

How downstream users can handle
exposure scenarios
Practical Guide 13

ABC

LEGAL NOTICE

This document provides technical advice explaining how companies can fulfil their legal obligations under Regulation (EC) No 1907/2006 (REACH Regulation). However, users are reminded that the texts of the REACH Regulation are the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency (ECHA) does not accept any liability with regard to the content of this document.

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How downstream users can handle exposure scenarios

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The purpose and nature of practical guides

Practical Guides are produced by ECHA, under its sole responsibility. They do not replace the formal Guidance (which is established under the formal guidance consultation process involving stakeholders) that provides the principles and interpretations needed for a thorough understanding of the requirements of REACH. However, they communicate and explain the Guidance in a practical way for a specific issue.

This practical guide aims to assist downstream users to comply with their obligations in relation to exposure scenarios. It has been developed with input from industry representatives and Member State competent authorities. Where practical experience and practice in handling exposure scenarios is available, it is reflected in this guide. Good practices in this area are emerging and improving, as the implementation of REACH develops and experience grows. The current document will be adapted in future to incorporate these developments.

ECHA will maintain this practical guide as a “living document” and invites interested parties to submit experiences and examples to be incorporated in future updates of this document. These can be submitted via the ECHA Information Desk at:
http://echa.europa.eu/about/contact_en.asp

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1. INTRODUCTION

1.1 What is this document about?

Downstream users of substances on their own and in mixtures have duties under Regulation (EC) No 1907/2006 (the REACH Regulation). Some of these duties relate to actions they need to take as a result of information on uses and conditions of use in the safety data sheet (SDS) received from their suppliers. This information may be communicated to downstream users as part of the SDS by attaching exposure scenarios to it. An SDS with one or more exposure scenario attached is often referred to as an extended SDS. For mixtures, the information may be included in the main body of the SDS or appended to the SDS. Downstream user sector organisations have agreed a format to append to the SDS of mixtures, called safe use of mixture information (SUMI).

Downstream users need to check whether their use (of substances on their own or in a mixture) and their conditions of use are covered in the SDS received. This check may include the foreseeable use of these substances further down the supply chain.

This document gives practical advice on how to carry out such a check and the actions that should be undertaken, based on the outcome of that check.

1.2 Who should read this document?

This document is addressed to downstream users who receive exposure scenario information from their suppliers. They are likely to be formulators or end users.

Many different types of companies can be downstream users. They may use chemicals in their processes for synthesis, as a processing aid, for formulation into mixtures, for incorporation into articles, refilling or for cleaning. Site-based or workshop-based workers and service providers who use chemicals are also downstream users.

The sectors that use chemicals are wide-ranging and include pharmachem, coatings, cosmetics, detergents, textile finishing, fertilisers, food, electronics, engineering, automotive and many more.

1.3 How is this document related to other information?

It is assumed that readers are familiar with the REACH Regulation and their duties under it, and have a general understanding of exposure scenarios and risk assessment.

This practical guide is published on the European Chemicals Agency (ECHA) website (<http://echa.europa.eu//practical-guides>). It complements other information for downstream users, which is provided by ECHA. It is not intended as a comprehensive overview of all downstream users' legal obligations. These are described mainly in Title V of the REACH Regulation (Articles 37 to 39 inclusive)

A useful first point of information for downstream users is the downstream user section of **ECHA's website** (<http://echa.europa.eu/regulations/reach/downstream-users>). This can also be accessed from the "Regulations" tab on the ECHA website home page. This provides an overview of the entitlements and obligations of downstream users, the format and examples of exposure scenarios and links to relevant support information.

The following additional information on topics related to this Practical Guide is available on the ECHA website:

- Guidance for downstream users, both full and nutshell versions, is available in 22

languages.

<http://www.echa.europa.eu/guidance-documents/guidance-on-reach>

- User-friendly eGuide on Safety Data Sheets describes the content of the SDS and exposure scenarios and how a downstream user can check them.
<http://echa.europa.eu/regulations/reach/downstream-users>
- Overview of the key aspects regarding safety data sheets and exposure scenarios is presented in the REACH Fact Sheet “Safety Data Sheets and Exposure Scenarios – key information for Downstream Users”
<http://echa.europa.eu/publications/fact-sheets>
- Annotated examples of the exposure scenario format
<http://www.echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats>
- Some practical examples of exposure scenario
<http://echa.europa.eu/support/practical-examples-of-exposure-scenarios>
- Practical advice on preparation of a downstream user chemical safety report is presented in ECHA Practical guide 17
http://www.echa.europa.eu/documents/10162/13655/pg17_du_csr_final_en.pdf
- The ECHA Navigator tool might be helpful in identifying key obligations. It can be accessed at:
<http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/identify-your-obligations>
- Questions and answers relating to downstream user issues and downstream user reports. These Q&A pairs have been prepared in response to questions frequently asked to the national REACH and ECHA Helpdesks.
<http://echa.europa.eu/support>

Sector organisations, including Cefic (the European Chemical Industry Council) and Ducc (Downstream Users of Chemicals Coordination Group), have also issued guidance on exposure scenarios and communication in the supply chain through their websites, www.cefic.org and www.ducc.eu.

A glossary of terms used in this document is provided in Appendix 1.

1.4 How are the downstream user duties under REACH related to other legal obligations?

Downstream users have a number of duties under REACH, and are also subject to the requirements of other regulations, including environmental, health and safety (EHS) legislation based on national laws implementing European Directives¹.

One of the aims of existing EHS legislation is to promote the safe use of chemicals in the workplace and the environment by identifying, assessing and controlling exposure

¹ National environmental legislation implements a range of European directives including Integrated Pollution Protection and Control (IPPC) 2008/1/EC. Occupational health and safety legislation implements, among others, the European Community ‘Framework Directive’ (89/391/EC), collectively with other relevant Directive requirements including exposure to chemical agents at work (98/24/EC), and exposure to carcinogens or mutagens at work (2004/37/EC).

emissions as well as through effective waste management. Many manufacturers and users of chemicals operate in accordance with environmental permits or licences issued by competent authorities, which impose specific conditions of use and emission limits to protect the environment.

The entry into force of REACH does not affect the existing EHS legislation, which remains applicable. The REACH Regulation and existing EHS legislation complement and support one another. Downstream users should comply with all legal requirements applying to them. In general, if different pieces of legislation set different requirements, the more restrictive requirements apply.

With regard to workplace exposure, the Advisory Committee on Safety and Health at Work (ACSHW) issued a guidance document '*REACH and CAD in the workplace – Guidance for employers on controlling risks from chemicals*' in 2009². It provides an overview of the interface between the Chemical Agents Directive 98/24/EC (CAD) and REACH, and demonstrates that one process of assessing risks can often meet the relevant requirements of both REACH and CAD.

