



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

## Part 1 – 3



**May 2009**

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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.

The document describes the status of development as per Q1 2009. Many activities, both in industry working groups as within ECHA are still ongoing and are expected to deliver later this year. The guide is therefore not to be regarded as complete, but as a status overview. The intention is to update the guidance by end of 2009. Updates foreseen are, but not limited to, Ecetoc TRA, CSAT, ES template, Use descriptors, examples on DPD+ etc.

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



## Preface

This practical guide gives an overview of REACH tasks related to the exposure assessment and the communication in the supply chains. It deals with chemical safety assessment, chemical safety reports, 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. For these, it clarifies what they must do, and what they do not have to do. In this way, we hope to facilitate the understanding of these particular REACH tasks, and assist in the decision of whether to undertake some or all of these tasks themselves or to engage an external expert.

The document is divided into four main parts:

- 1. General introduction and overview of the chemical safety assessment, exposure assessment and related tasks (“in brief”, chapter 1-4).**

This first part helps companies to understand the objective of a chemical safety assessment and to decide whether they have to perform one or not. In addition, it helps to identify their roles and tasks within their own company and the communication requirements, both upstream and downstream, with suppliers and customers.

- 2. Details on the preparation of exposure scenarios, exposure assessment and risk characterisation, use of existing knowledge and communication in the supply chains (chapter 5).**

In this part, the new elements of the chemical safety assessment under REACH are described in more detail. The contents are: exposure scenarios and the various ways to prepare and structure them; the use of existing knowledge (in-house knowledge as well as external knowledge); communication of uses, conditions of uses (operational conditions as well as risk management measures) and exposures.

This chapter presents the main approaches to fulfilling the above tasks. This is based upon approaches and guidance that have been developed (or are currently being developed) by

several institutions in Europe (CEFIC, ECETOC, BDI, BusinessEurope, FECC, DUCC, VCI and others).

The practical guide focuses on exposure assessment and on communication within the supply chains. Therefore, it does not explicitly address the assessment of hazardous properties of substances. The new requirements in this field demand intensive expert knowledge. This is especially the case for the derivation of limit values (levels at which there is no concern regarding adverse effects) for human health and the environment (e.g. DNELs and PNECs).

In this regard the practical guide gives references to the related parts of the comprehensive guidance of ECHA on information requirements and the chemical safety assessment. [The hazard assessment is addressed in detail in parts B, C, R8, R9, R10 and R11.1 of the above mentioned ECHA Guidance. An overview is given in table A below (see also [http://guidance.echa.europa.eu/guidance\\_en.htm](http://guidance.echa.europa.eu/guidance_en.htm))]. In addition, the OECD has developed tools supporting the grouping of chemicals and the analysis of structure-activity relationships<sup>1</sup>.

### **3. Glossary and annexes with practical examples (chapter 6 and 7 and materials volume)**

The practical guide uses examples to demonstrate different options for performing a chemical safety assessment, preparing exposure scenarios and communicating exposure scenarios within extended safety data sheets. Readers of the practical guide may find these examples helpful for identifying the best tools and methods for their own circumstances.

### **4. Supplement on exposure estimation (workers, environment and consumers)**

This supplement is aimed at “advanced” readers who have decided to perform a chemical safety assessment (or parts of it) themselves. They will find an overview on the approaches and tools and techniques for exposure estimation. The supplement provides an initial guidance on how to find and use the tools which are currently available.

#### **Note:**

- This practical guide is not a detailed and comprehensive guide on all of the individual steps of a chemical safety assessment. Neither does it intend to give a detailed description of which information has to be compiled and used for the hazard assessment.

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<sup>1</sup> For details see [http://www.oecd.org/document/23/0,3343,en\\_2649\\_34379\\_33957015\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/23/0,3343,en_2649_34379_33957015_1_1_1_1,00.html)

As stated above, reference is provided to the relevant ECHA guidance (see table A below).

- Some of the topics presented in this practical guide are currently still under intense discussion, e.g. the structure of the exposure scenarios for communication and the details of the Use Descriptor System. Specific changes could still take place in the near future. Nevertheless, we decided to show the current, not final, versions in this practical guide in order to facilitate the understanding of these elements.

**Before the reader starts working with the information, tools and formats presented in our guide, it is important to ensure that the most current versions of relevant guidance documents are being used. The updated versions are available at the ECHA homepage.**

Table A Reference between the process steps of the chemical safety assessment and the communication in the supply chains and the elements of the ECHA guidances. Parts A-G and parts R1-R20 are parts of the Guidance on information requirements and chemical safety assessment. The Guidance for downstream users is abbreviated in the table as “DU Guidance” (see also chapter 2 of the practical guide). For the current versions of the ECHA guidances see [http://guidance.echa.europa.eu/guidance\\_en.htm](http://guidance.echa.europa.eu/guidance_en.htm).

Process steps	Elements of the ECHA Guidances
Introduction to information requirements and the chemical safety assessment	A
Hazard Assessment	B, C, R8-10, R11.1
Information requirements, information gathering, evaluation of available information, adaptation of information requirements, QSAR and grouping of chemicals	R2, R3, R4, R5, R6, R7
Endpoint-specific guidance	R7
Derivation of DNELs / Characterization of dose [concentration] response for human health	R8
Physico-chemical hazards	R9
Derivation of PNECs / Characterization of dose [concentration] response for the environment	R10
PBT Assessment	C, R11
Exposure Assessment	D, R12, R13, R11.2, R14-18
Exposure scenario building	D
Risk management measures and operational conditions	R13
The Use Descriptor System	R12
Risk Characterisation	E, R19
Chemical Safety Report	F
Extension of the Safety Data Sheet	G
Table of terms	R20
REACH and Downstream Users / Scaling / Compliance check	DU Guidance



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## Part 1 General introduction and overview

### 1 Exposures

Completely “closed systems”, where substances are completely contained, are unusual in manufacture and particularly in the use of chemicals. The use of chemicals, preparations and articles manufactured from them usually infers the potential for some forms of “exposure” in most cases.

Exposure infers some form of contact and potential interaction e.g. – the contact of humans and, or the environment with different substances. This may be short-term or long-term, once or repeatedly, by different pathways, possibly in low or possibly in high concentrations.

This contact can be intentional and happen consciously, e.g. with fragrances, skin care products, food additives.

Exposure can also take place unintentionally: e.g. where in a dyeing process part of the dyestuff is not taken up from the dye liquid onto the fibres, despite the best intentions of the process, and thus is discharged with the process wastewater into the sewage treatment and hence the aqueous environment.

For cost reasons, chemical users already endeavour to keep these losses to a minimum.

For industrial safety and environmental and consumer protection, the question of where substances with hazardous characteristics ultimately exist, where exposures to the population and the environment can arise, 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.

“Safe use of chemicals” is a central aim of REACH, the new European chemicals policy. This also means that all potential exposures must be assessed. Manufacturers (and importers) of chemicals have obligations in this regard, as do their customers who may, as formulators, manufacture preparations from the substances, or who directly use substances and preparations for various purposes. 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. The REACH practical guide aims to familiarise companies with the most important terms and methods of the exposure assessment. This is to help with completing the relevant tasks required by REACH. Emphasis here is on the exposure assessment, the risk assessment and any resultant steps of communication of the conditions of safe uses up and down the supply chains.

## 2 Introduction

The safe use of chemicals is dependent on several preconditions:

- good knowledge of the properties of the substances and preparations<sup>2</sup> used;
- good knowledge of the conditions of use and the surroundings (e.g. the size of the river into which the wastewater stream is finally discharged after passing through the sewage treatment plant);
- good knowledge of any exposures while directly handling the substances and also of exposures which can result from the use of the substances (“indirect exposures“, e.g. by substance release from articles);
- development of appropriate risk management measures, if hazardous substances are involved, and their communication to the users;
- Implementation of the risk management measures by everyone who deals with the substances.

In REACH, a set of instruments, which are related to each other are prescribed:

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

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 shall include the following steps (see also 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.

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<sup>2</sup> The term „preparation“ is replaced in the GHS regulation by the term „mixture“. In the practical guide we use the term “preparation” which is – at least at present – more common.

If, as a result of carrying out steps (a) to (d), the registrant concludes that the substance meets the criteria for classification as dangerous (in accordance with Directive 67/548/EEC) or is assessed to be a PBT or vPvB substance<sup>3</sup>, then the chemical safety assessment must additionally include the steps of the exposure assessment and the risk characterisation.

In the context of the chemical safety assessment, it should be determined which risk management measures are necessary for adequate control of the risk resulting from handling the involved substance. The chemical safety assessment is an **analytical and an assessment instrument**.

The chemical safety report documents, in writing, the results of the chemical safety assessment. It is a **documentation instrument**. (In the materials volume of this practical guide there are exemplary chemical safety reports – for acetonitrile, potassium tertiary butylate, HDDA and NaOH).

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 in the annex of the safety data sheet<sup>4</sup>. (In annexes 7.11, 7.14–7.19 of this practical guide you will see examples of exposure scenarios. Further explanations to exposure scenarios are given in chapters 3.2 and 5.1 of this practical guide). At present the structure of the exposure scenario is under discussion and changes may occur in near future.

The (chemical) safety data sheet is, and remains, the central **communication instrument** for the supply chains for industrial and professional users. Under REACH it is extended with Exposure Scenarios and called eSDS. For safe use, the central results of the chemical safety assessment are transferred directly to the safety data sheet. Details for this are described in the practical guide in chapter 3.4. (In this chapter the BDI standard phrases catalogue is also introduced. In annexes 7.17 and 7.19 of the practical guide an example is provided of an extended safety data sheet according to REACH).

To achieve the goal of the safe use of substances and preparations – dependent on the individual case, the co-operation between manufacturers, importers and downstream users (formulators and further users) is necessary, together with inclusion of the trade as required.

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<sup>3</sup> "PBT" substances are persistent, bioaccumulative and toxic, "vPvB" substances are very persistent and very bioaccumulative (vPvB).

<sup>4</sup> 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.

This particularly applies if adequate information or assessments are not already available. This will be covered in the following part of the practical guide and in detail in chapter 5.4.

### **Improved communication in the supply chains**

For substances and preparations which are delivered in the European Union, REACH requires more and improved communication. Even before REACH, there was an obligation for the suppliers of substances and preparations to provide information to their customers with the assistance of the safety data sheet. These duties were extended still further 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 performing of the chemical safety assessment requires data and knowledge on the substance properties and conditions of use, which are often already available somewhere in the value added chains but piecemeal i.e. scattered in fragments. By initiating exchange between substance manufacturers, formulators and users it can be guaranteed that, the necessary knowledge of the users on the existing use conditions and practical recommendations for risk management measures are communicated in the supply chains.

This communication between the participants occupies a large proportion of both the REACH legal text and the associated guidance. It is assumed that the manufacturers/importers should have sufficient information on their own uses. Practical options of structured and standardized communication processes between manufacturers/importers and downstream user are presently being developed in different projects. In this practical guide we give recommendations on the use of the different tools and what the next steps will be (in particular in chapters 5.1.7 and 5.4).

### **The principle of shared responsibility**

Under REACH, companies are primarily responsible for the assessment and the safe use of chemicals. In future, the tasks of the European and national authorities are to be limited to controlling whether industry follows its obligations under REACH. **The principle of shared responsibility** in the supply chains leads to the following task distribution:

- The registration of the substances is made by the manufacturer and/or importer of the substances. In the context of the chemical safety assessment the manufacturer and/or importer decides, for dangerous substances, under which conditions they can be used safely and communicates these conditions for their safe use to the downstream users.

(Downstream users may already be involved in information exchange during the registration. Here it is strongly recommended to involve the trade associations in the communication process (see also chapters 5.4 and 5.4.2).

- Downstream users are obliged to examine their own uses of substances and preparations to see whether they are considered within the scope of the exposure scenarios described in the safety data sheet of the manufacturer/importers/formulators (see chapter 4).

Additional uses can be notified to the supplier so that they can be considered in the context of that registration and included in the safety data sheet. Alternatively, the downstream user can perform his own chemical safety assessment.

From the obligation to examine his own uses it follows that the downstream user 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. This communication will become of great importance for the implementation of REACH. 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.

### **What will you find in this practical guide?**

**This practical guide focuses on the exposure assessment in the context of the chemical safety assessment and the related communication tasks in the supply chains. This includes<sup>5</sup>:**

- the individual work procedures of the chemical safety assessment ;
- the structure of the chemical safety report;
- the structure, the use and the development of exposure scenarios;
- the instruments necessary for the exposure assessment;
- the changes in the safety data sheet;
- the various tasks of downstream users;
- the communication processes in the supply chains.

Introductory presentations of the individual topics are found in chapters 3 and 4 and advanced illustrations of individual tasks are given in chapter 5.

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<sup>5</sup> We do not deal in detail with the task of determining hazardous properties (hazard assessment) in this practical guide.

There are several topics which are still under active discussion (e.g. the structuring of exposure scenarios used in chemical safety assessment and details of the Use Descriptor System): In our practical guide we focus on steps which can currently be completed. The results of the on-going-discussions will be incorporated in the next versions of this practical guide as soon as they become available.

Work procedures, instruments and results are described using examples whenever possible.

### **The associated REACH documents**

The remarks in this practical guide refer to the REACH legal text (in particular articles 14, 31, 32, 34, 37-39, annexes I + II) and to the guidances for the implementation of REACH, published by the European Chemicals Agency. Two of these guidances are of special importance for the following chapters 3 to 5:

- The Guidance on information requirements and chemical safety assessment (ECHA 2008a, [http://reach.jrc.it/docs/guidance\\_document/information\\_requirements\\_en.htm](http://reach.jrc.it/docs/guidance_document/information_requirements_en.htm)).
- This guidance is based on the work of the REACH Implementation projects (RIP). 3.2 and 3.3. An overview on the structure of this guidance can be found in the associated Fact Sheet of the ECHA ([http://echa.europa.eu/doc/reach/echa\\_08\\_gf\\_06\\_inforeq\\_csr\\_part\\_a\\_en\\_20080721.pdf](http://echa.europa.eu/doc/reach/echa_08_gf_06_inforeq_csr_part_a_en_20080721.pdf))
- Also for part D of the guidance, which is concerned with the structure of exposure scenarios, an overview is available in the form of a Fact Sheet [http://echa.europa.eu/doc/reach/echa\\_08\\_gf\\_07\\_inforeq\\_csr\\_part\\_d\\_en\\_20080721.pdf](http://echa.europa.eu/doc/reach/echa_08_gf_07_inforeq_csr_part_d_en_20080721.pdf)
- The Guidance for downstream users (ECHA 2008d (status: January 2008)) ([http://reach.jrc.it/docs/guidance\\_document/du\\_en.htm](http://reach.jrc.it/docs/guidance_document/du_en.htm)) is based on the work in the REACH implementation project (RIP) 3.5. An overview on the structure of this guidance is available in the appertaining Fact Sheet of ECHA (ECHA 2008e) [http://echa.europa.eu/doc/reach/echa\\_08\\_gf\\_02\\_du\\_de\\_20080627.pdf](http://echa.europa.eu/doc/reach/echa_08_gf_02_du_de_20080627.pdf). The Association of German Construction Chemistry (Deutsche Bauchemie e.V.) has published, in co-operation with Ökopol, a recommendable German-language elaboration to this ECHA guidance ("REACH Guideline for the manufacturers of construction chemicals", German Construction Chemistry (Deutsche Bauchemie e.V.), Frankfurt/Main, 2008 ([www.deutsche-bauchemie.de](http://www.deutsche-bauchemie.de))). The English version of this publication can be downloaded from the following website: <http://db.vci.de/publikation/index.php?sid=6403fe5930a38e06cfe87d4c3412cecc&cl=details&cnid=&anid=7674803505e2972d5.33445896>).

### **3 The chemical safety assessment, the chemical safety report and the communication in the supply chains**

#### **3.1 The chemical safety assessment**

##### **3.1.1 Aims and principles of the chemical safety assessment**

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 in circumstances such that the risk can be 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 from 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 physicochemical, 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“<sup>6</sup>). The limit values for the environment are called PNECs (“Predicted No-Effect Concentrations“)<sup>7,8</sup>.

From the knowledge of the conditions of use, statements about the resultant exposures are made in the chemical safety assessment. This concerns the kind, duration, frequency and level of the exposure. The basis of the statements on the exposure level can ultimately 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.

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

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

<sup>8</sup> 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).

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 3.2 and 5.1 of this practical guide).

The following illustration shows a typical application situation of a preparation in the printing industry. The arising release (emissions) of the constituent substances in water, soil and air depends crucially on the substance and preparation 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 1).

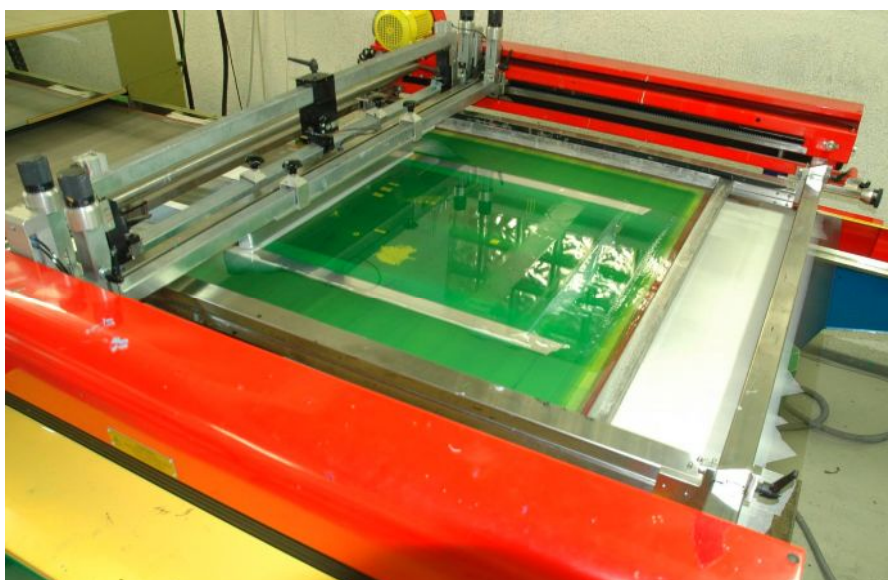


Figure 1 Use of a colouring substance preparation for the printing industry. Source: Thorn 2008.

Preparations can differ in their properties considerably from the properties of the individual substances contained in them. The assessment of preparations and/or of substances in preparations can thus make additional assessment steps necessary in certain cases. The methodology for this is not yet sufficiently developed in the relevant REACH guidance of the European Chemicals Agency. Some remarks on chemical safety assessments for preparations are included in the guidance of the ECHA for downstream users in chapter 14 (ECHA 2008d p. 112ff).

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**.

In the risk characterisation the exposures for humans and environment, which can be expected, are compared to the limit values (DNEL and/or PNEC values). In addition, a judge-

ment is made regarding the probability and the severity of impacts from the physicochemical substance properties. It is assumed that the **risk management measures** described in the exposure scenarios have been implemented.

For effects for which no quantitative limit value can be indicated, below which no damage is to be expected, a qualitative assessment is made as to whether 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 problematic physicochemical properties (flammability, oxidising potential, explosiveness) 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 implementation of the recommended risk reduction measures<sup>9</sup>.

If the first risk characterisation shows that the limit values will be exceeded, iteration is required. Changes are necessary in the assumed conditions of use<sup>10</sup>, the risk management measures or additional testing that can be used until, in the context of the chemical safety assessment, a sufficient reduction of the exposure can be proven (iterative process). The procedure during the exposure assessment for workplace, consumer and environmental protection will be presented in the supplement on exposure estimation (Part IV of the practical guide).

### 3.1.2 Chemical safety assessments as part of the registration of substances

For substances with an annual production quantity starting from 10 tonnes (for each manufacturer/importer) as part of registration, the chemical safety assessment must be made by the registrant (substance manufacturer and/or importer). In these cases the chemical safety report, in which the results of the chemical safety assessment are documented, is submitted by the registrant to the European Chemicals Agency (the registration dossier consists of two

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<sup>9</sup> 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 really safe.

<sup>10</sup> "Conditions of use" means the operational conditions (e.g. quantity, temperature, content of the substances in the preparation etc.) and the risk management measures, see also chapters 3.1.7–3.1.10).

parts: the technical dossier and the chemical safety report<sup>11</sup>). The chemical safety assessment for dangerous substances also includes the exposure assessment and the risk characterisation (see chapter 3.1.5).

### 3.1.3 Chemical safety assessments by downstream users

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. (The chemical safety report of the downstream user does not however have to be sent to ECHA but need to be available for inspection authorities.)

This is the case if downstream users apply substances and preparations under conditions which are not covered by the exposure scenarios of their suppliers (see chapter 4.1 and 4.2). To a certain degree parameters of exposure can vary in individual application situations. The downstream user can consider whether or not his specific conditions of use are in the safe range as described in the exposure scenario. He can use scaling to do this examination (see chapter 4.2).

If his use is not covered, and he decides not to communicate with his supplier about this use, the downstream user must carry out his own chemical safety assessment (for details and exceptions see chapter 4.1). This will presumably arise often if formulators produce preparations with several hazardous ingredients and these are uses not covered in the safety data sheet of the individual substances. Annex XII of REACH contains general provisions for chemical safety assessments by downstream users. More detailed information is contained in the guidance for downstream users of the ECHA in chapter 7. In this practical guide we go into this briefly in chapter 4.4.

**Practical tip:** The downstream user is obliged to develop exposure scenarios himself under the conditions specified in chapter 4.2 and to document these in an internal chemical safety report. However, no chemical safety reports must be sent to the European Chemicals Agency (or to customers). The obligation to send the CSR (to the European Chemicals Agency) applies only to the substance manufacturer and/or importer in the context of the registration.

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<sup>11</sup> Exception: see REACH article 14, 2.

### 3.1.4 General regulations for the chemical safety assessment and its structure

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

- a) Assessment of harmful effects on human health (“human health hazard assessment”);
- b) Assessment of harmful effects through physicochemical characteristics (“human health hazard assessment of physicochemical properties”);
- c) Assessment of harmful effects on the environment (“Environmental hazard assessment”);
- d) Assessment of the PBT and vPvB characteristics (“PBT and vPvB assessment”);
- e) Exposure assessment having two steps
  - (a) Development of exposure scenarios
  - (b) Exposure estimation;
- f) Risk characterisation

Exposure assessment and risk characterisation only have to be performed if, as a result of steps 1–4, the substance has to be classified as dangerous or is assessed as a PBT or vPvB substance<sup>12</sup>.

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 and/or GHS Regulation) or a substance is categorised as a PBT and/or vPvB- substance<sup>13</sup>, then steps 5 and 6 of the chemical safety assessment are also necessary; namely the determination of the exposure and the risk characterisation.

When the chemical safety assessment is complete, the results are documented in the chemical safety report and considered in the safety data sheet<sup>14</sup> insofar as the substance is supplied to users in the European Union. The chemical safety report is not submitted to the customers, but the essential information from the CSR is transferred to the extended safety data sheet.

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<sup>12</sup> 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.

<sup>13</sup> PBT substances: Substances which are persistent, bioaccumulative and toxic / vPvB substances: Substances which are very persistent and very bioaccumulative.

<sup>14</sup> It is to be noted that the safety data sheet is not to be submitted with the registration of a substance to the European Chemicals Agency.

The substance manufacturer/importer submits the chemical safety report as part of the registration dossier – in the context of the registration – to the European Chemicals Agency. The extended safety data sheet, which contains results from the chemical safety assessment, is used as the central instrument of communication in the supply chain. It is passed on by the manufacturer and/or importer to customers together with the substance.

### 3.1.5 The individual steps of the 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 GHS 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. The hazard assessment is made in four steps:
  - Step 1: Evaluation of non-human information;
  - Step 2: Evaluation of human information;
  - Step 3: Classification and Labelling;
  - Step 4: Derivation of the DNELs.

Objectives and approach are comparable with the determination of the **harmful effects on the environment**. Here the goals are

- the classification and labelling of a substance in accordance with the Directive 67/548/EEG and/or GHS Regulation;
- the derivation of limit values below which no harmful effects are expected for the environmental sphere concerned. 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).

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 GHS (this also includes the derivation of limit values for the explosion potential of substance/air mixtures). For each physicochemical property the assessment covers an examination as to what extent the substance can elicit this effect during the production, and the identified uses.

The results of the determination of the harmful effects are then documented in the chemical safety report.

### **3.1.6 The exposure assessment**

The goal of the exposure assessment is an estimation of the dose and/or concentration of the substance to which humans and the environment are exposed, or could be exposed. This estimation should take place quantitatively if possible, in order to enable a comparison of the expected exposure level with the exposure-related limit values (DNELs and/or PNECs).

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

- In the first step, exposure scenarios are developed. Exposure scenarios are the core element of the chemical safety assessment. They describe how substances can be used safely. Initial exposure scenarios may act as starting point of a (quantitative) risk assessment and the final exposure scenarios describe the conditions including risk management measures that allow control of the risk associated with the handling of a substance. Detailed information on exposure scenarios is given in chapter 3.2 and the advanced chapter 5.1.
- In the second step, an estimation of the exposure is made. This estimation 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 and the estimation of the exposure level. 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 the advanced chapter on “exposure estimation” in the practical guide). Exposure estimation models are also used for the estimation of the exposure level in many cases

In the advanced chapter “exposure estimation” we deal in detail with the exposure estimation for workers, consumers and the environment. Consideration should be given as to what determines, in practice, actual exposures and, if so, at what level?

### **3.1.7 What determines the exposure/exposure level?**

Operational conditions of use of substances and preparations 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”<sup>1516</sup>. 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, 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 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<sup>17</sup>).

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 7.7 of this practical guide.

**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:

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<sup>15</sup> 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.

<sup>16</sup> In the case of high concentrations of dust, even substances which are not classified as dangerous can cause health problems.

<sup>17</sup> The values can be different in different assessment tools. You will find more information on such default values in the advanced chapter of the practical guide on exposure estimation.

- 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 exposure-determining parameters.
- In the different sections of the exposure scenarios only those exposure-determining parameters which are of importance for the respective use are described. As part of the preparation for REACH we recommend that you prepare an overview of the exposure-determining parameters for your substances and preparations. For this we provide references to possible priority setting in chapters 5.3 and 5.3.1.4 of this practical guide.

### 3.1.8 The conditions of use

Some of the exposure-determining parameters can be influenced or controlled by the user of the substances, others cannot.

Things which cannot be influenced usually include the respective substance properties and the characteristics of the surroundings (e.g. the average body weight of an adult, which one assumes in the chemical safety assessment or the quantity of receiving stream water into which the substances are released).

Things which may be influenced are the characteristics of the processes and the products, which are important for the substance to be assessed, e.g. the type of process, the operational conditions or the applied risk management measures. 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 use conditions.

REACH differentiates between two kinds of changeable exposure-determining parameters:

- Operational conditions (of use) ("OCs") and
- Risk management measures ("RMMs").

Operational conditions and risk management measures together form the use conditions, under which a substance (as such, or in a preparation) is used<sup>18</sup>.

