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

Part II: Exposure Scenarios and Communication in the Supply Chains

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Important note to the reader

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

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

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

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

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

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

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

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

Part II: Exposure Scenarios and Communication in the Supply Chains

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9 Exposure scenarios: Function, structure, development

Exposure scenarios are of central importance for the registration the information in the supply chain the tasks of the downstream users and the authorisation Exposure scenarios in REACH have been described as the core of the process to carry out a chemical safety assessment.

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

- The procedures under which the substance is manufactured, processed and used;
- The associated operational conditions (OCs) of use; see Part I of the practical guide, chapter 6;
- 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.

In addition information about the exposure estimation and the models uses for this and the risk assessment (ratio PEC/PNEC or human exposure / DNEL) may be included in the ES but they are not legally required.

In annexes A2.11 and A2.14–A2.16 four examples of exposure scenarios are described.

A first introduction to exposure scenarios has been given in chapter 3.4.1, Part I of the practical guide. The following sections focus on several aspects of exposure scenarios in more detail:

- Function of exposure scenarios
- Standard formats for exposure scenarios
- The Use Descriptor System and the title section of exposure scenarios
- Different types of exposure scenarios: generic and specific exposure scenarios
- Modification of exposure scenarios in the supply chain
- How to develop an exposure scenario
- Processes for the development of exposure scenarios
- The iterative 3-step approach for exposure assessment

An additional chapter deals with exposure scenarios for internal uses which are not communicated in the supply chains (see chapter 9.9).

Before REACH most companies were not familiar with chemical safety assessments and exposure scenarios. Exposure scenarios and the required information are new for the companies concerned. It will require practical experience, before the exposure scenario can become established as an important information component in the supply chains.

9.1 Functions of exposure scenarios

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

- In exposure scenarios, the exposure-determining parameters are documented. In addition the models used for the exposure estimation may be mentioned (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 mixtures) can be used safely. Therefore they provide information on the necessary risk management measures and also describe further factors which are important for safe handling.
- 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 mixture is used in higher quantities) on the exposure. Guidance is given on how to adapt different use conditions.

Note: Exposure scenarios cover the entire life cycle of a substance with the different applications at each stage. If a substance is used in different supply chains, several exposure scenarios may become necessary. Exposure scenarios may also be provided for the safe use of mixtures that contain one or more dangerous ingredients (see Part III, “Mixtures under REACH”).

9.2 Standard format for 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 (ECHA2010, part D, review under preparation), a standard format and four examples of a final exposure scenario are presented. This format should be used to include exposure scenarios in section 9 of the chemical safety report. The format can be used as well to include the exposure scenarios as annex to the extended safety data sheet.

The four examples refer to the following:

- Worker's use
- Consumer's use;
- Service life of substance in articles including conditions controlling worker's exposure;
- Service life of substance in articles including conditions controlling consumer's exposure.

Each example consists of the following four sections:

- Section 1: Title. This section describes the uses and activities which are covered by the exposure scenario. It is foreseen to use free-text elements as well as standardized categories to describe uses, taken from the Use Descriptor System (see chapter 9.3).
- Section 2: Operational conditions (OCs) and risk management measures (RMMs). In this section information is described how to ensure safe use of the chemicals. Section 2 is subdivided into parts related to protection of workers and protection of the environment (if relevant for the uses covered by the exposure scenario). Section 2 relates to all determinants of exposure which have to be taken into account for safe use.
- Section 3: Exposure estimation and reference to its source. In this chapter information can be communicated on the results of exposure estimation (related to the different routes of exposure) and to the methods and tools applied to get these results. There is no legal obligation to give this information, however it can be useful for the downstream user to decide whether his conditions of use are covered by the exposure scenario or not.
- Section 4: Guidance to downstream user to evaluate whether he works inside the boundaries set by the exposure scenario. This section can contain information how to assess whether own conditions of use are covered by the exposure scenario. This can include information on scaling related to specific determinants of exposure (see chapter 7.7 for more information on scaling).

The formats are not obligatory. Everyone who prepares his own safety data sheets can decide in which way they present the required information for the safe use of chemicals.

Often suppliers give additional good practice advice for the handling of their products beyond the chemical safety assessment of REACH. This advice can be described in an additional, last part of the exposure scenario.

Table 9 Revised standard format for exposure scenarios related to uses of substances carried out by workers. Source: ECHA Guidance on information requirements and chemical safety assessment, Part D, Exposure Scenario Building (version June 2009, table D.2.2.1).

Exposure Scenario Format (1) addressing uses carried out by workers	
1. Title	
Free short title	*Short free text (in supply chain specific language) describing the scope of the exposure scenario*
Systematic title based on use descriptor	*List of identified uses covered in the exposure scenario*
Processes, tasks activities covered	*Additional free text specification of the activities or tasks covered (if needed)*
Assessment Method*	*Assessment methods applied to create the final exposure scenario (specify the routes if relevant)*
2. Operational conditions and risk management measures	
2.1 Control of workers exposure	
Product characteristic	**Frequency and duration of use/exposure** **Amounts used**
Human factors not influenced by risk management	**Other given operational conditions affecting workers exposure**
Technical conditions and measures at process level (source) to prevent release	
Technical conditions and measures to control dispersion from source towards the worker	
Organisational measures to prevent /limit releases, dispersion and exposure	
Conditions and measures related to personal protection, hygiene and health evaluation	
2.2 Control of environmental exposure	
Product characteristics	**Amounts used** **Frequency and duration of use**
Environment factors not influenced by risk management	**Other given operational conditions affecting environmental exposure**
Technical conditions and measures at process level (source) to prevent release	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Organizational measures to prevent/limit release from site	
Conditions and measures related to municipal sewage treatment plant / to external treatment of waste for disposal	
Conditions and measures related to external recovery of waste	
3. Exposure estimation and reference to its source	
4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES	
Additional good practice advice beyond the REACH CSA **Note: The measures reported in this section have not been taken into account in the exposure estimates related to the exposure scenario above. They are not subject to obligation laid down in Article 37 (4) of REACH**	

9.3 The Use Descriptor System and the Title Section of exposure scenarios

In accordance with annex I, only data which is actually relevant for exposure must be provided. The level of detail required is to be determined in such a way that the goal of safe use is ensured. It is reasonable to use a common standardized language in the exposure scenario to alleviate the understanding. If possible generic exposure scenarios should be used. They cover a larger number substances and uses, which reduces the expenditure of chemical safety assessments. Generic exposure scenarios are described in Chapter 9.4.

Registrants of substances intend to cover the different uses of their substances in a manageable number of broadly defined exposure scenarios. Nevertheless 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.

The Use Descriptor System and the title section of exposure scenarios indicates in brief which uses of a substance are addressed in an exposure scenario. Short titles will help suppliers and customers to structure their communication with each other. The short title can describe the scope of the scenario in a supply chain specific language. In addition, the uses and activities may be described in a standardised way using the so-called "**Use Descriptor System**".

The short title and the information from the five descriptor types allow a compact, standardized report. 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 systems of the companies and in the REACH IT tools from ECHA.

9.3.1 The Use Descriptor System

The **Use Descriptor System** supports standardized communication on uses in the supply chains. It helps to structure the following four tasks (ECHA Guidance on Information Requirements and the Chemical Safety Assessment, chapter R.12, version 2):

- the fast identification of uses to be provided in the registration dossiers
- the identification of suitable exposure estimation entries in one of the available Tier 1 exposure estimation tools
- the building of an ES by suppliers, based on communication up and down the supply chain
- the generation of short titles for exposure scenarios.

The use description is based on five elements. 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)

- **"Sectors of use" (SUs)**: Substances are used in different industry sectors. 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, 25 different sectors are defined (SU1-SU24, SU01, SU02). The sectors of uses are divided in two groups. Main user groups as so-called "key descriptors" indicate whether the substances are used at industrial sites (SU 3), in private households ("consumer use", SU 21) or in the public domain by professional users (SU 22). The remaining sectors of use allow to indicate more in detail the sector of end-use of the substances (e.g. "Manufacture of pulp, paper and paper products" (SU 6b), "Manufacture of rubber products" (SU 11), "Building and construction work" (SU 19)
- **"Chemical Product Categories" (PCs)**: The categories describe in which kind of chemical products (substance as such or in mixtures) the substance is finally contained when it is supplied to end-users. Substances are used for different types of mixtures (e.g. as adsorbents (PC 2), as hydraulic fluids (PC 17), as paper and board dye (PC 26), as photo-chemicals (PC 30)). The type of mixture can give an indication of the expected release of the substances. For the categorization of chemical products, more than 35 categories are available in the Use Descriptor System (Chemical Product Category PC1-PC40). (see annex R.12-2.1 of the ECHA Guidance IR & CSA Part R.12 and chapter R12.3.2)[1].
- **"Process Categories" (PROCs)**: The processes in which substances and mixtures 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, when handling a substance, often have a large influence on the level of exposure which can be expected. The Use Descriptor System provides more than 20 different process categories to describe the application techniques or the process types from the occupational perspective (e.g. "Use in closed process, no likelihood of exposure" (PROC 1); "Calendering operations" (PROC 6); "Industrial spraying" (PROC 7) (see annex R.12-3 of the ECHA Guidance IR & CSA Part R.12 and chapter R.12.2.3).
- **"Environmental Release Categories"** describe the broad conditions of use from the environmental perspective (e.g. "Manufacture of substances" (ERC 1), "Formulation of mixtures" (ERC2), "Wide dispersive outdoor use of long-life articles and materials with low release" (ERC10a)). They characterize the release of substances into the environment which are expected for specific process types. More than twenty of such release categories are defined (ERC1 – ERC 12b, with subcategories, see annex R.12-4.1 of

[1] In practice it is often not clear, to which product category a chemical product is to be assigned. Often a different understanding exists in the different countries, as to which products are involved.

the ECHA Guidance IR & CSA Part R.12 and chapter R12.3.4). 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 chapter on "environmental exposure estimation" in the supplement "Exposure estimation", Part IV of the practical guide). In addition, sector groups can describe more detailed the conditions of use related to the environment. They can define sector-specific environmental release categories. They are called "specific Environmental Release Categories" (spERCs).

- **"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 release has to be accounted for in the exposure assessment. In the Use Descriptor System, more than 15 article categories are available (e.g. "electrical batteries and accumulators" (AC 3), "paper articles" (AC 8), "rubber articles" (AC 10), see annexes R.12-5.1 and R.12-5.2 of the ECHA Guidance IR & CSA Part R.12 and chapter R12.3.5). Distinctions can be made depending on whether the substance is released intentionally (e.g. "scented paper articles" (AC 35)), or not (see examples above). The indication of an article category is only reasonable if the substances can actually be introduced into articles.

The five elements of the Use Descriptor System allow a rapid characterisation of uses. They give a first indication, for which uses an exposure scenario is developed. It offers the possibility to describe processes and activities briefly and generally in section 2 of the ES standard format.

The actual version of the Use Descriptor System is expected to be published in 1st. Q/ 2010 (Part R.12 of the ECHA Guidance on IR & CSA). This publication includes guidance for converting description of uses based on the previous descriptor pick-lists (in version 1, May 2008) into information compatible with the refined descriptor pick-lists of version 2.

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.

Note: The Use Descriptor System should be used by individual industries in order to get an overview of which uses are typical for a specific industry ("Mapping of uses", see chapter 10.2).

However, the Mapping of uses alone (e.g. on the basis of the five descriptors) cannot replace an exposure scenario (the use descriptors themselves are not 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 section 2 of the exposure scenario.

The 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 these categories can be used in different exposure estimation tools:

- For the assessment of worker's exposure in the ECETOC Targeted Risk Assessment model (ECETOC TRA, see the supplement "Exposure estimation" of this practical guide) it is important whether industrial, professional or private uses occur. This information is taken from the sector of use categories (main user groups, sector of use 3, 21 or 22).
- Within ECETOC TRA 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 Part IV of the 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 Estimation", Part IV 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 registrants. The Use Descriptor System is currently under review. However, other descriptions using free text fields are also possible. Consequently, the five descriptor types will also be considered in IT-tools for the preparation of chemical safety reports which are currently under development.

Practical tip: The Use Descriptor System is 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 Annex A2.1 – A2.4). 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;
- 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.

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.

9.3.2 The short title of an exposure scenario

The short title should give a first indication for downstream users, whether their uses are covered by an exposure scenario or not.

Practical tip 1: 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. If further uses with deviating conditions of use are included later-on the registrant has to update his registration.

Practical tip 2: 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.

Note: 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).

9.4 Different types of exposure scenarios

REACH does not specify in detail how exposure scenarios are to be arranged. Experience 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.[2]

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 (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. CEFIC published a guidance on how to develop GESs. The related template for the dialogue between suppliers and downstream users is described in chapter 10.2 and annex A2.12.