The ACSHW document emphasises the potential for improving worker health and safety due to better information and new channels of communication due to REACH. They also highlight that REACH does not mean that employers' obligations are duplicated.

² <http://ec.europa.eu/social/main.jsp?catId=716&langId=en&intPageId=223>

2. OVERVIEW OF DOWNSTREAM USER DUTIES WITH REGARD TO EXPOSURE SCENARIOS

2.1 Introduction to exposure scenarios

If you are a downstream user and you use hazardous substances registered under REACH in quantity greater than 10 tonnes/year, your suppliers should provide you with an extended SDS that includes exposure scenarios.

Exposure scenarios are one of the main innovations of the REACH Regulation, and aim to support the safe use of substances. The scenarios include the conditions of safe use, (i.e. operational conditions and risk management measures) that have to be applied during manufacturing, industrial, professional and consumer use of these substances and during the service life of articles. Most importantly, an exposure scenario describes how the manufacturer or importer controls, or recommends downstream users to control, the exposure of humans and the environment to the substance in order to ensure its safe use.

The situations where the supplier must provide exposure scenarios are described in the eGuide on safety data sheets and exposure scenarios and Q&A476. .

2.2 What to do when you receive an exposure scenario

When you receive an extended SDS with a registration number³ for a substance, you need to establish what your obligations are, and decide how to fulfil your obligations.

First, you need to establish whether your use and/or your conditions of use are covered in the exposure scenario. If you are a formulator or re-filler, you also have to consider the foreseeable use by your customers.

To do this, you need to gather and evaluate information on the actual uses as outlined in Figure 1 and described below:

1. Gather information on how the substance is used in your company: consider aspects such as: In which mixtures or articles is the substance incorporated? In which production processes or cleaning/maintenance operations is it used? What are the risk management measures applied, if any?
2. Assess the differences between your actual conditions of use and the conditions described in the exposure scenarios. Three principal conclusions can be reached:
 - a. **Actual use and/or conditions of use are covered in the exposure scenario.**
 - b. **Actual use is covered but the conditions of use slightly differ from the exposure scenario.** Even though the use is covered, there are sometimes differences in the parameters influencing the exposure (such as concentration of substance, duration of exposure, quantity of substance used). However, it may be possible to demonstrate that the actual conditions are still covered in the exposure scenario received by applying the so-called *scaling* approach (see section 8 of this document and the *Guidance for downstream users* for more information).

³ The registration number is assigned to a substance which has been registered at ECHA according to REACH provisions.

c. Actual use and/or conditions of use are not covered in the exposure scenario.

3. Check to see whether foreseeable uses by your customers are included within the identified uses indicated in subsection 1.2 of the SDS and in the attached exposure scenarios. For example, there is a mismatch if you sell mixtures containing the substance to consumer markets, but your supplier does not cover any consumer uses in the exposure scenarios

Practical examples are included in sections 4 to 7 of this document to help you in the process described above. Additional questions that might arise are addressed in section 10. The procedure is described fully in Chapter 4 of the ECHA *Guidance for Downstream Users*.

If you are not able to establish whether your uses and/or uses by your customers are covered in the set of exposure scenarios, you need to contact your supplier for clarification, or your sector organisation for support.

An overview of Downstream Users obligations and the associated time frames is presented in Table 1.

2.2.1 What to do if the use and/or conditions of use are covered by the exposure scenario

If your use is covered in the exposure scenario, no further action is needed in that regard. Document your actions by describing how you reached such a conclusion and make this information available to enforcement authorities upon request. Clear documentation helps you to justify your assumptions in a transparent way and helps the authority to better understand the criteria adopted by you in your decisions.

If you supply the substance down the supply chain (e.g. in mixtures) you have the obligation to inform your customers about conditions of safe use. They, in turn, are responsible for performing their own check concerning their uses and conditions of use, based on the information provided by you.

The possible ways in which you can forward this information to your customers are described in section 7.2 of the *Guidance for downstream users*.

2.2.2 What to do if the use and/or conditions of use are not covered by the exposure scenario

If your use/use conditions are not covered by any of the exposure scenarios received from your suppliers, you have different options available which are summarised below. Once you have decided the most suitable option for you, document your actions and conclusions and make them available to enforcement authorities upon request⁴.

- a. Ask your supplier to include your use/conditions of use in their chemical safety report and to provide you with an exposure scenario for it. You need to make sufficient information available to your supplier to enable them to make such an assessment. Your sector organisation may have developed a convenient means of
-

supplying this information specifically for your sector⁵.

- b. Implement the conditions of use described in the exposure scenario you have received. This option may require changes in your processes and/or products.
- c. Eliminate or substitute the substance or the activity with a safer alternative.
- d. Find another supplier who can provide the substance with SDS and exposure scenario covering your use
- e. Carry out your own chemical safety assessment and prepare your own downstream user chemical safety report (DU CSR) for your uses and conditions of use, unless exemptions apply. See Practical Guide 17⁶ "How to prepare a downstream user chemical safety report" for details.

The most suitable option will depend on your own situation. A more comprehensive overview is presented in Chapter 4 of the ECHA Guidance for Downstream Users.