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

**Risk management measures** are all actions, use of equipment (e.g. Local extract ventilation, dust scrubbers or local waste water treatment), or parameters, during the production or the use of a substance (as such, or in a preparation) to be introduced with the goal to prevent, to control or to reduce the exposure of humans and/or environment.

Borderlines between both kinds of use conditions are often fluid. Operational conditions and risk management measures can crucially affect the real exposures<sup>19</sup>.

Therefore we deal with this in greater detail in the following two subchapters.

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.

A **quantitative specification** (e.g. quantity required in kg product/day, effectiveness of the risk management measured in per cent) should be made during the exposure estimation if possible, so that it can be included in the context of the exposure estimation.

**Note:** An introduction to the importance of conditions of use for the chemical safety assessment is found in part D, chapters 4.5 and 4.6 of the ECHA Guidance for Chemical Safety Assessment. 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. In the practical guide we will go into these parameters in the next two subchapters.

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<sup>18</sup> In the REACH legal text, annex I, “operational conditions“are alluded to. This is translated into German with “Verwendungsbedingungen“. In the ECHA guidance a distinction is made between “the conditions of use“ and “operational conditions“ (OCs) and/or “operational conditions of use “. In the standard format of the exposure scenario likewise one speaks of “operational conditions of use“. We recommend using the term “use conditions“, for all of the use conditions which can be divided into the application conditions (“operational conditions“) and the risk management measures.

<sup>19</sup> **Note:** A clear allocation of a measure or an application condition to the group “application conditions“ or “risk management measure“ is not always possible from a technical aspect. Application 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 application conditions and risk management measures, which was already presented in the text. The application 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 **purposefully** in order to decrease exposures.

### 3.1.9 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 preparation 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 preparation 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 preparation, 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 preparations – but not necessarily from the manufacturers and/or importers, who need these data for the chemical safety assessment.

### 3.1.10 Risk management measures

Risk management measures – **and compliance with them!** – are of central importance for the safe use of substances. They are already prescribed in other pieces of legislation. Examples for this are the EC Chemicals Agents Directive (CAD) and the IPPC Directive (Integrated Pollution Prevention and Control). Thus 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 5.3 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 preparation. In this case, manufacturers and/or importers have to implement appropriate measures for their own uses, and communicate to the downstream users the appropriate measures appli-

cable to their uses, via the e-SDS. The DU will examine whether such use(s) is/are covered by the ES. If so, it is necessary to comply with the ES and implement the necessary RMM. However, scaling may be performed, based on the determinants of exposure provided, in order to address minor deviations from the received ES and demonstrate control of risk.

If this should not be the case, it should be communicated to the supplier.

Note: It is possible that as a result of the substance chemical safety assessment it may be concluded that less sophisticated risk management measures, than those practices already being used in the industry, may appear to be needed. This does not necessarily mean that present practice is not a necessary requirement. Existing regulatory and other specifications for the workplace and for environmental protection can consider the entirety of the impact on the workplace and/or in the environment and thus may prescribe more rigorous risk management measures than those that may be required from the REACH regulation chemical safety assessment.

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;
- organizational measures;
- technical measures;
- personal protection measures.

Instructions are always necessary for the implementation of risk management measures. When considering different options for minimizing the risk, process and/or product-related measures, generally have priority over emission reducing measures applied at the end of the processes. 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 production 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 preparation 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 preparation; 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.

**Note:** 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.

**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:

- organizational 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 preparation 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<sup>20</sup> remains under 1).

Examples of typical emission reduction measures, and their effectiveness, are presented below in table 1. The reduction factor specified in the third column can be inserted directly into the formulas for the calculation of the predicted environmental concentration (PEC)

Table 1 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

Note: Detailed descriptions of the inclusion of risk management measures are given in chapter R.10 of the ECHA guidance for chemical safety assessment. The European association of Chemical Manufacturers CEFIC has collected descriptions of risk management measures in a so-called “library of risk management measures” (RMM: <http://www.cefic.org/files/downloads/RMM%20Library%20.xls&039;IndividualMeasures!A1>). This library and its use are described more exactly in chapters D4.6.2 and R.13.4 of the ECHA guidance for chemical safety assessment (ECHA 2008a).

### 3.2 Exposure scenarios

Exposure scenarios, in the sense of REACH, inform the manufacturers and users of substances under which conditions of use specific substances can be regarded as “safe”. The resulting exposures described in these scenarios are sufficiently low that no harmful effects are to be expected to either persons or to the environment

- Exposure scenarios cover all life cycle stages of a substance. They are developed within the chemical safety assessment and they become part of the chemical safety report.

<sup>20</sup> 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)).

- Exposure scenarios which only refer to internal uses of substances by the manufacturer or importer do not have to be communicated in the supply chain. They are documented in the chemical safety report.
- Exposure scenarios, which refer to uses in the supply chains, have to be communicated to the downstream users – as an annex of the extended safety data sheets.

Exposure scenarios provide communication, within the supply chains, of how substances can be used safely. To achieve this, exposure scenarios must be provided as an annex to the safety data sheet. Exposure scenarios are first prepared by the manufacturer or importer of substances (which are classified as dangerous or which have PBT/vPvB properties), if they are manufactured or imported in quantities of 10 tonnes or more per year (per manufacturer/importer).

Formulators may communicate their own exposure scenarios, for the preparations that they manufactured, as an annex of their safety data sheets.

Another possibility is for formulators to include the information from the exposure scenarios supplied by their suppliers in their own safety data sheets (instead of preparing their own exposure scenarios)<sup>21</sup>.

Exposure scenarios gather all the information which is necessary for the safe use of a substance or preparations in one or more uses. The exact nature of this information will differ depending upon the substance under consideration. Exposure scenarios will contain information on the following points, if they are important for the safe use:

- The procedures under which the substance is manufactured, processed and used;
- The associated operational conditions (OCs) of use; see chapters 3.1.7–3.1.9);
- Risk management and waste treatment measures which are necessary for safe use;
- Information about the exposure estimation and the models used for this;
- Assistance for the user of the substances, in order to find out whether his uses are in the range of the uses which the exposure scenario describes.

A standard format for structuring the information which can be contained in an exposure scenario was compiled in the REACH implementation projects (RIPs). This is intended to facilitate communication in the supply chains by a means of a uniform structure. This standard format arranges the exposure scenario into sections relevant for different targets, e.g. worker exposure, consumer exposure, environmental exposure; see the following table 2

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<sup>21</sup> In the ECHA guidance for chemical safety assessment part G is concerned with the extended safety data sheet. In chapter G.2.3 different possibilities are presented for including information from substance-related exposure scenarios into the safety data sheets of downstream users (ECHA 2008a, part G, p.8). In the second phase of the practical guide project the different possibilities will be examined more closely.

Table 2 Standard format of an exposure scenario (ES). This ES format is currently under review by ECHA and may change. Source: related to ECHA Guidance on information requirements and CSA, part D, p. 12, table D.2-2 (see preface of the practical guide).

1	Short title of the exposure scenario	
2	Processes and activities covered by the exposure scenario	
<b>Operational conditions of use</b>		
3	Duration and frequency of use	
4.1	Physical form of substance or preparation; surface to volume ratio of articles	
4.2	Concentration of substance in preparation or article	
4.3	Amount used per time or activity	
5	Other relevant operational conditions of use	
<b>Risk Management Measures</b>		
6.1	Risk management measures related to human health (workers or consumers)	
6.2	Risk management measures related to the environment	
7	Waste management measures	
<b>Information on estimated exposure and DU guidance</b>		
8	Exposure estimation and reference to its source	
9	Guidance to DU to evaluate whether he works inside the boundaries set by the ES	

At present the European Chemicals Agency restructures the format of the exposure scenario. It is expected that the new version allows to better differentiate between information regarding workers protection, environmental protection and consumer protection. As soon as the new format is available it will be presented in the next version of the practical guide.

Exposure scenarios are of central importance for the registration (REACH title II), the information in the supply chain (REACH title IV), the tasks of the downstream users (REACH title V) and the authorisation (REACH title VII). Exposure scenarios in REACH have been described as the core of the process to carry out a chemical safety assessment (REACH annex I, 5.1.1).

Just how detailed the descriptions in exposure scenarios are to be is not fixed in the REACH text. In accordance with annex I, only the data which are actually relevant for exposure must be given. The level of detail required is to be determined in such a way that the goal of safe use is reached.<sup>22</sup> In so far as exposure scenarios must be communicated in the supply chain, it is important that these descriptions – as far as possible – are uniformly arranged in order to optimise ease of understanding. If possible they should be generic i.e. cover a larger number of uses and substances for all relevant life cycle stages. With such generic exposure scenar-

<sup>22</sup> Those substances, which manufacturers and importers only use themselves and do not deliver to customers in the European Union, may already be covered in internal evaluations and these could be submitted if necessary.

ios, which are valid for many substances and/or many uses, the expenditure connected with the chemical safety assessment for the registration can be substantially reduced. At the same time standardized and broadly composed exposure scenarios also simplify for the user the task of determining whether his specific applications of substances are covered in the exposure scenarios.

**Development of exposure scenarios:** At present differently structured exposure scenarios are being developed on different levels. They can refer to individual industries or to certain classes or groups of substances (e.g. solvents). In the advanced chapter 5.1 of this practical guide on exposure scenarios we deal in greater detail with these different approaches. In that chapter the stepwise / iterative procedure with which exposure scenarios can be prepared is also described.

In annexes 7.10 and 7.14 to 7.17 you will find five examples of exposure scenarios.

Before REACH most users of substances and preparations will not have been familiar with chemical safety assessments and exposure scenarios. Exposure scenarios and much of the information contained within them may be new for these companies. It will require some practical training, before the exposure scenario can become established as an important information component in the supply chains.

**Note:** Exposure scenarios cover the entire life cycle of a substance. If a substance is used in different applications, several exposure scenarios can become necessary. Exposure scenarios can also be provided for the safe use of preparations that contain one or more dangerous ingredients.

**Practical tip: For how many substances will exposure scenarios become necessary? Which of these exposure scenarios will be communicated?**

Exposure scenarios are only necessary for those substances registered with a production/import volume of 10 tonnes and more per year/registrant, which have, in the context of the chemical safety assessment, proved to be dangerous or PBT or vPvB substances. The number of existing substances with such production volumes is in the order of approximately 10,000 substances<sup>23</sup>. A portion of these substances are only used as intermediates in the manufacture of further substances; here no exposure scenarios are necessary. A further proportion will be classified as not dangerous and/or not a PBT/vPvB substance and will thus

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<sup>23</sup> The number of existing substances with a production volume of less than 10 t/year, but 1 t/year or more is estimated at approximately 20,000 substances.

not require exposure scenarios. According to first estimates, the proportion of the substances, for which exposure scenarios will be necessary, will be approx. 4,000 substances<sup>24</sup>.

Registrants, (manufacturers and importers), will first use exposure scenarios to assess their own uses for the substances registered by them; in many cases they will be able to refer to existing risk assessments for their own uses. On the basis of these data they may be able to document the safe – internal – use in the chemical safety report.

For those substances that are exclusively used internally, no communication of exposure scenarios in the supply chain is necessary. For the exposure scenarios which are not communicated, which refer to purely internal uses, the selected form of the presentation in the chemical safety report is less significant. In many cases the registrant will document the already available assessments (in their specific structure) in the chemical safety report. There is no obligation to restructure.

With many substances the manufacturer and/or importer will not bring the substances into the market as pure substances, but rather make preparations. Probably most first preparations are made by the substance manufacturers themselves. In this case the manufacturer's own uses exposure scenario also covers the production of the preparation.

Many producers of preparations (M/I/DU) aim to produce only non dangerous / non PBT / non vPvB preparations due to the demands of the market. If the thresholds for classification are not exceeded, a SDS is not required and there is no need for exposure scenarios<sup>25</sup>.

The same is valid if the substance has already been put into an article by the manufacturer/importer. Exposure scenarios also do not have to be provided if dangerous substances/preparations are exported into a non European Union country.

In all these cases, there is no obligation to communicate an exposure scenario in the supply chain. This obligation only exists if hazardous and/or PBT / vPvB substances (or preparations which contain these substances in quantities above the thresholds specified in REACH) are placed on the European market.

To summarise: exposure scenarios will **not** be communicated in the supply chains:

- for substances with a production/import volume under 10 t/year/registrant;

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<sup>24</sup> Estimation: of approx. 10,000 substances over 10 t/year, only about 50% will have to be classified as dangerous and will thus require an ES. A considerable portion of these dangerous substances are used only as an intermediate and thus require no ES. Furthermore, many substances are imported (possibly also manufactured) only in the form of non-dangerous preparations; here the production of an ES is technically not necessary, either.

<sup>25</sup> Nevertheless in these cases exposure scenarios are also required for the handling of the substances and for the internal manufacturing steps. Importer has to prepare these exposure scenarios for each dangerous/ PBT / vPvB substance which they import in an amount of 10 tons/year.

- for non-dangerous substances (not classified, no PBT /vPvB substance);
- for substances which are used only as intermediates;
- for substances which are used only internally by the manufacturer/importer;
- for substances which “disappear” in preparations which are classified as not dangerous;
- for substances which are already put into articles by the registrant;
- for substances which are exported into non-European Union countries.

The exposure scenarios for own uses are documented in the chemical safety report, but there is no need to communicate them in the supply chain.

Therefore not all of the exposure scenarios of the chemical safety report are communicated but only those which refer to the uses by the downstream users. For the exposure scenarios communicated, there is a standard format presented in the ECHA guidance (see table 2)<sup>26</sup>. In the exposure scenarios which are communicated, the contents should be in a language which is understood by the customers in order to reach the objective of safe use. (In general, safety data sheets have to be provided in the official language of the Member State of the customer).

### 3.3 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 here. 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 individual steps of the chemical safety assessment and the information presented here (table 3).

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<sup>26</sup> This exposure scenario format is currently under review by ECHA. It is expected that the new version allows to differentiate better between information regarding workers protection, environmental protection and consumer protection. As soon as the new format is available it will be presented in the next version of the practical guide.

Table 3 The individual chapters in the chemical safety report. Source: REACH annex I, chapter 7.

<b>Part A</b>	
<b>1.</b>	<b>Summary of risk management measures</b>
<b>2.</b>	<b>Declaration that risk management measures are implemented</b>
<b>3.</b>	<b>Declaration that risk management measures are communicated</b>
<b>Part B</b>	
<b>1.</b>	<b>Identity of the substance and physical and chemical properties</b>
<b>2.</b>	<b>Manufacture and uses</b>
2.1.	Manufacture
2.2.	Identified uses
2.3.	Uses advised against
<b>3.</b>	<b>Classification and labelling</b>
<b>4.</b>	<b>Environmental fate properties</b>
4.1.	Degradation
4.2.	Environmental distribution
4.3.	Bioaccumulation
4.4.	Secondary Poisoning
<b>5.</b>	<b>Human health hazard assessment</b>
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)
<b>6.</b>	<b>Human health hazard assessment of physicochemical properties</b>
6.1.	Explosivity
6.2.	Flammability
6.3.	Oxidising potential
<b>7.</b>	<b>Environmental hazard assessment</b>
7.1.	Aquatic Compartment (including sediment)
7.2.	Terrestrial Compartment
7.3.	Atmospheric Compartment
7.4.	Microbiological Activity in Sewage Treatment Systems
<b>8.</b>	<b>PBT and vPvB assessment</b>

<b>9.</b>	<b>Exposure assessment</b>
9.1.	[Title of Exposure Scenario 1]
9.1.1.	Exposure Scenario
9.1.2.	Exposure Estimation
<b>10.</b>	<b>Risk Characterisation</b>
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 production of a chemical safety report was prepared by the European Chemicals Agency (“CSR Template “; see [http://reach.jrc.it/formats\\_en.htm](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 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;
- 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.

### 3.4 The extended safety data sheet

#### 3.4.1 Changes in the safety data sheet through REACH

With REACH the previous safety data sheet Directive 91/155/EEC has been replaced. Under REACH the safety data sheet still remains the central means of information for the supply chain – related to individual substances and preparations in industrial and commercial uses. It 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 preparation in an article (for articles however no safety data sheet is necessary).

**Structural changes:** There are two changes from the past structure of the safety data sheet: chapters 2 and 3 are interchanged in sequence and – more importantly – the extended safety data sheet can contain an annex with exposure scenarios.

**Content changes:** Content wise, in several chapters of the safety data sheet there are additions that are important for the assessment of individual substances and preparations (see table 4).

Table 4 The extended safety data sheet in accordance with REACH: 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/preparation, use of the substance/preparation, company undertaking identification, emergency telephone	
1.1	Identification of the substance or preparation	Registration number
1.2	Use of substance/preparation	(if CSR is required) identified uses
1.3	Company/undertaking identification	email address
<i>Attention:</i> 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. Registration numbers for dangerous substances above threshold
8	Exposure controls/Personal Protection	DNEL- and PNEC-values 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) Results from the <b>PBT</b> assessment

13	Disposal considerations	(if CSR is required) 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 approvals and restrictions
16	Other information	Recommended restrictions of uses
Annex 1	<b>Exposure scenario</b>	
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 preparations than previously.

### 3.4.2 IT-implementation of safety data sheets and the standard phrases catalogue of the BDI

Safety data sheets must be made available by substance manufacturers and formulators in many languages and updated as content changes. Since in many cases hundreds or thousands of substances and/or preparations are involved, the safety data sheets are usually produced not manually, but by the use of special software. Here the necessary contents are compiled as far as possible from an extensive set ("catalogue ") of **text** modules, which are available in all the required languages. These text modules are called "standard phrases".

**Examples of such standard phrases** from the Standard Phrases Catalogue of the Federation of German Industries (Bundesverband der Deutschen Industrie e.V., BDI)

(<http://reach.bdi.info/378.htm>) are:

- Vapours/aerosols must be exhausted directly at the point of origin. (ch. 07, subch. 01.01.02.01.);
- Use a closed dosage system (chapter 07, subchapter 01.01.02.01.);
- Observe and ensure the proper conditions of sealings and connection threads. (ch. 07, subch. 01.01.03.).
- Unsuitable container/equipment material: Iron (ch. 07, subch. 01.01.03, combination of standard phrase codes 11001 and 11012).

Standard phrases are text modules for contents in the safety data sheet. Thus they are a valuable tool in order to prepare the (extended) safety data sheets necessary for REACH. 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; both of which are of fundamental interest for the companies involved. Harmonised phrases ensure recognition by all users.

Before REACH, the standard phrases illustrated contents which were necessary for the safety data sheets, with the 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 should also cover environmental and consumer protection, the structure and data of the exposure scenarios in the annex and additional structuring data (like e.g. the Use Descriptor System (see chapter 5.1.3) and the UEC-Matrix (see annex 7.15).

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 at the website of the BDI REACH Helpdesk<sup>27</sup> and may also be the Business Europe standard phrases catalogue. 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.

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 including sector-specific communities/associations or initiatives.

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

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 BDI working group makes additional modules available, e.g. for the new “Globally Harmonized System for Classification and Labelling “(GHS), for exposure scenarios as an annex to the extended safety data sheet and for the VCI use and exposure categories (UEC matrix). In addition there are blank forms for REACH conforming safety data sheets (with consideration of GHS) in German and English. The standard form for safety data sheets of the BDI is also available as an annex in the materials volume of the practical guide.

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<sup>27</sup> <http://reach.bdi.info/378.htm>; the catalogue is available free of charge in German and English; with a further 30 languages available on a cost basis.

Furthermore, at the Federal Institute for Occupational Safety and Health (BAuA), “Bekanntmachung 220” is available for downloading<sup>28</sup>. 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 BDI catalogue 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 BDI working group can be used for different formats. The blank form provided for an extended safety data sheet enables the use of both the Use Descriptor System and the UEC matrix.

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

**Practical tip:** Before REACH, voluntary measures (such as product stewardship information) were also communicated in the safety data sheet. In general, voluntary measures refer to non-hazardous properties of substances, e.g. degreasing of skin. This supported the safe handling of products, without being legally obligatory. Under REACH, the downstream user has to comply with all of the conditions of use and risk management measures described in the exposure scenario (and/or comparable or stricter conditions). Therefore, voluntary measures should be mentioned in the main body of the SDS and not in the exposure scenarios.

## 4 Downstream users and the implementation of REACH

In this chapter you will find an overview of the tasks and the possibilities, which users of chemicals have under REACH. In the ECHA guidance for downstream users (ECHA 2008d) assistance is given for all these tasks. Here in the REACH practical guide we will deal in greater detail with the tasks connected with the exposure estimation.

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

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<sup>28</sup> [http://www.baua.de/nn\\_16700/de/Themen-von-A-Z/Gefahrstoffe/TRGS/pdf/Bekanntmachung-220.pdf](http://www.baua.de/nn_16700/de/Themen-von-A-Z/Gefahrstoffe/TRGS/pdf/Bekanntmachung-220.pdf)

- **Formulators (if they are not themselves manufacturers/importers of the substance):** They manufacture preparations from substances (which in part are then used by following formulators as raw materials).

**Note:** 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 preparations from them. These manufacturers of preparations, 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.

- **End users**, who use substances or preparations in industrial or professional applications, without the substance or the preparation 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 preparations are used.
- Users who repack substances and/or preparations 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 preparations.
- 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 identical with those which were 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 likewise not downstream users in the sense of REACH art. 3.13. Here, it is crucial that distributors only store a substance (as such or in a preparation) and market it to third parties. Here no changes, re-packing or re-filling activities take place. The distributors also include retailers and storage providers. Retailers sell substances and preparations in stores to private, professional or industrial customers.

Distributors, however, have obligations under REACH, particularly in the passing on of the relevant information in accordance with REACH articles 31 and 32. They are also obligated to pass on requests for a specification on an identified use to the next actor in the supply chain.

**Note:** Here in the practical guide we will not deal more closely with the obligations of distributors. They are presented in detail in chapter 15 of the ECHA guidance for downstream users<sup>29</sup> (ECHA 2008d, p. 126 et seq.).

#### 4.1 Tasks of downstream users in overview

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

- Task 1: Their own roles and obligations are to be identified.
- Task 2: Suppliers are to be informed about all new information on hazardous properties, also relating to classification and labelling.
- Task 3: Exposure scenarios contain data on risk management measures. If downstream users have information that the measures communicated here are inappropriate, this is to be communicated to the supplier.
- Task 4: **Distributors** 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).
- Task 5: **Formulators**<sup>30</sup>, **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 preparations, as communicated in the safety data sheets and in any further information.
- Task 6: **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 4.2).

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<sup>29</sup> The ECHA manual for downstream users also presents the REACH requirements for distributors, although distributors are not downstream users in the sense of REACH.

<sup>30</sup> 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.

- Task 7: **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<sup>31</sup>.
- Task 8: **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 9: 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 10: 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.

**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 concentrate on following 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.

**Practical tip:** Downstream users are obligated under REACH to examine their own uses. The preparation for this activity should start in 1Q 2009. When the downstream user receives a safety data sheet that contains an exposure scenario the verification of the downstream user’s use, with use descriptors included in the exposure scenario, can be done immediately. (see the following chapter). Beyond that, REACH also grants downstream users the right to participate in the effective implementation of REACH by targeted communication of their knowledge.

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<sup>31</sup> 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.

Downstream users can support<sup>32</sup> 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 chapter 5.4 of the practical guide.

## 4.2 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<sup>33</sup>.

**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 preparation).**

Regardless of the amount of the substance he uses, each downstream user must consider and adopt the given risk management measures. This implies e.g. to examine whether the indicated risk management measures are actually in place in his company. Also included is to control whether and with which effectiveness the measures taken actually work. The manufacturer and/or importer can obligate the downstream user in his exposure scenario also to control certain specified use conditions concretely.

If the risk management measures are not suitable for the uses, the downstream user has to communicate this to his supplier.

The core task “examination of the own conditions of use” consists of two steps for a specific substance or preparation:

- Step 1: The evaluation of the extended safety data sheet, which the supplier of the substance or preparation makes available.
- Step 2: The examination whether the operational conditions and the risk management measures for his use agree with the information in the exposure scenario, and initiation of further steps, if this is not the case (e.g. the assessment of their uses in the form of their own exposure scenarios according to annex XII<sup>34</sup>).

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<sup>32</sup> This concerns a voluntary possibility, it is not legally prescribed.

<sup>33</sup> 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.

<sup>34</sup> With deviating uses a chemical safety report must usually be made by the downstream user. The procedure for this is described in annex XII of REACH. Here the assessment of the substance properties can be taken from the safety data sheet – main focus is particularly on the description and assessment of his own use.

If the use of the substance or the preparation differs from the exposure scenario, the downstream user has a number of options.

- He can decide to adapt his conditions of use to the ones included in the exposure scenario.
- He can communicate the use to the supplier and ask him to provide an exposure scenario which corresponds to his conditions.
- He can make 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;
- He can decide to change to another supplier who covers his uses in the extended safety data sheets.

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 preparation) outside the conditions described in the exposure scenario which has been communicated to him by his supplier (REACH art. 38). These obligations for downstream users to report information to ECHA are described in more detail in chapter 4.5.

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 make 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<sup>35</sup>). This is valid in particular,

- if, for the substance or preparation, the communication of a safety data sheet is not prescribed;
- if a safety data sheet is supplied, but it contains no exposure scenario (because the supplier did not have to make a chemical safety report for the substance on its own or in the preparation in accordance with REACH article 14);

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<sup>35</sup> In article 37(f) a further reason is described: the use for research and development (see REACH art. 37 (4f)).

- 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 preparation in a total quantity of less than 1 tonne per year
- if the substance is present in a preparation 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.

**Practical tip:** Downstream users should first inform their suppliers about their uses which the manufacturer and/or importer may not know of (general well-known/usual uses and conditions need not be involved; these uses are presumably already considered by the substance manufacturers). DU can receive from individual suppliers, lists of uses they intend to cover in the registration dossier in 2009. In this case DU are invited to double check these lists with their own internal lists and inform suppliers of those uses which are not covered in the lists. CEFIC has provided the requirements for an IT tool and templates for the communication between M/I and DU.

DUs are also encouraged to contact their industry associations to give input to the development of Generic Exposure Scenarios. In case where the uses are really specific, they can contact their suppliers in order to get involved in the Specific Exposure Scenario process (details on this are given in chapter 5.1 and 5.1.7. The specific terms are explained in the glossary (chapter 6)).

In other cases where downstream users do not receive such lists, the following recommendation is given: downstream users should focus initially on dangerous high volume substances (substances with a production volume above 1000 tonnes per year (HPVCs, "high production volume chemicals"). They should check whether they have uses to be considered which the manufacturer and/or importer does not know of (also here, general well-known/usual uses and conditions are not involved; they are presumably considered by the substance manufacturers). They will find the respective dangerous high volume substances in their safety data sheets, where some current uses are already given (only with other uses action is possibly needed). Whether a substance specified in the safety data sheet is a high volume substance, can be examined on the basis of the HPVC list of the Joint Research Centre of the European Commission (ESIS list, reports for existing substance regulation, <http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=hpv>). For these high volume substances unknown uses should be communicated to the suppliers directly or preferably through the

respective trade association at short notice. Then they can be included as identified uses during the development of generic and specific exposure scenarios (see chapter 5.1.7).

