of emissions arising from previous regulations can be of a diverse nature.

In-house knowledge can be:

- expertise in handling substances and mixtures;
- expertise relating to conditions of use and risk management measures;
- operational measurement data and estimates on the processing operations and process control for the monitoring of emissions to air and wastewater effluents, e.g. according to the "Easy-to-use workplace control scheme for hazardous substances" (EMKG) that was developed by the German Federal Institute for Occupational Safety and Health (BAuA)[34];
- operational measurement data and estimates of dangerous substance concentrations at the workplace, e.g. Occupational Hygiene monitoring data in accordance with the CAD (Chemical Agents Directive).

External existing knowledge can be:

- measurement data of the authorities from the control and from monitoring programs relating to environmental and worker exposures;
- industry knowledge of the best available technology;
- industry sector specific investigations regarding the content and fate of hazardous substances in articles;
- descriptions of safe uses, e.g. in the form of characterisation of exposure of the Employer's Liability Insurance Association.

In this chapter, advice on the use of existing data will be given. The emphasis here is on the use of existing in-house data (chapter 8.2). Chapter 8.3 deals with the use of externally available data.

[34] The "Easy-to-use workplace control scheme for hazardous substances" (EMKG: "Einfaches Maßnahmenkonzept für Gefahrstoffe") is based on the approach COSHH Essentials (Control of Hazardous Substances to Health Regulations) from Great Britain.

## 8.2 Use of knowledge existing in one's own company

In the context of the chemical safety assessment, in-house knowledge can be used for two different purposes:

- for the registration of substances (preparation of the chemical safety reports, the exposure scenarios and the extended safety data sheets). Knowledge of the substance properties, the exposure and the risk characterisation are necessary;
- for the examination of the internal data on uses in the exposure scenario of the manufacturer or importer and for the examination of the data in the exposure scenario for the customers. The downstream user must then confirm whether safe uses also exist for his own uses and whether the arising exposures are covered by the exposure scenario provided by the supplier. Like the supplier, the downstream user can often also utilise existing available data and knowledge.

The knowledge of the exposure situation existing in the company originates from diverse areas:

- experiences from application technology and from quality control;
- experiences arising from existing legal obligations, e.g. while handling dangerous substances, to carry out risk assessments, to implement industrial safety measures, and to monitor the effectiveness of risk reduction measures;
- experiences from the implementation of product related standards and plant and/or process related authorisations e.g. compliance with workplace exposure standards and environmental emission authorisations.

For exposure determination and for the description of the risk management measures a larger number of data relating to different subject areas are necessary. It is important to have a clear presentation and a standardized structuring of the compiled information. The methods and processes already in use within a company (e.g. hazardous substances inventory) should be used and, if necessary, amended or extended.

### 8.2.1 Characterisation of the general use situation in the company

Some basic operational conditions, e.g. the discharge of wastewater into a local sewage treatment plant, are important for many substances used by the company. They represent the basic conditions which need to be taken into account during the exposure assessment of individual substances. It is recommended that there is clarity about these basic conditions before exposure assessments are made for individual substances. The following fundamental questions are involved:

- What happens with the substances in the company (e.g. where do chemical conversions take place, after which the substance, as such, no longer exists)?

- Where do the substances remain in the company (e.g. how high is the yield (% chemical conversion) in the different processes, and how much ends up in the waste-water or is emitted to atmosphere)?
- Are special measures taken for emission reduction? How efficient are these measures and what do they achieve?

In most cases there is sufficient knowledge in one's own company to answer the following key questions.

- Does chemical decomposition of the substances take place in the course of the process?
- Processing: How much of the substance is lost during the individual processes (e.g. knowledge of the degree of depletion)? Is the substance consumed during the process (e.g. polymerization, incorporation into a matrix, fixation, hydrolysis, degradation etc.[35] and with what level of efficiency)?
- Wastewater: Do wastewater streams arise in the company? If so, does an effluent pre-treatment take place before discharge to municipal sewer or receiving water? If so, how high (substance-related) are the emission reduction factors achieved by these measures?
- Wastewater: Does the company introduce wastewater into a local sewage treatment plant? If so, how large is the receiving stream of the local sewage treatment plant? If not, how large is the receiving stream, into which the company discharges directly? (Here, for indirect dischargers an enquiry with the operator of the local sewage treatment plant may be necessary, if the volume of the receiving stream is not known).
- Exhaust air: What direct and indirect emissions to atmosphere occur? Are measures taken to decrease the exhaust air emissions? How effective are the measures, in relation to substances?
- Exposure level – environment: What measured values and estimates for dangerous substances are available from the operational supervision of the process (e.g. data gathering for the surveillance authorities)?
- Exposure level – workplace: Which measured values and estimates for dangerous substances are available from the risk assessment, monitoring data or from the documents provided for the surveillance authorities?

