ECHA
EUROPEAN CHEMICALS AGENCY

How downstream users can handle exposure scenarios

Practical Guide 13

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The purpose and nature of practical guides

Practical guides aim to help stakeholders interact with the European Chemicals Agency (ECHA). They provide practical tips and advice and explain the Agency's processes and scientific approaches. 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 included in the exposure scenarios attached to the SDS (hereinafter referred as extended SDS) and/or in the core section of the SDS

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 scenarios 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 which 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/publications_en.asp). 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/reach/du_en.asp. 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 and links to relevant support information.

An 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" - ECHA 2011

http://echa.europa.eu/documents/10162/13652/du_fact_sheet_en.pdf

Detailed information for downstream users is presented in the **ECHA Guidance for Downstream Users** (It is available in 22 languages but the link for the English version is http://echa.europa.eu/documents/10162/17226/du_en.pdf.)

The ECHA website contains a wide range of **supporting information** at all levels. The main access point for the support material is http://echa.europa.eu/web/guest/support.

The Support section of ECHA's website includes **frequently asked questions,** including downstream users' questions. These question and answer pairs have been prepared in response to questions frequently asked to the national REACH and ECHA Helpdesks. For questions relating to downstream user reports, there is also a link to **questions and answers on downstream user reports** from the downstream user main page of the website.

Examples of **exposure scenarios** and how they are developed are available at: http://echa.europa.eu/web/guest/support/practical-examples-of-exposure-scenarios

The ECHA Navigator tool might be helpful in identifying key obligations. It can be accessed at: http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/identify-your-obligations.

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.duccplatform.org.

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 also subject to the requirements of other regulations, including environmental, health and safety (EHS) legislation based on national laws implementing European Directives[1].

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 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 discharge 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 – Guid-*

[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).

ance for employers on controlling risks from chemicals' in 2009[2]. 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 (DU) and you use hazardous substances registered under REACH, your suppliers may have to provide you with an extended safety data sheet (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 describe how people and the environment may be exposed to a substance during manufacture; industrial, professional and consumer use; 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 Section 10.

2.2 What to do when you receive an exposure scenario

When you receive an extended SDS with a registration number[3] 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 is covered in the exposure scenario. If you are a formulator or re-filler, you also have to consider the foreseeable use by your customers. (Note that reference to “your use” includes foreseeable customer use where this is applicable.)

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. Check to see whether your uses are covered in Section 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

3. Assess the differences between the actual conditions of use and conditions described in the exposure scenarios. Three principal conclusions can be reached:

    a. **Actual use and/or conditions of use are covered by the exposure scenario.**

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

b. **Actual use and / or conditions of use are covered by the exposure scenario after applying scaling.** 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 within the boundaries of the exposure scenario received using a scaling approach (see Section 8).

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

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 5 of the ECHA Guidance for Downstream Users.

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

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 by the set of exposure scenarios (outcome 3a or 3b above), no further action is needed in that regard. Document your actions and conclusions and keep them available for enforcement authorities upon request[4].

If you supply the substance in mixtures, 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 10, Question 4.

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 the set of exposure scenarios (outcome 3c above), the main options available to you are summarised below. Document your actions and conclusions and keep them available for enforcement authorities upon request[5].

If you supply the substance in mixtures, 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 10, Question 4.

a. Ask your supplier to include your use in their chemical safety report and to provide you with an exposure scenario for it. You need to make sufficient information

[4] 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. Check lists and guides on how to document your check are being provided by relevant sector organisations. Contact your sector organization for 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 sector.

b. Check if you are exempt from the requirement to undertake a DU-CSR. This may be because:

- an SDS is not required for the substance or the mixture
- a CSR is not required for the substance
- the substance is exempted in a mixture in concentrations below threshold limits set in Article 14(2) of REACH
- your total annual usage is less than one tonne
- the substance is used for product and process oriented research and development (PPORD). The definition of PPORD is in Article 3(22) of REACH

c. Carry out your own chemical safety assessment and prepare your own “downstream user” chemical safety report (DU-CSR) for your uses and conditions of safe use. This is described further in Section 9.