For the substances in smaller volume bands, which must only be registered in 2013 and/or 2018, it is at present generally not necessary to collect uses and communicate these to suppliers. The uses of these substances can still change considerably in future years. Communication on uses of these substances will mainly take place later. Nevertheless it cannot be ruled out that for commercial reasons individual manufacturers/importers decide to register low production volume chemicals earlier than legally required.

### 4.3 Examination of one's own uses and Scaling

Also within one industry the uses for the same substance can differ widely between companies. Neither the manufacturer of an individual substance nor the formulator, who brings the preparation with 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 lie in the safe range or not. This procedure is called **Scaling**.

**Note:** The following examples show cases in which a linear relationship between determinants of exposure and the resulting exposure has been found. In specific cases 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 individual chemical safety assessment the scaling options have to be checked in detail.

**An example:** If double the quantity is used 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<sup>36</sup>. This

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<sup>36</sup> Note: Strictly speaking, 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.

means: The downstream user finds the indication in the exposure scenario of a preparation where a maximum of 120 kg of preparation/day can be used, if the receiving water body after the sewage treatment plant has a water volume of 200,000 m<sup>3</sup>/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 preparation/day. (In this 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).

**Example – textile finishing**<sup>37</sup>: A typical textile-finisher uses 120 kg of a preparation, 30% of the dye substance quantity arrives in the wastewater, the receiving stream volume amounts to 20,000 m<sup>3</sup>/day, no special additional risk reduction measures are used. These assumptions were compiled together with the textile associations and thus illustrate well the average values for this industry.

As soon as the exposure scenario arrives at the user, it is the task of the user to examine whether the use situation in his company is also covered. However, this only concerns some emission-determining parameters, because others remain constant: The physicochemical properties of the substance are constant and thus also its behaviour in the sewage treatment plant. The content of the dangerous substance in the preparation is also constant. Differences depending upon the user can include e.g.:

- the daily quantity used;
- the proportion which does not bind to the material, but remains in the process water;
- the use of industrial safety measures;
- the application of additional emission-reducing measures;
- the sewage treatment plant situation;
- the receiving stream situation.

So far relatively few experiences are available with the task step “examination of their own conditions of use”. In annex 7.8 the procedure used for scaling is clarified by an example from the area of textile finishing, with the emphasis on the estimation of the environmental exposure in the environmental medium water.

If the substance user, in the example a textile-finisher, knows the exposure-determining parameters for his uses, he can calculate and also evaluate the environmental concentration which can be expected here. This is made easier for him, if he uses the Excel table – developed together by the formulators and downstream users of textile auxiliaries and their associations – for the determination of the PEC/PNEC ratio. This procedure is presented in annex

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<sup>37</sup> The following example was won in the context of the development of exposure scenarios for textile refinement. Advanced elaboration of the topic “examination of their own uses” will proceed in phase 2 of the practical guide project (planned for autumn 2009).

7.8 of the practical guide. It was also used with the example substance acetonitrile within the practical guide project. Details for this can be found in the accompanying chemical safety report of acetonitrile (materials volume) and in the exposure scenario of acetonitrile (annex 7.13 of this practical guide).

A direct adaptation is easily possible with the parameters, for which a linear relationship exists between the exposure-determining parameter and the expected substance concentration. Such a simple, linear relationship is not given with all exposure-determining parameters.

**Note:** The examination of the conformity with the conditions of use and the risk management measures is described in detail in the ECHA guidance for downstream users in chapter 5 (ECHA 2008d, p. 44 et seq.). A flow chart for the examination is also shown (ECHA 2008d, P. 48, Fig. 5-1). In annex 3 of the ECHA guidance there is a check list, on the basis of which the examination takes place stepwise and the results can be documented. Assistance for Scaling is given in the ECHA guidance to chemical safety assessment in part G (ECHA 2008d, part G, annex G-1, p. 18 et seq.).

**Note:** The short title of an exposure scenario and the characterisation of the uses by the elements of the Use Descriptor System (see chapter 5.1.3) can give a first reference point whether or not the own uses are covered in the exposure scenario. **Crucial for the compliance check, however, are the exposure-determining parameters, in particular the operational conditions and the risk management measures (see chapters 3.1.7 – 3.1.10).**

**Note:** The **short title** alone does not permit the downstream user to make a statement of whether his use is covered by the exposure scenario or not. A substance from two manufacturers can be used e.g. in two different industries. If in the short title of the exposure scenario the respective industry is named, the short titles in this case will be different. It is nevertheless possible that in both industries the substance can be used with the same conditions of use and under the same risk management measures. Then the essential contents of the two exposure scenarios are alike, despite different short titles.

On the other hand, a substance can be safely used by application of different risk management measures in the same industry and in the same process category. The short title of two exposure scenarios which describe these different risk management measures can be identical in this case, but sections 3-9 of the exposure scenarios will differ substantially in contents notwithstanding the same short title.

**Practical tip:** With the examination of one's own uses it is most important to clarify whether these uses are safe or not. That means: the limit values (PNECS, DNELs) are not exceeded<sup>38</sup>. Accordingly the downstream user has **several possibilities for the examination** of his uses:

- He can go through the individual exposure-determining parameters which are indicated in the exposure scenario.
- He can alternatively or additionally examine whether he has internal measurement results or knowledge for his own uses, which already permit an assessment of the exposure situation.

Hereby it can be shown:

- All conditions of use and risk management measures are implemented, but nevertheless limit values are exceeded. In such a case this should be communicated to the supplier – with the obligation for both sides to clarify why the use represented in the exposure scenario as being safe, is in practice not safe. (This can have different reasons. One reason can be that the registrant has taken assumptions for exposure modelling which does not fit to the real conditions of use).
- In the company other conditions of use are present and other risk management measures are accomplished. By a change in the exposure estimation according to the specifications of the supplier in the exposure scenario (Scaling, see chapter 4.3) the downstream user can prove that his own uses are safe.
- The downstream user has other conditions of use and other risk management measures, than indicated in the exposure scenario. But he can show on the basis of measured values that all substance-related limit values (DNELs, PNECs) are complied with. In this case he can prove that his uses are safe, without having to deal in detail with the data in the exposure scenario of the supplier.

**Practical tip:** In the examination of own uses, all exposure-determining parameters are to be considered. The distinction between conditions of use and risk management measures is of little importance for actual practice here. Crucial is what concrete values these parameters have with the individual downstream user (e.g. actual quantity required in kilograms/day, actual efficiency of the totality of the risk management measures taken, actual quantity of

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<sup>38</sup> For substances without effect threshold (see chapter 2 of this practical guide) this is valid: the emissions and exposures are reduced as far as possible, according to the specifications in the exposure scenario or to a greater extent.

river water, into which the wastewater of the company is finally discharged) and which actual load levels for humans and environment result<sup>39</sup>.

#### 4.4 Consequences of the examination and courses of action

If the examination of the data in the exposure scenario by the downstream user reveals that his own use is not covered, there is the possibility of communication with the formulator, with the request for inclusion of the 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 5.4.2.

If the manufacturer, for environmental and health protection reasons, advises against the use (and this is also documented in the registration dossier and in the safety data sheet), or if the user – for reasons of know-how protection – would not like to communicate his special use to the manufacturer, there are the following courses of action for the downstream user:

- He can independently make 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. (He only has to prepare his own chemical safety reports if he uses the substance in a volume of 1 ton/year or more).
- 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 preparation by switching to another product, for which his uses are safe.

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<sup>39</sup> In the development of the guidance for exposure assessment the basic idea had been to illustrate - with the help of the "use conditions" the actual use conditions existing in the chain ("current conditions of use"), independently of questions of the risk minimisation. In practice application conditions and risk management measures often mutually influence each other.

**Remark 1:** If the use of the substance takes place rarely, i.e. more rarely than once a month (and/or 12x/year)<sup>40</sup>, in the chemical safety assessment for the environment it is assumed that in the interim the ecological system can recover to a certain extent from the loads. This means that in these cases it is possible to use a different PNEC value for intermittent releases. It becomes permissible to use up to a 10 fold higher amount of the substance, without further measures being necessary. With readily degradable substances the chronic toxicity is not of importance in these cases, since through the fast degradation a long-term impact on the aquatic organisms does not occur.

The downstream user can reduce the exposures to the substance by changes in the processing of the substance (e.g. by an increase of the absorption degree for dyeing agents). The downstream user can also bring in additional risk management and thus reduce the quantity of the emission to wastewater.

**Remark 2:** 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 limit values (PNEC values), important for the risk characterisation, 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. Thus 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 should 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.

**Remark 3:** Assistance for the execution of one's own chemical safety assessment is given in the ECHA guidance for downstream users in chapter 7 (ECHA 2008d).

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<sup>40</sup> Examples of rare applications are e.g. dyeing in colors, which are only rarely requested by the customers (e.g. 2x/year).

#### 4.5 Information obligations in accordance with article 38

If a downstream user deviates in his uses of a substance (as such or in a preparation) from the conditions of use described in the exposure scenario or if he applies the substance in deviating uses under certain circumstances, 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 is 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 preparation 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 preparation 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.

## Part 2 Details on the individual tasks

The following descriptions in part 2 of the practical guide aim to support the „advanced“ reader who decided to perform by himself some of the REACH tasks presented before in chapters 1–4.

### 5 How does it work? Details on the individual tasks

In the following chapters, we discuss in more detail:

- Exposure scenarios: Function, structure, development
- Exposure estimation and risk characterisation
- The use of existing knowledge and the use of specifications from other regulations.

These topics have already been introduced in chapter 3 and 4. The objective of chapter 5 is to give additional help for all which will become more deeply in contact and involved with these instruments and processes.

#### 5.1 Exposure scenarios: Function, structure, development

Exposure scenarios were introduced in chapter 3.2. This chapter focuses on the following aspects of exposure scenarios in more detail:

- Function of exposure scenarios
- Tools for information structuring within exposure scenarios
- Short title and the Use Descriptor System: Guidance for the definition of uses in the exposure scenarios
- Different exposure scenario types
- Amending exposure scenarios in the supply chain
- How do I compile an exposure scenario?
- The concept of generic exposure scenarios
- The iterative 3-step approach for exposure assessment
- Communication of exposure types and associated risk management measures.

### 5.1.1 Functions of exposure scenarios

According to REACH, exposure scenarios have to fulfil several functions:

- In exposure scenarios, the exposure-determining parameters are documented as well as the models used for the exposure estimation (section 8 of the exposure scenario). The uses can be described in a uniformly structured way by the Use Descriptor System. Hence, exposure scenarios are the basis for the exposure assessment within the chemical safety assessment.
- Exposure scenarios specify under which conditions of use substances (as such and in preparations) can be safely used. Therefore they provide information on the necessary risk management measures and also describe further factors which are important for safe handling.
- The registrant documents, in the exposure scenario, how the substance can be safely used in his own company. If the substance is placed on the market, the exposure scenario also includes information for downstream users, which enables them to safely use the substance for their own uses.<sup>41</sup>
- On the basis of the data in the exposure scenario, the downstream user should be able to judge whether his own uses are safe. He must examine whether the use conditions in his company comply with the specifications in the exposure scenario. It might be necessary to estimate the influence of differing use conditions (e.g. the substance or preparation is used in higher quantities) on the exposure. For such an estimation, guidance and instructions are to be communicated in the exposure scenario (section 9 of the exposure scenario).

### 5.1.2 Guidance in the structuring of exposure scenarios

A standardized structuring of exposure scenarios facilitates the understanding and the use of this instrument in the supply chains. Therefore, in the ECHA guidance to the chemical safety report (ECHA2008a, part D), a standard template of an exposure scenario is provided, which should be used for communication in the supply chains. This template was already introduced in chapter 3.2 of this practical guide (see table 2). It is at present under discussion by ECHA which will probably result in a further differentiation between worker protection, consumer protection and environmental protection.

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<sup>41</sup> **Practical tip:** In some cases companies manufacture a part of the quantity of a substance for their own use (and will register this), but will also buy a part of the quantity for which they are downstream users. In theory the chemical safety assessment of this company refers only to that part of the substance, which the company manufactures. In practice it is advisable to handle the total quantity of the substance as documented as being safe in its own registration.

Exposure scenarios should also help to structure and illustrate, the large number of different application situations of substances and preparations in the different industries. The number of exposure scenarios should be limited as far as possible. For that purpose, the so-called “Use Descriptor System” should be used. (The Use Descriptor System supports the communication within the supply chains. It may not be necessary for those exposure scenarios, which refer only to internal uses). An additional descriptor element, the Environmental Release Categories, is linked to the release of substances to the environment. On the basis of five descriptor types, information is provided on what the exposure scenario covers.

These descriptors are the SUs (Sector of Use), the PCs (Product Categories), the PROCs (Process Categories), the ACs (article Categories) and the ERCs (Environmental Release Categories)<sup>42</sup>. They define in short form, which industry; which chemical products; which processes; and, if necessary, which kind of articles, an exposure scenario refers to. descriptors are best provided in sections 1 and 2 of the exposure scenario. The following chapter focuses on the Use Descriptor System as a tool for the structuring of the exposure scenario.

### 5.1.3 The short title and the Use Descriptor System: Guidance for the definition of uses in the exposure scenarios

An exposure scenario always refers to one or more uses (of a substance, a group of substances or of preparations). In the REACH legal text, exposure scenarios which cover a broad range of uses has been defined as use and exposure scenarios.

Manufacturers and importers of substances will try to cover the different uses of their substances in the different industries as far as possible in a manageable number of broadly defined exposure scenarios. These should cover a large part of their product range. In individual cases it can become necessary to develop more specific exposure scenarios for specific uses.

Also for downstream users it is more convenient to work with a limited number of standardized exposure scenarios than with a large number of differently structured exposure scenarios from different manufacturers.

**Practical tip:** The heading of the exposure scenario and the short title should indicate to what uses an exposure scenario refers to. Registrants, who supply their substances to broad application fields in different industries, will use a broad definition or a generic phrase as the short title. Thereby, the short title can cover different uses. This is also important, because changes in the short title (e.g. due to the inclusion of further identified uses) triggers a notification at the European Chemicals Agency.

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<sup>42</sup> At present, the environmental release categories are used in parallel to the Use Descriptor System. It may be that in future they will become a part of the Use Descriptor System.

**Practical tip:** The short titles of exposure scenarios for substances that are supplied to many industries and have a broad application field, should be as generic as possible, e.g. formulation and packaging of solvent-based mixtures, coatings (industrial use, professional use, use by consumers), cleaning agents (industrial use, professional use, use by consumers). Specific titles, which limit the use to individual industries, process categories, product types and article categories, will be adequate where customers with specific uses are to be served.

The Use Descriptor System, already mentioned above, will standardize communication on uses. Beyond that, it offers the possibility to describe processes and activities briefly and generally in section 2 of the ES standard format. These specifications are voluntary and can be made in section 1 (short title) or 2 of the exposure scenarios.

- **“Sectors of use” (SUs):** Substances are used in different industries. The short title of an exposure scenario should provide information on the industry sector, in which the substance is handled. In the Use Descriptor System, 23 different sectors are defined (SU1-SU23); others can be added using the NACE code (see annex 7.3). **Note:** In contrast to the following specified elements of the Use Descriptor System, the reporting of the sector(s) of use do not allow estimation of exposures.
- **“Chemical Product Categories” (PCs):** Substances are used for different preparations (e.g. as adsorbents, as dyeing agents, as photo chemicals). The type of preparation can give an indication of the expected release of the substances. For the categorization of preparations, 38 preparation types are available in the Use Descriptor System (Chemical Product Category PC1-PC38) (see annex 7.4)<sup>43</sup>. **Note:** Further categories should only be added, if none of these types is appropriate. This should be done using a common structure. Additional categories should be documented in a standard database – in order to avoid communication problems in the supply chains.
- **“Process Categories” (PROCs):** The processes in which substances and preparations are used can be very different, ranging from industrial settings in closed systems, where practically no substance release is to be expected, to open professional uses. Thus the process and/or activity, which are performed with a substance, often have a large influence on the level of exposure which can be expected. The Use Descriptor System provides more than twenty different process categories, which can be mentioned in the short title of an exposure scenario (see annex 7.5. The current version of the Use Descriptor System can be found on the ECHA homepage, see the preface of this practical guide.).
- **“Article Categories” (ACs):** During their life cycle, many substances will appear in articles. If the substances can be released from the articles which contain them, this

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<sup>43</sup> In practice it is often not clear, to which product category a preparation is to be assigned. Often a different understanding exists in the different countries, as to which products are involved.

release has to be accounted for in the exposure assessment. In the Use Descriptor System, 39 article categories are available to indicate whether or not this is a possibility, and if so, which articles have substances. Distinctions can be made depending on whether the substance is released intentionally, or not. (see annex 7.6). The indication of an article category is only reasonable if the substances can actually be introduced into articles. If the substances can be released, emission estimation has to be performed.

- Additional to these four elements of the Use Descriptor System, “**Environmental Release Categories**” can be added as a fifth element. These characterize the release of substances into the environment which are expected for specific process types. Eleven of such release categories (some with sub-categories) are defined. They indicate the maximum (in per cent) of a used quantity of a substance which can be released under realistic conditions. These **emission** estimates are the starting point for the exposure estimation (see also the advanced chapter on “environmental **exposure** estimation“(advanced part, chapter 1.3)

These five elements allow a rapid characterisation of uses. They give a first indication, of what uses an exposure scenario was developed for.

**Note:** The Use Descriptor System and the Environmental Release Categories should be used by individual industries in order to get an overview of which uses are typical for a specific industry (“**Mapping of uses**”).

However, the Mapping of uses alone (e.g. on the basis of the five descriptors) cannot replace an exposure scenario. For an individual exposure scenario it is crucial to provide information about the exposure-determining parameters (in particular the conditions of use and the risk management measures) in sections 3-7 of the exposure scenario.

By itself, the Use Descriptor System and the Environmental Release Categories are not exposure estimation. But these categories can be used in different exposure estimation tools in order to describe typical exposure situations and to gain a first estimation of the expected exposure level:

- In the ECETOC Targeted Risk Assessment model (ECETOC TRA, see the advanced chapter of this practical guide), the process categories define typical exposure situations at the workplace. They are also linked – to a limited extent – with assumptions related to risk management measures (presence of a local exhaust ventilation), which can be different for different process categories.
- For the estimation of the environmental exposure the model EUSES is widely used (see advanced chapters of this practical guide). The different categories used in EUSES are connected with assumptions on the expected substance release into the environment. These assumptions are structured in the above-mentioned “Environmental Release Categories” (**ERCs**) (for details see also the supplement “Exposure Es-

timation” of the practical guide). They indicate conservative assumptions of the fractions of a used quantity of a substance released to air, waste water and soil.

- In models for the calculation of the consumer exposure, the product categories and the article categories are directly linked to assumptions on the release potential.

The Use Descriptor System and the Environmental Release Categories are also implemented in the software IUCLID-5 which is used for the preparation of substance registration dossiers by manufacturers and importers. The Use Descriptor System is at the moment being updated incorporating missed descriptors. Once the UD system has been updated by ECHA this guidance will be revised accordingly. However, other descriptions using free text fields are also possible. Consequently, the five descriptor types will also be considered in IT-instruments for the preparation of chemical safety reports which are currently under development.

**Practical tip:** If the process, product and article categories which are provided in the exposure scenario were also used for the exposure estimation, this should be documented in sections 8 and 9 of the exposure scenario (in sections 8 and 9 the models used are mentioned, and guidance is provided, on how the downstream user can adapt the exposure estimation for his own use conditions).

If the registrant uses models for the chemical safety assessment which are not based on the elements of the Use Descriptor System (e.g. EMKG of the BAuA, see advanced chapter of this practical guide), then these elements are of no direct importance for the calculations.

**Note:** The Use Descriptor System was presented in detail in chapter R.12 of the ECHA guidance to chemical safety assessment. An introduction is found in chapters A.2.4.1.3 and D.4.3 of the ECHA guidance (ECHA 2008a).

**Practical tip:** The Use Descriptor System and the Environmental Release Categories are a new, European harmonized system, designed to describe uses briefly and uniformly. The tables published in the ECHA guidance establish the basis of this system (see also annexes 7.1–7.5 of this practical guide). Due to the increasing importance this system will gain for the communication in the supply chains and for the performance of chemical safety assessments, we recommend the following:

- Make yourself familiar with the Use Descriptor System and the Environmental Release Classes (ERCs);
- Try to describe your most important uses with the help of the PCs, PROCs, ACs and ERCs. In addition, various industry sectors can develop more specific categories for the assessment of the environmental release (“specific” (sp) Environmental Release Categories (“spERCs”);

- Pay attention to the process categories, with which you characterize your uses. For your uses, estimate what fractions of the substance quantities are released into the environmental compartments. Compare whether the release quantities assumed by you are in line with the defaults in environmental release categories which are relevant for your process categories.
- If the assumptions in the models deviate too much from reality, contact your association. If this is not possible (or for confidentiality reasons you prefer another possibility), contact your suppliers.

**Note:** The short title and the information from the five descriptor types (SUs, PC, PROCs, ACs, and ERCs) allow for a compact, standard report, which is what the exposure scenario is about. All together, this information serves

- to facilitate communication in the supply chains,
  - to make it easier to understand the substance uses in different industries
  - to enable translation into different languages,
  - to support the transferability/usefulness of exposure scenarios for different uses
- and
- to implement and utilize exposure scenarios more easily into the REACH IT-system.

**Note:** The short title itself is not the exposure scenario!

From the information provided in the short title, the downstream user can possibly make a first assessment as to whether the exposure scenario covers his uses. However, basically the conditions of use and the risk management measures are crucial for such an assessment. Deviations only from the short title and the elements of the Use Descriptor System have no legal consequences for the downstream user. Legal consequences arise from deviations from the conditions for safe use, as presented in sections 3-9 of the exposure scenario (ECHA Guidance CSA, part A, chapter A.2.4.1.2, p. 25/ECHA Guidance 3.5, annex 3, table A-4, p. 140).

There is no necessary direct linkage between the short title and the conditions of use. For the same short title of a use, different risk management measures can be implemented and described in the subsequent sections of the exposure scenarios (see also ECHA Guidance 3, 2, part A, p. 25).

**Note:** The categories of the Use Descriptor System are only of importance for the exposure assessment if they were used in the appropriate models for the derivation of the exposure assessments. Therefore, TIER 1 assessment models are being developed to directly link the use descriptors as a starting point for a quantitative risk assessment. For other assessment methods a number of models input parameters need to be defined and justified.

Manufacturers should carefully examine whether they use the Use Descriptor System for the short title in the registration of a substance. Any new identified use requires the registrant to update his registration (REACH art. 22 (1d)). For the communication of exposure scenarios it is sufficient that the categories of the Use Descriptor System appear in chapter 2, which is where the description of the processes/ activities is provided.

It is to be noted that the use of the Use Descriptor System is not mandatory, however the Use Descriptors are the starting point for an effective communication in the supply chains and support Tier 1 assessment tools used by the registrant. For a harmonized communication in the supply chains it is essential that the same Use Descriptor System (including the Environmental Release Categories) is used by all actors.

#### 5.1.4 Different types of exposure scenarios

REACH does not specify in detail how exposure scenarios are to be arranged. Experience to date shows that exposure scenarios may exhibit a different degree of detail depending on their purpose (e.g. communication between manufacturer and formulator or between formulator and end users) and the relevant operational area.

In the REACH legal text, it is pointed out that exposure scenarios can cover a specific procedure or a specific use or different procedures or uses as appropriate. Where exposure scenarios are broadly defined and many procedures or uses are covered, they are called use and exposure categories:<sup>44</sup>

**Definition Exposure Scenarios (REACH art. 3, 37):** means the set of conditions, including operational conditions and risk management measures, that describes how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate.

**Definition use and exposure categories (REACH art. 3, 38):** means an exposure scenario covering a wide range of processes or uses, where the processes or uses are communicated, as a minimum, in terms of the brief general description of use.

In the ECHA guidance on chemical safety assessment (ECHA 2008, part A, A.2.4.3.3, p. 27) another term for broadly defined exposure scenarios is used: Generic Exposure Scenarios

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<sup>44</sup> **Use and exposure categories** as broadly defined exposure scenarios are part of the chemical safety report for substances with an output of 10 tonnes/year. For substances with a production volume of 1 tonne/year up to 10 tonnes/year a chemical safety report is not necessary and thus also no exposure scenarios. In order to also obtain basic information for exposure for the latter substances, in the context of the registration, exposure-related data must be given in accordance with REACH annex VI section 6. This includes the main use categories, the significant exposure routes and the kinds of exposure.

(GESs). According to the ECHA guidance document a generic exposure scenario refers to a whole series of uses of certain substances and/or groups of substances in different industries. It describes the relevant conditions of use and the risk management measures which should be applied.

The “counterpart” to the use and exposure categories (UECs) and to the broadly defined generic exposure scenario is the “specific exposure scenario“. This term was not used in the REACH legal text or in the guidance documents. However, CEFIC and user associations are currently working intensively on a methodology for the preparation of exposure scenarios. In this work the term “**specific exposure scenarios**” (**SESSs**) has been introduced.

**Note:** In the context of the CEFIC working group “Generic Exposure Scenarios“ the approach to development of exposure scenarios has been further developed. The approach and the specifics of the methodology will be presented in a CEFIC publication “GES development“(CEFIC 2009). In the practical guide we will present this approach in chapter 5.1.7 in more detail and also in annexes 7.10 and annex 7.12. An example for a generic exposure scenario is given in annex 7.11.).The related templates for the dialogue between suppliers and downstream users is described in chapter 5.4.2 and annex 7.12.

**Practical tip:** Since an individual company would often have to evaluate a large number of chemical substances in parallel, together with a large number of related different uses, the number of specific exposure scenarios resulting would not be practicably manageable. Thus, there is a fundamental agreement that exposure scenarios should be as broadly applicable as possible, and should cover as many different uses and use conditions as is practicable. Moreover, the communication of individual specific use conditions and/or exposure scenarios within the industry would lead to a substantial bureaucratic workload. The REACH regulation stipulates that as the first step the manufacturers and/or the importers provide exposure scenarios to their customers.

Within CEFIC two processes have been developed which individually, or in combination, offer the flexibility to develop exposure scenarios that suit the needs of companies and their customers in an effective and efficient way.

In the VCI project these processes have been integrated in a proposal for an exposure assessment in three stages. This proposal for the exposure assessment covers the most diverse activities and actively provides exposure assessments for as many use categories (PROCs, PCs, ERC, ACs) as possible. Communication in the supply chain is limited to cases where an exchange of detailed information is actually necessary. The iterative 3-step approach will be presented in the practical guide in chapter 5.1.8.

There are two further terms, which are often used in connection with exposure scenarios:

- Initial exposure scenarios: which are still “in development”, see below
- Final exposure scenarios: these are ready for documentation in the chemical safety report and/or “ready for communication” in the supply chains.