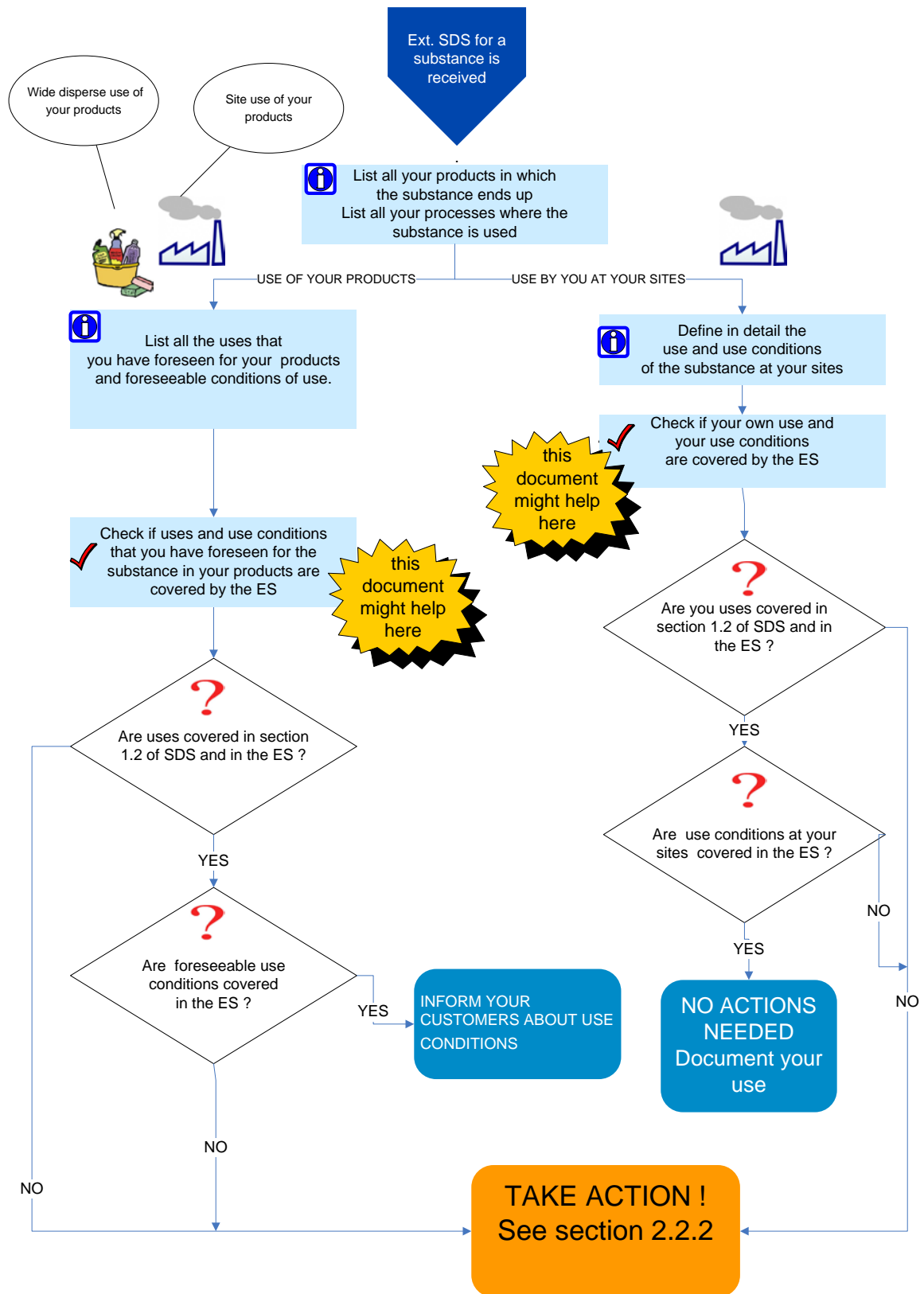
Depending on the action undertaken, you may have to report certain information to ECHA. Details are provided on the ECHA website.⁷

⁵ A standardised format to describe the uses and conditions of uses is available (called use maps), and is being used by sector organisations. Additional information on use maps can be found here: <http://echa.europa.eu/csr-es-roadmap/use-maps>

⁶ http://echa.europa.eu/documents/10162/13655/pg17_du_csr_final_en.pdf

⁷ <http://echa.europa.eu/regulations/reach/downstream-users/downstream-user-reports>

Figure 1: Workflow for responding to the exposure scenarios received from suppliers



Note: The right hand workflow refers to the formulation of the substance and any other end use of a substance. The left hand workflow refers to use by a customer of a mixture containing the substance.

Table 1: Overview of main Downstream User (DU) obligations and timeframes relating to exposure scenarios

| Downstream User Activity | Timeframe | Comment * |
|---|--|---|
| Inform your supplier of your use: <i>substances not yet registered</i> | Supplier to assess the risk of that use, provided DU makes request one year before registration deadline. | 31 May 2017 for 2018 registration (quantities >1t/y). This is a voluntary action |
| Inform your supplier of your use: <i>registered substances (use not covered in SDS)</i> | Supplier to comply with obligations before next supply or within one month after DU request, whichever is later. | Ensure full details are provided. This is an optional action, based on your review of the SDS. If the supplier decides not to support your use, they should provide you with the reason in writing without delay. |
| Implement the measures communicated to you in the SDS or take alternative actions. | One year from receipt of SDS for registered substance. | Possible alternative actions are: <ul style="list-style-type: none"> ➤ Ask supplier to include use and implement measures ➤ Conduct DU chemical safety report (DU CSR) ➤ Change supplier, if feasible ➤ Eliminate or substitute the substance Remember to check if an exemption from DU CSR applies. |
| Communicate information to your suppliers | If required, without delay | You should inform your supplier about (<i>Article 34</i>): <ul style="list-style-type: none"> ➤ New information on hazards ➤ Inappropriateness of suggested risk management measures |
| Communicate information regarding safe use to own customers | When you first supply the substance to your customers (e.g. in a mixture). This is done through the SDS of the mixture if required or by providing information on safe use (<i>Article 32 of REACH</i>) If an update of the SDS is required, the updated version has to be provided without delay | Update SDS if (<i>Article 31(9)</i>): <ul style="list-style-type: none"> ➤ New information on risk management measures or hazards becomes available ➤ An authorisation was granted or refused ➤ A restriction has been imposed Note that the general obligations to recommend appropriate measures to adequately control risk apply. |

| | | |
|--|--|--|
| Prepare DU Chemical Safety Report (CSR) | One year from receipt of SDS for registered substance. | Prepare the DU CSR according to Annex I and XII. You do not submit the CSR to ECHA but report to ECHA that you prepare a DU CSR. |
| Report uses not covered in the exposure scenario to ECHA | Six months from receipt of SDS for registered substance. | This applies if you are: <ul style="list-style-type: none"> ➤ Preparing a DU CSR ➤ Claiming exemptions due to use <1 tonne/year or used for PPORD |
| Report your classification to ECHA | Six months from receipt of SDS for registered substance. | Disagree with the substance classification from all your suppliers |

*REACH Articles 37-39 (Title V) is the relevant legal text unless otherwise specified. This table does not include obligations with respect to producers of articles and use of restricted or authorised substances.

3. INTRODUCTION TO THE PRACTICAL EXAMPLES

Information and requirements on the content of the exposure scenario and risk characterisation are included in Annex I, Sections 5 and 6 of REACH. Exposure scenario formats and examples developed by ECHA in cooperation with stakeholders are available on the ECHA website (see section 1 of this document for more details). ECHA, in cooperation with industry associations, has developed practical examples to illustrate some common situations that arise when matching exposure scenarios to your actual conditions. The examples, presented in sections 4 to 7, have been simplified to highlight key issues.

The examples are structured according to the exposure scenario format for worker uses and consumer uses agreed with stakeholders.