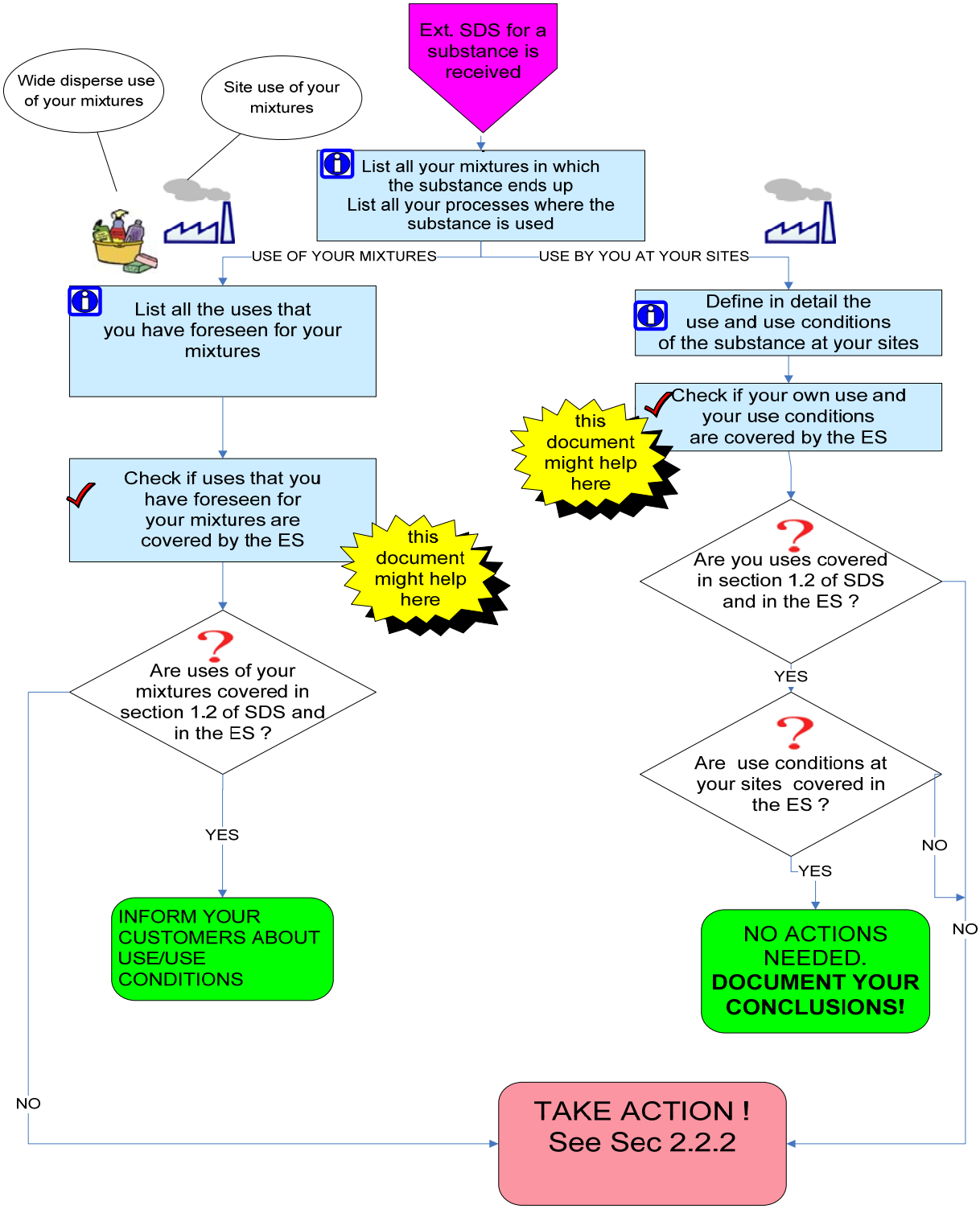
d. Investigate whether other suppliers incorporate your use in their exposure scenarios, and change to one of these suppliers if feasible

e. Eliminate or substitute the substance or the activity

The most suitable option will depend on your own situation. A more comprehensive overview is presented in Chapter 6 of the ECHA Guidance for Downstream Users.

Depending on the action undertaken, you may have to report to ECHA. The obligations in this regard are described in section 2.2.3.

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.