What does this mean? Exposure scenarios are developed in a multi-level process, which was presented in chapter 5.1.2. The result of this process is a final exposure scenario, which describes how substances and/or preparations can be used safely. In the process of the chemical safety assessment the steps “determination of the exposure” and “risk characterisation” were accomplished<sup>45</sup>.

In order to prepare the final exposure scenario, various information on the exposure-determining parameters has to be collected. This may be an iterative process. The provisional sets of information generated in this process are called **initial** exposure scenarios. Here **initial** means there has not yet been an examination of whether the conditions of use described in the initial exposure scenarios are safe or not. Since the preparation of a final exposure scenario may require the repetition and refinement of estimates there can be a whole set of preliminary drafts, which can all be called an “initial exposure scenario”<sup>46, 47</sup>.

Only the final exposure scenario is

- documented in chapter 9 in the chemical safety report and
- communicated in the supply chain as an annex of the safety data sheet (if it refers to uses of downstream users).

The finished exposure scenario must fulfil the requirement to describe, on the basis of a chemical safety assessment, how substances can be safely handled in the supply chains.

**Practical tip/reference:** In practice the different definitions of exposure scenarios are not relevant. The only consideration of importance is which conditions of use (operational conditions of use and risk management measures) are explicitly presented. It is the decision of

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<sup>45</sup> The original term used for “initial exposure scenarios” was “tentative exposure scenarios”, which is actually more applicable.

<sup>46</sup> Descriptions of typical uses in certain industries, occasionally with references to arising exposures, are also sometimes called initial exposure scenarios. These descriptions are important compilations of information, which can be used in the preparation of an exposure scenario. However, they do not represent a complete exposure scenario.

<sup>47</sup> In part A of the ECHA guidance for chemical safety assessment, it is briefly explained that the initial exposure scenario describes the typical application conditions, as they exist in the market, on the basis of easily available standard information. If it can be shown that these conditions of use control the risks appropriately, then the “initial scenario” becomes the “final scenario”. If risk control cannot be shown for current practice or on the basis of available information or if parameters other than the standard determining parameters play a significant role, then the chemical safety assessment must be repeated (ECHA 2008, part A, p.26).

each individual supplier of the ES, whether he considers his exposure scenario for its purposes as sufficient/conclusive and communicates it (market decision). When relevant new information (e.g. new operational conditions, new intrinsic characteristics) becomes available, any final exposure scenario already communicated by the manufacturer, must be revised. This update obligation is similar to the obligation for the updates of safety data sheets.

### **5.1.5 Changes of the exposure scenarios in the supply chain**

Exposure scenarios are firstly prepared in the context of the registration of substances by the respective manufacturer and/or importer. In many cases the substances are used in different industries, mostly in the form of preparations. The exposure scenarios of substances with broad application fields will cover various uses. For the chemical safety assessment, the registrant can use generic models for the exposure estimation; in which standard risk management measures are assumed for the most common process categories.

The registrant will prepare an exposure scenario which describes a safe use for a range of conditions of use. This range of conditions of use should be as large as possible. It is to be expected that with this procedure the registrant cannot consider all the special aspects of all uses of the substance in individual industries.

In many cases, formulators will be the first recipients of the exposure scenarios of the substance manufacturers. They manufacture preparations for special application fields in individual industries. Usually they know the conditions of use, for their preparations, better than the substance manufacturer. Several ingredients are usually contained in the preparations. If these are substances which have to be classified as hazardous, the formulator will receive a safety data sheet with one or more exposure scenarios for each of these ingredients.

It is the duty of the formulator to communicate the conditions for a safe use of the preparation together with his safety data sheet for the preparation. This can be done by merging the information from the exposure scenarios of the substance suppliers to one specific exposure scenario for the preparation. In this step the formulator will consider his knowledge of the conditions of use of the preparation within the respective industry. Furthermore, he will ensure that the extended safety data sheet and the associated exposure scenario are understandable for his customers. For this a "translation" into the technical language typical for the respective industry is necessary. To a certain degree the use of standard phrases for this task is also required to enable an efficient translation in all official EU languages.

Just forwarding the substance-related exposure scenarios received from the suppliers will, in most cases, probably not provide the desired information in an understandable format. The building of a specific exposure scenario for the preparation seems to be more appropriate<sup>48</sup>.

Thus, through the supply chain, i.e. from the registrant to the formulator and further to the final user, the contents and the language of the exposure scenarios can change in many cases. The exposure scenarios can become increasingly more specific on their way through the supply chains<sup>49</sup>.

In the annexes to this practical guide you will find both: a broadly defined exposure scenario (for sodium hydroxide in all industries; annex 7.16), which is attached to the safety data sheet for a substance; as well as a specific exposure scenario, which was developed for the use of a preparation in leather production (see annex 7.15).

### **5.1.6 How do I prepare an exposure scenario?**

In the ECHA Guidance on information requirements and the chemical safety assessment (ECHA 2008a, part D) the following main steps are suggested for the preparation of an exposure scenario (in practice these can be varied depending upon the starting situation; see below):

- Collection of information on the uses of the substances and the conditions of use in the different user industries;
- Collection of information on the exposures expected there;
- Performance of a first quantitative exposure assessment and risk characterization to check whether the exposures which can be expected are assessed as safe.
- If the uses are in the safe range: Communication with the users and/or their associations with the request for comments regarding the assumptions made. If necessary, incorporation of the additional information received from the users. For this step the CEFIC dialogue template for SES building can be used (see chapter 5.4.2, chapter 7.10 and figure 5).
- Documentation of the exposure scenario in chapter 9 of the chemical safety report and elaboration into a form which one communicates in the supply chain as an annex to the safety data sheet. Communication to the customers through the safety data sheet.

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<sup>48</sup> Several methods are under discussion on how to prepare a chemical safety assessment for a preparation (e.g. the critical component approach and the DPD+-approach). They will be described in detail in the second version of the practical guide.

<sup>49</sup> In this simplified case it was assumed, that the substance manufacturer supplies a formulator/ who manufactures preparations directly for end users of an industry. In practice further formulators are often involved. They manufacture preparations that are used by downstream formulators as raw materials (e.g. dye or flame retardant formulations). Also in these cases the exposure scenarios will become increasingly more specific along the supply chains from the registrant to the users.

- If the uses are not safe: Repetition of the exposure assessment with consideration of further data, additional assumptions (also related to risk management measures) and if necessary refined calculation methods. This can be carried out several times, until the conditions of use described in the exposure scenario allow for a safe use.
- Documentation of the exposure scenario in the chemical safety report and communication with the safety data sheet also take place here.

**Note:** In the ECHA guidance on information requirements and the chemical safety assessment the steps for the development of an exposure scenario, specified above, are presented as a workflow with 14 steps (see annex 7.6 of this practical guide). For each work step, detailed guidance is given and information on how to find any existing knowledge (see ECHA guidance chemical safety report, Part D, chapter D.3, p. 15ff. Regarding the use of existing knowledge see also chapter 5. 3 of the practical guide).

**In practice, to carry out systematically all individual steps for many substances could lead to a difficult to manage and very labour intensive process. The same is the case for the early inclusion of individual downstream user communications. It is essential to simplify the development of exposure scenarios. To achieve this, experiences from the development of exposure scenarios on the European level are used:**

- For many industries exposure assessments are already included in extensive existing reports which are available on workplace, environmental and consumer protection. This information can and should be used directly for the development of exposure scenarios.
- At the European level, CEFIC has compiled standardized procedures for the communication in the supply chains, which are designed to facilitate the preparation of exposure scenarios. This involves participation of the downstream users and their various trade associations. Here two approaches are being developed, firstly generic exposure scenarios (GES) and secondly specific exposure scenarios (SEs), these are presented in this practical guide in Chapter 5.1.7 and in annexes 7.10–7.12.
- For individual hazard profiles of substances (e.g. flammability or corrosivity) specific sets of risk management measures can be developed for use in the exposure scenario. For the example caustic soda solution, this was tested for substances with corrosive effect in the context of the preparation of the practical guide. The (broad) exposure scenario for caustic soda solution can be found in annex 7.16.
- Substance manufacturers will frequently develop exposure scenarios for a great many substances with wide varieties of areas of uses. The market analysis and collection of information on the conditions of use, planned in the standard procedure, can be very complex. Alternatively, it is possible to use generic models for exposure estimation in order to provide an initial first identification of safe and critical uses for a large number

of standardized uses. Advanced calculations and contacts with customers and/or associations are then only necessary for uses which did not prove to be safe based on this first calculation. This procedure is called the iterative 3-step approach. It was developed by BASF in the context of the practical guide project. The iterative 3-step approach uses, among other things, existing generic models for exposure estimation (e.g. ECETOC TRA). The main objective of this approach is not the development of exposure scenarios, but the use of available generic and/or specific exposure scenarios for the exposure estimation and risk characterisation. This approach is presented in Chapter 5.1.8 of this practical guide.

- A short overview on the types of exposure to be expected, and which risk management measures are used and/or are intended, is helpful for the execution of the chemical safety assessment. For this, the matrix of the use and exposure categories developed by the VCI can be used as an additional information element. Based on this instrument, formulators can also rapidly examine which kinds of exposure were considered by their supplier in the registration of the individual ingredients. In annex 7.13 of this practical guide the matrix and its application are discussed.

**Practical tip: Procedure and priority setting of manufacturer/importer in the development of exposure scenarios and for “downstream“ communication.**

Based on previous experience the following recommendations can be given for the development of exposure scenarios:

Before starting with the development of exposure scenarios by collecting information on uses, options for priority setting and the limitation of the tasks that have to be performed should be used.

- The first step should be to examine whether certain uses should be **excluded due to either the characteristics** of the substance or due to **existing legal requirements**. Thus substances that are carcinogenic, mutagenic and toxic to reproduction cannot be used in consumer products in concentrations of > 0.1%. There are similar restrictions for explosive substances, which may only be handled by specialists. Toxic substances and preparations may not be marketed to consumers except under special arrangements.
- Strongly sensitizing substances should likewise be excluded from use by consumers wherever possible<sup>50</sup>.

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<sup>50</sup> It will hardly be possible to handle corrosive substances in the same way. It is to be anticipated that numerous preparations for consumers, which are currently still classified as “irritating“, will be reclassified as “corrosive“ during the implementation of GHS.

- If generic or specific exposure scenarios have already been developed for the substance, or for similar substances and/or similar uses, on the sector level, then they should be used (see Chapter 5.1.7 of the practical guide).
  - In the specific situation that all conceivable uses can apply to a substance, then it is appropriate to start the assessment by use of a tier 1 tool. This is the first step of the iterative 3-step procedure described in Chapter 5.1.8 of this practical guide.
- The second step can then further clarify, for which uses the substance is to be supplied<sup>51</sup>.

On the basis of these steps, it may be possible to establish, more precisely, for which uses exposure scenarios are to be provided. It can then be documented, in the next step, whether specifications for exposure limitation can be found in existing regulations. This can be e.g.:

- Specifications from wastewater regulations on certain downstream measures, e.g. precipitations;
- Specifications to comply with certain pH values in the wastewater (if necessary by neutralization);
- Emission limitations, which arise from the technical instructions on air quality (in Germany: Technische Anleitung Luft).

Ultimately, knowledge on the use situations and the necessary risk management measures were also considered in these above specifications. Also, in many cases, knowledge of handling substances will be available, which can be used in the exposure assessment (e.g. that mineral oils should not be introduced into the wastewater even in the smallest quantities). The registrant will also use evaluations he has already made, e.g. workplace-related hazard assessments in accordance with CAD (Chemical Agents Directive), in his chemical safety assessment.

With substances which are characterized by physicochemical hazard characteristics for which no limit values are derived, the exposure assessment will be made qualitatively.

With substances for which a quantitative determination of the exposure is necessary for the assessment of the exposure situation (substances with DNEL and/or PNEC values), in many cases the models for exposure estimation presented in the advanced chapter to this practical guide will be applied. Here the registrant will decide which models to use. This specifies, at the same time, which model-specific input parameters are needed for the calculations (and whether the Use Descriptor System (together with the Environmental Release Categories) can be used as a starting point to feed the relevant default values into the models).

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<sup>51</sup> With this procedure it is to be noted that downstream users may communicate to the suppliers' further uses, which thereby become identified uses (which the registrant has to consider in his registration, unless he does not support it).

After consideration of this existing knowledge the registrant will provide his exposure scenarios, which include the exposure estimation and the risk characterisation.

If important data for the assessment of the uses by downstream users are missing, the registrant will try to get these data, preferably from the associated downstream user trade association (see also the following Chapter 5.1.7 on the CEFIC proposal for developing generic and specific exposure scenarios).

The manufacturer and/or importer will then communicate an exposure scenario (if he supplies downstream users) which he considers to be complete ("final exposure scenario"). If new information becomes available, this exposure scenario must also be revised. A comparable updating requirement exists between exposure scenarios and safety data sheets.

### **5.1.7 Processes for the development of exposure scenarios**

Within CEFIC two processes have been developed and are recommended for use in developing exposure scenarios: the Generic Exposure Scenario process and the Specific Exposure Scenario process.

Generic exposure scenarios (GES) are broad exposure scenarios. They are particularly meaningful for commodity chemicals with wide application fields and extensive delivery chains.

A methodology for the development of generic exposure scenarios was developed by the two trade associations ESIG (European Solvents Industry Group) and ESVOC (European Solvents VOC (Volatile Organic Compounds) Coordination Group). This occurred in close cooperation between the federations of the manufacturers and importers and the federations of the downstream users. The starting point was a listing of industrial use fields of solvents, which was compiled by the European Federation of Solvent Manufacturers ("Mapping of uses"). The methodology was developed with reference to the principles of substance safety evaluation.

A detailed presentation of the concept of generic exposure scenarios can be found in annex 7.9 of the practical guide.

Specific exposure scenarios (SES) describe exposure scenarios for individual substances in both specific and general uses. They are particularly useful to develop ESs for substances with relatively short supply chains (speciality applications) or supply chains lacking well structured sector organizations. They are developed in dialogue with selected representative customers. To facilitate the dialogue a standardized dialogue template has been developed. More details on this process are presented in annex 7.10 of the practical guide.

### 5.1.8 The iterative 3-step approach for exposure assessment

REACH requires that the manufacturers and/or the importers primarily produce exposure scenarios, which they communicate to their customers<sup>52</sup>.

Since individual companies must often assess a multiplicity of substances and a multiplicity of quite different uses simultaneously, the high number of specific exposure scenarios is not, or hardly, manageable in practice. There is thus a fundamental agreement that exposure scenarios should, if possible, be designed to cover different uses and operational conditions of use. Besides, communication of individual specific conditions of use and/or exposure scenarios within the industry would lead to a substantial bureaucratic expenditure.

This has been recognized by industry. Within the chemical industry/CEFIC two processes (developing generic exposure scenarios and/or specific exposure scenarios) have been developed. Both approaches can be used alone or in combination. They offer the flexibility to develop exposure scenarios that suit the needs of companies and their customers in an effective and efficient way.

In the VCI project these processes have been included in a proposal for a 3-step approach for exposure assessment. The proposal also includes the step of the risk characterisation, which follows after the exposure assessment.

The iterative 3-step approach for exposure assessment aims to use, and integrate into a clear overall structure, the most diverse activities for the development and design of exposure scenarios.

According to this approach, the exposure assessment can take place, in a 3-step process:

#### **Step 1: Basic exposure assessment**

The manufacturers and/or importers assess the exposure for **all uses**<sup>53</sup> of a substance with a generic assessment tool. This means that, for a specific substance, all possible uses which are taken into account in the ECHA guidance (all process categories PROCs, all product categories PCs, all environmental release categories ERCs) are assessed on the basis of the intrinsic characteristics of the substance (physicochemical characteristics, toxicological and ecotoxicological characteristics) using the standard specifications of a generic model.

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<sup>52</sup> If they do not place the substances (as such or in preparations) on the market, they only have to assess their internal uses and handling and document this in the chemical safety report. The related exposure scenarios for the internal uses are only communicated to ECHA.

<sup>53</sup> It is left to the manufacturers/importers whether they evaluate all uses in individual cases, or whether to only do it for all relevant and plausible process categories (if this information is available).

The assessment should preferably take place according to the new ECETOC TRA version 2<sup>54</sup>.

ECETOC TRA is a conservative assessment tool (“realistic worst case”), includes no specific risk management measures for the protection of humans and environment except general hygiene measures and local exhaust ventilation (LEV). (ECETOC TRA is described in the supplement “Exposure Estimation”, section 1.2.2)). One may thus assume that an assessment of the uses that results in a conclusion of “Safe use”, with consideration of the boundary conditions of this assessment tool delivers a sufficient level of confidence.

The standard parameters used in ECETOC TRA and the results of this Tier 1 tool permits the development of exposure scenarios in a structure as described in chapter 3.2.

The procedure not only corresponds to the requirements of REACH to consider at least all identified uses but it also provides the downstream user a first reference point for consideration of additional or new uses at an early stage.

In the following table a typical result from the use of ECETOC TRA version 1 is shown for the example HDDA for the process categories PROC 1–5. You can find the complete result in the extended safety data sheet of HDDA, which is contained in the materials volume of the practical guide.

Table 5 The results from step 1 of the exposure assessment and risk characterisation in the iterative 3-step approach. The results for the assessment of process categories 1–5 are presented.

Process Category [PROC]	Use Scenarios	Duration of activity [hours]	LEV (Y/N)	Estimated Exposition [ppm]	MoE [DNEL/est expo]	Further assessment required
PROC 1	Use in a closed process with no likelihood of exposure	> 4 hours	Yes	0,01	31,8	No
PROC 2	Use in closed process with occasional controlled exposures e.g. during sampling	> 4 hours	Yes	0,5	0,636	Yes no refinement done – if needed, please contact manufacturer
PROC 3	Use in a closed batch process i.e. where only limited opportunity for breaching arises e.g. sampling	> 4 hours	Yes	0,1	3,18	No
PROC 4	Use in a batch or other process (including related	> 4 hours	Yes	1	0,318	Yes no refinement

<sup>54</sup> In ECETOC TRA version 2, worker, consumer and environmental assessment will be integrated.

	process stages e.g. filtration, drying) where opportunities for exposure arise e.g. sampling, discharging of materials					<b>done – if needed, please contact manufacturer</b>
PROC 5	Use in a batch process including chemical reactions and/or the formulation by mixing, blending or calendaring of liquid and solid-based products	> 4 hours	Yes	1	0,318	<b>Yes for refinement see chapter 9.2</b>

LEV: local exhaust ventilation. MoE: margin of exposure. DNEL: Derived no effect level, see also chapter 6.

## **Step 2: Generic exposure assessment**

For the uses of a substance being assessed **as not safe** according to the ECETOC TRA Tool (i.e. there is a risk with a corresponding use), a further refinement of the assessment with additional information is necessary. Here information from generic exposure scenarios or sector-specific scenarios can be used. Downstream User industries should thus make available any additional information about existing conditions of use and implemented risk management measures. These can be:

- individual parameters of the conditions of use (e.g. different application durations, other quantities, other site conditions),
- individual additional risk management measures (such as e.g. organizational, technical measures);
- comprehensive sector-specific descriptions of exposure/industry-specific packages of measures (sector-specific exposure scenarios, application information e.g. from the Gefahrstoffinformationssystem Bau [GISBAU, dangerous substance information system construction] among others);
- generic exposure scenarios (GES, e.g. generic exposure scenarios for solvents).

This additional, non-Confidential Business Information (CBI) should be accessible over an IT-platform/library for all persons concerned (manufacturers, importers, as well as downstream users, who would perform their own assessments). Possible use of the CEFIC website is currently under discussion. In a first step CEFIC already makes several relevant CEFIC guidances available on the following web-site:

<http://cefic.org/Templates/shwStory.asp?NID=719&HID=714>

The manufacturers and importers can make an assessment with consideration of and/or based of this information for **all uses, for which sector-specific information is available**.<sup>55</sup>

<sup>55</sup> It is left to the manufacturers/importers in individual cases whether they consider all industry-specific uses.

One assumes that, with this refined assessment, most cases which are relevant for the market can be covered and allow for a safe use.

In the following table a typical result for a refined assessment according to step 2 is presented. (You can find the complete result for step 2 in the extended safety data sheet of HDDA, which is included in the appendix of the practical guide). The refined assessment refers to process category 5, which was assessed as “not safe” in the first step. This assessment was accomplished using additional information on conditions of use and risk management measures, which was made available by downstream user associations. With consideration of these additional risk management measures one can now assume a safe use of the substance.

Table 6 Example for the result of an advanced exposure assessment with use of sector-specific information in the iterative 3-step approach. It includes the result of the risk characterisation step. The results are shown for the advanced assessment of process category 5, which was classified as “not safe” in the first step of the exposure assessment.

Type	Scenario Title	Duration of activity (hours)	additional OC / RMM	Est. Exposure [ppm] (refined)	Margin of exposure [[DNEL/est expo]]	Safe use
SU 7, 10 UV/EB 1	FORMULATION  (covering PROC 5)	< 4 hours	<ul style="list-style-type: none"> <li>• Ambient temperature (&lt; 30°C) and</li> <li>• Room ventilation rate &gt; 6/h and</li> <li>• Chemical resistant protective gloves (EN 374), nitrile rubber (NBR) – 0.4 mm coating thickness and</li> <li>• Safety glasses with side-shields (frame goggles) (e.g. EN 166)</li> </ul>	0.016 (PROC 5)	19.9 (PROC 5)	YES (PROC 5)

### **Step 3: Specific exposure assessment**

A specific exposure assessment in direct contact and with communication and coordination with the respective individual customers is necessary, if

- in step 2 certain uses are assessed as not safe
- no industry information is available for certain specific uses or
- the conditions of use in the individual company deviate from the customary conditions.

Here specific exposure scenarios are developed using the process as described in chapter 5.1.7 of the practical guide. Often this company-specific information will be confidential busi-

ness information. Therefore it must always be an individual decision whether a customer makes his own assessment according to art. 37(4) REACH or contact his suppliers directly. The iterative 3-step approach permits each concerned party (manufacturer, importer, downstream users) to step in at each stage and assess this substance. Likewise it is not always necessary that each step of the process has to be passed through. If, for example, special risk management measures are used in a company for a certain substance and if measured values are available for these uses, then the assessment is appropriately completed using only step 3. In principle it is also up to the concerned party to decide which of the different generic assessment models he finds most suitable for the individual case, and then to use it. The iterative 3-step approach was successfully tested in the practical guide-project for the example of HDDA. In annex 7.15 the exposure scenarios for HDDA are shown, which result in steps 1 and 2. The substance safety report for HDDA and the complete extended safety data sheet are contained in the appendix of the practical guide.

### **Communication platform**

The establishment of a central communication platform for evaluation instruments, exposure information and substance assessments has been suggested. In practice, it is helpful if all relevant information for substance assessments and for the preparation of exposure scenarios is available in one central place. The maintenance of the contents would be the task of the respective responsible persons, who furnish the specific information, e.g. the respective industry for the sector-specific information.

## **5.2 Advanced aspects of the exposure estimation and risk characterisation**

The goal and structure of the chemical safety assessment were described in general form in chapter 3.1. Additional advanced descriptions were made to the following work procedures in the practical guide:

- Estimation of the exposure at the workplace;
- Estimation of the exposure of consumers;
- Estimation of the exposure of the environment.

In these sections one also deals in each case with the step of risk characterisation. You will find these advanced considerations as an independent document (Supplement "Exposure estimation").

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

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

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

Details on the models and how to use them are given in the supplement “Exposure estimation”.

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

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

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 preparations;
- 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)<sup>56</sup>.
- 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 advanced chapter, advice on the use of existing data will be given. The emphasis here is on the use of existing in-house data (chapter 5.3.1). Chapter 5.3.2 deals with the use of externally available data.

**Note:** In this chapter, the attention is on the use of existing knowledge relating to exposure and risk management measures. Further information on the substance and preparation characteristics may also be available from companies.

### 5.3.1 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

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<sup>56</sup> 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.

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.

#### **5.3.1.1 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 wastewater 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 high is the loss of substances used in 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.<sup>57</sup> and with what level of efficiency)?

- Wastewater: Do wastewater streams arise in the company? If so, does an effluent pre-treatment 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 preparations can soon gain a good, detailed overview of the basic conditions of exposure that are important for his company and of that knowledge which is already available in the company, before he begins specific exposure assessment for single substances.

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

After clarifying the basic conditions under which substances and preparations 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).

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<sup>57</sup> 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.

**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. You will find more reference to options of priority setting in the chapter after next (chapter 5.3.1.4).

- For how long (8 hours? 15 minutes?) and for how often (each day? 1x per week?) do workers come into 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<sup>58</sup>?
- 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?
- 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). 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.

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<sup>58</sup> 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.

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

In the company the conditions of work, under which substances and preparations 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 preparations 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 preparations 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 preparations 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 chapter

5.1.3 of this practical guide and the annexes 7.1–7.5). (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)?

#### **5.3.1.4 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 preparations 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 preparations can be structured on the basis of the following questions:

- Where and when are the highest exposures to be expected? Where – e.g. at workplaces 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 processes?

- 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 environment 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 4.2 and in annex 7.8. You can use the Excel sheet in this annex, in order to calculate your own use situation of application. (You will find further details in the advanced chapter “environmental-related exposure estimation“.)

The users of substances and preparations 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 physicochemical 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.

### **5.3.2 Use of external knowledge and information**

There is already extensive knowledge and many publications on the safe use of substances and preparations 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 COSHH Essentials approach).
- The library of generic exposure scenarios which will be organized by CEFIC;
- Information on uses by manufacturers and downstream users generated by the trade associations

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, 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<sup>59</sup>.

Table 7 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](http://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.

<sup>59</sup> Rühl, R.; Kleine, H.: Expositionsbeschreibungen für REACH-Stoffsicherheitsberichte. In: Gefahrstoffe Reinhaltung der Luft 68 (2008), S. 129–133, April 2008.

## 5.4 Communication of uses, conditions of use and exposures

“Use“ is often related to the intended function of a substance, e.g. as colorant, as catalyst or as solvent. Since the main objectives of REACH are the “safe uses“, consideration must apply to all identified intended uses of the substance. Use is any activity which is carried out with a substance as such or in a preparation, which could lead to an exposure to that substance (ECHA guidance for downstream users, section 5.2.1/REACH art. 3 (24)). Such activities include, for example, mixing, transfer from one container to another, processing in closed or open equipment.

Communication on uses under REACH should allow and facilitate the description of safe conditions of use. Therefore information is required not only on the function of the substance, but on all exposure-determining parameters, in particular on the operational conditions of use and the risk management measures (see also chapters 3.1.6 – 3.1.9 of the practical guide). Such information is necessary to make the “conditions of safe use“ communicated by the substance manufacturer realistic and allow for effective implementation of appropriate risk management measures.

### 5.4.1 Communication of uses and exposures: Background

In view of the variety of substances and associated uses, structured communication between manufacturers and downstream users is urgently needed, in order to avoid an unmanageable number of individual communication procedures. Industry associations of downstream users can play an important role by compiling information from individual users into “typical“ features for a sector.