Apart from the broadly defined generic exposure scenarios “specific exposure scenarios“ (SES) can be developed. Such an exposure scenarios is related to a detailed use of a defined substance handled under specific conditions.

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[2] **Use and exposure categories** are broadly defined exposure scenarios which 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.

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 registrants 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 (see chapter 9.7).

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 is described in chapter 9.8.

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.

Exposure scenarios are developed in an iterative process (see chapter 9.6). The result of this process is a final exposure scenario, which describes how substances and/or mixtures can be used safely. In the process of the chemical safety assessment the steps “determination of the exposure“ and “risk characterisation” were accomplished.

In order to prepare the final exposure scenario, 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.

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 final 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 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.

9.5 Modifications of 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 mixtures. 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. 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 mixtures for special application fields in individual industries. Usually they know the conditions of use, for their mixtures, better than the substance manufacturer. . If the substances contained in the mixture are 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 mixture together with the respective safety data sheet. This can be done by merging the information from the exposure scenarios of the substance suppliers to one specific exposure scenario for the mixture. In this step the formulator will consider his knowledge of the conditions of use of the mixture within the respective industry. Furthermore, he will ensure that the extended safety data sheet and the associated exposure scenario are understandable for his customers. The use of standard phrases for this task is also recommended to enable an efficient translation in all official EU languages.

Another possibility is to forward the substance-related exposure scenarios received from the suppliers. This will in most cases not provide the desired information in an understandable format. The building of a specific exposure scenario for the mixture seems to be more appropriate (see Part III of the Practical Guide and related examples for exposure scenarios of mixtures in Part V).[3]

9.6 How to 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 (e.g. using in-house knowledge)
- Collection of information on the exposures expected there (e.g. using in-house knowledge), performing 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 9.7, chapter 10.2 and annex A2.10).
- 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.
- 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 of safe use in the safety data sheet.

In practice, to carry out systematically all individual steps for many substances could lead to difficulties to manage all information and to very labour intensive processes. This is also the

[3] Approaches to assess mixtures and to prepare extended safety data sheets of mixtures are described in Part III of the Practical guide (including the DPD+ approach for identification of lead substances).

case for the early inclusion of individual downstream user communications. It is essential to simplify the development of exposure scenarios. To achieve this, experience from the development of exposure scenarios on the European level is used:

- For many industries exposure assessments are already included in extensive existing reports which are available on workplace, environmental and consumer protection. This information 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 sector groups. Two approaches were developed, firstly generic exposure scenarios (GES) and secondly specific exposure scenarios (SESs). These are presented in this practical guide (see Chapter 9.7 and in annexes A2.9 – A2.12).
- 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 sodium hydroxide (solution), this was tested for substances with corrosive effect in the context of the preparation of the practical guide. The exposure scenario for sodium hydroxide (solution) can be found in annex 0.
- Substance manufacturers will often develop exposure scenarios for 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. For more details see chapter 9.8.
- 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 preparation 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 A2.13 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 mixtures may not be marketed to consumers except under special arrangements.
- Strongly sensitizing substances should likewise be excluded from use by consumers wherever possible [4].
- 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 9.7).
- 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 9.8.

The second step can then further clarify, for which uses the substance is to be supplied[5].

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 for instance:

- 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. In many cases, knowledge of handling

[4] 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.

[5] 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).

substances will be available as well, which can be used in the exposure assessment . 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 Part IV of the Practical Guide will be applied. Here the registrant will decide which models he will 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).

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

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 9.7 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.

It will largely depend on the knowledge of the registrant on the use of his substances, which way fits best for the preparation of exposure scenarios for a given substance.

9.7 Processes for the development of exposure scenarios

CEFIC developed two processes that 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 co-

operation between the federations of the manufacturers and importers and the federations of the downstream users.

A detailed presentation of the concept of generic exposure scenarios can be found in annex A2.9.

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 A2.10.

In December 2009 CEFIC published a new version of a template addressing specifically exposure of workers: the GES CSA Worker Template.

The GES CSA Workers Template: The development of Generic Exposure Scenarios requires input from individuals knowledgeable in the identification of uses through the supply chain and those competent in human health and environmental risk assessment processes under REACH. The CEFIC ES Project Team has developed a template for further support for the development of Generic Exposure Scenarios and its use for the development of substance specific exposure scenarios (see http://www.cefic.be/Files/Publications/2009-12-11-Cefic-GES-CSA-Worker-Template-Version-01.xls).

This template addresses GES development for occupational exposure. Templates for environmental and consumer exposure are under separate development.

The Microsoft Excel®-based spreadsheet template can be used for developing Generic Exposure Scenarios (GESs). Table 1 provides a structured format for the standardized collection of use information (use description) and associated typical operational conditions (OCs) and risk management measures (RMMs). Table 2 provides the means to document the chemical safety assessment for each use, termed Contributing Scenario, and to record the relevant RMMs required or recommended for the demonstration of safe use. These are then captured in an Exposure Scenario narrative document for subsequent communication. The combination of both Tables 1 and 2 supports consistency and transparency in the development of sector-specific GES for occupational exposure.

The template will also help Lead Registrants to translate available sector-specific GES's into substance- specific exposure scenarios for occupational exposure. Therefore Lead Registrants are encouraged to use this structured format within Consortia and SIEFs.

The template contains:

1. Outline procedure – Using the Worker CSA Template
2. Worker CSA Template (Tables 1 and 2 GES process)

2.a. Phrase Pick lists – list of phrases used in the pick lists contained in the Worker CSA Template

3. Worker - Example ES Annex (for use in communicating the ES Narrative)

Additionally the template can be used to support data transfer into certain IT systems. An example is given how data elements (standard phrases) can be transferred into an extended safety data sheet structure.

9.8 The iterative 3-step approach for exposure assessment

REACH requires that the manufacturers and/or the importers primarily develop exposure scenarios, which they communicate to their customers.

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. Therefore CEFIC developed two processes, which have been described earlier (see Chapter 9.7).

In the VCI project these processes have been included in a proposal for a 3-step approach for 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[6] 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.

[6] It is left to the manufacturers/importers whether they evaluate all uses in individual cases, or whether they only do it for all relevant and plausible process categories

The assessment should preferably take place according to the current ECETOC TRA version 2, which includes worker, consumer and environmental assessment.[7].

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 Part IV, 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 9.2..

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 10 a typical result from the use of ECETOC TRA version 1 is shown for the example HDDA for the process categories PROC 1–5 how it was prepared for the VCI project. Meanwhile the formats how to report the results have changed due to continuous discussion with ECHA and further development of the CHESAR tool.. You can find the complete result in the extended safety data sheet of HDDA, which is available as a separate document (http://www.vci.de/default~cmd~shd~docnr~125022~lastDokNr~102474.htm).

Table 10 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**

[7] In ECETOC TRA version 2, worker, consumer and environmental assessment are integrated.

Process Category [PROC]	Use Scenarios	Duration of activity [hours]	LEV (Y/N)	Estimated Exposition [ppm]	MoE [DNEL/ est expo]	Further assessment required
PROC 4	Use in a batch or other process (including related process stages e.g. filtration, drying) where opportunities for exposure arise e.g. sampling, discharging of materials	> 4 hours	Yes	1	0,318	**Yes no refinement done – if needed, please contact manufacturer**
PROC 5	Use in a batch process including chemical reactions and/or the formulation by mixing, blending or calendering of liquid and solid-based products	> 4 hours	Yes	1	0,318	**Yes for refinement see chapter 9.2**

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 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 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). CEFIC promotes the use of libraries to support the implementation of REACH, especially for the development of exposure scenarios – see chapter 10.6.

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.[8]

In the following table 11 a typical result for a refined assessment according to step 2 is listed. More detailed results are shown in the appendix (SDS of HDDA) 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 11 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. Exposition [ppm] (refined)	Margin of exposure [[DNEL/ est expo]]	Safe use
SU 7, 10 UV/EB 1	FORMULATION (covering PROC 5)	< 4 hours	• Ambient temperature (< 30°C) and • Room ventilation rate > 6/h and • Chemical resistant protective gloves (EN 374), nitrile rubber (NBR) – 0.4 mm coating thickness and • Safety glasses with side-shields (frame goggles) (e.g. EN 166)	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.

[8] It is left to the manufacturers/importers in individual cases whether they consider all industry-specific uses.

Here specific exposure scenarios are developed using the process as described in chapter 9.7. Often this company-specific information will be confidential business 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 A2.17 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

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. CEFIC supports these activities with several libraries and an overview of the activities of the European actors in this field (see chapter 10.6 on public libraries and the related web site: (http://www.CEFIC.be/en/reach-for-industries-libraries.html).

9.9 Exposure scenarios for internal uses of substances

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. A part 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 not require exposure scenarios.

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 only refer to internal uses, the respective guidance recommends a format for the presentation of exposure scenarios.

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

Many producers of mixtures (M/I/DU) aim to produce only non dangerous / non PBT / non vPvB mixtures due to the demands of the market. If the thresholds for classification are not exceeded, a SDS is not required and therefore no exposure scenarios are needed[9].

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/mixtures 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 mixtures 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;
- 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 uses of substances below certain concentration thresholds according to art. 14 and 31
- for substances which are already put into articles by the registrant (if no relevant release according to art. 7);
- 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.

[9] 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.

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.

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).

10 Communication in the supply chains

10.1 The task and the present situation

Registrants need information on uses[10] in order to perform realistic chemical safety assessments and to describe in their exposure scenarios risk management measures which can be implemented in the supply chains. 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 chapter 6, Part I of the practical guide).

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 play an important role by compiling information from individual users into “typical“ features for a sector.

Early in 2009, a structured communication on uses and conditions of uses started in Europe. Standardized templates had been developed by several sector groups (e.g. DUCC) and by CEFIC to allow a harmonized collection of uses. In the CEFIC working group “Supply Chain Communication“ an approach for the structured communication in the supply chains was developed together with DUCC and FECC, which, in particular, involves the user associations. This approach is directly connected with the procedures for the development of generic

[10] The term “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 mixture, 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 and transfer from one container to another and processing in closed or open equipment.

and specific exposure scenarios[11]. This approach is described in chapter 10.2 and in Annex A.2.12.

For the communication of uses and operational conditions, the trade associations of downstream users play an important role. Together with their member companies they compile the existing sector knowledge on uses and characterize their typical applications. The European Downstream Users Coordination Group (DUCC) developed a template for the standardized reporting of uses, the UseR format. This format helps the registrants to use the information directly for the chemical safety assessment. The DUCC UseR format is based on the Use Descriptor System (which is described in chapter 9.3.1).

In the meantime an increasing number of downstream user associations have performed the mapping of their uses. This information has been made publicly available by CEFIC in an overview table (see chapter 10.6).

Manufacturers and importers are using this information in preparing generic and specific exposure scenarios. End of 2009 it became evident that most of them still will need some time until the first generic and specific exposure scenarios can be sent to the downstream users. Registrants use the 3 step approach of exposure assessment to perform Tier 1 assessments and to start communication with key customers if uses are assessed as being not safe in the first step.

In single cases downstream users are informed by their suppliers which uses the registrants intend to take into account (referring to the use descriptor system). The downstream users gave feedback to their suppliers that specific conditions of use are not covered.

This experience from large manufacturers, formulators und downstream user associations shows that the elements presented in the CEFIC/DUCC/CEPE approach on supply chain communication can be used successfully from registrants and downstream users. The whole communication process as foreseen in the working scheme does not yet take place. It is expected to start when the first generation of generic exposure scenarios will be sent from the manufacturers and importers to their customers.

10.2 Communication of uses in the supply chains: Recommendations

Based on the experiences gained so far with different approaches and tools for the communication of uses, the following recommendations can be given:

- If not already done, downstream users should rapidly identify the typical use situations in their industry – together with their associations. For the mapping of uses the applica-

[11] These types of exposure scenarios are described in chapter 9.7.

tion of the Use Descriptor System and the DUCC UseR format has become common practice (see chapter 9.3.1 and below).

- In the description, the parameters which are critical in determining the exposure should be specified (see chapter 6, Part I of the practical guide). In particular the operational conditions, the risk management measures and knowledge about compliance with limit values are important.
- Downstream users 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 9 and 9.7).
- Also important is an estimation of the expected releases into the environmental compartments. This 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 9.3.1). 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 Part IV, Supplement “Exposure Estimation”).
- 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 to give an overview on these libraries (see chapter 10.6) .

Chapter 10.5 gives additional recommendations for downstream users which intend to inform their suppliers about specific uses of individual substances “bottom-up”.