2.2.3 Obligation for downstream users to report information

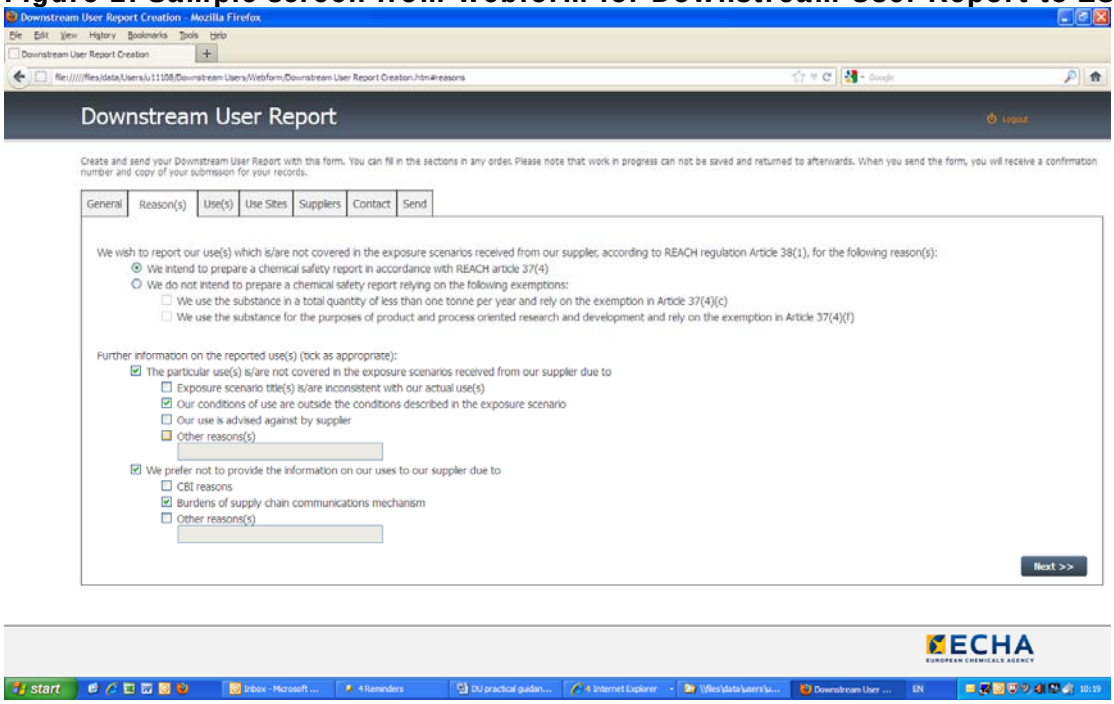
If you are a downstream user, you may have to report to ECHA in a number of situations[6]. These are when:

- you need to prepare a downstream user chemical safety report
- you are exempt from preparing a chemical safety report because you use the substance in total less than one tonne per year
- you are exempt from preparing a chemical safety report because you use the substance for product and process oriented research (PPORD)
- your classification of a substance is different to that of your supplier

You can report to ECHA using a Downstream User Report webform, which is accessed from the downstream user pages of the ECHA website:
http://echa.europa.eu/web/guest/regulations/reach/downstream-users

A screen shot from the webform for reporting to ECHA is shown in Figure 2. Instructions for completing this form are provided in the website and within the webform itself.

Figure 2: Sample screen from webform for Downstream User Report to ECHA



2.2.4 Overview of obligations and timelines

An overview of the main downstream user obligations and the associated timeframe are presented in Table 2.1 and summarised below. The deadlines specified for compliance start from the day you receive an SDS with a registration number.

a. If your use is not covered, you should inform your supplier or take alternative actions without delay, as you have **12 months** to implement whatever measures you decide to take.

[6] See article 38 of REACH for the full legal text

b. If you inform your supplier that your use is not covered (in writing), the supplier must comply with their obligations **before the next supply**. However, if the next supply is within one month of the notification, the supplier has **one month** to comply with their obligations.

c. If the supplier decides that they cannot support your use, they should inform you about it **without delay** (Article 37(3)).

d. If you intend to carry out your own chemical safety assessment, you have **12 months** to do so and to implement any measures necessary.

e. If you have to report to ECHA because you intend carrying out a CSA or if any exemptions apply, you have **6 months** to do so.

f. If you supply the substance to your own customers, you must update the SDS **without delay** if new information which may affect the risk management measures, or new information on hazards, becomes available. You must also update immediately if an authorisation has been granted or refused or a restriction has been imposed. Otherwise, the transitional periods specified in Commission Regulation (EU) 453/2010 Article 2 apply. This is detailed further on the ECHA website in the FAQ's regarding "Information in the Supply Chain".