At present different options for the structuring of the dialogue between registrants and downstream users are being tested. Here different systems are used, in order to characterize and type the uses, conditions of use and exposures linked to them. Examples for this are the 4 descriptors of the Use Descriptor System, the environmental-related release categories (ERCs) and the matrix of the use and exposure categories of VCI. For communication in the value chains it is important to clarify:

- What is communicated?
- Who communicates with whom?
- When does communication take place?

**Practical tip** for downstream users communication on uses “upstream“:

Universal disclosure is not advised. Downstream users should, initially, sit together with their associations (see below) and identify their most important uses, clarify the typical boundary operational conditions of use, and organize this in standardized formats (Mapping). In the second step a meeting with some experts of the formulators and substance manufacturers should take place, in order to establish a common language for the description of these uses.

It should be clarified, what kind of data substance manufacturers and/or formulators need for their chemical safety assessments. This depends on the models which they use for their calculations.

In the CEFIC working group “Supply Chain Communication” an approach was developed, which picks up these questions and, in particular, also involves the user associations. The approach was presented at a CEFIC Workshop on Exposure Scenarios in October 2008 and is under further development. It is directly connected with the procedures for the development of generic and specific exposure scenarios, which were presented in chapter 5.1.7. The CEFIC approach for communication in the supply chains concerns a so called “Top-down approach”<sup>60</sup>. This approach starts with determining the strategy for ES development. Where a M/I has demonstrated safe use based on available in-house information and using Tier 1 assessment tools, he may decide to proceed directly to the description of Final ESs (iterative 3-step approach, see chapter 5.1.8). An M/I may also decide to develop ESs based on both in-house information and available information within the supply chain, using either the Generic Exposure Scenario or the Specific Exposure Scenario development process (see chapter 5.1.7). Which strategy is adopted will depend on the specific needs of the M/I, its customers and the characteristics of the supply chain. Before actually engaging in ES development, a mapping of uses and use conditions is undertaken, using the ECHA Use Descriptor System. Based on this information, uses (described by Use titles and Use Descriptors), are communicated to direct customers with a request for further communication in the supply chain and feedback on uses.

For the communication of uses and operational conditions, the trade associations of downstream users can play an important role. Together with their member companies they can compile the existing sector knowledge on uses and characterize their typical applications. This should be done in a form which helps the registrants to use the information directly for the chemical safety assessment.

An approach for this was developed and tested in practice by the Deutsche Bauchemie (German industrial association for the manufacturers of chemical products for the building industry) which we present in chapter 5.4.3.

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<sup>60</sup> **Top-Down.** In the connection of communication in supply chains: communication begins with the manufacturer of the substance (in the supply chain “above”, as a manufacturer/ causer/”origin“ of the flows of substance) and addresses the downstream user. The opposite of this is the “**bottom-up**”-approach, with which the downstream user contacts his suppliers.

#### **5.4.2 The CEFIC/FECC/DUCC approach for the structuring of communication on uses**

On behalf of the European chemical industry, a proposal on the communication on uses was developed by CEFIC together with industry sector associations such as the Downstream Users Coordination Platform (DUCC) and the European Association of Chemical Distributors (FECC). This can contribute substantially to the successful structuring of the information exchange between manufacturers/importers and downstream users – with special consideration of the tasks which the associations of those involved can take on.

This approach has been published in the CEFIC „Guidance on ES development and supply chain communication“ (March 2009)

[http://cefic.org/Files/Publications/Guidance\\_Use\\_and\\_ES\\_dvlpt\\_and\\_SCCm.doc](http://cefic.org/Files/Publications/Guidance_Use_and_ES_dvlpt_and_SCCm.doc)

According to current planning, the communication of uses for products from the European chemical industry to their downstream users is to take place as of early to mid-2009. Exposure scenarios should be communicated early to mid 2010.

A dialogue template was developed by Cefic for the structured collection of the information which substance manufacturers need from their customers for the preparation of specific exposure scenarios in cases which are not covered by Generic Exposure Scenarios. Dialogue Template for SES building:

[http://cefic.org/files/Downloads/Final\\_Template\\_09\\_03\\_09.xls](http://cefic.org/files/Downloads/Final_Template_09_03_09.xls)

The communication with the downstream users will be more efficient if it is done using IT tools. Cefic has published a document including the functional requirements for companies to put in place IT tools for supply chain communication on uses:

[http://cefic.org/Files/Publications/SCC\\_Functional\\_Requirements\\_052009.pdf](http://cefic.org/Files/Publications/SCC_Functional_Requirements_052009.pdf)

Details of this approach are described in annex 7.12 of this practical guide and in detail in the CEFIC „Guidance on ES development and supply chain communication“ (March 2009).

The communication with the downstream users will be more efficient if it is done using IT tools. CEFIC has published a document including the XML format for functional requirements for companies to put in place IT tools for supply chain communication on uses.

(<http://cefic.org/en/reach-for-industries-IT-tools.html>)

#### **5.4.3 Recommendations for the communication of uses in the supply chains**

Based on the experiences, which the companies and associations taking part in the practical guide project have so far gained with different approaches and tools for the communication of uses, we can give the following recommendations:

- Together with their associations, downstream users can already be identifying the typical use situations in their industry and describing conditions of use for these. For the

mapping of their supply chains the Use Descriptor System and the Environmental Release Categories should be used (see chapter 5.1.3 and below).

- In the description, the parameters which are critical in determining the exposure should be specified (see chapters 3.1.6–3.1.9 of this practical guide). In particular the operational conditions, the risk management measures and knowledge concerning compliance with limit values are important.
- In order to allow a direct integration of the information into the chemical safety assessment of the manufacturers/importers, the Use Descriptor System should be applied to make a short description of the uses (see chapter 5.1.3 of this practical guide).
- Also of importance is an estimate of the expected releases into the environmental compartments. These data can refer e.g. to the amount of substance used per day. In other cases estimates are perhaps already available on the quantity released in the wastewater. (It should be possible to check, at association level, whether the actually occurring emission levels agree with assumptions which are made in the context of the exposure modelling in the associated environmental release categories (see also chapter 5.1.3 of this practical guide). Therefore, it is important that the collected data, with regard to their structure, fit with the calculation models which are used by the registrants. (You will find a description of the currently most important calculation models in the advanced chapter on exposure estimation in this practical guide).

**Practical tip:** Sector information communicated by this means (e.g. "typical daily applied amounts of an optical whitener in textile finishing: 150 kg of the preparation/day") can then, in the exposure scenario, specify a permissible quantity to be applied daily. This also then becomes a default risk management measure! (If this permissible applied quantity is exceeded, limit values for human health and environment will be exceeded with regard to the specifications made in the exposure scenario).

- The user associations, should inform their manufacturers/importers which descriptions and assessments of the expected exposures are already available – e.g. in the form of sector-specific emission scenario documents, descriptions of the best available techniques (BREF documents/BATs), in the form of recommendations of the professional associations on occupational safety. This also includes operational risk assessments in accordance with CAD (Chemical Agents Directive, Council Directive 98/24/EG) and requirements according to the legislation on protection of waters (e.g. the German Federal Water Act). It would be optimal to have this information stored in a library on an industry platform, where manufacturers and importers could retrieve the data necessary for a chemical safety assessment. The CEFIC website will be used for these libraries.

The successful implementation of these recommendations in practice is shown in the following chapter for the example of the users of construction chemistry products.

#### 5.4.4 The communication model of Deutsche Bauchemie

The communication process between registrants and downstream users can, depending upon the special characteristics of the respective industry, be organized differently. An approach was developed for the formulators of construction chemistry products by Deutsche Bauchemie, considering the following initial situation:

- The different uses of the construction products can be allocated ultimately to a manageable number of typical uses.
- The total number of the substances applied in preparations is high. The substance concentrations in the individual preparations, and the quantities contained in the finished preparations, differ depending on the formulator. Here a single substance related indication on the part of the association with regard to “typical concentrations“ and/or “typical applied amounts“ for the individual product areas is not possible. However, where necessary, these can be added subsequently by the individual member companies. In the communication model of the Deutsche Bauchemie several work steps are planned, which are accomplished by the sector association, by the registrants and by the individual formulators.

#### Information on typical uses and exposures of an industry / a sector

In the first step by the association, the uses of substances within the building area are listed and assigned to use categories (e.g. industrial production of preparations, consumer products for indoor uses). This has resulted in a total of ten different use categories. For these uses, general descriptions of the applied procedures and activities and the expected kinds of exposure, (relevant exposure routes), are compiled at the association level.

These descriptions represent industry information on typical uses and the exposures associated with them. They still do not represent a complete exposure scenario, but are developed in such a way that it will be possible to directly transfer the supplied information to the chapters of an exposure scenario which is developed later. They do not contain substance-related data<sup>61</sup>.

For substances in construction chemistry products, ten such descriptions were compiled. For preparations which are used as professional products in interior rooms, such a description is documented in the materials volume of the practical guide.

For the characterisation of the use in these descriptions one also documents which industry sectors, product categories, process categories and, if necessary, article categories can be

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<sup>61</sup> These descriptions were called “initial generic exposure scenarios“, since they can be used as components for the development of exposure scenarios. The terminology of exposure scenarios and its forerunners is not yet a finally closed subject. Here contents are located in the centre, not the names (see also chapter 5.1.4).

assigned to the respective use (“Mapping“ of the typical uses related to the Use Descriptor System (see chapter 5.1.3)). These specifications are important, because the substance manufacturer can refer to these categories during the assessment of the safety of uses (if e.g. he makes exposure estimates with the model ECETOC TRA)<sup>62</sup>. Additionally the environmental release categories could be indicated for the description of the substance releases into the environment.

In addition, in the descriptions compiled, in the first step the formulator represents qualitatively those exposures to humans and environment that are to be expected, based on his knowledge. Relevant exposure routes are identified versus those which are not relevant. In order to get a clear representation here, the new structure of exposure scenarios as currently discussed by ECHA is used as a template. Thus it facilitates the processing of the information for the registrants.

As a result of this work procedure a list of the typical uses of construction chemical products, with structured descriptions of the uses, together with types of exposure associated with them, is available for the construction industry. From this information on use and exposure it also follows which product and process categories are important for the respective industry and which exposure situations are expected.

### **Exposure assessment of standardized processes by the registrant (Step-1 assessments)**

Independently, and possibly parallel to the development of industry sector information by the user associations, the substance manufacturers are calculating, in the context of the registration, exposure assessments for all uses of substances, which are to be used as standard cases in the generic models for exposure estimation (process categories). This corresponds to step 1 in the iterative 3-step approach of exposure assessment (see chapter 5.1.8). The results of these assessments are communicated to the formulator by the substance manufacturers – as an annex in the safety data sheet. It is important here that the downstream user, in our example the formulator of construction chemical products, is also informed about the assumptions made for the operational conditions on which the calculation is based.

As a result of this work, assessments are available for standardized process types on whether the uses of substances are safe or not, under the specified process conditions. For process types which are not classified as safe, either the registrant will perform more exact

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<sup>62</sup> The most important currently available models for the estimation of the exposure levels are presented in the advanced chapter. The process categories (PROCs) and environmental-related release categories (ERCs) only have a relevance for the exposure assessment where the models used refer to these categories, in that they are linked with assumptions on exposure-determining parameters (see also chapter 5.1.3 ).

exposure assessments using sector-specific information (step 2 in the iterative 3-step approach) or these uses will not be supported.

### **Examination of the step-1 assessments by downstream users (e.g. manufacturers of construction chemical products)**

As soon as the results of the exposure assessment for the different process categories are available, the formulator<sup>63</sup> of construction chemical products can examine whether the process categories, important for him, were included and check for the conclusion as to safe use or not. For this he uses the characterisation of typical uses made at association level, from which the process categories important for him are identified. If the process categories were considered and classified as “safe” use, the formulator examines the details of the assumed basic conditions (see below). If the process categories important for the formulator were not classified as “safe“, the formulator makes further more specific information available to the substance registrant<sup>64</sup> which will make it possible for him to perform a refined exposure assessment for his substance and his preparations. (Otherwise the formulator would have to perform his own substance safety assessment).

The formulator also examines whether the conditions of use assumed by the registrant in the exposure assessment (e.g. concentration of the substance in the preparation, maximum processing quantity per day, expected releases into the environment etc.) are in accordance with those of his own actual uses of preparations.

If the examination shows that in the exposure assessment both the applicable process categories were considered and the use conditions of the formulator comply with the assumptions made in the exposure assessment, then the formulator is covered in the exposure scenario that was prepared by the registrant (assuming that the result for these process categories in the calculations of the registrant was “safe use“). If this is not the case, the formulator will communicate his specific conditions of use to the registrant, so that the registrant can perform a more exact exposure assessment. This corresponds to the third step of the 3-step approach for exposure assessment (see chapter 5.1.8).

### **Communication of product-specific information by the formulator**

Only for the uses which were not classified as “safe“ by the registrant in the step-1 assessments, the formulator compiles product-specific information for the registrant, which allows for a more exact exposure assessment. Respectively the formulator makes use of the rele-

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<sup>63</sup> Here “formulator” is understood to refer to a downstream user who manufactures construction chemical products directly, using the substances and/or preparations of his supplier. As already indicated in chapter 4, in practice many formulators are not only downstream users under REACH, but at the same time also manufacturers and/or importers of substances (if they themselves manufacture and/or import substances and do not exclusively use substances and/or preparations from upstream suppliers for their formulations).

<sup>64</sup> Here, “formulator” is understood to refer to a downstream user of construction chemical products who obtains the substances and/or preparations used by him, directly from the registrant. When this is not the case, he will contact his supplier, who then passes this information on to the registrant.

vant categories from descriptions of use and exposure standardized by the sector association having confirmed that these are relevant to the substance and his conditions of use. He himself is not obliged to perform an exposure assessment.

This section covers both preparation-specific data, e.g. the maximum concentration in the preparation, and information on sector-specific risk management measures recommended for the product. The recommendations from GISBAU regarding the individual product groups can be communicated in the construction field.

The formulator can also convey substance-related measured data on exposure to the registrant. In the example of preparations containing benzyl alcohol these are e.g. values from emission chamber measurements and the results of workplace measurements by association of commercial and industrial workers compensation insurance carriers.

**Practical tip:** In the example of a preparation containing benzylalcohol the Deutsche Bauchemie could make available both measuring data from test chamber measurements and data from workplace measurements which have been collected by the Deutsche Bauchemie (and graciously made accessible). This puts the chemical safety assessment by the substance manufacturer on a very good basis in terms of data based exposure estimations.

### **Execution of advanced exposure assessments by the registrant**

On the basis of the additional information on exposure determining parameters the substance manufacturer can now repeat and refine his exposure assessment. Based on the information on risk management measures he will, in most cases, be able to describe conditions for the safe use which take into account the experiences from practice elsewhere (“read across”). He communicates these conditions for safe use to his formulator in terms of a revised substance-related exposure scenario. In this revised exposure scenario the data of the formulator will have been taken into account in producing this final exposure scenario for communication in the supply chain.

### **Compiling information from substance-related exposure scenarios in the safety data sheet for the preparation.**

The formulator prepares a safety data sheet with an exposure scenario for his preparation. For this he uses the information which he received from the manufacturers of the ingredients of the preparation. If several substances are contained in the preparation, for each of which the respective manufacturer has provided an exposure scenario, the formulator will consolidate the information from the different exposure scenarios.

The exposure scenario in the safety data sheet of the preparation will be configured by the formulator in such a way that it can be understood and used by the user in the construction industry. Such an “end user“ safety data sheet is shown in annex 7.19 for a preparation

containing benzyl alcohol. Additionally the sector-specific recommendations for safe handling of the substance, e.g. the GISBAU product information, should be communicated.

The procedure presented here provides some advantages:

- For the formulators in the sectors it is made clear which use categories are important for them, and these are grouped into a manageable number of categories.
- The formulator gains a basis from which he can determine whether his uses are covered in the exposure scenarios of the registrant.
- Communication between registrants and formulators is focused, and thereby limited, to those uses where a more exact exposure assessment is actually necessary.
- Where necessary, the registrant can consider sector-specific use conditions in the exposure assessment.
- Substance and preparation specific information from the formulators is taken into account where this is necessary. The formulator does not need to perform his own chemical safety assessment.
- The existing knowledge of the sectors on uses, operational conditions and risk management measures can be provided.
- The elements used in the different work steps are consistent.

The first work step in the procedure described here, the categorization of the important uses of an industry by the user associations, is independent from the substances and preparations used in each case.

The information about a sector, which is gathered in this step, can be used by substance manufacturers who intend to develop broad exposure scenarios for certain substances and/or groups of substances. The approach described here supports the development of “substance-group” related exposure scenarios in this way.

**Note:** Communication of the sector related categories should be done via a central web-based IT-platform. The industry associations will make their sector-related concepts available on this IT-platform and each registrant can access this information over the Internet (see also chapter 5.4.6).

#### 5.4.5 Main focus of communication of substance-related information by downstream users (and their associations)

**Practical tip: If I provide substance-related industry information on uses as downstream user and/or as associated association; which substances should I start with?**

If substance-related information is compiled for uses of downstream users, this should start with the substances which are to be registered first in the coming years, and with those for which exposure scenarios have to be developed. These are large volume substances (annual production quantities of 1,000 tonnes and more); substances which are harmful to the environment (R50/53, N) with > 100 tonnes; and substances with CMR 1+2 properties with > 1 tonne. With small-volume substances there is more time for the registration (up to 31 May 2013 for substances with 100 tonnes per year and/or up to 31 May 2018 for substances with 1 tonne per year), if the substance was pre-registered.

In the safety data sheets of the substances and preparations, downstream users can see which dangerous substance and/or PBT/vPvB substance they use. On the Internet site of the Joint Research Centre of the European Commission (Ispra) two lists are available on which are listed the high-volume substances and the substances with a production volume between 10 tonnes per year and 1,000 tonnes per year

(<http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=hpv>). Therefore it is possible to make a fast first estimate of the production volume albeit on the basis of older data, which were collected in the context of the existing substances data gathering. More current data for this are available from the list of the pre-registered substances that was published by the European Chemicals Agency (January 2009), but these data are not reliable because many preregistrations have been made for precautionary reasons – this means without the intention to make registrations of these substances later on.

#### 5.4.6 Central documentation and publicly available data platforms

**Practical tip:** Previous experiences with chemical safety assessments show that there are a large number of different activities and methods available in this field. Therefore a central documentation of the methodologies and the information available in the sectors on uses, operational conditions and risk management measures is of crucial importance in order to use this information effectively.

The following information should thus be documented centrally and made publicly available:

**Information from model developers:**

- Introductions to the models which are used for the execution of the chemical safety assessments;
- Current, validated versions of the models;
- Background information on the assumptions in the models,
- Information based on which exposure determining parameters the downstream user can modify to adjust to the exposure estimates and how these adjustments should be implemented (including Scaling).

**Information to the downstream users and from the downstream users**

- Documentation of the sector information on uses, operational conditions and risk management measures are already available; this includes e.g. OECD Emission Scenario documents and descriptions of the best available techniques (BREFs)
- Documentation of exposure scenarios already existing in the sector (see also below),
- Documentation of existing industry information and existing regulations on safe handling of products (e.g. documentation of VSKs, LASI recommendations, BG/BGIA recommendations for the respective sector). If possible, it should also be specified here, for which substances and/or groups of substances these regulations are important.

**Information on the registrants and from the registrants**

- Documentation of the final exposure scenarios developed by them (generic exposure scenarios, specific exposure scenarios, use and exposure categories).
- If necessary, also documentation of the results of the application of the generic models for exposure estimation on the substances (results of the exposure assessments from stage 1 in the iterative 3-step approach) (see chapter 5.1.8).
- Standard phrases for the preparation of safety data sheets including exposure scenarios.

The catalogue of standard phrases for the preparation of extended safety data sheets of the BDI (see chapter 3.4.2) and the CEFIC Risk Management Library (chapter 3.1.10) are examples of information centres already publicly available today. Further similar activities are planned on a European level.



## Part 3 Glossary and annexes with practical examples

### 6 Glossary

<b>AC</b>	Article category
<b>Bottom-Up approach</b>	With regard to the communication in supply chains: the downstream user contacts his suppliers. The counterpart for this is the Top-Down approach.
<b>BREF</b>	Best Available Technique (BAT) Reference Notes
<b>CAD</b>	Chemical Agents Directive 98/24/EC
<b>Conditions of use</b>	Here a distinction is made between operational conditions of use (OCs, see below) and risk management measures (RMMs, see below).
<b>ConsExpo</b>	Model for exposure estimation and risk description for exposures of consumers
<b>COSHH</b>	Control of Substances Hazardous to Health. Approach from Great Britain for the derivation of risk management measures for workplace.
<b>CSA</b>	Chemical safety assessment (see chapter 3.1)
<b>CSR</b>	Chemical safety report (see chapter 3.3)
<b>DEO</b>	Dermal Exposure Operations
<b>DMEL</b>	Derived Minimal Effect Level
<b>DNEL</b>	Derived No-Effect Level
<b>DPD</b>	Dangerous Preparation Directive
<b>ECETOC-TRA</b>	Model for exposure estimation and risk description (see Advanced chapter annex 4.1-3). In the spring of 2009 a new revised version is expected, with which it will be possible to model exposures of workers, consumers and environmental media.
<b>EMKG</b>	“Einfaches Maßnahmen-Konzept Gefahrstoffe”. “Easy-to-use workplace control scheme for hazardous substances”. Generic model for exposure estimation at the workplace worked out by the BAuA.
<b>ERC</b>	Environmental Release Categories. Categories for release of chemical substances into the environment.
<b>ESIG</b>	European Solvents Industry Group
<b>ESVOC</b>	European Solvents Volatile Organic Compounds
<b>EUSES</b>	Generic model for environmental-related exposure assessment.

<b>Exposure</b>	Exponere (lat): to be set out; contact between a chemical substance or a physical or biological agent on the one hand and an organism or an environmental compartment on the other.
<b>Exposure scenario</b>	<u>REACH art. 3.37</u> : Exposure scenario means the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposures may cover one specific process or use or several processes or uses as appropriate.
<b>Generic exposure models</b>	Models for the calculation of the exposure which proceeds from assumptions, which are defined as default values (e.g. average quantities required per day for textile additives, e.g. average size of the receiving waters of a municipal sewage treatment plant). Examples are ECETOC TRA, EUSES, Risk of Derm, EMKG (see supplement "Exposure Estimation" of the practical guide). These assumptions should be selected in a way that under realistic conditions the highest exposures to be expected are also considered by them ("realistic worst case" - assumptions). With this procedure the characteristics of individual applications are not considered.
<b>GES</b>	Generic exposure scenario. The term "generic exposure scenario" is not defined in the REACH regulation. Part R.20 of the ECHA CSA Guidance provides a preliminary definition. A GES thereafter refers to the typical conditions of use for certain types of substances (e.g. solvents, pigments, detergents) in a specific sector for the risk control with regard to substances with a certain typical hazard profile (e.g. low toxicity, low volatility) <sup>65</sup> . The term has been further specified on European level, see chapter 5.1.7 and annexes 7.9 – 7.11.
<b>Initial exposure scenario</b>	First or tentative exposure scenario
<b>IPPC</b>	Integrated Pollution Prevention Control
<b>Iterative Procedure</b>	Iterativ (lat.): repeating. Process with repetition of individual working steps.
<b>Mapping</b>	Overview in which industries, processes and if necessary products substances or groups of substances are used. Here it can also be specified, which categories from the Use Descriptor System and which Environmental Release Categories are of importance (see chapter 5.1.3).
<b>NACE</b>	Nomenclature Générale des Activités dans les Communautés Européennes (French): Classification system of the EU

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<sup>65</sup> ECHA CSA Leitlinie, Part R.20: "Generic Exposure Scenario: Exposure: Exposure scenario(s) for the typical conditions of use(s) of a certain type of substance (e.g. solvents, pigments, resins, detergents) within a certain sector of industry (area of use), suitable to control risks for substances with a certain generic hazard profile (e.g. low toxicity, low volatility). Such a GES aims to cover the whole life cycle of the type of substance".

<b>OCs,</b>	Operational conditions (of use) such as duration and frequency of substance use, application temperature, state of aggregation of the substance (see chapter 3.1.7)
<b>PBT</b>	Persistent, bioaccumulative and toxic substances.
<b>PC</b>	Product category
<b>PEC</b>	Predicted Environmental Concentration
<b>PNEC</b>	Predicted No-Effect Concentration
<b>PROC</b>	Process category
<b>RCR</b>	Risk Characterisation Ratio
<b>RMM library</b>	Library of risk management measures. Compilation of risk management measures for exposure assessments with data on the efficiency of the measures ( <a href="http://www.cefic.org/files/downloads/RMM%20Library%20.xls">http://www.cefic.org/files/downloads/RMM%20Library%20.xls</a> 'Individual Measures'!A1).
<b>RMMs</b>	Risk management measures (e.g. local exhaust, closed equipment, gloves of a certain specification, instructions and more, see chapter 3.1.9).
<b>Scaling</b>	Here: Use of simple arithmetic operations, in order to be able to calculate with exposure estimates based on one's own specific input values. This is simple where there is a linear dependence between the exposure level and the input. (Example: with a doubling of the receiving waters volume, the calculated concentration of a substance which can be expected there, if the other input parameters remain equal, is halved.)
<b>SES</b>	Specific exposure scenario. SESs describe the uses (general and specific) for an individual substance. They are meaningful in particular for substances with short supply chains (special applications) or for supply chains without a well structured sector organization.
<b>SU</b>	Sector of use
<b>SVHC</b>	Substances of very high concern
<b>Scenario (general)</b>	"Comprehensible picture". Description of a situation, which depends on several input parameters, with options for development. The term "scenario" is particularly used if supported by models of different situations which are dependent on the input parameters.
<b>Tiered approach</b>	Graded procedure for the exposure assessments. In step 1 for the estimation of the exposure level, assumptions are made for the exposure-determining parameters, which are to cover, under realistic conditions, the highest emissions to be expected. In step 2 substantially more detailed information on the conditions of use is utilized for the calculations.

<b>Top-Down approach</b>	With regard to the communication in supply chains: communication starts with the manufacturer of the substance (in the supply chain “above”, as a manufacturer, originator/”source“ of the substance flow) and addresses the downstream user. The opposite of this is the “Bottom up” approach.
<b>TWA</b>	Time-weighted average
<b>Use Descriptor System</b>	System for the short description of uses. The abbreviations specified in this system can be used in the short title of an exposure scenario, in order to give a first indication, in which industries a substance is used, to which type of product it belongs, during which processes it is used and – if of importance – in which products it can appear later on.
<b>UEC</b>	Use and exposure category. An exposure scenario, which is designed broadly and covers many applications and processes. <u>Definition in REACH (art. 3,38)</u> : means an exposure scenario covering a wide range of processes or uses, where the process or uses are communicated, as a minimum, in terms of the brief general description of use.
<b>vPvB</b>	Very persistent and very bioaccumulative substances.