The following chapter 10.3 describes the CEFIC/FECC/DUCC approach for the structured supply chain communication. It is a general methodology which can be used in all branches. Depending on the characteristics of an industry sector, the communication process can differ in reality from sector to sector. Chapter 10.4 describes a specific communication model

developed and tested by the Deutsche Bauchemie. (German industrial association for the manufacturers of chemical products for the building industry).

10.3 The CEFIC/FECC/DUCC approach for the structuring of communication on uses

The CEFIC approach for communication in the supply chains describes a so called “Top-down approach“ which means that .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.

This approach starts with determining the strategy for exposure scenario (ES) development. Where a registrant 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 (e.g. iterative 3-step approach, see chapter 9.8). A registrant 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 9.7). 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.

In order to support the structured dialogue about uses in the supply chains, CEFIC and European industry associations have published the following specific guidances and tools related to the process of supply chain communication.

1. Guidance on ES development and supply chain communication: 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 Group (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. Details of this approach are described in annex A2.12.

The communication of uses for products from the European chemical industry to their downstream users started mid-2009. Exposure scenarios should be communicated early to mid 2010.

This document is helpful for all actors involved in the supply chain communication to understand the structure of the communication process. The sections on generic and specific exposure scenarios are primarily important for registrants who are preparing exposure scenarios.

2. GES CSA Workers-Template: This template supports the development of Generic Exposure Scenarios and its use for the development of substance specific exposure scenarios (see description above, chapter 9.7) (http://www.cefic.be/Files/Publications/2009-12-11-Cefic-GES-CSA-Worker-Template-Version-01.xls).

3. Template for the dialogue in supply chains: 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 (SES) in cases which are not covered by Generic Exposure Scenarios.

(http://CEFIC.org/files/Downloads/Final_Template_09_03_09.xls).

This document should be used by registrants who start the dialogue with their key customers on specific uses. It is recommended not to send the document to the customers, but to use it as an instrument during the meeting with the customer and to explain it to him.

4. IT Tools for supply chain communication: 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/Files/Publications/SCC_Functional_Requirements_052009.pdf,
http://CEFIC.org/en/reach-for-industries-IT-tools.html.

This tool aims to support manufacturers and importers as well as formulators.

5. Template for the reporting of uses: The European Downstream Users of Chemicals Coordination group (DUCC) has developed a common format for reporting uses under REACH. This format is called "**UseR**": **Use R**eporting Template. It provides a tool to downstream user associations and their members for mapping and reporting uses for their respective sectors. (The template can be downloaded from the CEFIC website on REACH documents and tools (http://www.CEFIC.be/Files/Publications/DUCC-Use-and-ES-Mapping-Template-revised-Final15072009.xls).

Uses are mapped using the Use Descriptor System (see chapter 9.3). Additional information can be provided to allow a first exposure assessment at screening level, using exposure estimation tools as ECETOC TRA (see chapter 3.4.1, Part I and the supplement "Exposure estimation", Part IV of the practical guide). The DUCC "UseR" excel file provides the common format. Each downstream user association is responsible for filling and updating the use

information for its sector. Downstream user associations are advised to make their lists of uses publicly available and/or accessible to manufacturers and importers as relevant.

This tool should be used by downstream users for “upstream” communication.

In the meantime the approaches and tools have been used by several companies and associations. CEFIC provides an overview on the status of these activities on its website on REACH libraries, see chapter 10.6. It includes links to the information from mapping activities which are available from the different sector associations.

10.4 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 mixtures is high. The substance concentrations in the individual mixtures, and the quantities contained in the finished mixtures, 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 the sector group listed the uses of substances within their working area and assigned them to use categories (e.g. industrial formulation of mixtures, consumer products for indoor uses). This resulted in a total of thirteen different use categories. For these uses, general descriptions of the applied procedures and activities and the expected kinds of exposure were 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 were developed in such a way that it is possible to directly transfer the supplied information to the chapters of an exposure scenario which will be developed later and to apply the ECETOC Targeted Risk Assessment Tool. For the description no substance-related data was collected. An example for a use category is given in Annex A2.19.

For the characterisation of the use in these descriptions it is also documented which sector of use, product categories, process categories and, if necessary, article categories can be assigned to the respective use (see chapter 9.3.1). Furthermore the descriptions of the Construction Chemicals Industry give information regarding duration and frequency of use (exposure time) and some risk management measures like local exhausted ventilation, respiratory protection, goggles and gloves.

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

Independently the substance manufacturers calculate 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 9.8). 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 is also informed about the assumptions made for the operational conditions on which the calculation is based.

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

The formulator[12] of construction chemical products can examine on the basis of the eSDS whether the process categories, important for him, were included and check for the conclusion whether his use is safe or not. More details about the so downstream user compliance check have been given in Part I of the Practical Guide, chapters 7.2 and 7.3.

If the compliance check 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 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 9.8).

[12] Here “formulator” is understood to refer to a downstream user who manufactures construction chemical products directly, using the substances and/or mixtures of his supplier. As already indicated in chapter 7.1, Part I of the practical guide, 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 mixtures from upstream suppliers for their formulations).

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 relevant 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 mixture-specific data, e.g. the maximum concentration in the mixture, 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 mixtures 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 mixture 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 mixture.

The formulator prepares a safety data sheet with an exposure scenario for his mixture. For this he uses the information which he received from the manufacturers of the ingredients of the mixture. If several substances are contained in the mixture, 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 mixture 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 mixture 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 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 mixture 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 mixtures 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.

10.5 Bottom-up communication of substance-related information by downstream users (and their associations)

In some cases downstream users are invited by their suppliers to double check lists of uses intended to be registered 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 registrants and DU.

If downstream users did not receive such lists, the following recommendations are given:

- Downstream user associations should collect the information from their members and structure them using the DUCC UseR template.
- 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")[13]. These substances will be most probably registered in 2010. For the substances in smaller volume bands, which must only be registered in 2013 and/or 2018, it is generally not necessary to collect information on uses and communicate it already in 2010 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 (well in advance of the respective registration deadlines). Nevertheless it cannot be ruled out that for commercial reasons individual manufacturers/importers decide to register low production volume chemicals earlier than legally required.
- Downstream users should check whether they have uses to be considered which manufacturers and/or importers do not know of. (General well-known/usual uses and conditions should not be communicated, they are presumably already considered by substance manufacturers). These 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 9.7).

10.6 Central documentation and publicly available data platforms

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.

Already in the first publication of the Practical Guide recommendations have been given to document the following information centrally and to make it publicly available:

[13] In the safety data sheets of the substances and mixtures, 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 estimation 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.)

Information from model developers:

- Introductions to the models which are used for the preparation 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

- 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 5.2, Part I of the practical guide) and the CEFIC Risk Management Library (chapter 6.3, Part I of the practical guide) are examples of information centres already publicly available today. Further similar activities take place on a European level. Since the first publication of the Practical Guide, CEFIC promotes the use of libraries where industry can store and retrieve information to comply with REACH requirements, in particular to develop exposure scenarios. The use of these libraries by all actors enhances the harmonisation of the implementation of REACH.

CEFIC publishes on its website an overview of activities relevant to REACH libraries carried out by industry associations (see http://www.CEFIC.be/en/reach-for-industries-libraries.html (for an introduction) and http://www.cefic.be/files/downloads/Overview_associations_activities_TO_PUBLISH_21012010.xls (the table itself)). It provides a summary of the work done by associations and the contact details of these associations in a table which is continuously updated http://www.CEFIC.be/files/downloads/Overview_associations_activities_TO_PUBLISH_1109.xls). At present (updated January 2010) information from more than 25 associations, sectors

groups and consortia are documented. The following table lists the organisations which have given information so far.

AISE	International Association for Soaps, Detergents and Maintenance Products
ATC	Technical Committee of Petroleum Additive Manufacturers in Europe
ATIEL	Technical Association of the European Lubricants Indsutry
CEFS	European Committee of Sugar Manufacturers
CEPE	European Council of producers and importers of paints, printing inks and artists' colours
COLIPA	European Cosmetics Association
Concawe	The oil companies' European association for Environment, Health and Safety in refining and distribution
ECCA	European Coil Coating Association
ECMA	European Catalyst Manufacturers Association
ECPA	European Crop Protection Association
EDANA	International association serving the nonwovens and related industries
EFCC	European Federation for Construction Chemicals
EPMA	European Powder Metallurgy Association
ERMA	European Resin Manufacturers Association
ESIG	European Solvents Industry Group
ESVOC	European Solvents Industry Platform
ETAD	The Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers
ETRMA	European Tyre & Rubber Manufacturers' Association
Eurométaux	European Association of non-ferrous metals
FECC	European Association of Chemical Distributors
FEICA	Association of European adhesives and sealants manufacturers
ISOPA	European Diisocyanates and Polyols Producers Association
PEST	Plastics Exposure Scenarios Team
PPRM	Polyester Powder Resin Manufacturers
RECONSILE	Silicon consortia
SRM	Solvent Resins Manufacturers
TEGEWA	German Textiles association

The CEFIC overview table contains the following information for each association:

- Activities on mapping: Use of the Use Descriptor System by individual associations / information, whether sector specific language is used in the documentation of uses / information which templates are used
- Definition of risk management measures (e.g. local exhaust ventilation); information, whether this is part of the work of the associations;
- Definition of operational conditions typical for sector's uses; information, whether this is part of the work of the associations;
- Development of generic exposure scenarios; information, whether this is part of the work of the associations; indication of cooperation with suppliers organisations to develop GES, if applicable (e.g.: ATIEL/ATC (lubricants and lubricant additives) indicate that they cooperate with suppliers (ESIG/Concawe) and DU associations in the process);
- Description of additional sector-specific standard phrases not yet published, if this is part of the work of the associations – or reference to existing phrases in the BDI/European standard phrases catalogue
- Status of the sector activities (ranging from "non started" until "all actions complete")
- Contact person and link to relevant information (if available).

The table enables downstream users to get a fast overview on mapping activities which are relevant for him.

The CEFIC homepage on libraries (http://www.CEFIC.be/en/reach-for-industries-libraries.html) describes four libraries which are important for the chemical safety assessment and the communication in the supply chains.

- The library on Risk Management Measures (see chapter 6.3, Part I of the practical guide, http://www.cefic.org/files/downloads/RMM%20Library%20.xls). The library is a "Look-up"-Tool which can be used to find appropriate risk management measures for workers and consumers protection as well as options for protection of the environment. The efficiency of the measures can be reviewed. The library documents individual measures as well as packages of operational conditions and risk management measures for specific sectors. In addition it describes integrated risk management measures. The reference part lists available sources which can help to develop risk management measures e.g. COSHH Essentials (http://www.coshh-essentials.org.uk/) and the ILO toolkit (http://www.ilo.org/safework/lang--en/index.htm).
- The European Phrases Catalogue with standard phrases for extended safety data sheets, http://reach.bdi.info/378.htm). The content of this library has been described in Part I of the Practical Guide, chapter 5.2.

- The library of Generic Exposure Scenarios. It will contain the generic exposure scenarios which have been developed by associations of manufacturers and downstream users. The concept of generic exposures scenarios has been described in chapters 9.4 and 9.7). At present (January 2010) these generic exposure scenarios are under development. As soon as they are publicly available, the library will get started.
- The library of Use Descriptor Mapping. This library intends to support the communication of uses up and down the supply chains. It aims to facilitate the consistency between brief general description of uses and short titles in exposure scenarios. Finally the library is foreseen to provide a link between description of uses and Tier 1 exposure estimations. The library should support these activities by making the present work of the industry associations available and transparent.
- The Use Descriptor System has been described in general in chapter 9.3.1. At present in different industries more specific Use (Descriptor) Mapping exercises are under preparation. It is planned that the library of Use Descriptor Mapping with the results of these exercises will be available soon. In the mean time, the overview table described above can be used to get informed about the present state of mapping activities and the results available yet (http://www.cefic.be/files/downloads/Overview_associations_activities_TO_PUBLISH_21012010.xls).

At present, the libraries of Generic Exposure Scenarios and Use (Descriptor) Mapping are not yet available. The overview table described above can be used by downstream users to contact relevant sector associations for more information on GES and mapping.

In order to support the structured dialogue, sector associations should inform CEFIC on their activities in this regard to be included in the next update of the respective libraries (for contact see http://www.CEFIC.be/en/reach-for-industries-libraries.html).

11 References and 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 exposure assessment and supply chain communication.

1. The **Guidance on information requirements and chemical safety assessment** (ECHA 2008a, new versions of specific parts from 2009, 2010) 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). 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

2. The **Guidance for downstream users** (ECHA 2008d (status: January 2008)) (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.

Further guidance is available from European institutions. 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). 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).