By answering these questions the user of substances and mixtures can soon gain a good, detailed overview of the basic conditions of exposure that are important for his company and

[35] If the knowledge for this is lacking in one's own company, this can be clarified if necessary for important substances by further enquiry with the association or if necessary with the supplier.

of that knowledge which is already available in the company, before he begins specific exposure assessment for single substances.

### 8.2.2 Single substance related central questions for clarification of operational conditions of use and exposures

After clarifying the basic conditions under which substances and mixtures are used in one's own company, the parameters which determine the exposure and release of single substances can then be determined with a manageable number of key questions, (ECHA 2008, D, p.19 and additions).

**Practical tip:** Before considering the exposures of individual substances a priority setting should be made to afford a first quick estimation of the exposure situations which can be expected. To do this: begin with those substances which are of particularly high hazard. Consider these substances in the context of processes and activities for which high substance release and exposures can be expected. More reference to options of priority setting is given in chapter 8.2.4.

- For how long (8 hours? 15 minutes?) and for how often (each day? 1x per week?) do workers have contact with the substance?
- Is the substance used as powder, as granules or as liquid?
- Which risk management measures are used? Here a distinction should be made between instructions, product-related measures, organizational measures, technical measures and personal measures. What is the estimated efficiency of these measures[36]?
- What quantity is used, per day, in the company?
- Is the substance used for the production of articles (e.g. dyeing of clothing)? Is it to be expected that the substance remains in the manufactured articles? If so, in what concentration?
- What proportion of the quantity added remains in the process (e.g. by fixation on a fibre)? What proportion is released – in the wastewater or into the exhaust air?
- Substance degradation: Can it be assumed that the substance is biologically degraded?
- What kind of wastewater treatment is provided?

[36] Data on the efficiency of risk management measures is dependant, in many cases, on the exact configuration and application of the measure. Information on the local implementation, combined if necessary with statements of the manufacturer/operator of the plant on the efficiency may be required.

- What quantities of the substance are sold, per year, to the downstream users in the different industries? (This question is important for manufacturers/importers of substances).

**Practical tip:** These questions refer to the use conditions of single substances in the company. Answering them will be easier if the user has first clarified, on the basis of the existing information, what the general basic conditions are for the use of all substances which are used by him (see the previous subchapter) (some information may refer to the substances, other information to the products). Thus it may not be necessary to give detailed answers to all of these questions for each substance. In many cases there will already be adequate knowledge in the company, particularly for the exposures and emission scenarios associated with the use of hazardous substances in the workplace.

### 8.2.3 Knowledge in the company on dangerous substances in the workplace

In the company the conditions of work, under which substances and mixtures classified as dangerous are used, should be known precisely. This is a requirement of the Chemical Agents Directive (CAD). The knowledge from the operational risk assessment readily permits confirmation of whether the conditions for a safe use of the substances and mixtures are established. This will apply both to the registrant with his own uses and to the downstream user. This particular aspect is of validity for the assessment of the exposure at the workplace as distinct from consumer exposures.

For the estimation of the emission situation at the workplace knowledge of a qualitative and, if available, quantitative nature should be used. Example: If it is known that the application of the substances and mixtures in the company, in closed systems, is controlled from a central control room (process category 1), then exposures, during continuous production, should be very small. For the exposure assessment at the workplace, cleaning and maintenance work must also be considered. For environmental exposure an analysis or estimate of the arising wastewater and exhaust air emissions will be required. Where mixtures are manufactured by mixing in a batch process, a repetitive exposure arising from the production should be assumed (process category 5).

Central questions for the characterisation of the workplace regarding expected exposures are:

- Which processes and activities are carried out at the workplace?
- What risk management measures are applied and how effective are they? (In determining the effectiveness of technical measures (e.g. closed systems, exhaust ventilation, separation by distance, sumps and retention basins) and personal preventive measures (e.g. respiratory protective equipment, gloves etc) it may be necessary to obtain information from the manufacturers of the respective equipment.) As already

stated above, there should be differentiation here between instructions, product-related, organizational, technical and personal risk management measures.