## 7 Annexes to the practical guide

### 7.1 The Use Descriptor System: Sectors of Uses (SUs)

**Note:** The following annexes contain the Use Descriptor System, version February 2009. There might be some changes in the Use Descriptor System in future. The current version of the system can be found on the ECHA website.

Sector of use (SoU)	
SU 0.1	Other activity related to manufacturing of chemical products
SU 0.2	Other activity related to manufacture and services
SU 1	Agriculture, forestry, fishery
SU 2	Mining, (including offshore industries)
SU 3	Industrial Manufacturing (all)
SU 4	Manufacture of food products
SU 5	Manufacture of textiles, leather, fur
SU 6	Manufacture of paper and paper products
SU 7	Printing and reproduction of recorded media
SU 8	Manufacture of bulk, large scale chemicals (including petroleum products)
SU 9	Manufacture of fine chemicals
SU 10	Chemical formulation and/or re-packaging
SU 11	Manufacture of rubber products
SU 12	Manufacture of plastics products, including compounding and conversion
SU 13	Manufacture of other non-metallic mineral products, e.g. plasters, cement
SU 14	Manufacture of basic metals
SU 15	Manufacture of fabricated metal products, except machinery and equipment
SU 16	Manufacture of computer, electronic and optical products, electrical equipment
SU 17	General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment.
SU 18	Manufacture of furniture
SU 19	Building and construction work
SU 20	Health services
SU 21	Private households (= general public = consumers)
SU 22	Public domain (administration, education, entertainment, services, craftsmen)
SU 23	Recycling

## 7.2 The Use Descriptor System: Products Categories (PCs)

**Note:** The following annexes contain the Use Descriptor System, version February 2009. There might be some changes in the Use Descriptor System in future. The current version of the system can be found on the ECHA website.

Product Category (PC)	
PC 0	Other products
PC 1	Adhesives, Sealants
PC 2	Adsorbent
PC 3	Air care products
PC 4	Anti-Freeze and De-icing products
PC 5	Artists Supply and Hobby preparations
PC 6	Automotive Care Products
PC 7	Base metals and alloys
PC 8	Biocidal Products (e.g. Disinfectants, pest control)
PC 9	Coatings and Paints, Fillers, Putties, Thinners
PC 10	Building and construction preparations not covered elsewhere
PC 11	Explosives
PC 12	Fertilizers
PC 13	Fuels
PC 14	Metal surface treatment products, including galvanic and electroplating products,
PC 15	Non-metal-surface treatment products
PC 16	Heat Transfer Fluids
PC 17	Hydraulic Fluids
PC 18	Ink and Toners
PC 19	Intermediate
PC 20	Products such as pH-regulators, flocculants, precipitants, neutralization agents, other unspecific
PC 21	Laboratory Chemicals
PC 22	Lawn and Garden Preparations, -
PC 23	Leather tanning, dye, finishing, impregnation and care products
PC 24	Lubricants, Greases and Release Products
PC 25	Metal Working Fluids
PC 26	Paper and Board dye, finishing and impregnation products
PC 27	Plant Protection Products
PC 28	Perfumes, Fragrances
PC 29	Pharmaceuticals
PC 30	Photochemicals
PC 31	Polishes and Wax Blends

PC 32	Polymer Preparations and Compounds
PC 33	Semiconductor
PC 34	Textile dyes, finishing and impregnating products
PC 35	Washing and Cleaning Products (including solvent based products)
PC 36	Water softeners
PC 37	Water treatment chemicals
PC 38	Welding and soldering products, flux products
PC 39	Cosmetics, personal care
PC 40	Extraction agents

### 7.3 The Use Descriptor System: Process Categories (PROCs)

**Note:** The following annexes contain the Use Descriptor System, version February 2009. There might be some changes in the Use Descriptor System in future. The current version of the system can be found on the ECHA website.

Process category (PROC)	
PROC 0	Other process
PROC 1	Use in closed process, no likelihood of exposure
PROC 2	Use in closed, continuous process with occasional controlled exposure
PROC 3	Use in closed batch process (synthesis or formulation)
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises
PROC 5	Mixing or blending in batch processes (multistage and/or significant contact)
PROC 6	Calendering operations
PROC 7	Industrial spraying
PROC 8	Transfer of chemicals from/to vessels/large containers at non dedicated facilities
PROC 9	Transfer of chemicals into small containers (dedicated filling line)
PROC 10	Roller application or brushing
PROC 11	Non industrial spraying
PROC 12	Use of blowing agents for foam production
PROC 13	Treatment of articles by dipping and pouring
PROC 14	Production of preparations or articles by tableting, compression, extrusion, pelletisation
PROC 15	Use of laboratory reagents in small scale laboratories
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected
PROC 17	Lubrication at high energy conditions and in partly open process
PROC 18	Greasing at high energy conditions
PROC 19	Hand-mixing with intimate contact (only PPE available)

PROC 20	Heat and pressure transfer fluids (closed systems) in dispersive use
PROC 21	Low energy manipulation of substances bound in materials and/or articles
PROC 22	Potentially closed operations with minerals at elevated temperature
PROC 23	Open processing and transfer of minerals at elevated temperature
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles
PROC 25	Hot work operations with metals

## 7.4 The Use Descriptor System: Article Categories (ACs)

**Note:** The following annexes contain the Use Descriptor System, version February 2009. There might be some changes in the Use Descriptor System in future. The current version of the system can be found on the ECHA website.

<b>Part A: Article Category (AC) for articles without intended release</b>	
AC 0	Other articles with no intended release
AC 1-1	Passenger cars and motor cycles
AC 1-2	Other vehicles: Railway, aircraft, vessels, boats, trucks, and associated transport equipment
AC 2	Machinery and mechanical appliances thereof
AC 3-1	Electrical and electronic products, e.g. computers, office equipment, video and audio recording, communication equipment
AC 3-2	Electrical batteries and accumulators
AC 3-3	Electrical and electronic products: Household appliances (white ware)
AC 3-4	Photographic and reprographic articles: cameras, video cameras
AC 4	Glass and ceramic products: dinner ware, pots, pans, food storage containers
AC 5-1	Fabrics, textiles and apparel: bedding and clothing
AC 5-2	Fabrics, textiles and apparel: curtains, upholstery, carpeting/flooring, rugs,
AC 6	Leather products: apparel and upholstery
AC 7-1	Metal products: cutlery, cooking utensils, pots, pans,
AC 7-2	Metal products: toys
AC 7-3	Metal products: furniture
AC 8-1	Paper products: tissue, towels, disposable dinnerware, nappies, feminine hygiene products, adult incontinence products, writing paper
AC 8-2	Paper products: newspaper, packaging
AC 9	Photographic and reprographic articles: films, printed photographs
AC 10-1	Rubber products: tyres
AC 10-2	Rubber products: flooring
AC 10-3	Rubber products: footwear
AC 10-4	Rubber products: toys

AC 10-5	Other general rubber products
AC 11-1	Wood and wood furniture: flooring
AC 11-2	Wood and wood furniture: furniture
AC 11-3	Wood and wood furniture: toys
AC 12-1	Constructional articles and building material for indoor use: wall construction material ceramic, metal, plastic and wood construction material, insulating material.
AC 12-2	Constructional articles and building material for outdoor use: wall construction material, road surface material, ceramic, metal, plastic and wood construction material, insulating material.
AC 13-1	Commercial/consumer plastic products like disposable dinner ware, food storage, food packaging, baby bottles
AC 13-2	Plastic products: Flooring
AC 13-3	Plastic products: Toys
<b>Part B: Article categories (AC) for articles with intended releases</b>	
AC 30	Other articles with intend release of substances
AC 31	Scented clothes
AC 32	Scented eraser
AC 34	Scented toys
AC 35	Scented paper articles
AC 36	Scented CD
AC 37	Other scented articles
AC 38	Packaging material for metal parts, releasing grease/corrosion inhibitors
AC 39	Other articles releasing grease or corrosion inhibitors

## 7.5 The Environmental Release Classes (ERCs)

**Note:** The following annex contains the Environmental Release Classes (ERCs), version February 2009. There might be some changes in the Use Descriptor System in future. The current version of the system can be found on the ECHA website.

The Environmental Release Classes are described in the ECHA Guidance on information requirements and the chemical safety assessment in part R16 (Environment-related exposure estimation, chapter R.16.2.1 and annex R.16-1).

In all, 22 classes are distinguished (ERC 1 through ERC 11B):

<b>Environmental Release Classes (ERC)</b>	
ERC1	Production of chemicals
ERC2	Formulation of preparations
ERC3	Formulation in materials
ERC4	Industrial use of processing aids
ERC5	Industrial use resulting in inclusion into or onto a matrix

ERC6A	Industrial use of intermediates
ERC6B	Industrial use of reactive processing aids
ERC6C	Production of plastics
ERC6D	Production of resins/rubbers
ERC7	Industrial use of substances in closed systems
ERC8A	Wide dispersive indoor use of processing aids in open systems
ERC8B	Wide dispersive indoor use of reactive substances in open systems
ERC8C	Wide dispersive indoor use resulting in inclusion into or onto a matrix
ERC8D	Wide dispersive outdoor use of processing aids in open systems
ERC8E	Wide dispersive outdoor use of reactive substances in open systems
ERC8F	Wide dispersive outdoor use resulting in inclusion into or onto a matrix
ERC9A	Wide dispersive indoor use of substances in closed systems
ERC9B	Wide dispersive outdoor use of substances in closed systems
ERC10A	Wide dispersive outdoor use of long-life articles and materials with low release
ERC10B	Wide dispersive outdoor use of long-life articles and materials with high or intended release
ERC11A	Wide dispersive indoor use of long-life articles and materials with low release
ERC11B	Wide dispersive indoor use of long-life articles and materials with high or intended release

For each Environmental Release Class pre-specified values are determined for the exposure-determining parameters. Using these pre-specified values an exposure estimation is then made. In table R.16-23 of the ECHA CSA guidance these pre-specified values are listed (see

[http://guidance.echa.europa.eu/docs/guidance\\_document/information\\_requirements\\_r16\\_en.pdf?vers=20\\_08\\_08](http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r16_en.pdf?vers=20_08_08), p. 121).

## 7.6 Working steps for the preparation of exposure scenarios

Source: ECHA Guidance on information requirements and chemical safety assessment. ECHA 2008.

1. Map uses of substance (in-house information)
2. Compile available information on conditions of use
3. Select appropriate process and product categories
4. Build initial ES and run first exposure estimation
5. Complete initial ES (short title, covered activity, OCs, RMM)
6. Invite and receive feedback from representative DUs
7. Identify additional information (if needed)
8. Carry out further CSA runs (iterations) with the selected tool
9. Decide whether measured data or higher tier model needed

10. Apply other models or measured data if needed, run CSA
11. Conclude exposure estimation and risk characterisation
12. Derive integrated ES by linking all OCs and RMMs
13. Merge different ES into a broader ES (= UEC) (optional)
14. Document

**Abbreviations:** CSA = Chemicals Safety Report; DU = Downstream User; ES = Exposure Scenario; OC = Operational Conditions; RMM = Risk Management Measures; eSDS = extended Safety Data Sheet; UEC = Use and Exposure Category

## 7.7 Determinants of exposure

Source: ECHA Guidance on Information Requirements and chemical safety assessment. ECHA 2008.

Determinants of exposure	Examples (not exhaustive)	Remarks
<b>Substance characteristics</b>		
Molecular properties	Molecular weight Molecular size	Gives an indication of bioavailability
Physico-chemical properties of substance	Vapour pressure Octanol-water partitioning coefficient Water solubility	Exposure determinant at workplace and in the environment
Stability	Biological degradation, hydrolysis, photodegradation, atmospheric degradation (half-life in water, soil, air)	Exposure determinant related to degradation in environmental compartments incl. sewage treatment
<b>Characteristics of processes and products</b>		
Life cycle stage of substance or product to which the ES refers	Manufacture of substance, formulation, final use of chemical products, service life of substances in articles, waste phase	Identify relevant exposures for all target groups, supports selection of suitable broad ES; support the selection of pre-set process or product categories in tier 1 tools for exposure assessment
Type of activity or process	For example: synthesizing substances, mixing substances, using substances as process aids, using chemicals by spraying or by dipping or by brushing; using substances in articles e.g. wearing textiles, spending time in house	
Time pattern of use	Duration of activity/use Frequency of activity/use	Determinant related to pattern of exposure (short term vs. long term) and corresponding choice of PNEC or DNEL
Technical conditions of use	Level of containment of process Temperature, pH, etc.	Determinant related to exposure of humans and environment
Characteristics of chemical product	Weight fraction of substances Fugacity, dustiness, volatility of product	Determinant related to exposure of humans and environment for preparations or products
Used quantity	Kg [t] per time or activity	Determinant for the exposure potential per time or per activity

Risk Management Measures	Local exhaust ventilation (workplace) Personal Protective Equipment (workplace) On-site waste(water) treatment e.g. oil-water-separation Municipal sewage treatment, waste treatment Package design preventing dermal or inhalation exposure (product safety)	RMMs as integrated element of the technical product or process, or as additive measure; determinant of the extent to which exposure can be mitigated or prevented;
<b><i>Characteristics of surrounding</i></b>		
Surrounding absorbing or diluting releases	Room size and ventilation size; river water flow; capacity of sewage system	Exposure determinant based on the assumption that even distribution of substance takes place
Biological exposure factors	Inhalation system, body weight	Determinant of the dose to which a human is exposed and corresponding choice of PNEC or DNEL

## 7.8 Example of an environment-related scaling

### Environmental Exposure Estimation, Water, Product: Orange 703-R MountainCHEM\_1

Parameter		Formula	Downstream User (Textile finisher)		
Nr.			Default values**	DU situation	Dim
1a	Biological degradation	$F_{\text{biol}}$	40%	40%	%
1b	Adsorption on sewage sludge	$F_{\text{ads}}$	0%	0%	%
2	Emitted fraction (not fixed)	$F_{\text{nfix}}$	30%	30%	%
3	Concentration of substance in the preparation	$C_{\text{stoff}}$	45%	45%	%
4	Effectiveness of additional risk management measures	$Red_{\text{min}}$	0%	90%	
5	Amount of product used per day	$Q_{\text{THM}}$	122,0	85	kg/d
	Amount of substance per day	$Q_{\text{stoff}}$ $C_{\text{stoff}} \times Q_{\text{THM}}$	54,9		kd/d
6	Receiving water volume	$Q_{\text{wasser}}$	20.000	10.000	m <sup>3</sup> /d
	Water volume STP per day	$Q_{\text{klär}}$	2.000	2.000	m <sup>3</sup> /d
	Receiving river, volume per day	$Q_{\text{vorfl}}$	18.000	8.000	m <sup>3</sup> /d
<b>PEC</b>			<b>494</b>	<b>OK</b>	<b>69</b> <b>OK</b> <b>µg/l</b>
<b>PNEC</b>		<b>500</b>			
Less than 12 applications/year?		PNEC * 10	<b>PEC/PNEC = 1,0</b>	<b>PEC/PNEC = 0,1</b>	

\*\*.: Default values defined by the formulator for a generic description of the use.

Figure 2 The comparative calculation of the expected substance concentration in the receiving stream.

- A finisher uses the dyeing substance orange 703-R to dye curtains. Compared to the assumptions of the manufacturer (specified in the left column), the following differences are present with this user:
- The daily quantity required is not 122 kg/day, but only 85 kg/day (see figure 2);
- 90% of the emitted fraction in the wastewater is removed by new additional risk reduction measures, before the wastewater comes into the sewage treatment plant;
- The receiving stream of the finisher is very small. Here a volume of 8.000 m<sup>3</sup>/day must be assumed. The corresponding values are entered in the Excel table in the right column (lines 4, 5 and 6). The concentration in the receiving stream, which can be expected, for the user is under 100 microgram/litre – and thus below the PNEC value of 500 microgram/litre. The use is to be classified as safe under environmental criteria regarding the wastewater emissions<sup>66</sup>.

Such an adaptation is easily possible with the parameters, with which a linear relationship exists between the exposure-determining parameter and the substance concentration which can be expected. Not all exposure-determining parameters give such a simple, linear relation.

## 7.9 The approach of Generic Exposure Scenarios (GES)

Generic exposure scenarios (GESs) are broad exposure scenarios. They describe exposure scenarios for substances and/or preparations or groups of substances and preparations in their industrial applications. They are particularly meaningful for commodity chemicals with broad application fields and extensive supply chains. Two trade associations, ESIG and ESVOC (European Solvents Industry Platform), have developed a methodology for working out generic exposure scenarios. This was done with close co-operation between the federations of the manufacturers and importers and the federations of the downstream users. The starting point was an initial listing of industrial application fields of solvents, which was compiled by the European Federation of Solvent Manufacturers (“Mapping of uses”). The methodology was developed with reference to the handbook for safety evaluation.

A generic exposure scenario describes the integrated risk management measures and the application conditions for a substance or a group of similar substances in an industrial area of application e.g. the industrial and professional use of cleaning agents or the use of coating and cleaning agents by consumers. This approach is consistent with the industrial safety measures which were developed for certain industrial application fields e.g. in the framework

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<sup>66</sup> The steps described here correspond to the development of own exposure scenarios with associated description of risk, which form the principal item of the chemical safety reports of downstream users in accordance with appendix XII of REACH.

of the British COSHH Essentials approach and the “Easy-to-use workplace control scheme for hazardous substances” which was added onto it (see chapter 1.2.2 “exposure estimation” in the advanced part of this practical guide). However, the approach of generic exposure scenarios also relates to consumer and environmental protection. A special feature of generic exposure scenarios is the use of different “risk ranges”. This means that for substances with similar exposure and risk determining characteristics the same (combinations of) risk management measures are suggested.

The specification of “the range of validity” is thus an important element of generic exposure scenarios. The range of validity is illustrated in the following table 8 on the basis of the generic exposure scenario for solvents. In this case, the following parameters determine whether a specific substance is covered by the generic exposure scenario: the limit value for effects on human health (the DNEL), the volatility of the substance, and the solvent content of the preparations for which the substance will be used.

Table 8 Description of the range of validity (“Application domain”, “range of application”) of generic exposure scenarios for the example of solvents. Source: Chris Money 2008.

<b>Validity Domain</b>	<b>Typically Characterised by</b>	<b>Typical Substance/mixtures Not Covered</b>
<b>Human Health</b>		
DNEL : 10-200ppm (8 hour)	Simple aliphatic solvents (except those containing n-hexane); simple alcohols and esters	R42, R43
Moderate volatility	Liquids with a vapour pressure of < 300hPa and used at ambient temperature	Liquids with a vapour pressure of > 300hPa or where operated at >50°C
Applicable for a solvent content to 50%	N/a	Preparations having a solvent content >50%

ESVOC – European Solvents Industry Platform; August 2008

The successful description of typical industrial areas of application requires a close co-operation between manufacturers’ associations and user federations. The approach in the pilot example “generic exposure scenarios for solvent applications” was developed together and optimized by the federations involved. The individual process steps are presented in the

publication "Developing Generic Exposure Scenarios Under REACH " (ESIV/ESVOC 2008). Here it is also recognized that essential methodological steps agree well with the general procedure for the generation of exposure scenarios, as presented in chapter 5.1.6 of the practical guide. The eight main steps in the development of generic exposure scenarios are shown in the following figure 3. (The models used in step 3 are only examples. As described in the supplement "Exposure estimation", several instruments are available (for an overview, see chapter 5.2)).

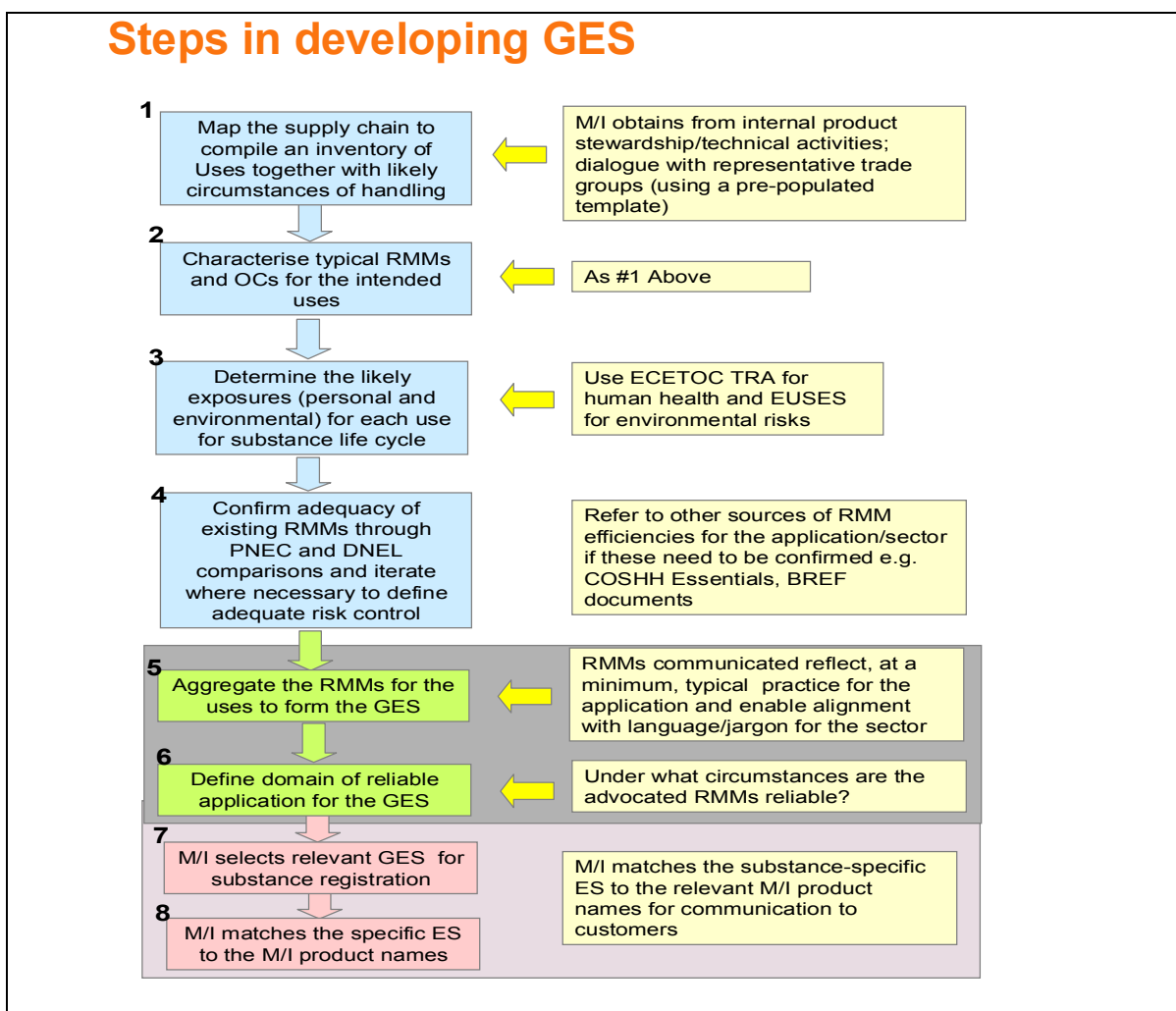


Figure 3 Main steps for the development of generic exposure scenarios. Source: Presentation of Chris Money, CEFIC, 1 August 2008

Table 9 Core considerations for the development and application of Generic Exposure Scenarios

Step	What	How
<b>I. Map substance applications and characterise exposures through the supply chain – action by M/I organisations with support from DU organisations</b>		
1	<p>For a substance or group of substances with similar applications, M/I maps the supply chain to compile an inventory of Uses involving potential for worker or consumer exposure or environmental release. This is carried out for each defined area of application and forms the basis of the GES.</p> <p>Identify the relevant Sector of Use (Reach Use Descriptor 1) for each life cycle stage, keeping the Sector as general as possible</p>	<p>Compile an inventory of applications for the substance(s) to be registered. For example: process chemicals, cleaning agents, coatings (e.g. paints/decorative coatings, inks, adhesives), lubricating agents (e.g. lubricants, greases). In addition general activities such as manufacture, storage and distribution, formulation and packing should be identified.</p> <p>For each application, opportunities for exposure are identified covering each lifecycle stage of the supply chain.</p> <p>Identify relevant Downstream User Associations to assist with verifying the mapping exercise</p>
2	<p>For each area of application, determine the contributing scenarios and those Operating Conditions (OCs) and Risk Management Measures (RMMs) that are currently used to control worker/consumer exposures and environmental releases.</p> <p>Map each Use involving potential for exposure to the relevant REACH Use Descriptor:</p> <p>Worker – Process Categories (PROC) Consumer – Product Categories (PC)/Article Categories (AC) Environment – Environmental Release Categories (ERC) or equivalent</p> <p>Review with relevant DU Organisation.</p>	<p>Use table 1 of the standardized mapping Microsoft Excel®-based spreadsheet format template.</p> <p>Separate templates are available for worker, consumer and environment.</p> <p>Review the outcome of the mapping exercise with representative DU Organisations for accuracy and completeness and adjust as needed. This may be done at this point, or for efficiency, combined with the DU review carried out as part of later steps.</p> <p>See examples given in chapter 5.1.</p>
<b>II. Evaluate risk and document the Chemical Safety Assessment – action by M/I organizations with support from DU organisations</b>		
3	<p>Carry out exposure estimates for workers, consumers and/or the environment for each identified Use included within the mapping exercise.</p> <p>Consider relevant routes of human exposure (inhalation, skin, oral) or environmental emission (air, water, land/sediment).</p>	<p>Estimate/predict exposures using available Tier 1 modelling tools, e.g. ECETOC TRA.</p> <p>Identify OCs/RMMs applied to modify the Tier 1 estimates</p> <p>Document results using table 2 of the standardized Microsoft Excel®-based spreadsheet format template for worker, consumer or environment.</p> <p>Divide analysis according to relevant health and environmental ranges, e.g. volatility or dustiness, log KOW</p>
4	<p>Confirm adequacy of the existing typical RMMs taking account of appropriate RMM efficiencies through comparison with actual or representative DNELs and PNECs. Iterate where necessary to define adequate risk control and demonstrate safe use.</p> <p>List the RMMs for each Use as standard phrases to support compilation of the required risk control measures for communication to Downstream Users using meaningful language. These may include recommended measures in support of product stewardship in addition to those required for demonstration of safe use</p>	<p>Compare the exposure estimates for the relevant volatility or dustiness ranges with relevant DNELs and/or PNECs.</p> <p>For the development of the GES it is only necessary to have available a DNEL or PNEC representative of a substance Footnote. Prior to final registration a verification step with the actual DNEL/PNEC is required.</p> <p>Safe use is demonstrated if the result is below unity. If safe use cannot be demonstrated carry out Tier 2 iteration to verify actual risk reduction is greater than the Tier 1 default for a particular RMM or identify</p>

	<p>under REACH.</p> <p>Review with relevant DU Org. Reality check that recommended RMMs are appropriate and practical.</p> <p>Where identified RMMs/OCs are not in line with existing practice work with DU Org to obtain further Tier 2 information</p>	<p>additional RMMs.</p> <p>Document results in table 2 in support of the Chemical Safety Assessment</p> <p>Draw on the RMM standard phrase library being prepared as part of the GES process to compile the relevant list of RMMs for communication purposes. Identify additional phrases if needed.</p>
<p><i>Footnote to 4) For certain groups of substances having similar hazardous properties it may be possible to use a DNEL/PNEC for the whole group. This requires expert judgment.</i></p>		
<p><b>III. Compile the GES and include within the industry or Sector GES library(ies) – action by M/I organizations with support from DU organisations</b></p>		
5	<p>Compile the GES for the area of application (divided by industrial, professional or consumer as required) using the REACH ES Template format</p> <p>Review with DU and incorporate refinements as appropriate</p>	<p>Aggregate the list of Uses (contributing scenarios) and associated RMM phrases.</p> <p>Include RMM phrases required for the demonstration of safe use</p> <p>Consider inclusion of additional RMM phrases in support of product stewardship recommendations</p>
6	<p>Define the domain of reliable application for the GES</p> <p>Make GES available for inclusion within the industry GES library for access by relevant stakeholders</p> <p>DUs may choose to develop a complementary GES to incorporate standard Sector-specific terminology</p>	<p>The domain of reliable application is defined by the list of Operating Conditions and substance characteristics against which the RMMs are relevant, e.g. relevant DNEL/PNEC range, volatility, exposure duration, emission volume, operating temperature</p>
<p><b>IV. Convert the GES into a substance-specific ES for registration and customer communication – action by Registrant with input from customers if required</b></p>		
7	<p>M/I selects the relevant GES to form the basis of their substance-specific registration</p> <p>M/I amends the GES and supporting CSA documentation as required and incorporates within their Chemical Safety Report</p>	<p>M/I confirms suitability of the GES by reference to substance-specific criteria e.g. DNEL/PNEC values, volatility, dustiness.</p> <p>GES is refined as necessary to form the substance-specific ES</p>
8	<p>M/I matches the substance-specific ES to the relevant M/I product names for communication to customers</p> <p>M/I makes available the product ES for review by customers pending finalization and inclusion within e-SDS.</p>	<p>M/I is advised to follow the supply chain communication model recommended by CEFIC, FECC and DUC in seeking feedback from their Downstream Users</p> <p>The use of coded standard phrases in the development of the GES allows for the ready translation into company-specific Safety Data Sheet systems.</p>
<p><i>Footnote to 8) For multi-component products, it is recommended to develop the product ES in line with the DPD-Plus1 methodology</i></p>		

The exchange between the federations, which is necessary for the preparation of generic exposure scenarios, is represented in the following .