Examples are provided for the following elements of exposure scenarios:

- Examples related to the **title section** of the exposure scenario.
- Examples related to the use of substances at industrial sites, focusing on exposure to the **environment**
- Examples related to the use of substances at industrial and professional sites, focusing on exposure to **workers**
- Examples related to the use of substances by **consumers**

Each example includes:

- A **case description**, outlining the relevant conditions of use and the conditions reported in the exposure scenario received from the supplier
- An **analysis** of the situation, highlighting areas of agreement and of deviation
- The main **options** available as a consequence of the analysis.

Table 2 presents an overview of the main parameters to compare between actual conditions and those specified in the exposure scenarios. It also includes links to the relevant practical examples, which illustrate the parameters in question.

Many of the examples describe a situation using standardised use descriptors (such as LCS, SU, PC, PROC, ERC). Details on these descriptors are provided in the Guidance on information requirements and chemical safety assessment *Chapter R.12: Use Description*, version 3.0 December 2015 available on the ECHA website (follow the guidance link): <http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation>

Table 2: Comparison between actual conditions and those in the Exposure Scenario

| Exposure Scenario | Check your conditions* and your customers' conditions for each of the following aspects | Practical Examples |
|--|--|--|
| <p>Title Section</p> | <p>Are all the uses identified in the title section of one or more of the exposure scenarios? The title section should specify if the exposure scenario addresses industrial, professional and/or consumer use.</p> | <p>T1, Exposure scenario for consumer end-use is missing</p> <p>T2 The relevant product category is not mentioned in the title section</p> |
| | <p>Does the exposure scenario cover all tasks or processes relevant for the uses?</p> | <p>T3, Contributing scenario for process step is missing</p> <p>T4 Process Categories are missing</p> |
| <p>Environmental exposure Section</p> | <p>Is the daily and annual amount of the substance used within the amount assumed in the exposure scenario? (Note: If the substance is in a mixture, take into account the concentration of the substance in the mixture)</p> | <p>E1 Daily use amount likely to be exceeded</p> |
| | <p>Are the risk management measures (RMM) in line with the exposure scenario? Are the specific technologies used (such as wastewater treatment processes, filters, air abatement systems) compatible? Does the effectiveness equal or exceed the effectiveness of RMM indicated in the exposure scenarios?</p> | <p>E2 Risk Management Measure differs from exposure scenario assumption</p> |

| | | |
|----------------------------------|---|---|
| Worker exposure Section | Do product characteristics (such as concentration of substance in mixture, viscosity, form [powder/-granular/pellet], packaging design) match those specified in the exposure scenario? | W1 Substance concentration exceeds the limit set in the ES |
| | Are general ventilation conditions (such as room volume, indoor/outdoor) met? | W2 Use indoors by professionals is not covered. |
| | Are the processes, technologies and the conditions which control the release of the substance into the working environment (such as transfer systems, containment, temperature, application techniques) in line with the recommendations in the exposure scenario? | W3 Closed system not available at customer level |
| | Are the risk management measures (RMM) indicated in the exposure scenarios, including local exhaust ventilation (LEV), available? If so, is the effectiveness in line with exposure scenario's requirements? Is the personal protective equipment (PPE) used consistent with the exposure scenario? | W4 Effectiveness of RMM less than exposure scenario specification W5 Absence of risk management measures at customer level |
| | Are any organisational measures (such as training and supervision) specified in the exposure scenario complied with? Is maintenance and training provided as required? | W6 Specified organizational measures are not complied with |
| Consumer exposure Section | Do product characteristics (such as product type, concentration, application form [spray, liquid, powder, package design] match those specified in the exposure scenario? | C1 Concentration exceeds the limits set in the exposure scenario |
| | Do the amount used (for each event), the frequency (e.g. number of events per day) and duration (e.g. of a single event) match the assumptions in the exposure scenario? | C2 Package design does not limit exposure as required |
| | Do the operational conditions assumed for consumers match with the exposure scenario? Conditions include aspects such as indoor / outdoor use, room volume and air exchange rate. | C3 Anticipated ventilation conditions during use do not match the exposure scenario |
| | Are specific PPE or hygiene practice recommendations for consumers reflected in the "instructions for use" for the consumer product containing the substance (e.g. on the label, or instruction sheet)? | C4 PPE is recommended for consumer use but you do not agree and do not provide it. |

*based on what you know of your customer sites, and what is foreseeable

4. EXAMPLES RELATED TO THE TITLE SECTION

Example T1 - Exposure scenario for consumer end-use is missing

Case description

Assume you are a formulator of laundry detergents for professional and consumer use. Substance A is present in most of your mixtures.

Your supplier of substance A sends you a set of exposure scenarios covering industrial use (formulation) and professional end use in cleaning and washing products. Use of the substance in consumer products is not mentioned in Section 1.2 of the SDS or in the titles of the exposure scenarios provided.

Analysis

- The use of substance A at your site and professional use of your mixtures are covered in the exposure scenarios. For your own use, check if your conditions of use are covered.
- No exposure scenario has been provided for the use of the substance in consumer goods implying that consumer use is not covered. There could be various reasons for that:
The supplier has mistakenly forgotten to provide an exposure scenario for consumer use.
The supplier has chosen not to support the use by consumers.

Options

- Ask your supplier why you did not receive an exposure scenario for consumer use of the substance A.
- If the consumer use has been mistakenly omitted from the exposure scenario you received, ask your supplier to send you the exposure scenario covering consumer use.
- If your supplier does not support consumer use in their exposure scenario, your **consumer use is not covered** and you must take action (see Section 2.2.2 for further advice).

Example T2– The relevant product category is not mentioned in the title section.

Case description

Assume that you are a producer of multipurpose cleaners and other washing products (product category PC35) and you use a substance Z in your mixtures. You receive a set of exposure scenarios from your supplier for substance Z which includes an exposure scenario for industrial formulation with no specific reference to the product category PC35 (washing and cleaning products) or any other product category. You wonder if this exposure scenario covers the formulation of your mixtures at your sites.

Analysis

- The exposure scenario for industrial formulation covers formulation at all industrial sites (including yours). As the next step, you need to compare the conditions of use described in the exposure scenario for industrial formulation (i.e. duration of activity, concentration of the substance, engineering controls, PPE etc.) with your actual conditions of use to check whether your conditions are covered in the exposure scenario.

Options

- You conclude that your actual conditions of use are within the conditions described in the exposure scenario for industrial formulation. Therefore **your use is covered** even though it is not specified in detail in the title (see Section 2.2.1 for further advice).

Example T3 - Contributing scenario for process step is missing

Case description

Assume you are a milk processing company. At your site, you use Substance A to sterilise your tanks and lines after each batch, based on a clean-in-place (CIP) closed loop system. You receive an exposure scenario for Substance A entitled "Cleaning and sterilisation of production machinery in food processing" with closed batch process (PROC3) assigned.