- Are there organizational measures which generally limit the exposure (e.g. entry-restrictions)? Does any exposure take place? If not then no further exposure assessment is necessary.
- How many persons are working in the processes where the hazardous substances may be present? How frequently and for how long are individual activities carried out?
- Which of the process categories and environmental release categories (ERCs) from the Use Descriptor System are relevant as descriptors? The allocation of such descriptors is important, in order to be able to check the respective data in the exposure scenario. This is particularly relevant where, in the context of the chemical safety assessment, estimations with models such as ECETOC TRA were relied on which link these data with mathematical procedures for the exposure assessment (see also Part II of the practical guide, chapter 9.3 and annexes A2.1–A2.5). (Note: If during the exposure assessment estimations were performed with other models (e.g. EMKG), then the process categories and ERCs are of less relevance).
- Which assessments of the exposures have already been made in house, maybe for CAD or environmental compliance purposes, and which models were used? Can the results of these evaluations (e.g. BAUA EMKG) be used for the confirmation of acceptability of one's own uses (because it was shown e.g. that with the conditions of use and the applied risk management measures the associated environmental emission and occupational exposure limits at the workplace are complied with)?

### 8.2.4 Setting of priorities: Examination of critical work procedures and critical substances (workers protection and environmental protection)

The individual activities accomplished in the company can differ substantially in the exposure level which they are likely to generate. Thus, with the continuous processing in "closed systems" relevant exposures will not be expected to arise during the ongoing operation, but only possibly during the opening of the equipment for cleaning or maintenance. The specific substances may inherently have very different release potentials. In the case of an application using granules, substantially less dust is expected to arise than when using powdered mixtures of small particle size in the same application. By a review of the operations with the potential to generate exposures it can be comparatively easy to determine whether, and where, problematic emission situations in the company are likely to occur. If no such problematic exposures or emissions are identified, then no further checks would need to be performed for other activities and substances that have lower potentials for generating exposures.

If potential problematic exposures or emissions are identified, then the most-urgent exposure-limiting steps can be identified as a priority. This procedure uses the existing operational knowledge on processes and activities. It limits the evaluations and, where necessary, measurements primarily to the critical situations. It is to be expected that this procedure can effectively minimise the total effort for exposure assessment.

The priority setting based on the exposure situation should be supplemented by a record of those substances which are of particularly high hazard and – identification of where particularly high exposures are to be expected when using these substances

This examination of the critical uses of substances and mixtures can be structured on the basis of the following questions:

- Where and when are the highest exposures to be expected? Where – e.g. at work-places without exposure-reducing measures, workplaces with low exchange of air rate etc. When – e.g. during cleaning or maintenance work.
- Which particularly hazardous substances are used in these operations and/or pro-cesses?
- For these identified situations of use, are results from workplace exposure and emission measurements available, which cover the highest exposures that can be expected (e.g. personal task based measurements.)
- When single substance related analytical measured values are not available, are there more exploratory measurements available, e.g. surveys with Draeger type test tubes or dust survey meters, which permit a first estimation as to the order of magnitude which can be expected for the substance concentrations?
- Are measurement results available for those substances, for which a particularly high release is to be expected due to their physicochemical characteristics? For example, measurements on solvents with a high vapour pressure which are used in a high concentrations in the process.
- Depending on the process, for which substances is complete release into the environ-ment expected (e.g. additives such as pH stabilizers)? What are the maximum resultant expected concentrations in the receiving waters? Here consideration of the maximum annual substance use, total receiving stream volume to the sewage treatment plant and the size of the receiving water will need to be considered.
- Which measurements of total, (non substance specific), emissions are available (e.g. absorbable organically bound halogens (AOX), total organic carbon)? From this can be derived, how high a maximum concentration can be expected for a single substance which contributes to these total parameters.

**Practical tip:** With knowledge relating to the relevant receiving stream, it is possible to calculate what the maximum acceptable use quantity applied may be for a specific example substance which goes to 100% into the wastewater. You must decide for your example

substance on a $PNEC_{local\ aquatic}$-value (e.g. 1 mg/l) and make another assumption on the degradability of the substance (e.g. in the worst case assume “not biologically degradable“).