Keep in mind that if you supply a substance further downstream, you in turn are a supplier and must meet the time requirements described for suppliers.

Downstream User Activity	Timeframe	Comment *
Inform your supplier of your use: *substances not yet registered*	Supplier to assess the risk of that use, provided DU makes request one year before registration deadline.	31 May 2012 for 2013 registration (quantities>100t/y) 31 May 2017 for 2018 registration (quantities >1t/y). This is a voluntary action
Inform your supplier of your use: *registered substances (use not covered in SDS)*	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: ➢ Ask supplier to include use and implement measures ➢ Conduct DU chemical safety report (CSR) ➢ Determine if exemptions apply ➢ Change supplier, if feasible ➢ Eliminate or substitute the substance
Communicate information to your suppliers	If required, without delay	You should inform your supplier about (*Article 34):* ➢ New information on hazards ➢ Inappropriateness of suggested risk management measures
Communicate information regarding safe use to own customers	If update is required, without delay	Update SDS if *(Article 31(9))*: ➢ New information on risk management measures or hazards becomes available ➢ An authorisation was granted or refused ➢ A restriction has been imposed
Conduct 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 unsupported uses to ECHA	Six months from receipt of SDS for registered substance.	This applies if you are: ➢ Preparing a DU CSR ➢ Claiming exemptions due to use <1 tonne/year or used for PPORD ➢ Classification is different to

3. INTRODUCTION TO THE PRACTICAL EXAMPLES

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 ECHA exposure scenario format for worker uses and consumer uses.

Examples are provided for the following elements of exposure scenarios:

Section 4 Examples related to the **title section** of the exposure scenario.

Section 5 Examples related to the use of substances at industrial sites, focusing on exposure to the **environment**

Section 6 Examples related to the use of substances at industrial and professional sites, focusing on exposure to **workers**

Section 7 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 SUx, PCy, PROCz, ERCw). Details on these descriptors are provided in the Guidance on information requirements and chemical safety assessment *Chapter R.12: Use Descriptor System*[7], available on the ECHA website (follow the guidance link): http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation

Regarding the format of the exposure scenarios, there are no specific requirements in REACH. The ECHA *Guidance on Information Requirements and Chemical Safety Assessment - Exposure Scenario Format*[8] recommends formats[9] for the exposure scenario for uses of substances. Examples of exposure scenarios are available at: http://echa.europa.eu/web/guest/support/practical-examples-of-exposure-scenarios

Additional information on Exposure Scenario building and Exposure Scenario format is available on the ECHA CHEmical Safety Assessment and Reporting tool (CHESAR) website.[10]

[7] http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf
[8] http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_ESformat_en.pdf.
[9] Although not a legal requirement, the *format* is a means to structure the relevant information to be documented in the exposure scenario in a standardised way. Sector organizations have also provided ES formats of their own.
[10] http://chesar.echa.europa.eu/

Table 2: Comparison between actual conditions and those in the Exposure Scenario		
Exposure Scenario	Check your conditions* and your customer conditions for each of the following aspects	Practical Examples
Title Section	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.	T1, Exposure scenario for consumer end-use is missing T2 The relevant product category is not mentioned in the title section
	Does the exposure scenario cover all tasks or processes relevant for the uses?	T3, Contributing scenario for process step is missing T4 Process Categories are missing
Environmental Section	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)	E1 Daily use amount likely to be exceeded
	Are the risk management measures (RMM) in line with the ? Are the specific technologies used (such as waste water treatment processes, filters, air abatement systems) compatible? Does the effectiveness equal or exceed the effectiveness of RMM indicated in the exposure scenarios?	E2 Risk Management Measure differs from exposure scenario assumption
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 RMM indicated in the exposure scenarios, including Local Exhaust Ventilation (LEV), available? If so, is the effectiveness in line with exposure scenario requirements? Is the personal protective equipment (PPE) used in compliance 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 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 incorporated in most of your mixtures, in differing concentrations.

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 nor in the titles of the exposure scenarios provided.

Analysis

- The use of substance A at your site and professional use of your mixtures is supported by the exposure scenario. For your own use, proceed to the next step, by checking 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 a contributing scenario for consumer use.
  - Consumer use has intentionally not been covered by the supplier.