Substance A is delivered in bulk in road tankers, transferred from the road tanker to onsite storage tanks and from these storage tanks to the dairy plant during the CIP. The transfer system from the storage tanks to the CIP is fully enclosed and automatically controlled. The transfer from trailer to onsite storage is performed semi-automatically at a dedicated facility. Some occasional exposure to workers may occur during connection/disconnection of lines and purging and maintenance operations. The exposure scenario you have received from your supplier does not address substance transfer (which you identify with PROC8b) in the title section.

Analysis

- A process step (substance transfer) is missing in the title section. This may be because:
 - The transfer process is covered in one of the contributing scenarios without being explicitly mentioned in the title section.
 - The transfer from/to the vessels is not covered by the exposure scenario.

Options

- Check the contributing scenarios for a task such as transfer from/to vessels (PROC8a/ 8b) and check your conditions of use against those described in this contributing scenario. If you have received a contributing scenario supporting your conditions of use, you conclude that ***your use is covered by the exposure scenario*** (see Section 2.2.1 for further advice).
- If none of the contributing scenarios you receive covers the transfer step, you need to check with your supplier why this information is missing. If you get the confirmation that this is a use not covered, then you must take action (see Section 2.2.2 for further advice)

Example T4 – Process categories (PROCs) are missing in the exposure scenario.

Case description

Assume you are a formulator of coatings and you use Substance Z in your formulations. Prior to registration you have informed your supplier about your use and you have provided the following information:

- industrial formulation of mixtures (LCS F) ;
- formulation in closed batch processes chemical industry (PROC3),
- mixing in batch processes (PROC5),
- transfer at dedicated facilities (PROC8b),
- transfer into small containers (PROC9)
- formulation into mixture (ERC2).

You also provided details of your operational conditions and risk management measures (OC/RMM).

You receive a set of exposure scenarios from your supplier, which include an exposure scenario for **formulation of mixtures**, with the following additional information in the title section:

- formulation of preparations LCS-F
- mixing in batch processes (industrial use) PROC5,
- transfer at non dedicated facilities (industrial use) PROC8a
- transfer in small containers (industrial use) PROC9;
- formulation into mixture ERC2.

You see that some of your processes (and related PROCs) are not listed in the title section of the exposure scenario and thus you wonder if there is a mismatch.

Analysis

- Activities under ERC2 are covered.
- The scope of process clearly describes the *formulation of mixtures in industrial facilities*, which corresponds to your industrial use. Your key processes are mentioned in the title section under: mixing in batch process (PROC5), transfer of raw material (PROC8a) and filling operations for the final product (PROC9). For these steps you can now check if your conditions of use match the corresponding contributing scenarios.

Other activities that you have indicated with PROC3 and PROC8b may be covered by the contributing scenarios for PROC5 and PROC8a assuming the conditions of use are comparable. You need to check all information in the exposure scenario to verify this.

Options

- You conclude that your conditions of use (including those you have identified under PROC3 and PROC8b) are covered, and thus **the exposure scenario covers your use**. (see Section 2.2.1 for further advice)

5. EXAMPLES RELATED TO ENVIRONMENTAL EXPOSURE

Example E1 - Daily amount used is likely to be exceeded

Case description

Assume you are a formulator of textile dyes and you use a Substance Y in your dyes. You receive an exposure scenario for the industrial use of the substance in textile dyes. In the exposure scenario, the supplier has specified a limit on the amount used per site of 50kg/day of Substance Y with no additional risk management measures needed to control exposure to the environment.

Normally, you do not exceed the daily use of 50kg/day and you have onsite risk management measures (RMMs) in place to control releases to the environment (to air and water). You face a high, temporary demand for your dyes from one of your major customers, which will require you to use about 80kg/day of Substance Y for a few weeks (3-4 weeks maximum) in one year. You wonder if the exposure scenario still covers your conditions of use in this temporary period.

Analysis

- Even though your daily use exceeds the maximum daily amount indicated in the exposure scenario only for a short period, your conditions of use differ from the exposure scenario. However, in some cases, increase in the effectiveness of onsite RMM may compensate for the increase in the daily quantity, thus the exposure scenario could be still covering the use.

Options

- If scaling instructions are provided by your supplier and scaling is applicable to your use, you can check if your use is covered by applying scaling.

Example E2 – Risk Management Measure differs from exposure scenario assumption

Case description

Assume you are an instrumentation manufacturer and undertake the powder coating of equipment panels. You receive an exposure scenario for “industrial use in coating applications” of an organic substance K which you use in your processes. In the exposure scenario, an abatement system for air emissions via wet scrubbers with 95% removal effectiveness is required to control emissions to the environment.

At your site, you use bag filters for air pollution abatement with 99% removal effectiveness. The particulate and exhausted filter bags are incinerated in line with the technical standards as laid down in the applicable EU Directive and national legislation on waste.

Analysis

- Although your bag filters are more effective than wet scrubber in removing air pollutants, the technology in your system differs from the exposure scenario. This could be a problem if the disposal of your bag filters generates an impact to the environment (e.g. on the soil) which was not foreseen by your supplier. However, for the current case, the waste generated by disposal of bag filters is incinerated and thus no impact to another release pathway is expected.

Options

- You assume that **your use is covered** by the exposure scenario (see section 2.2.1 for further advice)

6. EXAMPLES RELATED TO WORKER EXPOSURE

Example W1 – Substance concentration exceeds the limit set in the exposure scenario

Case description

Assume you are a formulator of metal working fluids. In your process, you use a substance A in pure form (>90% concentration). The concentration of the substance in your core products is up to 5%. You also formulate customized mixtures for some key customers with substance A in concentrations up to 25%.

Your supplier sends a set of exposure scenarios for use of substance A in formulation covering concentrations up to 100% and for end use in lubrication processes at high energy covering concentrations up to 10%.

Analysis

- The ES for the formulation of mixtures covers the use of the substance at your site (formulation).
- The ES for “use in lubrication processes” covers the use of the substance in your mixtures in concentrations up to 5%. The concentration of substance A in your customized mixtures for use in metal cutting (25%), is higher than the concentration foreseen in the ES for that use (10%). However, in some cases, higher concentrations might be compensated by changes in other conditions of use (e.g. by reducing exposure time) via scaling.

Options

- For uses covered by the exposure scenario – i.e. formulation of mixtures and use in lubrication processes in concentrations up to 10% see Section 2.2.1 for further advice
- For uses in higher concentrations (up to 25%) check if your supplier has provided scaling options and if they are applicable to your use. You should check if higher concentrations may be compensated for via scaling by changes in other parameters (e.g. a lower exposure time).