You will find details for this in chapter 7.7 and in Part II of the practical guide, annex A2.8. You can use the Excel sheet in this annex, in order to calculate your own use situation of application, if this has been recommended in the exposure scenario of your supplier.

The users of substances and mixtures classified as dangerous should, as described above, produce an overview of the critical use situations in their company. If exposure estimates then become necessary for activities giving rise to lower exposures or emissions or for substances that are less hazardous or whose physiochemical properties are less problematic, then these estimates can be integrated within this framework.

That means they need not to be further specifically considered in detail as the most critical situational risks are already under control. Conclusions drawn from use situations already examined (with substance A) can be extended to further use situations (with substance B, which is less hazardous than substance A); this is referred to as “read across“ of uses.

Further the pre-evaluation of the critical use situations in one’s own company, as suggested here, facilitates the “comparison work“ that is required by a downstream user when an extended safety data sheet with an exposure scenario is received from the supplier.

## 8.3 Use of external knowledge and information

There is already extensive knowledge and many publications on the safe use of substances and mixtures in many industries. Under REACH these available data and knowledge should, as far as possible, also be used and included in the chemical safety assessments. Examples for this are:

- Descriptions of industry-typical emission scenarios in “the Emission Scenario Documents' of the OECD, which have been published periodically since 1998; these and further associated documents are published in the OECD database of uses and releases of chemicals (http://www.oecd.org).
- Descriptions of the best available techniques, which were published in the BREF documents for many industries.
- Industrial safety-related measurements, which are collected and evaluated in exposure databases.
- Recommendations regarding safe handling of dangerous substances, e.g. “Control Guidance Sheets” in the British COSHH Essentials approach (they are similar to the protection guidelines of the “Easy-to-use workplace control scheme for hazardous substances” (EMKG, Einfaches Maßnahmenkonzept Gefahrstoffe) of the BAuA, which is based on the British COSSHH Essentials approach).

- The library of generic exposure scenarios which will be organized by CEFIC see Part II of the Practical Guide (chapter 10.6).
- Information on uses by manufacturers and downstream users generated by the trade associations.
- The International Fragrance Association (IFRA) publishes standards defining the safe use levels of individual fragrance ingredients. They are subject to regular amendments, based on new data and scientific developments. They are part of the IFRA Code of Practice. Information on approximately 180 fragrances are made public at the website of IFRA (http://www.ifraorg.org/Home/Code,+Standards+Compliance/IFRA+Standards/page.aspx/56).
- Calculation models for the migrating of non-volatile substances from textiles have been developed together with the industry association TEGEWA (www.tegewa.de). (This has been included in the ECHA Guidance on information requirements and the chemical safety assessment, Part R.15, p. 24 ff).

In addition, several national institutions can provide additional information, e.g.

- The industrial safety-related descriptions of exposure of the Federal States and the Employer's Liability Insurance Association. They are published in the form of procedure and substance-specific criteria (VSK), as LASI recommendations, as BG/BGIA recommendations regarding the hazard assessment and as descriptions of exposure of the building professional association (GISBAU).
- Product-related recommendations regarding industrial safety measures of individual industries, e.g. GISBAU product information.

In the following table 8, examples of currently available descriptions of exposure are given, which were published as BG/BGIA recommendations or in other publications of the Unfallversicherungsträger (Employer's Liability Insurance Association). The complete overview is contained in the publication of Rühl and Kleine[37].

[37] Rühl, R.; Kleine, H.: Expositionsbeschreibungen für REACH-Stoffsicherheitsberichte. In: Gefahrstoffe Reinhaltung der Luft 68 (2008), S. 129–133, April 2008.

Table 8 Examples for existing descriptions of safe use which can be used as elements for exposure scenario building. Descriptions of exposure of the BG/BGIA recommendations and other publications of the Unfallversicherungsträger (Employer's Liability Insurance Association). Source: Rühl and Kleine 2008.

| Activity/work area/procedure | Source |
|---|---|
| Ethyl oxide sterilization within the medical area | 1011* |
| Processing of Steam-roller asphalt in road construction | GISBAU |
| Spraying by hand in woodworking and processing | BGI 790-013 |
| Tungsten-inert gas-welding (TIG-welding) | BGI 790-012 |
| Electroplating and anodizing | BGI 790-016 |

** Identification number of the contribution in: BGIA working folder Measurement of dangerous substances (www.bgia-arbeitsmappedigital.de).*

The descriptions of exposure presented in the table are predominantly evaluations of workplace-related measurements of the Länder and the accident insurance carriers. A great many more hazardous substances-related measurements are contained in the **Exposure database of the BGIA** "measuring data for exposure to hazardous substances at the workplace – MEGA". The data contained therein originate from nearly all areas of the commercial economy and have been collected since 1972 as measurements of operational workplaces. They were usually concerned with questions of prevention, basic questions of substance emissions or investigations in the area of occupational disease legal procedures. The exposure assessment of dangerous substances can be substantially supported by a focussed analysis of these data.