CEFIC publishes a number of helpful documents and tools related to REACH tasks on its website “REACH for industries” (http://www.cefic.be/en/REACH-for-industry.html). Several of these documents have already been mentioned in this practical guide (see chapter 10.3)[14]:

[14] Additional documents are available referring to aspects not covered in this practical guide (e.g. Joint submission process in REACH-IT, position on polymers, substance information exchange fora (SIEFs) and related tasks (Guidance on SIEF formation, CEFIC model REACH data sharing agreement, CEFIC model REACH cooperation agreement between SIEF Lead members, CEFIC model SIEF agreement, check-list of SIEF tasks, FAQs on SIEFS, Working together in SIEF).

- the guidance on ES development and supply chain communication (http://CEFIC.org/Files/Publications/Guidance_Use_and_ES_dvlpt_and_SCCm.doc);
- the template for the dialogue in supply chain (http://CEFIC.org/files/Downloads/Final_Template_09_03_09.xls);
- the template for the reporting of uses (http://www.CEFIC.be/Files/Publications/DUCC-Use-and-ES-Mapping-Template-revised-Final15072009.xls);
- the template to perform chemical safety assessments related to workers when preparing specific exposure scenarios (http://cefic.org/Files/Publications/2009-12-11-Cefic-GES-CSA-Worker-Template-Version-01.xls).

12 Glossary

AC	Article category
Article	An object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition
Bottom-Up approach	With regard to the communication in supply chains: the downstream user contacts his suppliers. The counterpart for this is the Top-Down approach.
BREF	Best Available Technique (BAT) Reference Notes
CAD	Chemical Agents Directive 98/24/EC
CLP	EC Regulation 1272/2008 on Classification, Labelling and Packaging; implementation of the Globally Harmonised System (GHS) in Europe
CMR	Carcinogenic, mutagenic and of reproductive toxicity
Conditions of use	Here a distinction is made between operational conditions of use (OCs, see below) and risk management measures (RMMs, see below).
ConsExpo	Model for exposure estimation and risk description for exposures of consumers
COSHH	Control of Substances Hazardous to Health. Approach from Great Britain for the derivation of risk management measures for workplace.
Critical Component	Substance in a mixture which determine the risk management measures and operational conditions necessary for the safe use of the mixture. It is assumed that the risk management measures identified for the lead substances are adequate to control the risks of the other substances in the mixture too. The word “critical component” has been developed within the so-called “Critical Component Approach” for the assessment of mixtures. It has the same meaning as the word “lead substance” developed within the so-called DPD + approach (see Part III, chapter 7.1).

CSA	Chemical safety assessment (see chapter 3, Part I of the practical guide)
CSR	Chemical safety report (see chapter 4, Part I of the practical guide))
DEO	Dermal Exposure Operations
DMEL	Derived Minimal Effect Level. Value used to assess the remaining risk in case of substances without a threshold for toxic effects
DNEL	Derived No-Effect Level
DPD	Dangerous Preparation Directive
DPD+ approach	Approach to identify lead substances in mixtures (which are determining the risk management measures and operational conditions required for a safe use of the mixture) (see Part III, chapter 7.2 of the practical guide).
DUCC	Downstream Users of Chemicals Co-ordination Group
ECETOC-TRA	Model for exposure estimation and risk description ("Targeted Risk Assessment", TRA), developed by ECETOC (see Practical Guide Part IV for description and reference). Exposures of workers, consumers and the environment can be estimated.
EDC	Endocrine disrupting chemical
EMKG	"Einfaches Maßnahmenkonzept Gefahrstoffe". "Easy-to-use workplace control scheme for hazardous substances". Generic model for exposure estimation at the workplace worked out by the BAuA.
ERC	Environmental Release Categories. Categories for describing release of chemical substances into the environment.
ESIG	European Solvents Industry Group
ESVOC	European Solvents Volatile Organic Compounds
EUSES	Generic model for environmental-related exposure assessment.
Exposure	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.
Exposure scenario	REACH art. 3.37: 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.
Generic exposure models	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 Esti-

	mation" 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.
FECC	European Association of Chemical Distributors
GES	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)[15]. The term has been further specified on European level, see chapter 9.7 and annexes A2.9 – A2.11.
GHS	Globally Harmonised System on Classification and Labelling of Chemicals, GHS-UN
Initial exposure scenario	First or tentative exposure scenario
IPPC	Integrated Pollution Prevention Control
Iterative Procedure	Iterativ (lat.): repeating. Process with repetition of individual working steps.
IUCLID 5	IUCLID is the International Uniform Chemical Information Database. More information on http://www.iuclid.eu/. IUCLID 5 is used by REACH registrants to prepare the technical dossier.
Lead substances	Substances in a mixture which determine the risk management measures and operational conditions necessary for the safe use of the mixture. It is assumed that the risk management measures identified for the lead substances are adequate to control the risks of the other substances in the mixture too. Substances can be lead substances because they need an advanced evaluation (e.g. substances classified as carcinogenic class 1 or 2), or they can be identified in a mixture by specific approaches e.g. the DPD+ approach.
Mapping	Process to get an overview on main uses of substances and mixtures in an industrial sector. The Use Descriptor System facilitates a uniform description of uses during mapping activities in different sectors (see chapter 9.3.1).
Mixture	A mixture or solution composed of two or more substances (CLP Regu-

[15] 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".

	lation). This term replaces the term “preparation”.
NACE	Nomenclature Génèrale des Activités dans les Communautés Européenes (French): Classification system of the EU
OCs,	Operational conditions (of use) such as duration and frequency of substance use, application temperature, state of aggregation of the substance (see chapter 6.2, Part I of the practical guide)
PBT substance	Persistent, bioaccumulative and toxic substance
PC	Product category
PEC	Predicted Environmental Concentration
PNEC	Predicted No-Effect Concentration
Preparation	This term has been replaced by the term “mixture”. Mixture or solution composed of two or more substances.
Priority substances	Substances of a mixture which have specific problematic properties (e.g. substances classified as carcinogenic class 1 or 2) and therefore require an advanced evaluation to identify appropriate risk management measures and operational conditions required for a safe use of the mixture. These priority substances are lead substances (see above) for the mixture (see Part III, chapter 7).
PROC	Process category
RCR	Risk Characterisation Ratio
RMM library	Library of risk management measures. Compilation of risk management measures for exposure assessments with data on the efficiency of the measures (http://www.CEFIC.org/files/downloads/RMM%20Library%20.xls 'Individual Measures'!A1).
RMM	Risk management measure (e.g. local exhaust, closed equipment, gloves of a certain specification, instructions and more, see chapter 6.3, Part I of the practical guide).
Scaling	Adapting a given exposure estimation to the situation of an individual downstream user using simple arithmetic operations (see Part I, chapter 7.7).
SES	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.
SU	Sector of use
Substance	A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without effecting the stability of the substance or changing its composition.

SVHC	Substance of very high concern
Scenario (general)	"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.
spERC	Specific environmental release category
Tiered approach	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 (tier 1). In step 2 substantially more detailed information on the conditions of use is utilized for the calculations (tier 2).
Top-Down approach	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.
TWA	Time-weighted average
Use Descriptor System	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.
vPvB substance	very persistent and very bioaccumulative substance.

Supplement "Mixtures under REACH" (Part III)

This part of the practical guide is available as a separate document
(CEFIC: http://cefic.org/templates/shwPublications.asp?HID=750,
VCI: http://www.vci.de/default~cmd~shd~docnr~125022~lastDokNr~102474.htm).

Supplement "Exposure estimation" (Part IV)

This part of the practical guide is available as a separate document
(CEFIC: http://cefic.org/templates/shwPublications.asp?HID=750
VCI: http://www.vci.de/default~cmd~shd~docnr~125022~lastDokNr~102474.htm).

Examples

Examples are available as separate documents.
(VCI: http://www.vci.de/default~cmd~shd~docnr~125022~lastDokNr~102474.htm).

Annexes

A2.1 The Use Descriptor System: Sectors of Uses (SUs)

Note: The following annexes A2.1–A2.5 show elements of the Use Descriptor System, version May 2010. 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 (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

Key descriptor: Main user groups		
SU 3	Industrial uses: Uses of substances as such or in preparations* at industrial sites	
SU 21	Consumer uses: Private households (= general public = consumers)	
SU 22	Professional uses: Public domain (administration, education, entertainment, services, craftsmen)	
Supplementary descriptor: Sectors of end-use		**NACE* codes**
SU1	Agriculture, forestry, fishery	A
SU2a	Mining, (without offshore industries)	B
SU2b	Offshore industries	B 6
SU4	Manufacture of food products	C 10,11
SU5	Manufacture of textiles, leather, fur	C 13-15
SU6a	Manufacture of wood and wood products	C 16
SU6b	Manufacture of pulp, paper and paper products	C 17
SU7	Printing and reproduction of recorded media	C 18
SU8	Manufacture of bulk, large scale chemicals (including petroleum products)	C 19.2+20.1
SU9	Manufacture of fine chemicals	C 20.2-20.6
SU 10	Formulation [mixing] of preparations and/or re-packaging (excluding alloys)	C 20.3-20.5
SU11	Manufacture of rubber products	C 22.1
SU12	Manufacture of plastics products, including compounding and conversion	C 22.2
SU13	Manufacture of other non-metallic mineral products, e.g. plasters, cement	C 23
SU14	Manufacture of basic metals, including alloys	C 24
SU15	Manufacture of fabricated metal products, except machinery and equipment	C 25
SU16	Manufacture of computer, electronic and optical products, electrical equipment	C 26-27
SU17	General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment	C 28-30,33
SU18	Manufacture of furniture	C 31
SU19	Building and construction work	F
SU20	Health services	Q 86
SU23	Electricity, steam, gas water supply and sewage treatment	C 35-37
SU24	Scientific research and development	C72
SU0	Other	
http://ec.europa.eu/comm/competition/mergers/cases/index/nace_all.html		

* *European Commission, Competition: List of NACE Codes (2007.11.19); http://ec.europa.eu/comm/competition/mergers/cases/index/nace_all.html*

***Please note**: This list is not complete with regard to uses potentially to be described under REACH. Describe other uses as appropriate.*

**** Please note**: For the sake of consistency with the descriptor system in IUCLID 5.2, in these lists the term "preparation" has not been replaced by "mixture"*

A2.2 The Use Descriptor System: Products Categories (PCs)

Note: The following annexes A2.2 – A2.5 show elements of the Use Descriptor System, version May 2010. 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 (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

Chemical Product Category (PC)		
Category for describing market sectors (at supply level) regarding all uses (workers and consumers)		**Examples and explanations**
PC1	Adhesives, sealants	
PC2	Adsorbents	
PC3	Air care products	
PC4	Anti-Freeze and de-icing products	
PC7	Base metals and alloys	
PC8	Biocidal products (e.g. Disinfectants, pest control)	PC 35 should be assigned to disinfectants being used as a component in a cleaning product
PC9a	Coatings and paints, thinners, paint removers	
PC9b	Fillers, putties, plasters, modelling clay	
PC9c	Finger paints	
PC11	Explosives	
PC12	Fertilizers	
PC13	Fuels	
PC14	Metal surface treatment products, including galvanic and electroplating products	This covers substances permanently binding with the metal surface
PC15	Non-metal-surface treatment products	Like for example treatment of walls before painting.
PC16	Heat transfer fluids	
PC17	Hydraulic fluids	
PC18	Ink and toners	
PC19	Intermediate	
PC20	Products such as ph-regulators, flocculants, precipitants, neutralization agents	This category covers processing aids used in the chemical industry
PC21	Laboratory chemicals	
PC23	Leather tanning, dye, finishing, impregnation and care products	
PC24	Lubricants, greases, release products	
PC25	Metal working fluids	
PC26	Paper and board dye, finishing and impregnation products: including bleaches and other processing aids	
PC27	Plant protection products	
PC28	Perfumes, fragrances	
PC29	Pharmaceuticals	
PC30	Photo-chemicals	
PC31	Polishes and wax blends	
PC32	Polymer preparations and compounds	

Chemical Product Category (PC)		
Category for describing market sectors (at supply level) regarding all uses (workers and consumers)		**Examples and explanations**
PC33	Semiconductors	
PC34	Textile dyes, finishing and impregnating products; including bleaches and other processing aids	
PC35	Washing and cleaning products (including solvent based products)	
PC36	Water softeners	
PC37	Water treatment chemicals	
PC38	Welding and soldering products (with flux coatings or flux cores.), flux products	
PC39	Cosmetics, personal care products	
PC40	Extraction agents	
PC0	Other (use UCN codes: see last row)	
http://www.rivm.nl/en/healthanddisease/productsafety/ConsExpo.jsp http://195.215.251.229/fmi/xsl/spin/SPIN/guide/menuguide.xsl?-db=spinguide&-lay=overview&-view#		

***Please note**: This list is not complete with regard to uses potentially to be described under REACH. Describe other uses as appropriate.*