Example W2 – Use indoors by professionals is not covered.

Case description

Assume your company specialises in the application of fire resistant coatings to structural steel, vessels and similar equipment. You apply the coatings both on construction sites (outdoor use) and in your workshop (indoor use).

You receive an ES for a substance which is incorporated in one of the coating mixtures that you use covering “outdoor use in manual coating operations” for more than 4 hours/day. The exposure scenario does not contain any inhalation control measures (either engineering controls or PPE) as they are not considered necessary to reduce risks to workers.

Analysis

- The exposure scenario supports outdoor applications.
- The exposure scenario does not support indoor applications where risks to workers may be not adequately controlled without RMM due to limited ventilation.
- The reasons could be:
 - the supplier has mistakenly forgotten to provide an ES for indoor use.
 - the supplier has decided not to cover indoor use.

Options

- **Outdoor use is covered by the ES** (see Section 2.2.1 for further advice)
- Regarding use at your workshop, ask your supplier to provide the ES covering indoor use and, once received, check if your conditions of use are covered by it (see section 2.2.1 of this document).
- Take action in case your conditions of use are not covered by the ES for indoor use or if your supplier cannot provide an ES for indoor use (see section 2.2.2 of this document for further advice).

Example W3 – Closed system not available at customer level

Case description

Assume you are a formulator of non-reactive processing aids for use by polymer converters. You use a volatile substance X as a solvent in your mixtures. You receive an exposure scenario from your supplier of substance X where closed systems are required as a measure to minimise exposure to workers by inhalation (corresponding to PROC3). No alternative RMMs are indicated in the ES to protect workers.

Processes at your site are contained. However, you are not sure if all your customers use your processing aids in closed systems.

Analysis

- The exposure scenario for use of the substance in closed systems supports the use at your site.
- The exposure scenario does not support uses in open systems.

Options

- **Use at your sites is covered** (see Section 2.2.1 for further advice).
- **Use by your customers:** Your customers are responsible for their own uses; you have to inform them that only use in closed systems is supported, by including safe use information in the SDS of the mixtures you sell to your customers. Your customers in turn, have to check if their conditions of use are covered and take action if their uses are not covered (see Section 2.2.2 of this document for further advice)

Example W4 – Effectiveness of Risk Management Measures less than ES specification

Case description

Assume you are a manufacturer of construction chemicals. In some of your formulations, you use a substance A in powder form. Your supplier of substance A sends a safety data sheet with exposure scenarios attached covering the use of substance A in construction chemicals. The exposure scenario contains a contributing scenario for transfer of substance A at non-dedicated facilities (PROC8a) and a contributing scenario for mixing in batch processes (PROC5). In these contributing scenarios, a local exhaust ventilation (LEV) with 90% effectiveness is specified as the RMM to protect workers from exposure to substance A and a full shift activity (duration >4 hours/day) is assumed.

From dust measurements conducted at your site with the LEV both on and off, you are aware that the effectiveness of your current LEV does not exceed 50%. However, the actual task duration (per shift) was < 1 hour for transfer and mixing. You have monitoring data of workers' exposure showing that personal exposure is below the exposure limits (OELs and DNELs) reported in the SDS.

Analysis

- The exposure scenario does not cover your own use because the removal effectiveness of your LEV system (50%) is lower than the minimum described by the exposure scenario (90%). However, in some cases lower effectiveness of RMM can be compensated by changes in other conditions of use via scaling.

Options

- If scaling options have been provided by your supplier you can check if lower effectiveness of your LEV can be compensated, via scaling, by other conditions which may be applicable at your sites (e.g. lower duration of activity/use). If, after applying scaling, you conclude that your conditions are covered, you have no additional action to take (see section 2.2.1 for advice). If your conditions are not covered or if scaling is not applicable, you must take action (see Section 2.2.2 for further advice). If you decide to perform your own CSA and prepare a downstream user CSR, you may use your monitoring results to support this assessment.

Example W5 - Absence of risk management measures at customer level

Case description

Assume you are a producer of oil based metal working fluids that are sold to a wide market. In your fluids, you use substance X as an additive to maintain a good performance at higher temperatures. Your supplier of substance X sends you an exposure scenario for industrial end-use where LEV with over 90% effectiveness is required to limit respiratory exposure. Based on your knowledge about the metal processing sector, you are aware that some metal processing companies have LEV systems of lower effectiveness and few companies have no LEV systems.

Analysis

- The exposure scenario may cover the uses of some of your customers. In some cases, a lower LEV effectiveness can be compensated by changes in other conditions via scaling.

Options.

- Check if scaling options are provided by your supplier of substance X in the ES. It is recommended you perform the scaling on their behalf. If scaling options are not provided by your supplier, you can prepare a downstream user CSR to cover the uses of substance X by your customers with a lower effectiveness of LEV. Your sector organisation may be able to help if a large number of companies in the sector are confronted with a similar situation. For example, they may collect appropriate consolidated information for a coordinated discussion with suppliers or develop generic DU CSRs.

Example W6 – Specified organisational measures recommended in the exposure scenario are not complied with

Case description

Assume you are a producer of car paints for industrial and professional use. You use solvent C in your paints. Your supplier of solvent C sends you an exposure scenario where specific training requirements are indicated (such as periodic training on substance properties and handling procedures) as a risk management measure (RMM) to ensure safe use of the substance. After checking your own use and use by your industrial customers you conclude that these uses are covered. However, your paints are also used by workers in small-scale car body repair shops where training programmes cannot be checked.

Analysis

- At industrial workplaces, the implementation of training is usually driven by the occupational health and safety legislation and corporate standards. Thus, it is reasonable to assume that industrial customers implement the conditions described in the exposure scenario.
- At small scale workplaces (such as car repair shops with single workers/owners), systematic training may not be undertaken so additional measures may be needed to guarantee safe use.

Options

- The exposure scenario covers the industrial use of substance C in car paints. No additional actions are required for that use (see Section 2.2.1).
- You can forward the information on training requirements to your professional customers with the SDS of the paints you supply. It is up to your customers to apply the training requirements described in the ES or to take action (section 2.2.2 of this document). Alternatively, you can consider changing the design of your paints for professional use to reduce the risks of exposure where proper training cannot be assured (e.g. reduced concentration of the substance, design of the containers, adding properties modifiers - volatility, viscosity etc.). In this case, warnings on the product label and additional supporting material (e.g. leaflets) could be sufficient to ensure the safe use of the substance. In such a case, you are still working in the boundaries of the ES (as the RMM you apply are more stringent than RMM described in the ES).