**Note:** The data from the MEGA-database are not publicly accessible. However, BG/BGIA, in co-operation with the trade associations, are examining in what ways analysis of the data can be made available for REACH, in order to support registrants during the chemical safety assessment.

# Annex A1.1: Format for documentation of DU Compliance Check

Table A.1 Format to support and document downstream user compliance check. Source: ECHA Guidance for downstream users, 2008, Table A-4, A-5 and A-6, p. 141ff. It refers to the structure of the ES with 9 sections.

## Compare your activities and processes with the short title and the description of uses in the exposure scenario.

*(Echa Guidance for downstream users, 2008, Table A-4)*

| Item | Information in exposure scenario | Present situation | Conclusion | Action need |
|---|---|---|---|---|
| Short title of exposure scenario | | | | No immediate need for action, as deviations from the use description does not trigger legal obligations, if you comply with the conditions of use indicated. |
| Description of activities/processes covered | | | | |
| Processing steps at own site not explicitly covered (not mentioned in Section 2 of the exposure | | | | |
| Considerations on exposures from missing activities and whether or not they are covered by the other activities or require more detailed assessment. | | | | |

## Compare your operational conditions with information in the exposure scenario.

*(Echa Guidance for downstream users, 2008, Table A-5)*

| Item* | Operational conditions in the exposure scenario | Present operational conditions | Consequence for exposure level** | Action need** |
|---|---|---|---|---|
| (Maximum) duration of use event | | | | |
| (Maximum) frequency of use event | | | | |
| (Maximum) amount used per time | | | | |
| (Maximum) processing temperature | | | | |
| Concentration of the substance in the mixture / article | | | | |
| Physical form of the substance | | | | |
| Other indicators such as maximum surface area of articles per sub-stance content… | | | | |

| Item* | Operational conditions in the exposure scenario | Present operational conditions | Consequence for exposure level** | Action need** |
|---|---|---|---|---|
| pH – value during use | | | | |
| … | | | | |
| Capacity of receiving environment<br>• Water flow<br>• Soil area<br>• … | | | | |
| Capacity of receiving workplace<br>• Air volume/room size<br>• Ventilation rate<br>• … | | | | |
| Capacity of consumer environment<br>• Room size<br>• | | | | |
| Emission or release factors specified | | | | |
| Specific conditions related to wear and tear of articles, e.g. abrasive conditions | | | | |

**Compare your risk management measures and their efficiencies with information in the exposure scenario.**

*(Echa Guidance for downstream users, 2008, Table A-6)*

| Item* | Risk management measures (and efficiencies) in the exposure scenario | Risk management measures (and efficiencies) | Consequence for exposure level** | Action needs |
|---|---|---|---|---|
| Containment of process | | | | |
| … | | | | |
| Occupational health | | | | |
| Organisational measures | | | | |
| Process controls | | | | |
| Technical risk management measures, e.g. ventilation (specified efficiency) | | | | |
| Personal protective equip-ment | | | | |
| Environment related measures | | | | |
| Organisational measures | | | | |
| Process controls | | | | |
| Technical risk management measures, e.g. waste water treatment (specified efficiency) | | | | |

| Item* | Risk management measures (and efficiencies) in the exposure scenario | Risk management measures (and efficiencies) | Consequence for exposure level** | Action needs |
|---|---|---|---|---|
| Consumer related measures | | | | |
| Product related risk management measures (e.g. pellets instead of powders, protective layers etc.) | | | | |
| Waste related measures | | | | |
| | | | | |
| | | | | |

** Not all of the items listed may be relevant for each exposure scenario and additional exposure drivers may be of relevance which has not been listed here. Information should be filled in only for differences!*

*** In the case of quantitative differences, the possibility of scaling should be assessed. For this, the supplier should specify which determinants are linear and can be scaled and which method can be applied for calculation.*