*** Please note**: For the sake of consistency with the descriptor system in IUCLID 5.2, in these lists the term "preparation" has not been replaced by "mixture"*

A2.3 The Use Descriptor System: Process Categories (PROCs)

Note: The following annexes A2.3 – A2.5 show elements of the Use Descriptor System, version May 2010. 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 (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

Process categories [PROC]		
Process categories		**Examples and explanations**
PROC1	Use in closed process, no likelihood of exposure	Use of the substances in high integrity contained system where little potential exists for exposures, e.g. any sampling via closed loop systems
PROC2	Use in closed, continuous process with occasional controlled exposure	Continuous process but where the design philosophy is not specifically aimed at minimizing emissions It is not high integrity and occasional expose will arise e.g. through maintenance, sampling and equipment breakages
PROC3	Use in closed batch process (synthesis or formulation)	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. through sampling
PROC4	Use in batch and other process (synthesis) where opportunity for exposure arises	Use in batch manufacture of a chemical where significant opportunity for exposure arises, e.g. during charging, sampling or discharge of material, and when the nature of the design is likely to result in exposure

Process categories [PROC]		
Process categories		**Examples and explanations**
PROC5	Mixing or blending in batch processes for formulation of preparations* and articles (multi-stage and/or significant con-tact)	Manufacture or formulation of chemical products or articles using technologies related to mixing and blending of solid or liquid materials, and where the process is in stages and provides the opportunity for significant con-tact at any stage
PROC6	Calendering operations	Processing of product matrix Calendering at elevated temperature an large exposed surface
PROC7	Industrial spraying	Air dispersive techniques Spraying for surface coating, adhesives, polishes/ cleaners, air care products, sandblasting Substances can be inhaled as aerosols. The energy of the aerosol particles may require advanced exposure controls; in case of coating, overspray may lead to waste water and waste.
PROC8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	Sampling, loading, filling, transfer, dumping, bagging in non-dedicated facilities. Exposure related to dust, vapour, aerosols or spillage, and cleaning of equipment to be expected.
PROC8b	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	Sampling, loading, filling, transfer, dumping, bagging in dedicated facilities. Exposure related to dust, vapour, aerosols or spillage, and cleaning of equipment to be expected.
PROC9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	Filling lines specifically designed to both capture vapour and aerosol emissions and minimise spillage
PROC10	Roller application or brushing	Low energy spreading of e.g. coatings Including cleaning of surfaces. Substance can be inhaled as vapours, skin contact can occur through droplets, splashes, working with wipes and handling of treated surfaces.
PROC11	Non industrial spraying	Air dispersive techniques Spraying for surface coating, adhesives, polishes/ cleaners, air care products, sandblasting Substances can be inhaled as aerosols. The energy of the aerosol particles may require advanced exposure controls.
PROC12	Use of blowing agents in manufacture of foam	
PROC13	Treatment of articles by dipping and pouring	Immersion operations Treatment of articles by dipping, pouring, immersing, soaking, washing out or washing in substances; including cold formation or resin type matrix. Includes handling of treated objects (e.g. after dying, plating,). Substance is applied to a surface by low energy techniques such as dipping the article into a bath or pouring a preparation onto a surface.
PROC14	Production of preparations* or articles by tabletting, compression, extrusion, pelletisation	Processing of preparations and/or substances (liquid and solid) into preparations or articles. Substances in the chemical matrix may be exposed to elevated mechanical and/or thermal energy conditions. Exposure is predominantly related to volatiles and/or generated fumes, dust may be formed as well.
PROC15	Use as laboratory reagent	Use of substances at small scale laboratory (< 1 l or 1 kg present at workplace). Larger laboratories and R+D installations should be treated as industrial processes.

Process categories [PROC]		
Process categories		**Examples and explanations**
PROC16	Using material as fuel sources, limited exposure to unburned product to be expected	Covers the use of material as fuel sources (including additives) where limited exposure to the product in its unburned form is expected. Does not cover exposure as a consequence of spillage or combustion.
PROC17	Lubrication at high energy conditions and in partly open process	Lubrication at high energy conditions (temperature, friction) between moving parts and substance; significant part of process is open to workers. The metal working fluid may form aerosols or fumes due to rapidly moving metal parts.
PROC18	Greasing at high energy conditions	Use as lubricant where significant energy or temperature is applied between the substance and the moving parts
PROC19	Hand-mixing with intimate contact and only PPE available	Addresses occupations where intimate and intentional contact with substances occurs without any specific exposure controls other than PPE.
PROC20	Heat and pressure transfer fluids in dispersive, professional use but closed systems	Motor and engine oils, brake fluids Also in these applications, the lubricant may be exposed to high energy conditions and chemical reactions may take place during use. Exhausted fluids need to be disposed of as waste. Repair and maintenance may lead to skin contact.
PROC21	Low energy manipulation of substances bound in materials and/or articles	Manual cutting, cold rolling or assembly/disassembly of material/article (including metals in massive form), possibly resulting in the release of fibres, metal fumes or dust
PROC22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting	Activities at smelters, furnaces, refineries, coke ovens. Exposure related to dust and fumes to be expected. Emission from direct cooling may be relevant.
PROC23	Open processing and transfer operations with minerals/metals at elevated temperature	Sand and die casting, tapping and casting melted solids, drossing of melted solids, hot dip galvanising, raking of melted solids in paving Exposure related to dust and fumes to be expected
PROC24	High (mechanical) energy work-up of substances bound in materials and/or articles	Substantial thermal or kinetic energy applied to substance (including metals in massive form) by hot rolling/forming, grinding, mechanical cutting, drilling or sanding. Exposure is predominantly expected to be to dust. Dust or aerosol emission as result of direct cooling may be expected.
PROC25	Other hot work operations with metals	Welding, soldering, gouging, brazing, flame cutting Exposure is predominantly expected to fumes and gases.
PROC26	Handling of solid inorganic substances at ambient temperature	Transfer and handling of ores, concentrates, raw metal oxides and scrap; packaging, un-packaging, mixing/blending and weighing of metal powders or other minerals*
PROC27a	Production of metal powders (hot processes)	Production of metal powders by hot metallurgical processes (atomisation, dry dispersion)*
PROC27b	Production of metal powders (wet processes)	Production of metal powders by wet metallurgical processes (electrolysis, wet dispersion)*

** no corresponding TRA entry*

***Please note**: This list is not complete with regard to uses potentially to be described under REACH. Describe other uses as appropriate.*

**** Please note**: For the sake of consistency with the descriptor system in IUCLID 5.2, in these lists the term "preparation" has not been replaced by "mixture".*

A2.4 The Use Descriptor System: Article Categories (ACs))

Note: The following annexes A2.4–A2.5 show elements of the Use Descriptor System, version May 2010. 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 (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

Article categories (and non exhaustive examples) for describing the type of article in which the substance is contained during service life and waste life	
Categories of complex articles	
AC1	Vehicles
	Examples: Trucks, passenger cars and motor cycles, bicycles, tricycles and associated transport equipment; other vehicles: Railway, aircraft, vessels, boats
AC2	Machinery, mechanical appliances, electrical/electronic articles
	Examples: Machinery and mechanical appliances; electrical and electronic articles, e.g. computers, video and audio recording, communication equipment; lamps and lightening; cameras; refrigerator, dish washer, washing machines
AC3	Electrical batteries and accumulators
Categories of material based articles	
AC4	Stone, plaster, cement, glass and ceramic articles
	Examples: Glass and ceramic article: e.g. dinner ware, drinking glasses, pots, pans, food storage containers; construction and isolation articles; natural or artificial abrasive powder or grain, on a base of textile material, of paper, of paperboard or of other materials
AC5	Fabrics, textiles and apparel
	Examples: Clothing, bedding, mattress, curtains, upholstery, carpeting/flooring, car seats, textile toys
AC6	Leather articles
	Examples: Gloves, purse, wallet, foot wear, furniture
AC7	Metal articles
	Examples: Cutlery, cooking utensils, pots, pans, jewellery, toys, furniture, construction articles
AC8	Paper articles
	Examples: Paper articles: tissue, towels, disposable dinnerware, nappies, feminine hygiene products, adult incontinence products; paper articles for writing, office pa-per; printed paper articles: e.g. newspapers, books, magazines, printed photographs; wallpaper
AC10	Rubber articles
	Examples: Tyres, flooring, gloves, footwear, toys
AC11	Wood articles
	Examples: Flooring, walls, furniture, toys, construction articles
AC13	Plastic articles
	Examples: Plastic dinner ware, food storage, food packaging, baby bottles; flooring, toys, furniture, small plastic articles of daily use e.g. ball pen, PC, mobile phone construction articles
	Other (use TARIC codes: see last row)
	http://ec.europa.eu/taxation_customs/dds/tarhome_en.htm

***Please note**: This list is not complete with regard to uses potentially to be described under REACH. Describe other uses as appropriate.*

Use descriptor for articles with intended release of substances	
Descriptor based on an indicative list of examples	
AC30	Other articles with intended release of substances, please specify*
AC31	Scented clothes
AC32	Scented eraser
AC33	*Entry has been removed after the REACH CA meeting in March 2008*
AC34	Scented Toys
AC35	Scented paper articles
AC36	Scented CD
AC38	Packaging material for metal parts, releasing grease/corrosion inhibitors

* *See previous footnote; please note that articles could also be relevant for occupational exposure, in particular with regard to abrasive processes (see PROC 21 and 24) and hot work operations (PROC 25). Electrodes for welding and soldering are listed under PC 38 as a preparation.*

***Please note**: This list is not complete with regard to uses potentially to be described under REACH. Describe other uses as appropriate.*

A2.5 The Environmental Release Categories (ERCs)

Note: This annex documents the Environmental Release Categories of the Use Descriptor System, version May 2010. 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 (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf).

The Environmental Release Categories 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, 12 classes are distinguished. Some of them are divided in subcategories.

Examples are:

- ERC 1: Manufacture of substances;
- ERC 6A: Industrial use resulting in manufacture of another substance (use of intermediates);
- ERC 9A: Wide dispersive indoor use of substances in closed systems;
- ERC 11B: Wide dispersive indoor use of long-life articles and materials with high or intended release (including abrasive processing)

For each Environmental Release Category 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, p. 121).

ERC NUMBER	Name	Description for Environmental Release Categories (ERC)
ERC1	Manufacture of substances	Manufacture of organic and inorganic substances in chemical, petrochemical, primary metals and minerals industry including intermediates, monomers using continuous processes or batch processes applying dedicated or multi-purpose equipment, either technically controlled or operated by manual interventions
ERC2	Formulation of preparations*	Mixing and blending of substances into (chemical) preparations in all types of formulating industries, such as paints and do-it-yourself products, pigment paste, fuels, household products (cleaning products), lubricants, etc.
ERC3	Formulation in materials	Mixing or blending of substances which will be physically or chemically bound into or onto a matrix (material) such as plastics additives in master batches or plastic compounds. For in-stance a plasticizers or stabilizers in PVC master-batches or products, crystal growth regulator in photographic films, etc.
ERC4	Industrial use of processing aids in processes and products, not becoming part of articles	Industrial use of processing aids in continuous processes or batch processes applying dedicated or multi-purpose equipment, either technically controlled or operated by manual interventions. For example, solvents used in chemical reactions or the 'use' of solvents during the application of paints, lubricants in metal working fluids, anti-set off agents in polymer moulding/casting.
ERC5	Industrial use resulting in inclusion into or onto a matrix	Industrial use of substances as such or in preparations (non-processing aids), which will be physically or chemically bound into or onto a matrix (material) such as binding agent in paints and coatings or adhesives, dyes in textile fabrics and leather products, metals in coatings applied through plating and galvanizing processes. The category covers substances in articles with a particular function and also substances remaining in the article after having been used as processing aid in an earlier life cycle stage (e.g. heat stabilisers in plastic processing).
ERC6a	Industrial use resulting in manufacture of another substance (use of intermediates)	Use of intermediates in primarily the chemical industry using continuous processes or batch processes applying dedicated or multi-purpose equipment, either technically controlled or operated by manual interventions, for the synthesis (manufacture) of other substances. For instance the use of chemical building blocks (feedstock) in the synthesis of agrochemicals, pharmaceuticals, monomers, etc.
ERC6b	Industrial use of reactive processing aids	Industrial use of reactive processing aids in continuous processes or batch processes applying dedicated or multi-purpose equipment, either technically controlled or operated by manual interventions. For example the use of bleaching agents in the paper industry.
ERC6c	Industrial use of monomers for manufacture of thermoplastics	Industrial use of monomers in the production of polymers, plastics (thermoplastics), polymerization processes. For example the use of vinyl chloride monomer in the production of PVC.
ERC6d	Industrial use of process regulators for polymerisation processes in production of resins, rubbers, polymers	Industrial use of chemicals (cross-linking agents, curing agents) in the production of thermosets and rubbers, polymer process-ing. For instance the use of styrene in polyester production or vulcanization agents in the production of rubbers.