7. EXAMPLES RELATED TO CONSUMER EXPOSURE

Example C1 – Concentration exceeds the limits set in the exposure scenario

Case description

Assume you are a producer of car wash products (such as soaps and shampoos) for professional and consumer use. In your cleaning products, you use substance X as a degreaser. The concentration of substance X is up to 25%. Your supplier of substance X sends you an exposure scenario covering the concentration of the substance up to 5% in consumer goods.

Analysis

- The concentration of substance X in your cleaning products is significantly higher than the concentration indicated in the exposure scenario therefore the exposure scenario **does not cover** the consumer use of substance X in your products. .

Options

You can reduce the concentration of substance X in your cleaning products to match the concentration indicated in the exposure scenario. If this is not a suitable option for you, you need to take alternative actions (see sec. 2.2.2 for further advice).

Example C2 – Package design does not limit exposure as required

Case description

Assume you are a producer of consumer cleaning products. You use a volatile substance A in your cleaning products and you receive an exposure scenario from your supplier of the substance covering the “use of substance A in consumer cleaning products”. In the scenario, it is stated that containers for consumer use have to be designed to limit the amount of substance A used in each application to less than 10mg/event. This is required to control exposure by inhalation.

The design of your containers does not meet the requirements of the exposure scenario making it more likely that the dose prevent would be exceeded.

Analysis

- The specific quantity per application (or event) indicated by the supplier is a fundamental parameter to reduce the exposure to consumers. The design of the container is a mechanism for ensuring that the correct quantity is used in each application in order to keep the exposure levels adequately controlled.

Options

- Consumer use of the substance in your mixtures **is not covered by the exposure scenario**. Consider changing the design of your containers (e.g. a dispenser, single unit dose design, no spraying possible) or the design of your cleaning products (e.g. into tablets, gels or foam) to match the quantity per event described in the exposure scenario.

Example C3– Anticipated ventilation conditions during use do not match the exposure scenario

Case description

Assume you are a formulator of floor coatings for consumer and professional uses. These coatings are typically applied in garages or basements, but are also suitable for outdoor applications. You use a substance Y (a volatile substance) in your formulations for which you receive an exposure scenario (covering the use of substance Y in consumers' applications). The exposure scenario requires that good natural ventilation (open windows) or forced ventilation is needed for an indoor use.

Analysis

- Absence of good ventilation must be assumed in some situations when your coatings are used by consumers. These applications are not covered in the exposure scenario. Furthermore, it may be difficult for consumers to judge when the ventilation is good enough.

Options

- **Outdoor use is covered by the exposure scenario.** If your coatings are intended primarily for outdoor use, it would be sufficient to include information for consumers (e.g. a label warning such as: "use only outdoor or in a well-ventilated area").
- **Indoor use is not covered by the exposure scenario.** If indoor use of your coatings is intended, a simple instruction might not be sufficient to ensure safe use. In this case, you could consider changing the design of your products or reduce the concentration of substance Y in your products to reduce the risks of exposure associated with evaporation of substance Y.

NOTE: If the hazardous properties of substance Y might lead to high risks for consumers, investigate the feasibility of removing substance Y from the consumer goods, and substituting it with a less hazardous substance.

Example C4 – Personal protection is recommended for consumer use

Case description

Assume you are a producer of a two-component adhesive for consumer use containing a registered substance in each component. You have received an exposure scenario covering the consumer uses for both substances. In the exposure scenario, your supplier advises that the components should be delivered in a package size of not more than 20 ml and that a mixing device, which prevents hand contact, should be included. In addition, the supplier recommends that chemical resistant gloves should be used.

Your current product is in line with the exposure scenario regarding the package design and the supply of a suitable mixing device. You do not supply gloves, or instruct the users to wear them, as you believe that the use of gloves may result in poorer manipulation of the micro amounts of adhesives, thereby giving rise to a greater risk of dermal exposure. Instead, you provide clear instructions on how to use the mixing device and on how to prevent dermal contact.

Analysis

- Although you are convinced that your current solution ensures safe use of your adhesive by consumers, there is a mismatch with the exposure scenario of your supplier.

Options

- Current consumer use of your mixtures **is not covered by the exposure scenario.** You may either:
 - Follow your supplier's advice and provide suitable gloves with your adhesives.
 - Contact your supplier to report that you consider gloves to be an inappropriate risk management measure for consumer uses. Provide suitable exposure information to support your assumption, and ask for a new exposure scenario.

8. SCALING

One possible outcome of the review of the exposure scenario is that the downstream user's conditions do not exactly match the conditions described in the exposure scenario. However, it may be possible to demonstrate that the downstream user's conditions provide for the safe use of the substance using an approach termed "scaling".

8.1 Introduction to Scaling

In an exposure scenario generated for REACH registration, the registrant defines one combination of conditions of use that provides for the safe use of the substance with respect to human health and the environment.

The registrant estimates the exposure the conditions of use described in the exposure scenario using measured data or mathematical models.

For many substances, the registrant is able to establish specific exposure limits such as Derived No-Effect Limits (DNELs) and Predicted No-Effect Concentrations (PNECs), which represent the levels of exposure for workers and the environment that should not be exceeded during a use in order to assure that the use of the substance is safe.

When a DNEL or PNEC has been established, safe use of a substance is assumed when the estimated exposure is below DNELs and PNECs established by the registrant. This is expressed by a risk characterisation ratio (RCR) less than 1, indicating that the risk is adequately controlled.

The conditions leading to a safe use are communicated by the registrant to downstream users through the relevant exposure scenarios for communication annexed to the SDS of the substance.

In practice, the conditions of use at downstream users' sites are likely to differ in some way from those described in the exposure scenario yet the risk may still be adequately controlled. It may be possible to demonstrate this by compensating a variation in one particular condition with a variation in other conditions. This process is called **scaling**.

Scaling is defined in ECHA's guidance for downstream users (Version 2 Dec 2014) as "a mathematical approach to check if actual conditions of use, differing from the exposure scenario, can be still covered by it.

The way parameters defining the conditions of use are inter-related, depend on the algorithms defined in the exposure estimation tool used by registrants for exposure estimation. Exposure estimation models assign modifying factors for the various parameters such as the exposure duration, concentration or the effectiveness of risk management measures that affect the exposure. A downstream user can undertake scaling by calculating the change in exposure due to the change in parameters and associated modifying factors. The factors for ECETOC TRA are provided in Appendix 2 of this document.

At the time of writing, a scaling/recalculation tool is under development by Cefic, termed ES Conformity Tool. The tool can be used to perform the ES check, and can also be used as a basis for a DU CSR if required. This tool is based on the Ecetoc TRA model and can only be used for exposure scenarios that were developed using this exposure estimation model, or tools based on it (such as EasyTRA).