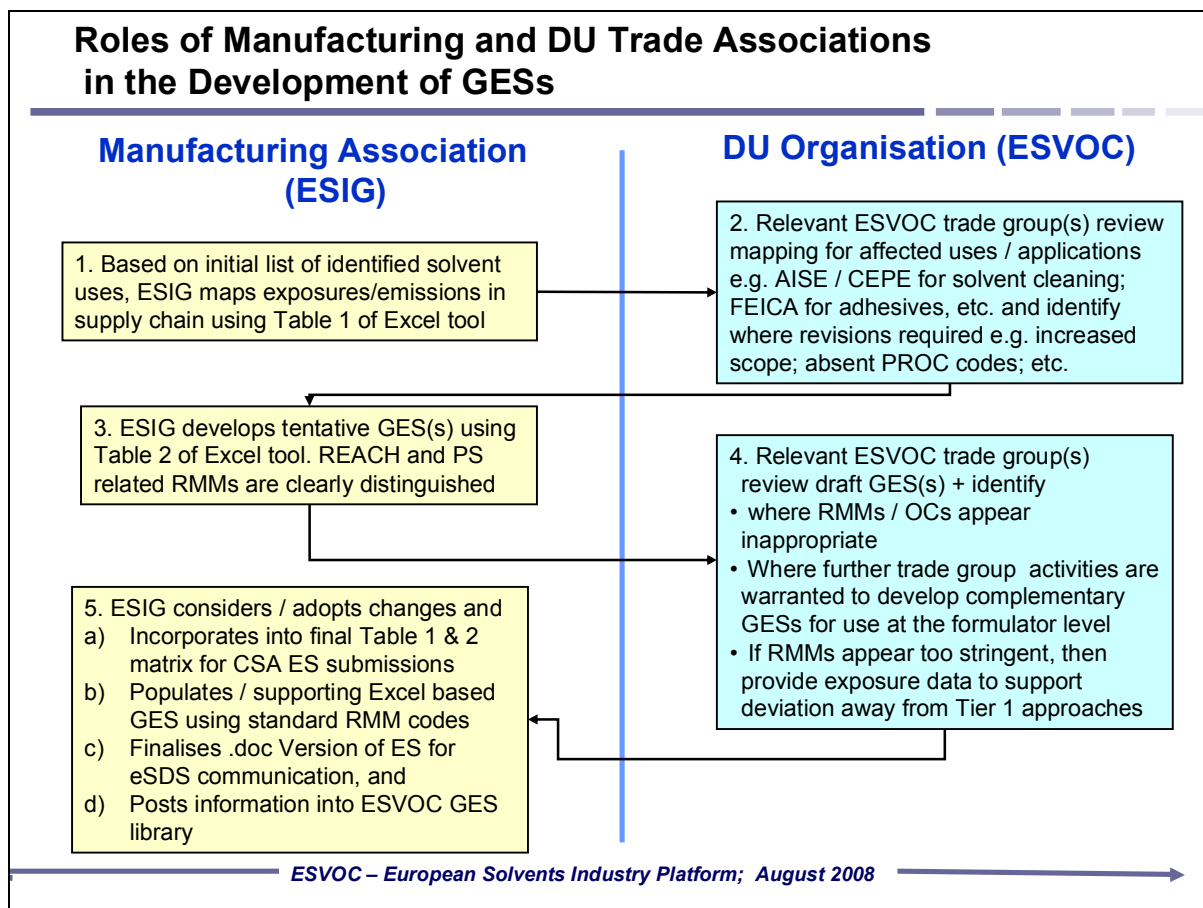


Figure 4 Steps and course of co-operation between manufacturer and user associations for the development of generic exposure scenarios. Source: Presentation of Chris Money, CEFIC, 1 August 2008

The experience from the development of these exposure scenarios shows that necessary information exchange and the feedbacks take place best in the framework of common working meetings. The completed generic exposure scenarios should be made available centrally by putting them on an Internet portal, in the form of a library, at the disposal of all interested circles where the title of the generic exposure scenarios uses terminology and concepts which are common in the respective industry. The elements of the Use Descriptor System are not indicated in the title, but are given in the presentation of the contents.

**Generic exposure scenarios (GES)** have, as a goal, the description of the safe application conditions of substances and/or groups of substances within a general area of industry. Hence, the finished exposure scenarios are communicated with the safety data sheet of the

formulated product planned for this use. You will find an example of a generic exposure scenario in the following annex 7.11 of this practical guide.

### **7.10 The approach of Specific Exposure Scenarios (SES)**

Specific exposure scenarios (SESs) are seen in this context as an addition to the methodology of the generic exposure scenarios. Like GES, specific exposure scenarios deal with industrial activities, as well as with the professional and private uses of individual substances. They are produced in the framework of the registration of substances by the manufacturer and/or importer. It is recommended to have them, particularly for substances with short supply chains and, even if not a regulatory requirement, to include industry-specific knowledge from user organizations. A comparison of the characteristics of generic and specific exposure scenarios is also contained in the methods paper for generic exposure scenarios, which is being published by CEFIC. The process of developing specific exposure scenarios is described in the following annex.

The process for the development of Specific Exposure Scenarios (SES) is first of all aimed at the development of Exposure Scenarios (ES) for uses of substances in relatively short supply chains. However, this process can also be used for substances with more wide-spread uses.

Although a generic sector approach is more favourable for this type of substances, it will not always be possible to develop Generic Exposure Scenarios (GESs) in joint cooperation between M/I and DU organizations. Not all DU organizations are well organised and not all of these organizations have the expertise available to contribute to the development of GESs in a meaningful way. In such situations use of the SES process can provide the information needed to perform a CSA and arrive at ESs.

The SES process follows a stepwise approach. A key element in the SES process is the use of a standardized template for a dialogue with DU on SES building (figure 5).

F	G	H	I	J
<b>CEFIC Dialogue Template for SES Building</b>				
<b>No.</b>	<b>Information item</b>	<b>Available options (plus explanatory notes)</b>	<b>Proposed ES1 (to be completed by</b>	<b>Deviation from (to be completed by</b>
<b>0 Product Identification</b>				
0.1	Product name as it appears on SDS	Free text		
<b>1 Short title exposure</b>				
1.1	Internal name	Free text		
1.2	Sector(s) of Use (SU)	Selection - multiple SU per ES possible. Press ctrl+tr to add a new Sector of Use	SU1	
Glazz.:				
1.3	Process Category(ies) (PROC)	Selection (preferably use descriptors from dropdown list without an *) [FS: consider to remove ALL - does only work in few]	PROC3	
Glazz.:				
1.4	Product OR Article category	Select EITHER product OR article category in 1.4.1 or 1.4.2		
1.4.1	Product Category(ies). (P)	Selection (preferably use descriptors from dropdown list without an "OR" or "n" after the PC no., full description in glazzary in line below) [FS: recommend to combine]	PC_5	PC_5_Artists_Supply_and_Hobby_preparations
Glazz.:				
1.4.2	Article Category(ies). (AC)	Selection (preferably use descriptors from dropdown list without an "OR" or "n" after the AC no., full description in glazzary in line below)	AC_0_n	AC_5_1_Fabric_textiles_and_apparel_bedding_and_clothing
Glazz.:				
1.5	Environmental Release Category(ies) (ERC)	Selection Press ctrl+tr to add a new Environmental Release Category	ERC4-air	
Glazz.:				
<b>2 Processor and activities</b>				
2.1	Life Cycle Stage	Selection Press ctrl+L should be inserted to allow more than 1 LCS to be covered. [FS: don't think this marker sense - compare also relation of EC to the LCS!]		
2.2	Optional: Provide additional information on processor and activities if			
2.3	Max. processor	Ambient temperature [°C] (default -20)		
<b>3 Human health - Workers</b>				
3.1	Type of use	Please select professional or industrial use or both		
3.2.1	Physical form under conditions of use	Select one of the following options:	Solid	
3.3.2	Dustiness category for solid substances.	In case of a solid (powder): select one of the dustiness options. Added indirect		
3.4	Max. duration of inhalatory exposure.	Explanation on exposure duration > 4 h: equal less than 8 hours 1h - 4 h: equal less than 4 hours 15 min - 1h: equal less than 1 hour < 15 min (short term)		
3.5.1	Indoor or outdoor operation [FS: merge with 3.5.2 - align with TRA]	*outdoor* will assume 33% reduction of exposure compared to indoor without LEV		

Figure 5 Example of (first part of) CEFIC dialogue template for SES building

The template is structured in the same way as the proposed template for ESs in the Technical Guidance Document on chemical safety assessment TGD (see annex 1). Each section of the template contains the basic information that is needed for description of the ES and evaluation of the ES using the ECETOC TRA tool. The MS Excel® template supports the dialogue between an M/I and the DU.

In the first step, the M/I enters all parameters relevant for the ES in the yellow column. In the second step, the DU checks this proposed ES against his use/exposure conditions. The DU

may provide feedback to the M/I on the proposed ESs. The DU needs to provide feedback only if his use/exposure condition is not, or not fully, covered. The DU enters these deviations from the proposed ES in the blue column and sends his feedback to the M/I.

The steps involved in the SES development process are shown in figure 6 and further explained below.

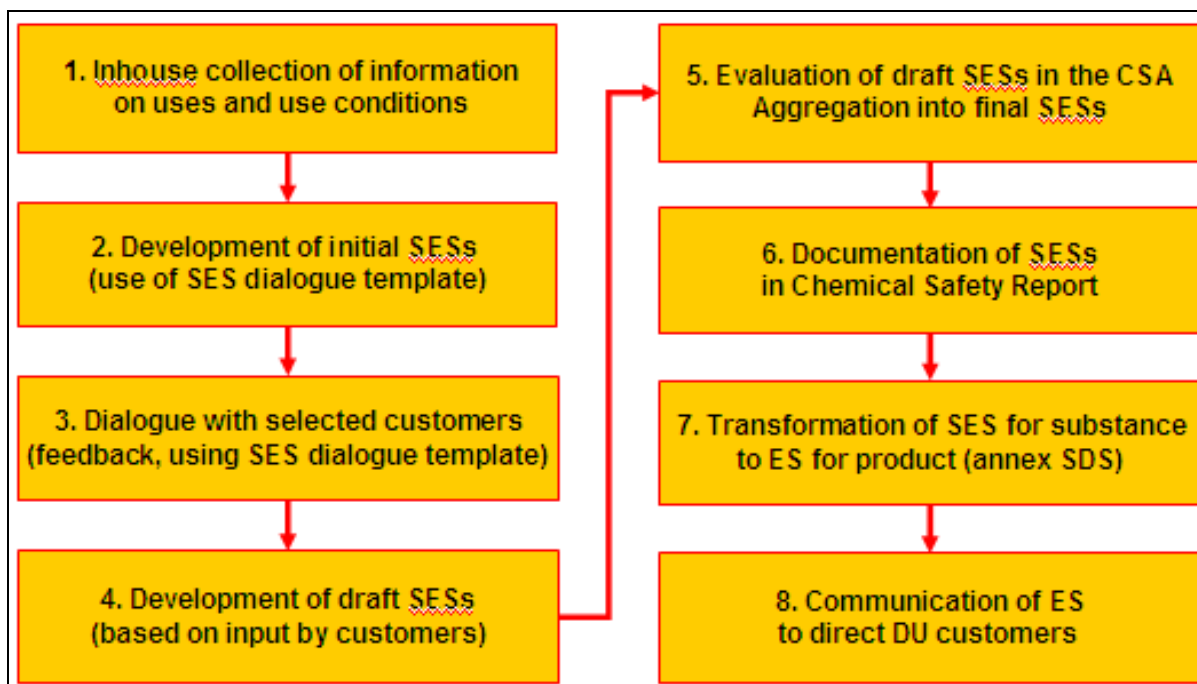


Figure 6 Steps in the Specific Exposure Scenario development process

1. **Collection of information:** the M/I starts with collection of information on uses and use conditions, from internal sources, for all products containing the relevant substance. Use of a mapping form can be beneficial in this activity, containing information on the following aspects:
  - task (e.g. manufacture, loading, storage, processing, maintenance, etc.);
  - user type (industrial/professional/consumer);
  - task/process details (continuous/batch operation, processes, type of equipment, etc.);
  - relevant use descriptors (SU, PC, PROC, AC, ERC) ;
  - exposure duration;
  - typical RMMs used (e.g. LEV, RPE, PPE).

Some DU associations are also carrying out mappings of uses relevant for their sectors. Such mappings can help the M/I in this first phase.

2. **Development of initial SESs:** the results of the mapping are used to develop initial ES by means of the template in the yellow column (see figure 5). Considering the type of products containing the relevant substance, the type of uses and the assumed level of expertise with DU customers, the combined template (worker + consumer exposure) is used, or the separate templates for worker and consumer use.

3. **Dialogue with selected customers**: based on information on customer characteristics, a limited number of representative customers is selected and approached to provide input on the initial SESs for the products containing the relevant substance. The dialogue with selected customers typically starts with a conference call in which:
  - the reasons for the dialogue are explained as well as the intended results;
  - a check is made to confirm that an appropriate customer has been selected;
  - an explanation on the template and the use of the template in the supply chain is given;
  - agreements are made on activities and timing. This dialogue should happen in a timely manner, bearing in mind the registration deadline and the communication to the supply chain.

Note that the dialogue can take place in different ways at different stages of the dialogue, depending on opportunities and needs: with each customer separately or with a group of customers; by telephone conferences, in face-to-face meetings or just by email contact.
4. **Development of draft SESs**: depending on the extent and content of the first feedback by customers, a decision has to be taken for continuation of the dialogue in order to gather additional or more specific information or to clarify the input of customers. When the M/I considers the input by customers sufficient, this input is then used to modify the initial SESs into draft SESs for the products. All draft SESs for the products, containing the relevant substance, are then assigned to the relevant substance for further processing in the Chemical Safety Assessment (CSA).
5. **Evaluation of draft SESs in the CSA**: for each draft SES a Tier 1 exposure assessment is performed, using the ECETOC TRA tool. The estimated exposures for worker and consumer and estimated environmental emissions are compared with the relevant DNELs (human exposure: inhalation, skin, oral) and PNECs (environmental emission: air, water, sediment, land) for the substance.

Where safe use is not demonstrated directly (exposure lower than the applicable DNEL or PNEC), iterations are carried out in the estimation of exposure using the available OC/RMMs in the ECETOC TRA tool. If safe use cannot be demonstrated using a Tier 1 approach, a Tier 2 exposure assessment will be performed, using (a combination of) higher Tier exposure estimation models and available exposure data. This might result in a renewed contact with selected customers to obtain additional information.

After demonstration of safe use, the SESs for separate tasks are as much as possible aggregated into final (composite) SESs. The (composite) SES includes the aggregation of ES where the risk assessment indicates that SESs for separate tasks include equivalent RMMs.
6. **Documentation in Chemical Safety Report (CSR)**: all final SESs and the results of the risk assessment are documented for inclusion in the CSR.
7. **Transformation of SES to ES format**: in order to develop an ES for a product, the final SESs for a substance in the SES template format are combined and evaluated with the SESs of other substances in a product to generate an ES for the product in the format for publication as annex to the Safety Data Sheet (SDS). Utilizing information in RMM libraries, the language in the SES will be adapted to more specific industry jargon in the ES to increase readability and facilitate comprehension by DUs.
8. **Communication to direct DUs**: as soon as the available product ESs are available, they are communicated to the direct DUs for communication in the supply chain, pending finalization and submission of the CSR and inclusion within the e-SDS.

### 7.11 Example of a generic exposure scenario (ESIG/ESVOG)

The following example of a generic exposure scenario was made available by Chris Money. This is a draft version. This exposure scenario relates to the professional use of isopropyl alcohol (IPA) in cleaning agents.

**Substance: Isopropyl alcohol (IPA); (OEL/DNEL = 200ppm)**

**CAS Number: 67–63–0**

**Exposure Scenario:** Professional use of IPA in preparations for cleaning

**Use Description (REACH):**

**Sectors of Use:** SU22 Public domain

**Process Category:** PROC2 Use in closed, continuous process with occasional controlled exposure PROC8 Transfer of substance or preparation into small containers; PROC9 Transfer of substance or preparation into small containers; PROC10 Roller application or brushing of adhesive and other coating; includes cleaning of surfaces; PROC11 Spraying outside industrial settings and/or applications; PROC13 Treatment of articles by dipping and pouring

**Environment** – assessed using EUSES, Industry category 5 Personal/domestic use, Use category, 9 Cleaning/washing agents and additives. The assumptions used for emissions and environmental exposure assessment are consistent with those reported in the Human & Environmental Risk Assessment (HERA) on Ingredients of Household Cleaning Products Isopropanol CAS No 67-63-0 Edition 1.0 May 2005.

Alternatively, release factors may use ERC 8a Wide dispersive indoor use of processing aids in open systems. Indoor use of processing aids by the public at large or professional use. Use (usually) results in direct release into the environment, for example, detergents in fabric washing, machine wash liquids and lavatory cleaners, automotive and bicycle care products (polishes, lubricants, de-icers), solvents in paints and adhesives or fragrances and aerosol propellants in air fresheners

**Article Category:** Not applicable.

Scope of process	Covers the use of cleaning products containing IPA and includes exposures during use (including spraying, brushing and other manual tasks); and equipment cleaning
Duration and frequency of use	Covers daily exposures up to 8 hours
Product specification	Covers use of up to 100% IPA in products
Physical form of product	Liquid

Maximum amount per time or activity	Health: Covers daily exposures up to 8 hours Environment: Covers use to 365 days / year
Other operational conditions of use	<u>Human health</u> Assumes use of IPA at not > 20°C above ambient Assumes a good basic standard of occupational hygiene <sup>67</sup> has been implemented <u>Environment</u> All product is assumed to be discharged to wastewater. If wastewater is not discharged via public sewer system, then the capacity of the receiving environment should at least be 1,000 m <sup>3</sup> /d.
Risk management measures	<u>Human health</u> - <i>Pouring from small containers</i> : undertake in a well-ventilated area (E50). Wear suitable gloves (type EN374, code FJ) if skin contact likely (PPE15). - <i>Spraying</i> : carry out in a vented spray booth (E51). If no suitable facility available, then use a respirator conforming to EN140 (with Type A filter) or equivalent and undertake in a well-ventilated area segregated away from other work activities (PPE18). - <i>Manual applications</i> e.g. brushing, rolling, spreading: undertake in well-ventilated area (E50). Use long handled brushes and rollers where possible (E52). Wear suitable gloves (type EN374, code FJ) if skin contact likely (PPE15). - <i>Equipment clean-down</i> : Wear suitable gloves (type EN374, code FJ) if skin contact likely (PPE15). Transfer wash-downs in sealed containers (ENVT17). Use liquors as recycle solvent or send for disposal or recycle (ENVT5). <u>Environment</u> - Preferably discharge cleaning water into sewer system (ENVT4). Do not discharge cleaning water directly into small waters (ENVT12).
Waste related measures	Dispose of used containers according to local regulations.
Prediction of exposure	<b>Worker RCR &lt;1</b> ; Inhalation: Estimated workplace vapour exposures to IPA not expected to exceed 100 ppm during spray, roller or brush activities performed up to 8 hours. Estimated dermal exposure to IPA not expected to exceed 10.7 mg/cm <sup>2</sup> /day to areas of unprotected skin resulting from manual spray, roller or brush activities. Values estimated using ECETOC TRA <sup>68</sup> . <b>Environment RCR&lt;1</b> ; The risk characterisation has been conducted by comparing the ratio of PECs derived from the EUSES calculation for the local scenario and the PNEC values for the different environmental compartments based upon PNECs referenced from HERA for IPA, 2005.

<sup>67</sup> Covers the regular supply and laundering of work clothing; provision of washing and changing facilities; eating and smoking is undertaken in areas separate from the workplace; provision of general ventilation to the workplace (typically > 5 air changes per hour)

<sup>68</sup> European Centre for Ecotoxicology and Toxicology of Chemicals, Targeted Risk Assessment (TRA) tool. See <https://www.ecetoc-tra.org/public/login/index.asp>

## **7.12 The CEFIC/DUCC/FECC approach for communication in the supply chains**

The following figure 7 shows, in simplified form, the essential steps of the communication of uses in the supply chains, as proposed by CEFIC/DUCC/FECC. This diagram was presented at the CEFIC Workshop on exposure scenarios and communication on uses on 27. and 28 October 2008. A description of this proposal has been published on the CEFIC website. (see CEFIC „Guidance on ES development and supply chain communication“, March 2009, <http://cefic.org/Templates/shwStory.asp?NID=719&HID=714>. See also Chapter 5.4.2 for further information.

This proposal contains four different elements:

- The collection of information for uses and exposure scenarios, essentially initiated by manufacturers and importers.
- Early communication on use (use titles and use descriptors) to downstream users
- Development of exposure scenario (generic exposure scenarios in partnership with trade industry organizations; specific exposure scenarios in dialogue with selected customers)
- The development of finished exposure scenarios, which are then communicated with the safety data sheets.

The special characteristic of this approach is that in the first step the manufacturers and/or manufacturers' associations become active and prepare exposure scenarios – on the basis of existing knowledge. In the second step these exposure scenarios are then put at the disposal of all users downstream in the supply chain. If the users determine in the first step that their uses are not contained in the exposure scenarios they can contact their suppliers with the goal that they incorporate their uses in a revised version of the exposure scenario.

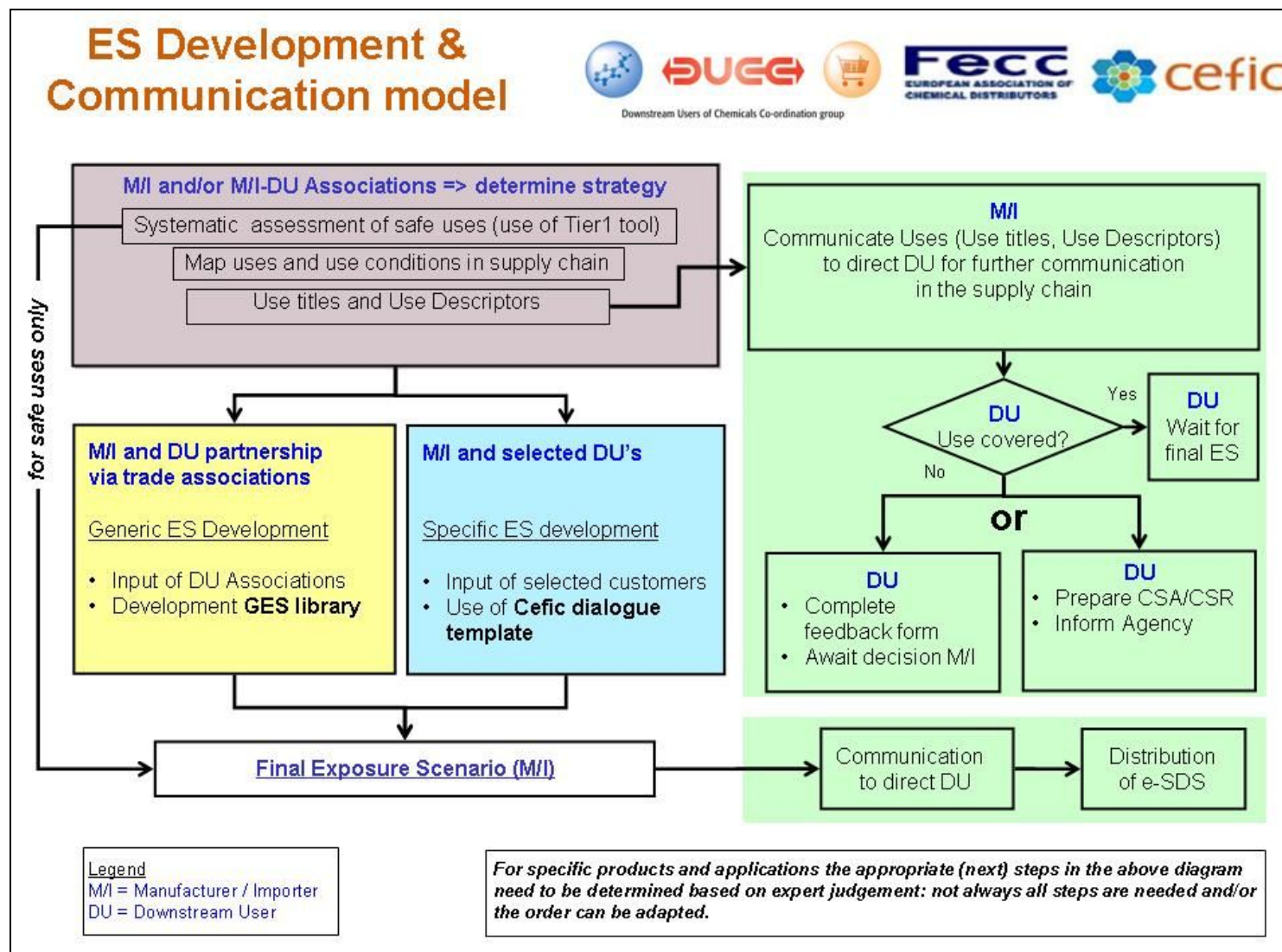


Figure 7 Flow chart for communication on uses in the supply chains.