ERC7	Industrial use of substances in closed systems	Industrial use of substances in closed systems. Use in closed equipment, such as the use of liquids in hydraulic systems, cooling liquids in refrigerators and lubricants in engines and dielectric fluids in electric transformers and oil in heat exchangers. No intended contact between functional fluids and products foreseen, and thus low emissions via waste water and waste air to be expected.
ERC8a	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/sewage system, 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.
ERC8b	Wide dispersive indoor use of reactive substances in open systems	Indoor use of reactive substances by the public at large or professional use. Use (usually) results in direct release into the environment, for example, sodium hypochlorite in lavatory cleaners, bleaching agents in fabric washing products, hydro-gen peroxide in dental care products.
ERC8c	Wide dispersive indoor use resulting in inclusion into or onto a matrix	Indoor use of substances (non-processing aids) by the public at large or professional use, which will be physically or chemically bound into or onto a matrix (material) such as binding agent in paints and coatings or adhesives, dyeing of textile fabrics.
ERC8d	Wide dispersive outdoor use of processing aids in open systems	Outdoor use of processing aids by the public at large or professional use. Use (usually) results in direct release into the environment, for example, automotive and bicycle care products (polishes, lubricants, de-icers, detergents), solvents in paints and adhesives.
ERC8e	Wide dispersive outdoor use of reactive substances in open systems	Outdoor use of reactive substances by the public at large or professional use. Use (usually) results in direct release into the environment, for example, the use of sodium hypochlorite or hydrogen peroxide for surface cleaning (building materials)
ERC8f	Wide dispersive outdoor use resulting in inclusion into or onto a matrix	Outdoor use of substances (non-processing aids) by the public at large or professional use, which will be physically or chemically bound into or onto a matrix (material) such as binding agent in paints and coatings or adhesives.
ERC9a	Wide dispersive indoor use of substances in closed systems	Indoor use of substances by the public at large or professional (small scale) use in closed systems. Use in closed equipment, such as the use of cooling liquids in refrigerators, oil-based electric heaters.
ERC9b	Wide dispersive outdoor use of substances in closed systems	Outdoor use of substances by the public at large or professional (small scale) use in closed systems. Use in closed equipment, such as the use of hydraulic liquids in automotive suspension, lubricants in motor oil and break fluids in automotive brake systems.
ERC10a	Wide dispersive outdoor use of long-life articles and materials with low release	Low release of substances included into or onto articles and materials during their service life in outdoor use, such as metal, wooden and plastic construction and building materials (gutters, drains, frames, etc.)
ERC10b	Wide dispersive outdoor use of long-life articles and materials with high or intended release (including abrasive processing)	Substances included into or onto articles and materials with high or intended release during their service life from outdoor use. Such as tyres, treated wooden products, treated textile and fabric like sun blinds and parasols and furniture, zinc anodes in commercial shipping and pleasure craft, and brake pads in trucks or cars. This also includes releases from the article matrix as a result of processing by workers. These are processes typically related to PROC 21, 24, 25, for example: Sanding of buildings (bridges, facades) or vehicles (ships).

ERC11a	Wide dispersive indoor use of long-life articles and materials with low release	Low release of substances included into or onto articles and materials during their service life from indoor use. For example, flooring, furniture, toys, construction materials, curtains, foot-wear, leather products, paper and cardboard products (magazines, books, news paper and packaging paper), electronic equipment (casing).
ERC11b	Wide dispersive indoor use of long-life articles and materials with high or intended release (including abrasive processing)	Substances included into or onto articles and materials with high or intended release during their service life from indoor use. For example: release from fabrics, textiles (clothing, floor rugs) during washing. This also includes releases from the article matrix as a result of processing by workers. These are processes typically related to PROC 21, 24, 25. For example removal of indoor paints.
ERC12a	Industrial processing of articles with abrasive techniques (low release)	Substances included into or onto articles and materials are released (intended or not) from the article matrix as a result of processing by workers. These processes are typically related to PROC 21, 24, 25. Processes where the removal of material is intended, but the expected release remains low, include for example: cutting of textile, cutting, machining or grinding of metal or polymers in engineering industries.
ERC12b	Industrial processing of articles with abrasive techniques (high release)	Substances included into or onto articles and materials are released (intended or not) from/with the article matrix as a result of processing by workers. These processes are typically related to PROC 21, 24, 25. Processes where the removal of material is intended, and high amounts of dust may be expected, includes for example: sanding operations or paint stripping by shot-blasting.
	Other environmental characteristics; please specify	

***Please note**: This list is not complete with regard to uses potentially to be described under REACH. Describe other uses as appropriate.*

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A2.6 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 (optional)
14. Document ES

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*

A2.7 Determinants of exposure

When a substance or a mixture is used, several factors influence whether exposures arise and to which extend. These factors are called "determinants of exposure". The following table shows important determinants of exposure influencing the release of substance and the related exposures.

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

Determinants of exposure	Examples (not exhaustive)	Remarks
Substance characteristics		
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
Characteristics of processes and products		
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 mixtures 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;
Characteristics of surrounding		
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

A2.8 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_{biol}		**40%**		**40%**		%
1b	**Adsorption on sewage sludge**	F_{ads}		**0%**		**0%**		%
2	**Emitted fraction (not fixed)**	F_{nfix}		**30%**		**30%**		%
3	**Concentration of substance in the mixture**	C_{stoff}		**45%**		**45%**		%
4	**Effectiveness of additional risk management measures**	Red_{min}		**0%**		**90%**		
5	**Amount of product used per day**	Q_{THM}		122,0		**85**		kg/d
	Amount of substance per day	Q_{stoff}	C_{stoff} x Q_{THM}	**54,9**				kd/d
6	**Receiving water volume**	Q_{wasser}	$Q_{klär}$ + Q_{vorfl}	20.000		10.000		m3/d
	Water volume STP per day	$Q_{klär}$		**2.000**		**2.000**		m3/d
	Receiving river, volume per day	Q_{vorfl}		**18.000**		**8.000**		m3/d
	PEC			**494**	OK	**69**	OK	**µg/l**
	PNEC		**500**					
	Less than 12 applications/year?		PNEC * 10	**PEC/PNEC =**	**1,0**	**PEC/PNEC =**	**0,1**	

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

Figure A.1-0 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 A.10 above)
- 90% of the emitted fraction in the wastewater is are 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 m3/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[16].

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.

[16] 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.

A2.9 The approach of Generic Exposure Scenarios (GES)

Generic exposure scenarios (GESs) are broad exposure scenarios. They describe exposure scenarios for substances and/or mixtures or groups of substances and mixtures 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 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 "workers exposure estimation" in Part IV of the 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 A1 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 mixtures for which the substance will be used.

Table A1 Description of the range of validity ("Application domain", "range of application") of generic exposure scenarios for the example of solvents. Source: Chris Money 2008.

Validity Domain	Typically Characterised by	Typical Substance/mixtures Not Covered
Human Health		
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 Part II, chapter 9.6 of the practical guide. The eight main steps in the development of generic exposure scenarios are shown in the following figure A1. (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 3.4.2, Part I of the practical guide)).

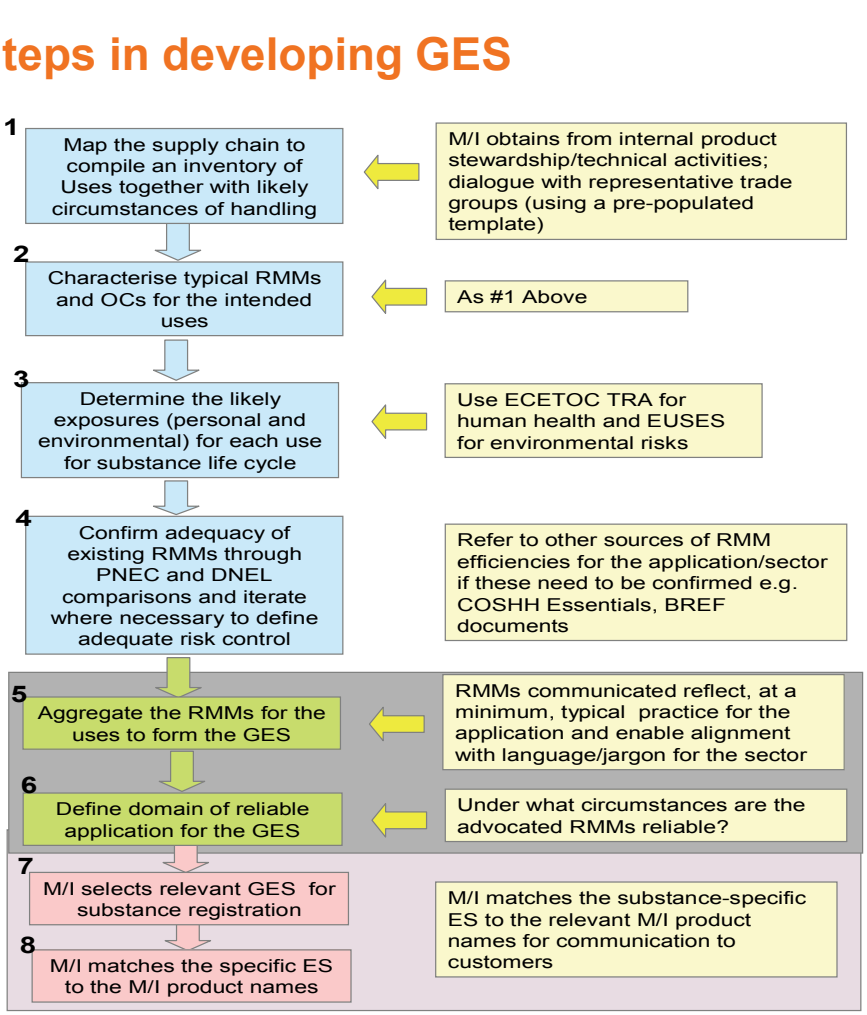

Figure A1 Main steps for the development of generic exposure scenarios. Source: Presentation of Chris Money, CEFIC, 1 August 2008

Table A2 Core considerations for the development and application of Generic Exposure Scenarios

Step	What	How
I. Map substance applications and characterise exposures through the supply chain – action by M/I organisations with support from DU organisations		
1	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. Identify the relevant Sector of Use (Reach Use Descriptor 1) for each life cycle stage, keeping the Sector as general as possible	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. For each application, opportunities for exposure are identified covering each lifecycle stage of the supply chain. Identify relevant Downstream User Associations to assist with verifying the mapping exercise
2	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. Map each Use involving potential for exposure to the relevant REACH Use Descriptor: Worker – Process Categories (PROC) Consumer – Product Categories (PC)/Article Categories (AC) Environment – Environmental Release Categories (ERC) or equivalent Review with relevant DU Organisation.	Use table 1 of the standardized mapping Microsoft Excel®-based spreadsheet format template. Separate templates are available for worker, consumer and environment. 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. See examples given in chapter 5.1.
II. Evaluate risk and document the Chemical Safety Assessment – action by M/I organizations with support from DU organisations		
3	Carry out exposure estimates for workers, consumers and/or the environment for each identified Use included within the mapping exercise. Consider relevant routes of human exposure (inhalation, skin, oral) or environmental emission (air, water, land/sediment).	Estimate/predict exposures using available Tier 1 modelling tools, e.g. ECETOC TRA. Identify OCs/RMMs applied to modify the Tier 1 estimates Document results using table 2 of the standardized Microsoft Excel®-based spreadsheet format template for worker, consumer or environment. Divide analysis according to relevant health and environmental ranges, e.g. volatility or dustiness, log KOW
4	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. 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	Compare the exposure estimates for the relevant volatility or dustiness ranges with relevant DNELs and/or PNECs. 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. 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