The scaling approach is described in detail in the *Guidance for downstream users* (chapter 4 and appendix 2).

Definition of methods and strategies for scaling are responsibilities of registrants. Industry associations are developing scaling methods, examples and tools to support downstream users in their scaling activities. Visit industry association websites for detailed information on scaling.

Appendix 1 - KEY TERMS

Use

Article 3(24)

Use: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;

In general, a 'use' is any activity carried out with a substance as such or in a mixture.

Identified Use

Article 3(26)

Identified use: means a use of a substance on its own or in a mixture, or a use of a mixture, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;

Where an exposure assessment and a risk characterisation are required, the identified use is a use that had been assessed by the registrant and which is covered in the exposure scenarios attached to the SDS.

Conditions of use

The "conditions of use" include the operational conditions and risk management measures (if required).

Exposure scenario

An "exposure scenario" is a set of information describing the conditions at manufacturing or use of a substance that may give rise to exposure to humans and/or to the environment. A final exposure scenario describes the conditions under which the risk is considered controlled.

Operational conditions

The "operational conditions" (OCs) are a set of information on the use of a substance. They describe the types of activities to which the exposure scenario relates, how frequently, how often and for how long a substance is used and in which types of process, at which temperatures etc. Only parameters influencing the exposure level are included in the exposure scenario.

Risk Management Measures

The term "risk management measure" (RMMs) means an activity or device that reduces or avoids the direct and indirect exposure of humans (including workers and consumers) and the different environment compartments to a substance during its use. Risk management measures applied in industrial uses include local exhaust ventilation (LEV), waste gas incinerators or onsite and municipal waste (water) treatment and personal protective equipment (PPE).

Uses advised against

The term “uses advised against” indicates those uses of a substance which are not supported by either a registrant or its supplier for reasons of protection of human health or the environment. If one or more uses is/are advised against, this must now be indicated in sub-section 1.2 “Relevant identified uses of the substance and uses advised against”⁸ of the SDS or in the information provided according to Article 32 of REACH.

Extended SDS

For those substances for which registrants are required to complete a chemical safety report (CSR) with exposure assessment and risk characterisation, the supplier of an SDS is required to place exposure scenarios covering identified uses relevant to the addressee of the SDS in an annex to the SDS, thus generating what is termed an “extended SDS”.

Risk Characterisation Ratio (RCR)

The risk characterisation ratio is the ratio of the exposure to the predicted no-effect concentrations (PNEC) or derived no-effect levels (DNEL), for environmental and human exposure respectively. When the RCR is less than 1, the risk is considered to be controlled for the conditions of use for which the exposure was determined.

Exposure Estimation Tools

- Ecetoc TRA
European Centre for Ecotoxicology and Toxicology of Chemicals, Targeted Risk Assessment
- Stoffenmanager
Consortium sponsored by Dutch Ministry of Social Affairs and Employment
- Advanced Reach Tool (ART)
International consortium of industry and member states
- EUSES
(EU System for Evaluation of Substance)
- ConsExpo
(RIVM, Dutch National Institute for Public Health and the Environment)

⁸ See “Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (O.J. L133 31.05.2010, p40)

Appendix 2 – EXPOSURE MODIFICATION FACTORS FOR ECETOC TRA V. 3

The tables below report the factors used in ECETOC TRA V.3 to modify the exposure levels in different conditions of use. They can be used by DUs to compare the levels of exposure related to their conditions of use to the ES received by the supplier. This is possible if the supplier has provided information on levels of exposure or RCRs in the ES (e.g. in Section 3 of the SDS).

Acronyms

ERF = Exposure reduction factor

EMF = Exposure modifying factor $EMF = 1/ERF$

RMM = Risk management measure

APF = Assigned protection factor

| Duration of activity | ERF | EMF | % |
|----------------------|-----|-----|-----|
| >4 hours (default) | 1 | 1 | - |
| 1 - 4 hours | 1.7 | 0.6 | 40% |
| 15 mins to 1 hour | 5 | 0.2 | 80% |
| less than 15 min | 10 | 0.1 | 90% |

| Concentration in mixture (w/w) | ERF | EMF | % |
|--------------------------------|-----|-----|-----|
| > 25% | 1 | 1 | - |
| 5 – 25% | 1.7 | 0.6 | 40% |
| 1 – 5% | 5 | 0.2 | 80% |
| < 1 % | 10 | 0.1 | 90% |

| General Ventilation | ERF *) | EMF | % | Explanation |
|---|-----------|-----|-----|--|
| indoor basic ventilation | 1 | 1 | - | natural ventilation without any equipment, closed doors and windows (1-3 air exchanges per hour) |
| indoor good general ventilation / outdoor | 1,4 | 0.7 | 30% | natural ventilation without any equipment, open doors and/or windows (3-5 air exchanges per hour); equivalent to outdoor |
| indoor enhanced general ventilation | 3 | 0.3 | 70% | engineered mechanical ventilation (5-10 air exchanges per hour) |

*) ERF is 1 independent of type of ventilation for PROCs 1, 10, 19 and 20

| LEV | ERF *) (dermal / inhalation) | EMF | % |
|-------------------------|------------------------------|------|-----|
| no | 1 | 1 | - |
| yes (80% efficiency)* | 5 | 0.2 | 80% |
| yes (90% efficiency) | 10 | 0.1 | 90% |
| yes (95% efficiency) ** | 20 | 0.05 | 95% |

* only PROC 12

** only PROC 7, 8b (use at industrial site)

| Respiratory protection | ERF | EMF | % |
|------------------------|-----|------|-----|
| no | 1 | 1 | - |
| yes (90% efficiency) | 10 | 0.1 | 90% |
| yes (95% efficiency) | 20 | 0.05 | 95% |

| Skin protection (Gloves) | ERF | EMF | % | Explanation |
|--|-----|------|-----|---|
| no or usual gloves | 1 | 1 | - | no gloves or any gloves without permeation data |
| suitable gloves (APF 5) | 5 | 0.2 | 80% | gloves with available permeation data indicating that the material offers good protection for the substance (80% or APF 5) |
| chemically resistant gloves with 'basic' employee training (APF 10) | 10 | 0.1 | 90% | gloves with available permeation data indicating that the material offers good protection for the substance + instruction and plan (90% or APF 10) |
| chemically resistant gloves with specific activity training (APF 20) | 20 | 0.05 | 95% | gloves with available permeation data indicating that the material offers good protection for the substance + procedures for removal and disposal (95% or APF 20) |

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