### 7.13 The communication of types of exposure and associated measures

Exposure situations can be very different. A matrix was developed by the German Association of the Chemical Industry (VCI), in which 36 different types of exposures are differentiated ("UEC matrix", matrix of the **Use** and **Exposure Categories**). This table does not replace an exposure scenario, but it is a structuring aid for the clear representation of the types of exposure and the risk management measures which are to be implemented in practice on the basis of the expected exposures. This table can be used as an additional information instrument in different parts of the chemical safety assessment and for communication in the supply chains.

It can give an overview in the chemical safety report, showing which types of exposures are expected with a substance. It can also indicate which of the expected exposures have been examined and which are not supported. In the following table this is shown by the example of the chemical safety assessment of sodium hydroxide (as pure solid or in aqueous solution (caustic soda solution)). Here, aerosol applications were not supported.

Table 10 Overview of the types of exposure (protected resource, exposure duration, uptake route, type of use) which were considered during the chemical safety assessment of sodium hydroxide (as pure solid or in aqueous solution (caustic soda solution)). Source: Fink 2008.

Exposure			Industrial use	Professional use	Consumer use
Human	oral	Short-term	1 –	2 –	3 –
		Long-term	4 –	5 –	6 –
	dermal	Short-term	7 +	8 +	9 +
		Long-term	10 +	11 +	12 +
	inhalation	Short-term	13 +	14 +	15 o
		Long-term	16 o	17 o	18 o
Environment	Water	Short-term	19 +	20 +	21 +
		Long-term	22 +	23 +	24 +
	Air	Short-term	25 +	26 +	27 +
		Long-term	28 +	29 +	30 +
	Soil	Short-term	31 +	32 +	33 +
		Long-term	34 +	35 +	36 +

**Explanation:**

- + Assessed exposure
- A priori excluded uses
- o Not assessed/not intended exposure

Depending upon the type of exposure, the risk management measures which can be recommended may be different. Risk management measures can be recorded directly into the individual fields of the table or assigned to the fields of the table.

**Practical tip:** The matrix gives an overview of which exposures of a substance or preparation have been assessed. It further allows direct assignment of the risk management measures to the respective exposures. The formulator can more easily align and compare the respective measures for the different ingredients of his preparation: all measures, which relate to the same specific exposure situation, are described in the same cell of the matrix. Furthermore the use of this structure makes it easier to use IT tools for this alignment.

Furthermore it is helpful that the specified measures (e.g. for skin protection) can be given, without having to deal in the overview for which substance specific property it was determined to be necessary (e.g. corrosive effect, sensitizing effect, acute dermal toxicity, chronic dermal toxicity). The measures that cover the most serious substance end point can be recorded.

For the use of the table, the following points should be considered:

- The meaning of the markings selected in the table should be clearly described (see example NaOH).
- The underlying understanding of the concepts “industrial” and “professional“ should be indicated by each user of the table.
- Exposures of the consumers are also possible even if no consumer use of a substance is intended. These exposures can occur if the consumer uses articles which contain the relevant substance and thereby a contact with the substance takes place. Since no direct consumer use is intended, a minus sign may be falsely recorded in many cases in the last column of the matrix under “consumer use“. Here an additional marking that consumer exposures can occur is recommended. With the example of Deutsche Bauchemie e. V. this was accomplished via a coloured marking of the cells.
- In the table, the exposures which are to be expected during an intended use of the substance by a direct emission (e.g. into the wastewater stream) should be recorded first. Depending upon the type of use exposure can go beyond those expected from direct emissions, to indirect exposures, e.g. if the substance will be released from articles later. These should also be indicated.
- The exposures for the compartments air and soil (and thus the appropriate marking of the matrix cells 25-36) depend substantially on the physicochemical substance properties. Thus e.g. volatile substances, which are contained in the process sewage, do not always remain solely in the water, but are partially released into air. Thus, further exposures arise, which are to be indicated in the table. This presupposes knowledge on the

fate of the substances in the environment. This also applies in the case for exposures to humans via the environment. Also in this case a specific assessment is required.

- The matrix can be used for communication between formulators and substance manufacturers, to make sure that in the context of the registration the exposure situations which can be expected are covered. For the individual substances of a preparation, it can also show which risk management measures for which types of exposure are intended. It can be included as an independent, additional information instrument in chapter 16 of the safety data sheet of the individual substances, so that the customer can recognize which exposures were actually assessed for an identified use. Thus e.g. if the supplier doesn't consider the consumer's inhalational exposure, which has to be expected for a substance being later inserted in articles and leading to indoor pollution, this is immediately discernible in the table.
- For professional end users of substances and preparations, the technical language used in the matrix is often very difficult to understand.<sup>69</sup> Thus the matrix is not required in sector-specific safety data sheets for users of preparations.

#### 7.14 Exposure scenario – Acetonitrile

<b>1</b>	<b>Short title of the exposure scenario:</b> Starting material/solvent in chemical synthesis
<b>2</b>	<b>Processes and activities covered by the exposure scenario:</b> <ul style="list-style-type: none"> <li>• Use in closed processes, no likelihood of exposure; industrial setting (PROC1): The use of the substances in a high integrity contained system where little potential exists for exposures e.g. any sampling is via closed loop systems.</li> <li>• Use in closed, continuous process with occasional controlled exposure (e.g. sampling); industrial setting (PROC2) A continuous process but where the design philosophy is not specifically aimed at minimizing emissions. It is not high integrity and occasional exposures will arise e.g. through maintenance, sampling and equipment break-ins.</li> <li>• Use in closed continuous batch process (synthesis or formulation); industrial setting (PROC3) Batch manufacture of a chemical or formulation where the predominant handling is in a contained manner e.g. through enclosed transfers, but where some opportunity for contact with chemicals occurs e.g. sampling</li> </ul>

<sup>69</sup> The same also applies to the structure and the data of the standard format to exposure scenarios. Deviating from this format might allow the necessary information to be communicated towards the professional end user in a simpler form, aligned to his needs and understanding. Extensive safety data sheets are already not understood by many addressees in professional end consumption.

<b>Operational Conditions of Use</b>	
<b>3.</b>	Duration and frequency of use <ul style="list-style-type: none"> <li>• 1–4 hours/day (worker)</li> <li>• 5 days/week (worker)</li> <li>• 365 days/year (environment)</li> </ul>
<b>4.1</b>	Physical form of substance or preparation; surface to volume ratio of articles <ul style="list-style-type: none"> <li>• Volatile liquid</li> </ul>
<b>4.2</b>	Concentration of substance in preparation or article <ul style="list-style-type: none"> <li>• 100%</li> </ul>
<b>4.3</b>	Amount used per time or activity <ul style="list-style-type: none"> <li>• worker: not relevant for this exposure scenario</li> <li>• environment: not relevant for this exposure scenario</li> <li>• consumers: not covered by this exposure scenario</li> </ul>
<b>5</b>	Other relevant operational conditions of use <ul style="list-style-type: none"> <li>• none</li> </ul>
<b>Risk Management Measures</b>	
<b>6.1</b>	Risk management measures related to human health (workers or consumers) <ul style="list-style-type: none"> <li>• Worker: <ul style="list-style-type: none"> <li>○ Oral route: <ul style="list-style-type: none"> <li>▪ Do not eat or drink when handling the substance (effectiveness in exposure reduction: 100%)</li> </ul> </li> <li>○ Dermal route: <ul style="list-style-type: none"> <li>▪ Wear gloves (effectiveness in exposure reduction: 90%)</li> <li>▪ Wear Coverall (effectiveness in exposure reduction: 90%)</li> </ul> </li> <li>○ Inhalation: <ul style="list-style-type: none"> <li>▪ Local exhaust ventilation (effectiveness in exposure reduction: max. 80%; for details see the supplement “Exposure Estimation”)</li> <li>▪ Limited duration of activity: 1–4 hours (effectiveness in exposure reduction: 40%)</li> </ul> </li> <li>○ General risk management measurements <ul style="list-style-type: none"> <li>▪ Wear goggles</li> <li>▪ Decontaminate equipment before maintenance</li> <li>▪ Substance should only be handled by trained workers</li> <li>▪ Carry out regular workplace measurements to ensure that DNELs are not exceeded</li> </ul> </li> </ul> </li> <li>• Consumer: <ul style="list-style-type: none"> <li>○ Consumer use is not covered by this exposure scenario</li> </ul> </li> </ul>
<b>6.2</b>	Risk management measures related to the environment: <ul style="list-style-type: none"> <li>▪ Wastewater: <ul style="list-style-type: none"> <li>○ Any potential releases to water should be avoided as far as possible.</li> <li>○ Wastewaters should be directed to an STP.</li> <li>○ Maximum daily release to wastewater per site<sup>1</sup>: 120 kg/day</li> </ul> </li> <li>▪ Air: <ul style="list-style-type: none"> <li>○ Any potential releases to air should be avoided as far as possible</li> </ul> </li> <li>▪ Soil: <ul style="list-style-type: none"> <li>○ Direct release to soil should be avoided.</li> </ul> </li> </ul>

	<p><sup>1</sup> STP effluent discharge = 2000 m<sup>3</sup>/day; Flow rate of effluent receiving river = 18000 m<sup>3</sup>/day; see section 9 for an equation to calculate the maximum release to wastewater on the basis of a known effluent discharge and a known flow rate of the receiving river.</p>
<p><b>7</b></p>	<p>Waste management measures</p> <ul style="list-style-type: none"> <li>▪ Any wastes should be incinerated</li> </ul>
<p><b>Information on estimated exposure and DU guidance</b></p>	
<p><b>8</b></p>	<p>Exposure estimation and reference to its source</p> <ul style="list-style-type: none"> <li>▪ Worker:             <ul style="list-style-type: none"> <li>○ Oral:                 <ul style="list-style-type: none"> <li>▪ no oral exposure</li> </ul> </li> <li>○ Dermal:                 <ul style="list-style-type: none"> <li>▪ Estimated:                     <ul style="list-style-type: none"> <li>• PROC1: no significant dermal exposure (ECETOC TRA)</li> <li>• PROC2: no significant dermal exposure (ECETOC TRA)</li> <li>• PROC3: no significant dermal exposure (ECETOC TRA)</li> </ul> </li> </ul> </li> <li>○ Inhalation:                 <ul style="list-style-type: none"> <li>▪ Measured:                     <ul style="list-style-type: none"> <li>• PROC1: no data available</li> <li>• PROC2: up to 7.3 ppm (MEGA database)</li> <li>• PROC3: up to 7.3 ppm (MEGA database)</li> </ul> </li> <li>▪ Estimated:                     <ul style="list-style-type: none"> <li>• PROC1: 0.006 ppm (ECETOC TRA; LEV<sub>eff</sub><sup>2</sup> = 0; EMF<sub>da</sub><sup>3</sup> = 0.6)</li> <li>• PROC2: 12 ppm (ECETOC TRA; LEV<sub>eff</sub> = 0.4; EMF<sub>da</sub> = 0.6)</li> <li>• PROC3: 12 ppm (ECETOC TRA; LEV<sub>eff</sub> = 0.2; EMF<sub>da</sub> = 0.6)</li> </ul> </li> </ul> </li> <li>▪ Consumer: Consumer use is not covered by this exposure scenario</li> </ul> <p><sup>2</sup> LEV<sub>eff</sub> = Exposure modifying factor by local exhaust ventilation  <sup>3</sup> EMF<sub>da</sub> = Exposure modifying factor by duration of activity</p> </li></ul>
<p><b>9</b></p>	<p><b>Guidance to DU to evaluate whether he works inside the boundaries set by the ES</b></p> <p>The exposure is inside the boundaries set by the ES if the following requirements are met:</p> <p>Human Health:</p> <ul style="list-style-type: none"> <li>▪ Worker:             <ul style="list-style-type: none"> <li>○ The processes and activities in question are covered by the PROCs listed in section 2.</li> <li>○ The effectiveness of the local exhaustive ventilation should be at least as given in section 8.</li> <li>○ The work duration should not exceed the figures given in section 6.1.</li> <li>○ The general risk management measurements in section 6.1 are followed.</li> <li>○ If RMM influencing inhalation exposure are modified, the inhalation exposure can be calculated by the following equations and should be below the DNEL<sub>inhal longterm</sub> of 20 ppm:                 <ul style="list-style-type: none"> <li>▪ PROC1: Inhalation exposure not significant compared to DNEL<sub>inhal</sub></li> <li>▪ PROC2: <math>Exp_{inhal} = 50 * LEV_{eff} * EMF_{da} * RPE</math></li> <li>▪ PROC3: <math>Exp_{inhal} = 100 * LEV_{eff} * EMF_{da} * RPE</math></li> </ul> <p>LEV<sub>eff</sub>: local conditions                      EMF<sub>da</sub>: factor 1 for duration &gt; 4 h, factor 0.6 for duration 1-4 h; factor 0.2 for duration 0.25-1 h; factor 0.1 for duration &lt; 0.25 h                      RPE: effectiveness of additional respiratory protection, e.g. mask                      if measured air concentration data are available, the equations above can be adopted appropriately.</p> </li> </ul> </li> </ul>

	<p>Environment:</p> <ul style="list-style-type: none"> <li>▪ Wastewater: <ul style="list-style-type: none"> <li>○ The maximum release to wastewater can be calculated by the following equation: <ul style="list-style-type: none"> <li>▪ Maximum release [kg/day] = <math>0.73 / 0.120 * (F_R + E_D) / 1000</math>  <math>F_R</math> = Flow rate of river (m<sup>3</sup>)  <math>E_D</math> = STP effluent discharge (m<sup>3</sup>)</li> </ul> </li> <li>○ The RMM in section 6.2 and 7 are followed.</li> </ul> </li> </ul>
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### 7.15 Exposure scenario – Preparation of Lederplex

The complete extended safety data sheet for the preparation of Lederplex 900 is contained in the materials volume of the practical guide.

#### Exposure scenario ES/C-15/TEGEWA 1.11/6\_Leather/Greasing agent/ Lederplex 900

1	Short title	1,1 production of leather (SU 5, production of textiles, leather, furs) 1,2 leather greasing agent (PC 23, LED suppl. hereditary substance, – paints, lacquers, – impregnating and – preservative agents) 1,3 batch procedures (PROC 5, production of preparations and products by mixing in the batch process) 1,4 products made of leather (AC 6: Leather products: Clothing and coverings))
2	Description of the processes/activities considered in this exposure scenario	The intended use is the industrial use for the greasing of leather in the batch procedure The following uses arise thereby: storage; pouring out and refilling; Mixing, employing/applying storage in delivery vessels (canisters, barrels, containers) and/or in one's own storage containers (tanks). Filling/refilling from the stirring kettles (production), fuel-truck-and-trailer rigs with time delivery and/or before use from the vessels and/or storage containers. Mix if necessary with water Application/use in tanning vats, addition undissolved and/or before mixing with water, batch procedures.
<b>Operational conditions of use</b>		
3	Duration and frequency of use	3.1.1 length of application: approx. 5-8 h per day (dependent on in-house prescriptions) 3.1.2 schedule of use: frequent application (> 1x/month)
4.1	Physical form	Liquid
4.2	Product specification	Content of exposure-determining component (environment, water): 4.5%.
4.3	Maximum quantity required per time or per action	Environment, load wastewater: For the leather preparation considered (section 4.3.1) under the application conditions specified in section 5, the maximal quantity of product permissible per 1.000 m <sup>3</sup> of water (surface water after the purification plant) is as specified in section 4.3.2, This value can be increased in the case of rare application (up to max. 12 times per year) by ca. a factor of 10 (see also sections 5, 8a, 8b and 9 of this table)
4.3.1		Greasing agent
4.3.2		4,1 kg/ day per 1.000 m <sup>3</sup> , with rare application: 41 kg/day per 1.000 m <sup>3</sup>

5	Further application conditions, which affect the exposure	<ul style="list-style-type: none"> <li>- consumption (dependent on the process conditions temp., pH value, time, dosage among other things): min. 70%</li> <li>- Wastewater treatment measures: Purification plant (biol., chem., mechanical).</li> <li>- Receiving quantity of water: 1,000 m<sup>3</sup>/day (purification plant volumes and water volumes of the receiving stream). Note: With a deviating quantity of water there is an appropriate change in the computation of the exposure, see Excel paper ex ES/IC07/01-2007.</li> </ul>
<b>Risk management measures for the individual target groups</b>		
6.1	Industrial safety	<p>Respiratory protection: provide for good ventilation</p> <p>Hand protection: wear suitable protective gloves (Nitrile, Level 2 &gt; 30 min, Material thickness 11 mm / Nitrile, Level 6 &gt; 480 min, Material thickness 0,5 mm</p> <p>Eye protection: tightly closing eye protector</p> <p>Body protection: Work clothes</p>
6.2	Consumer protection	Consumer protection: no special measures necessary for handling the leather product
6.3	Environmental protection	<p>Environmental protection, wastewater: Determine maximum consumption with good process control (temperature, concentration, pH value, time/control of the consumption, e.g. CSB.</p> <p>Do not permit uncontrolled entry in the wastewater or into the environment; Mechanical, chemical and biological wastewater pretreatment.</p> <p>The combination with wastewater related emission reduction measures (e.g. treatment with iron salts and polymer) and an increase of the consumption is recommended (see also section 9 of this table). In special cases separate collecting of the wastewater and/or decrease of the employed concentration.</p> <p>Environmental protection, exhaust air: to expect only light exposure. Environmental protection, soil: Procedure control, avoidance of leakages and spilling the product</p>
7	Waste treatment	No specific measures necessary (see chapter 13 SDB).
<b>Exposure prediction and examination of their own uses by downstream users</b>		
8.1.1	Exposure employee	Not relevant for this product.
8.1.2	Exposure environment	
8.1.2.1	Exposure environment, water	environmental exposure, water: see Excel-Worksheet Ex ES/IC07/01-2007 PEC/PNEC = 1 for the permissible quantity applied per 1,000 m <sup>3</sup> quantity of receiving water
8.1.2.2		Risk-determining component: alkylsulfonate, PNEC <sub>water</sub> : 8.4 microgram/l,
8.1.2.3		Safety factor PNEC derivation: 1.000
8.1.2.4		Receiving stream entry: max. 15% (biology. degradability min, 90%, sewage sludge adsorption max. 1%)
8.1.2.2	Exposure environment, air	Only light exposure, no limit value excess. EUSES modelling, see chapter 9.2
8.1.2.3	Exposure environment, soil	Only light exposure, no limit value excess. EUSES modelling, see chapter 9.2
8.1.3	Exposure consumer	Not relevant for this product.
8.2	Derived control values	See section 5 of this table (permissible quantity used: 4,4 kg/day per 1.000 m <sup>3</sup> quantity of receiving water, with rare application to 44 kg/day per 1.000 m <sup>3</sup> of receiving quantity of water (surface water after the purification plant).
9.1	Adjustments of exposure estimate	Modelling exposure environment: The level of consumption, the effectiveness of the risk management measures and the receiving quantity of water enter into the computations linearly (see Excel Worksheet Ex ES/IC07/01-

		2007).
9.2	Models used for the exposure-estimate	For the exposure estimates the following models were used: Industrial safety: ECETOC TRA 2007 Consumer protection: ConsExpo 4.1 Environment (water, air and soil: EUSES, incl. SimpleTreat (excel-version 2007)
	Version / explanations	November 2008, Version (3)

## 7.16 Use and exposure category NaOH solid/NaOH liquid in aqueous preparations

1	Short title of the exposure scenario	Every industrial, commercial and private application excluding applications of aerosols with attention to the RMM. (e.g. as intermediate product for the production of glass, paper, aluminium, the manufacture of detergents, the production of a multiplicity of chemical compounds, as process aids, as neutralization agents, as cleaning agents, e.g. PC 0, PC 10, PC 15, PC 19, PC 20, PC 21, PC 23, PC35, PC 37)
2	Description of the processes/activities considered in this exposure scenario	Every industrial, commercial and private application excluding applications of aerosols with attention to the RMM <sup>70</sup> (PROC 1 to PROC 24 with the exception of PROC 7, PROC 11, PROC 22, PROC 24 as a component of products: Accumulators, batteries, AC 3) <sup>71</sup>
<b>Operational conditions of use</b>		
3	Duration and frequency of use	- industrial, commercial < 0.5h/d for brief use - industrial, commercial > 0,5 h/d for long-term/repeated use - Consumer < 0.5h/week or < 1d/year for brief use - Consumer > 0.5h/week or > 1d/year for long-term/repeated use
4.1	Physical form	NaOH solid, NaOH liquid (in aqueous preparations)
4.2	Product specification	Caustic soda solution liquid > 1% to < 100% (only NaOH + H <sub>2</sub> O)
4.3	Maximum quantity applied per time or per action	Unlimited
5	Further application conditions that affect the exposure	None (no specific conditions, which are not at the same time to be rated as a risk management measure)
<b>Risk management measures for the individual target groups</b>		
	Workers	a) Instructions: Skin contact inadmissible – Touching forbidden

<sup>70</sup> Longer term inhalation exposures cannot occur, except with spray applications, because of the physical and chemical properties (NaOH solid is hygroscopic and has a very low vapour pressure), particularly when aerosol formation is prevented by a very high viscosity.

<sup>71</sup> Cleaning sprays for baking ovens are not evaluated (aerosol use)

	<p>Array nrs. 7, 8, 10, 11, 13, 14</p> <p>DNEL inhalative / long term: 2 mg/m<sup>3</sup>. For the applications mentioned, however, not relevant. A DNEL for inhalative / short term was not derived. Severe irritative effects on the respiratory passages can only be tolerated for a few seconds by those affected, independent of the actual concentration.</p> <p>The technical and person-related protective measures for short-term uses/possible exposures often differ from the measures for long-term/repeated applications.</p>	<ul style="list-style-type: none"> <li>- Use without protective gloves, eye protector banned</li> <li>- spilled caustic soda solution immediately eliminate or neutralize,</li> <li>- Do not inhale aerosols, fumes</li> <li>- additional instruction, e.g.</li> <li>- clean contaminated protective gloves with flowing water before taking off.</li> <li>- clean or take off protective clothing immediately after contaminating.</li> <li>- Examine protective gloves for damage before beginning the activity.</li> </ul> <p>Use caustic soda solution only after dilution with water to final concentrations of less than 1%.</p> <ul style="list-style-type: none"> <li>- Pour only with small heads (20 cm or less) or let liquid flow on the rim of container (avoidance of splashes) (valid for all activities/all PROCs - as well as for the array nrs. 7, 8, 11, 13, 14.).</li> </ul> <p>b) Product-related measures, e.g.</p> <ul style="list-style-type: none"> <li>- Dilution under 1% before further use as... (Cleaning agents), (in principle for all activities/PROCs, examine whether application in diluted form is possible - substitution principle).</li> <li>- High viscosity adjustment with aids to avoid splashes</li> <li>- Use in spray products inadmissible.</li> <li>- Delivery only as barrel commodity and/or in the tank car</li> </ul> <p>c) Organizational measures: Handling permissible only after instruction on the dangers. Regular control of the observance of the instructions - sanctioning for offence, regular control of the effectiveness of the technical measures, regular control of the application of the personal measures, (valid for all indicated activities/all aforementioned PROCs) Additional measures, e.g. Entrance to production/processing only for technical personnel, Delivery only to the specialized trade. Hold only the quantity necessary for the processing ready.</p> <p>d) Technical measures, e.g.: - closed systems (PROC 1 - PROC 3) Covering of open containers (e.g. screens) - Transport over pipes, technical barrel filling/emptying of barrel with automatic systems (suction pumps etc.) (PROC 8 - PROC 9): - Use of pliers, grip arms with long handles with manual use "to avoid direct contact and exposure by splashes (no working over one's head) (PROC 10, PROC 13, PROC 19).</p> <p>e) personal measures: - Disposable gloves for brief application - Gloves with 8-hour break-through security for longer application - Eye protector (all activities/PROCs)</p>
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		additional measures, e.g. Protective clothing, aprons, shield, protective helmet
	Consumer protection  Array Nrs. 9, 12	Instructions: Skin contact inadmissible - touching forbidden. **Specific RMMs for consumer protection will be elaborated together with DU organizations <sup>72</sup> ***
6.2	Environmental protection  Arrays Nr. 19 – 36 An allocation to the PROCs, PCs does not appear appropriate, since the measures must take place independently from the respective processes and products. Therefore also an allocation of ERCs is not relevant in this case.	Instructions, e.g.: May not be let undiluted into wastewater neutralize before introduction in open waters Remainders on application devices (e.g. putties) with much water clean. b) Product-related measures: none c) Organizational measures: regular control of the pH value during introduction into open waters. d) Technical measures: - Neutralization to the locally prescribed pH value - Dilution to the locally prescribed pH value.
7	Waste treatment	No special measures necessary. Only for larger quantities of waste, possible neutralization.
<b>Exposure forecast and examination of their own uses by downstream users</b>		
8.	Exposure employee	No significant exposure on adherence to the RMM
	Exposure environment	No significant exposure with neutralization and/or permissible pH value
	Exposure consumer	No significant exposure on adherence to the RMM
	Derived control values	Not relevant (and/or pH value control during release in open waters)
	Models applied for the exposure-estimate	None
9	Adjustments of the exposure estimate	None

### 7.17 Extended safety data sheet HDDA with exposure scenario (pointer)

The extended safety data sheet for HDDA is included in the materials volume of the practical guide.

<sup>72</sup> Examples for such risk management measures might be: use permissible only with protective gloves which are impermeable against caustic soda solution, and with eye protector (if possible, solution provided together with gloves/eye protector); Before application read instructions and obey; Clean protective gloves thoroughly with much water before taking off; Eating/drinking banned – (strongly) corrosive ; Store inaccessible for children (e.g. cleaning agents in a locked cabinet) b) Product-related measures, e.g.: – “Dilution under 1% “– Child-secured packing – Delivery only with integrated dosing equipment – Delivery only in small amounts – Delivery only in very viscous preparations – Providing together with protective gloves/eye protector c) Organizational measures: – Delivery only to persons over 18 years after instruction

### **7.18 Chemical safety reports Acetonitrile, KTB, HDDA and NaOH (pointer)**

The examples of chemical safety reports are included in the materials volume of the practical guide.

### **7.19 Extended safety data sheet for end users (pointer)**

An example of an extended safety data sheet for end users of construction chemical products is included in the materials volume of the practical guide.

## **Part 4 Supplement “Exposure Estimation”**

This supplement is available in form of a separate document.