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

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

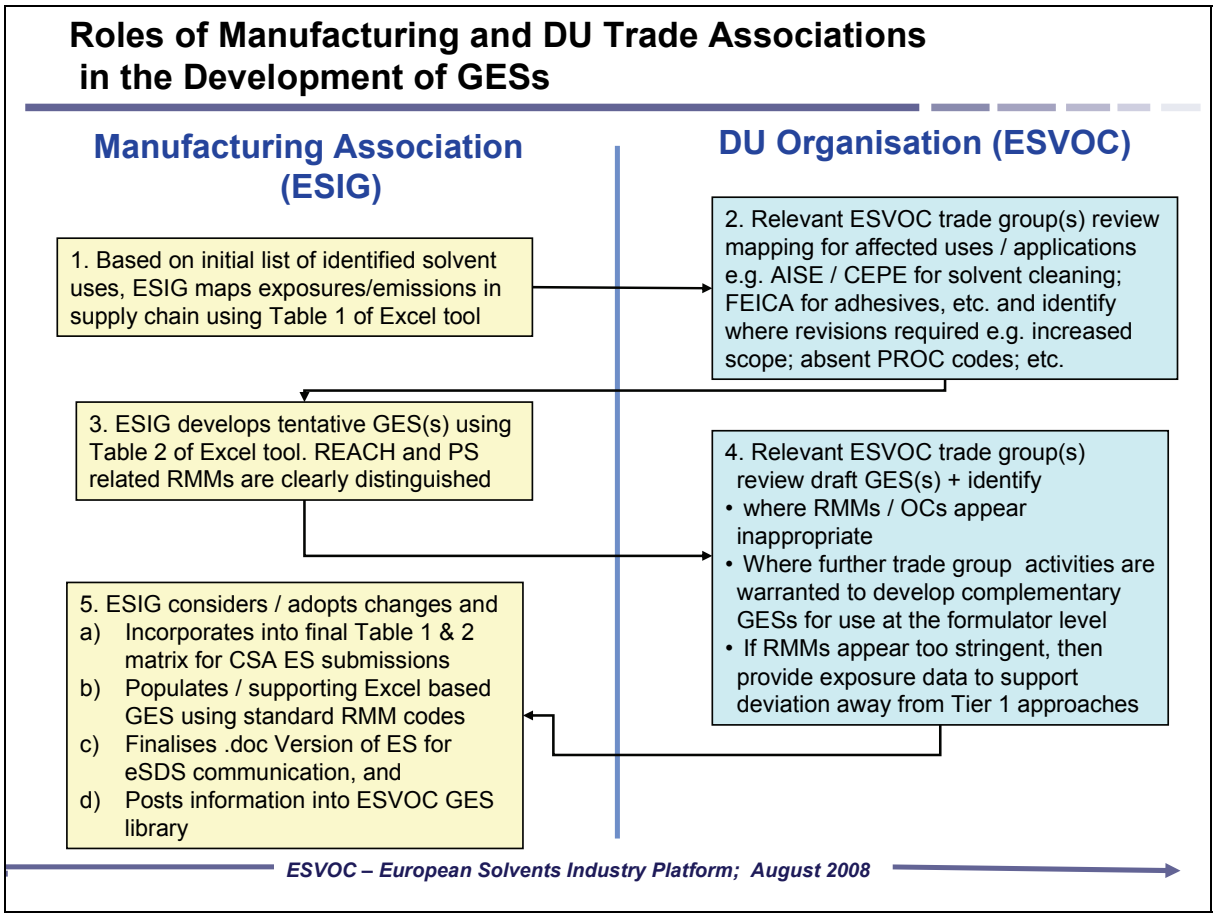

Figure A2 Steps and course of co-operation between manufacturer and user associations for the development of generic exposure scenarios. Source: Presentation of Chris Money, CEFIC, 1 August 2008

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 annex A2.11 of the Practical Guide.

Recently CEFIC published the **GES CSA Workers Template** which supports the development of generic exposure scenarios. It is described in chapters 9.7 and 10.3.

A2.10 The approach of Specific Exposure Scenarios (SES)

The following annex describes the development of specific exposure scenarios. It has been taken from the CEFIC publication. A short introduction into this approach has been given in chapter 9.7 of the Practical Guide.

Specific exposure scenarios (SESs) describe a specific use of a defined substance handled under specific conditions. 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 more detailed 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 A3).

CEFIC Dialogue Template for SES Building (version 1.0 - 6 March 2009)

No.	Information item	Available options (plus explanatory notes)	Proposed ES1 (to be completed by MI)	Deviation from proposed ES1 (to be completed by DU)
0	Product Identification			
0.1	Product name as it appears on SDS	Free text		
1	Short title exposure scenario			
1.1	Internal name	Free text		
1.2	Sector(s) of Use (SU)	Listing [full description in glossary in line below] multiple SU per ES possible. Please list as: SU 1, SU 3, …		
Glossary:				
1.3	Process Category(ies) (PROC)	Selection [full description in glossary in line below]		
Glossary:				
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). (PC)	Selection (preferably use descriptors from dropdown list without an "n" after the PC_no. allowing the consideration of process subcategories in consumer risk assessments) [full description in glossary in line below]		
Glossary:				
1.4.2	Article Category(ies). (AC)	Selection (preferably use descriptors from dropdown list without an "n" after the AC no. allowing the consideration of article subcategories in consumer risk assessments) [full description in glossary in line below]		
Glossary:				
1.5	Environmental Release Category(ies) (ERC)	Selection [full description in glossary in line below]		
Gloss.:				
2	Processes and activities			
2.1	Life Cycle Stage	Selection		
2.2	Optional: Provide additional information on processes and activities if needed	Free text		
2.3	Max. process temperature.	Ambient temperature [°C] (default = 20 °C)		
3	Human health - Workers			
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:		
3.3.2	Dustiness category for solid substances.	In case of a solid (powder): select one of the dustiness options.		
3.4	Max. duration of inhalatory exposure.	Explanation on exposure duration > 4 h: equals less than 8 hours 1 h - 4 h: equals less than 4 hours 15 min - 1 h: equals less than 1 hour < 15 min (short term)		
3.5	Outdoor or indoor operation and application of Local Exhaust Ventilation (LEV)	"outdoor" will assume 30% reduction of exposure compared to indoor without LEV, for indoor please specify whether LEV is used:		

Figure A3 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 A4 and further explained below.

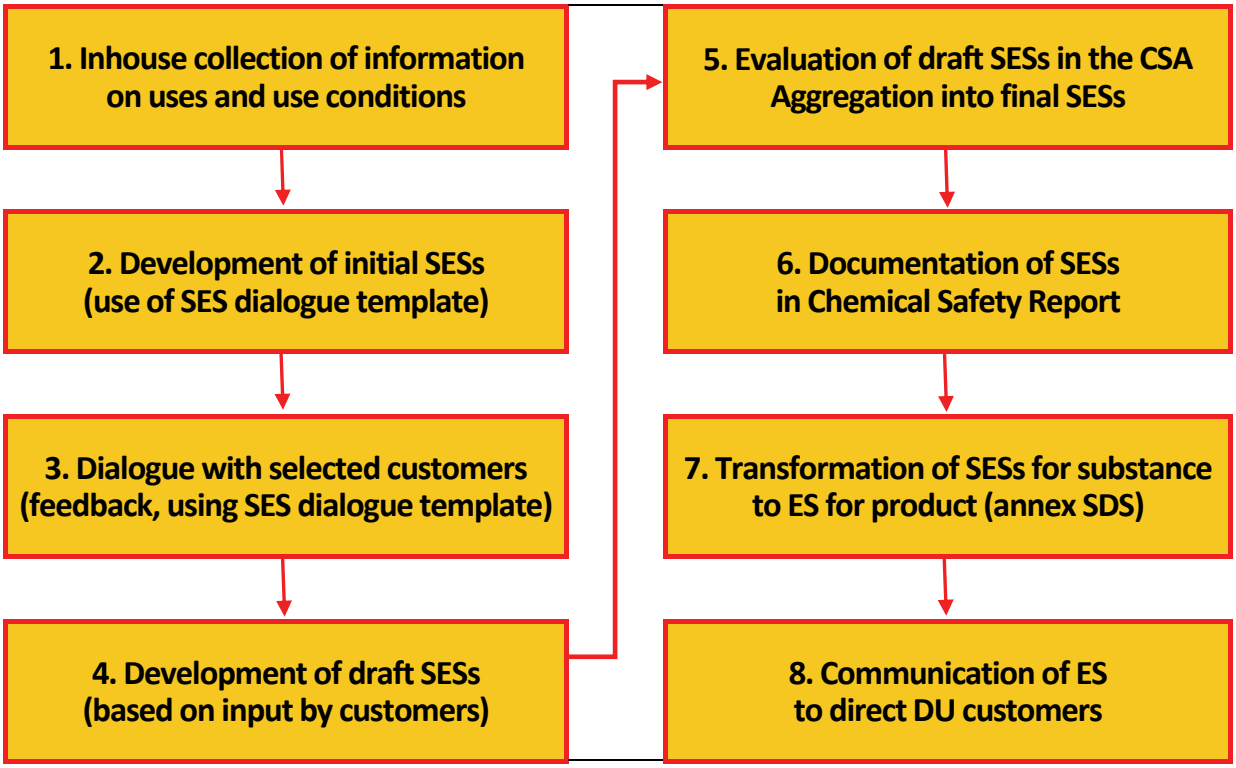

Figure A4 Steps in the Specific Exposure Scenario development process

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 A4). 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.

A2.11 Example of a generic exposure scenario (ESIG/ESVOG)

The following example of a generic exposure scenario was made available by Chris Money. 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 mixtures 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 mixture into small containers; PROC9 Transfer of substance or mixture 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	Human health Assumes use of IPA at not > 20°C above ambient Assumes a good basic standard of occupational hygiene[17] has been implemented Environment 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^3/d.
Risk management measures	Human health - *Pouring from small containers*: undertake in a well-ventilated area (E50). Wear suitable gloves (type EN374, code FJ) if skin contact likely (PPE15). - *Spraying*: 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). - *Manual applications* 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). - *Equipment clean-down*: 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). Environment - 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	**Worker RCR <1;** 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^2/day to areas of unprotected skin resulting from manual spray, roller or brush activities. Values estimated using ECETOC TRA[18]. **Environment RCR<1;** 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.

[17] 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)

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

A2.12 The CEFIC / DUCC / FECC approach for communication in the supply chains

The following figure A5 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.

In the meantime, experience has been gained with the approach. This is described in chapter 10.1. Information on additional tools for the supply chain communication are given in chapter 10.3.

In December 2009 CEFIC published the **GES CSA Workers Template** which supports the development of generic exposure scenarios. It is described in chapters 9.7 and 10.3.

The 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.

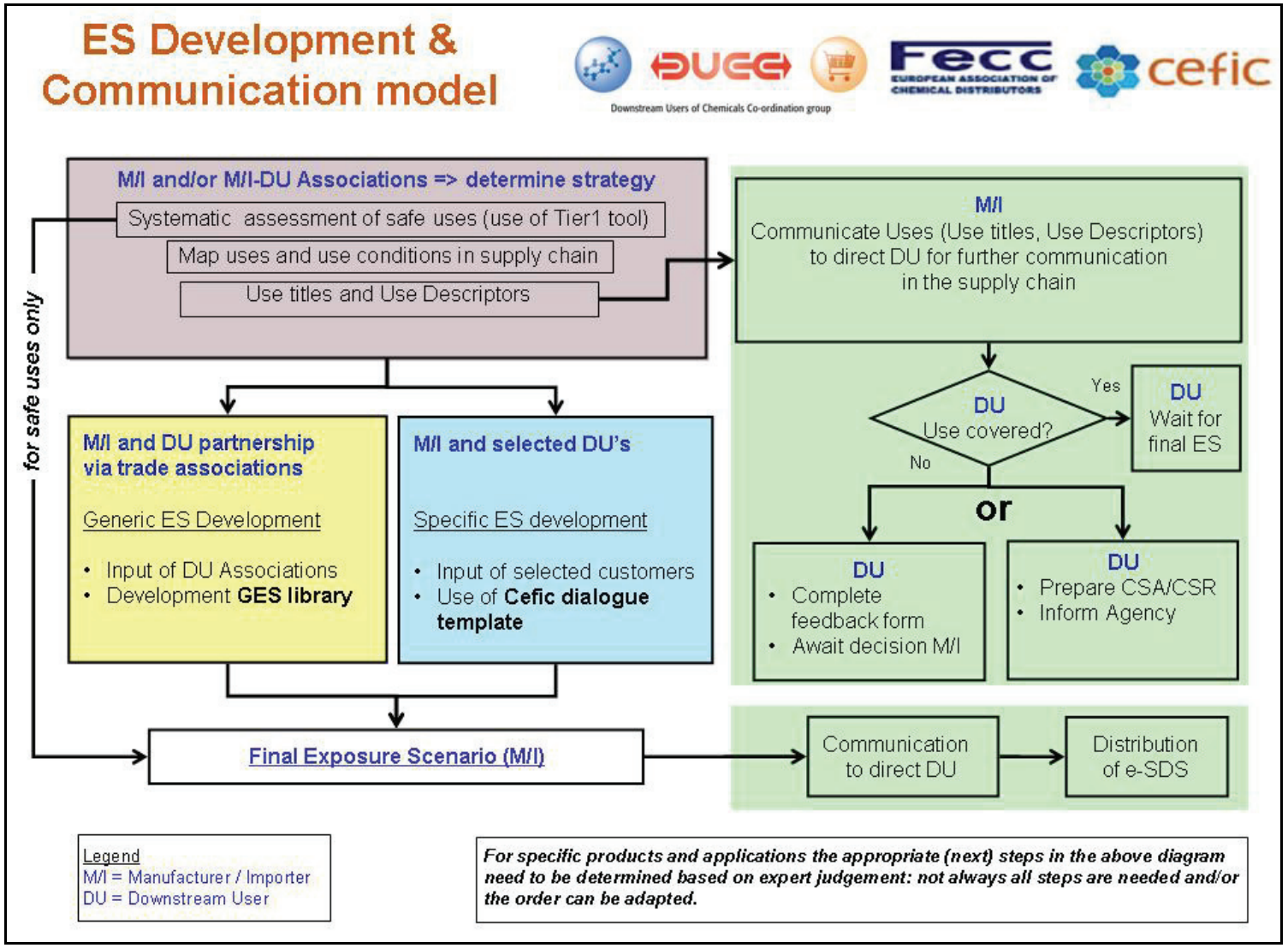

Figure A5 Flow chart for communication on uses in the supply chains.

A2.13 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 **U**se and **E**xposure **C**ategories). 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 A3 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 A3 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 mixture 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 mixture: 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 mixture, 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 mixtures, the technical language used in the matrix is often very difficult to understand.[19] Thus the matrix is not required in sector-specific safety data sheets for users of mixtures.

A2.14 Exposure scenario – Acetonitrile

1. Title

Reference number:	ACN1
Free short title:	Use in chemical synthesis and analytical laboratories
Systematic title based on use descriptor:	Exposure scenario covering the following activities SU: 3, 22 PROC: 1, 2, 3, 8a, 15 ERC: 1, 2, 4, 6a, 6b, 7, 8a
Processes, tasks activities covered:	See chapter 2
Assessment Method:	ECETOC TRA 2 (dermal and inhalative exposure) EUSES 2.0.3

[19] 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.

2. Operational conditions and risk management measures

The following activities results in an acceptable exposure if individually performed by an industrial/professional worker and considering the operational conditions and the risk management measures.

PROC	Frequency and duration of work	LEV [efficiency %]
PROC 1: Use in closed process, no likelihood of exposure, Industrial setting	daily, > 4 h	no LEV
PROC 2: Use in closed, continuous process with occasional controlled exposure (e.g. sampling), Industrial setting	daily, > 4 ho	90
PROC 3: Use in closed batch process (synthesis or formulation), Industrial setting	daily, > 4 h	90
PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non dedicated facilities	daily, 1 - 4 h	90
PROC 15: Use a laboratory reagent, Non-industrial setting	daily, > 4 h	90

The following environmental release categories (ERC's) result in the M-Safes presented below. M-Safe describes the amount of substance that can be daily used under the conditions displayed.

ERC	STP	Release to air [%]	Release to water from process [%]	Dilution to be applied for PEC derivation*	M-Safe [kg]**
ERC 1: Manufacture of chemicals	yes	5	6	10	2000
ERC 2: Formulation of preparations	yes	2.5	2	10	6000
ERC 4: Industrial use of processing aids	yes	100	100	10	120
ERC 6a: Industrial use of intermediate	yes	5	2	10	6000
ERC 6b: Industrial use of reactive processing aids	yes	0.1	5	10	2400
ERC 7: Industrial use substances in closed systems	yes	5	5	10	2400
ERC 8a: Wide dispersive indoor use of processing aids in open systems	yes	100	100	10	120

* STP effluent discharge = 2000 m^3/day; Flow rate of effluent receiving river = 18000 m^3/day
** M-Safe = 120 kg / Release to water from process [%] * 100

2.1 Control of workers exposure

Product characteristic
The substance is a liquid.

Amounts used
Not relevant for human health risk assessment.

Frequency and duration of use/exposure
See above.

Human factors not influenced by risk management
Not relevant.

Other given operational conditions affecting workers exposure
The work is usually performed indoors, see above.

Technical conditions and measures at process level (source) to prevent release
Please refer to the description of the activity.

Technical conditions and measures to control dispersion from source towards the worker
See above.

Organisational measures to prevent /limit releases, dispersion and exposure
Do not inhale vapours/aerosols; take up with absorbent material (e.g. Chemizorb®). Forward for disposal. Clean up affected area.

Conditions and measures related to personal protection, hygiene and health evaluation
Personal protection should be worn as given in Section 8 of the SDS.

2.2 Control of environmental exposure

Product characteristics
The substance is a liquid.

Amounts used
The amounts used in specific situations should be below or equal the above reported M-Safe figures for the respective ERCs. If local emission fractions differ from those of the respective ERCs M-Safes can be re-calculated (see equation below table).

Frequency and duration of use
Continuous use/release possible.

Environment factors not influenced by risk management
Not relevant.

Other given operational conditions affecting environmental exposure
The work is usually performed indoors, see above.

Technical conditions and measures at process level (source) to prevent release
See above.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil
Not relevant.

Organizational measures to prevent/limit release from site
Do not allow to directly enter sewer system; take up with liquid-absorbent material (e.g. Chemizorb®). Forward for disposal. Clean up affected area.

Conditions and measures related to municipal sewage treatment plant
Not relevant.

Conditions and measures related to external treatment of waste for disposal
Not relevant.

Conditions and measures related to external recovery of waste
Not relevant.

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3. Exposure estimation and reference to its source

The human health risk assessment and the environmental risk assessment were performed using the data and the concepts of ECETOC TRA v2.0. For details of the assessments please go to www.merck-supa-dupa-tool.de.

PROC	RCR_{inhal}	RCR_{dermal}	$RCR_{inhal+dermal}$
PROC 1	0,00	0,03	0,03
PROC 2	0,25	0,01	0,26
PROC 3	0,50	0,00	0,50
PROC 8a	0,75	0,01	0,76
PROC 15	0,25	0,00	0,25

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

   The DU is advised to check the operational conditions and the risk management measures described above. Please note that the worker activities (PROC) are individually calculated, i.e. that if a DU intends to perform a combination of activities/PROC he has to estimate the exposure resulting from the combination. This can be done by using the tool provided at the web address indicated above.

Additional good practice advice beyond the REACH CSA

Note: The measures reported in this section have not been taken into account in the exposure estimates related to the exposure scenario above. They are not subject to obligation laid down in Article 37 (4) of REACH, Thus, the downstream user is not obliged to i) carry out an own CSA and ii) to notify the use to the Agency, if he does not implement these measures.

Use specific measures expected to reduce the predicted exposure beyond the level estimated based on the exposure scenario.

A2.15 Exposure scenario – Mixture "Lederplex 900"

The complete extended safety data sheet for the mixture "Lederplex 900" is available as a separate document

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

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 mixtures 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.

Operational conditions of use		
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 mixture considered (section 4.3.1) under the application conditions specified in section 5, the maximal quantity of product permissible per 1.000 m3 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 m3, with rare application: 41 kg/day per 1.000 m3
5	Further application conditions, which affect the exposure	- consumption (dependent on the process conditions temp., pH value, time, dosage among other things): min. 70% - Wastewater treatment measures: Purification plant (biol., chem., mechanical). - Receiving quantity of water: 1,000 m3/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.
Risk management measures for the individual target groups		
6.1	Industrial safety	Respiratory protection: provide for good ventilation Hand protection: wear suitable protective gloves (Nitrile, Level 2 > 30 min, Material thickness 11 mm / Nitrile, Level 6 > 480 min, Material thickness 0,5 mm Eye protection: tightly closing eye protector Body protection: Work clothes
6.2	Consumer protection	Consumer protection: no special measures necessary for handling the leather product
6.3	Environmental protection	Environmental protection, wastewater: Determine maximum consumption with good process control (temperature, concentration, pH value, time/control of the consumption, e.g. CSB. Do not permit uncontrolled entry in the wastewater or into the environment; Mechanical, chemical and biological wastewater pre-treatment. 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. Environmental protection, exhaust air: to expect only light exposure. Environmental protection, soil: Procedure control, avoidance of leakages and spilling the product
7	Waste treatment	No specific measures necessary (see chapter 13 SDB).
Exposure prediction and examination of their own uses by downstream users		
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 m3 quantity of

		receiving water
8.1.2.2		Risk-determining component: alkylsulfonate, PNECwater: 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 m3 quantity of receiving water, with rare application to 44 kg/day per 1.000 m3 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)

A2.16 Use and exposure category NaOH solid/NaOH liquid in aqueous mixtures

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[20] (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)[21]

[20] 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.

[21] Cleaning sprays for baking ovens are not evaluated (aerosol use)

Operational conditions of use		
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 mixtures)
4.2	Product specification	Caustic soda solution liquid > 1% to < 100% (only NaOH + H20)
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)
Risk management measures for the individual target groups		
	Workers Array nrs. 7, 8, 10, 11, 13, 14 DNEL inhalative / long term: 2 mg/m3. 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. The technical and person-related protective measures for short-term uses/possible exposures often differ from the measures for long-term/repeated applications.	a) Instructions: Skin contact inadmissible – Touching forbidden - Use without protective gloves, eye protector banned - spilled caustic soda solution immediately eliminate or neutralize, - Do not inhale aerosols, fumes - additional instruction, e.g. - clean contaminated protective gloves with flowing water before taking off. - clean or take off protective clothing immediately after contaminating. - Examine protective gloves for damage before beginning the activity. Use caustic soda solution only after dilution with water to final concentrations of less than 1%. - 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.). b) Product-related measures, e.g. - 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). - High viscosity adjustment with aids to avoid splashes - Use in spray products inadmissible. - Delivery only as barrel commodity and/or in the tank car 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. 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). e) personal measures: - Disposable gloves for brief application - Gloves with 8-hour break-through security for longer application - Eye protector (all activities/PROCs) 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[22] ***
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.
Exposure forecast and examination of their own uses by downstream users		
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

[22] 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 mixtures – Providing together with protective gloves/eye protector c) Organizational measures: – Delivery only to persons over 18 years after instruction.

A2.17 Extended safety data sheet HDDA with exposure scenario (pointer)

The extended safety data sheet for HDDA is available as a separate document ((VCI: http://www.vci.de/default~cmd~shd~docnr~125022~lastDokNr~102474.htm).

A2.18 Chemical safety reports Acetonitrile, KTB, HDDA and NaOH (pointer)

The examples of chemical safety reports are available as separate doduments ((VCI: http://www.vci.de/default~cmd~shd~docnr~125022~lastDokNr~102474.htm).

A2.19 Use category from the Construction Chemicals Industry

The following table shows a use category description prepared by the Construction Chemicals Industry (see chapter 10.4). It gives information on typical processes and activities taking place during the professional indoor use of construction chemicals (use category CC-5-1).

Table 14 Use category description of the Construction Chemicals Industry.

Number	Code	Short title of the UseReport	Short description of process or activity	use descriptors						Life Cycle					Exposure Modifier					RMM	
				Sector of use (SU)	Process Category (PROC)	Product category (PC)	Product Sub-category	Article Category (AC)	Environmental Release Category (ERC)	Manufacture	Formulation	end use		Service Life	duration and frequency (exposure time)	Out-door	Indoor		respira-tory protecti on	Eye protection (goggles)	protection of hands (gloves)
												Industrial	Professional / Consumer				with LEV	with-out LEV			
1	CC-5-1	Professional use of Construction Chemicals, indoor	Roller application or brushing of adhesive and other coating	SU 19	PROC 10	PC 10		not applicable	ERC 8A (e.g. solvents) ERC 8C (e.g. binding agents)				X		8 h/d 5 d/w			X		Yes	Yes
2	CC-5-1	Professional use of Construction Chemicals, indoor	Spraying outside industrial settings or applications	SU 19	PROC 11	PC 10		not applicable	ERC 8A (e.g. solvents) ERC 8C (e.g. binding agents)				X		8 h/d 5 d/w			X	95%	Yes	Yes
3	CC-5-1	Professional use of Construction Chemicals, indoor	Treatment of articles by dipping and pouring	SU 19	PROC 13	PC 10		not applicable	ERC 8A (e.g. solvents) ERC 8C (e.g. binding agents)				X		8 h/d 5 d/w			X		Yes	Yes
4	CC-5-1	Professional use of Construction Chemicals, indoor	Hand-mixing with intimate contact and only PPE available.	SU 19	PROC 19	PC 10		not applicable	ERC 8A (e.g. solvents) ERC 8C (e.g. binding agents)				X		8 h/d 5 d/w			X		Yes	Yes
5	CC-5-1	Professional use of Construction Chemicals, indoor	Service life of cured/installed construction chemicals, indoor	SU 21	not applicable	PC 10		AC 12-1	ERC 11A					X	24 h/d 7 d/w			X			