Options

- Check with your supplier as to why you did not receive an exposure scenario for consumer use of the substance A. If consumer use has mistakenly omitted from the exposure scenario you received, ask your supplier to send you a new version of the exposure scenario covering consumer use. Your ***consumer use is covered*** in the new exposure scenario which you receive (see Section 2.2.1 for further advice)
- If your supplier cannot cover 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 PC 35) and you use a substance Z in your mixtures. You receive a set of exposure scenarios from your supplier 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 formulation of your mixtures at your sites is covered by this exposure scenario.

Analysis

- The general exposure scenario for industrial formulation should cover all industrial uses (including yours). To be sure that your use is covered, 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 conditions of use to check whether your conditions are covered by the exposure scenario.

Options

- You conclude that your conditions of use are covered by 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) system. At present, Substance A is shipped to you in 50-litre containers that are directly connected via “quick connectors”, to the closed loop system. Substance transfer and line purging steps are fully automated and enclosed.

You receive an exposure scenario for substance A entitled “Cleaning and sterilisation of production machinery in food processing” with closed batch process (PROC 3) assigned. You are satisfied you current use is covered by that.

To eliminate drum handling, you intend changing to tank supply of Substance A, delivered in bulk in truck trailers. With bulk delivery, the substance is transferred from the trailers to onsite storage tanks and from these storage tanks to the dairy plant during CIP. 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 PROC 8b) 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
  - The transfer from/to vessels is not covered by the exposure scenario

Options

- Check the contributing scenarios for a task such as transfer from/to mixing (PROC 8a/ 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 non supported use, then ***your use is not covered*** and 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 use descriptors:

- industrial formulation of mixtures (SU3, SU10);
- mixing in batch processes in closed system (PROC 3),
- mixing in batch processes (PROC 5),
- transfer at dedicated facilities (PROC 8b),
- transfer into small containers (PROC 9)
- formulation of preparations (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 ***industrial formulation of mixtures***, with the following use descriptors in the title section:

- formulation of preparations SU10;
- mixing in batch processes (industrial use) PROC 5,
- transfer for mixing (industrial use) PROC8a
- transfer in small containers (industrial use) PROC9;
- formulation of preparations 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,* so your industrial use (SU3 and SU10) is covered. Your key processes are also covered: mixing in batch process (PROC5), transfer of raw material (PROC 8a) and filling operations for the final product (PROC9).
- Assuming the conditions of use are comparable (such as, concentration of substance, ventilation conditions, risk management), PROC 8a should cover PROC 8b and PROC 5 should also cover PROC 3. You need to check all information in the exposure scenario to verify this. In particular, you need to check whether the conditions of use for semi-open mixing (PROC 5) and for transfer (no dedicated equipment) (PROC 8a)) in the exposure scenario, cover the conditions of use at your site which you have identified with PROC 3 (mixing in batch processes in closed system) and PROC 8b (transfer for mixing at dedicated facilities).

Options

- You conclude that your conditions of use (including PROC3 and PROC8b) are covered, and thus ***your use is covered by the exposure scenario***. (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 dye-stuffs and you use a Substance Y in your dyes. You receive an exposure scenario for 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. No onsite risk management measures are indicated in the exposure scenario to control exposure to the environment.

Normally, you do not exceed the daily use of 50kg/day and you have onsite RMM in place to control releases to the environment (air and water). You face a high temporary demand of your dyes from one of your major customers, which will require you to use about 60kg/day of Substance Y for a few weeks (3-4 weeks maximum) in one year. You wonder if your conditions of use are still covered by the exposure scenario in this temporary phase.

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 cannot be considered to be covered by the exposure scenario. However, in some cases, changes in daily quantity might be compensated by changes in other conditions (for example, by increasing effectiveness of RMM).

Options

- You should check with your supplier if the maximum exposure scenario quantity of 50kg/day may be exceeded and if so, ask them to provide applicable conditions of use to compensate for the higher quantity. Scaling may be a suitable option in this case. After applying scaling, you may conclude that ***your use is covered*** by the exposure scenario (see Section 2.2.1 for further advice)

Example E2 – Risk Management Measure differs from exposure scenario assumption

Case description

Assume you are an instrumentation manufacturer and undertake powder coating of equipment panels. You receive an exposure scenario for industrial use of an organic substance K in coating applications. In the exposure scenario, an abatement system for air emissions via wet scrubbers with a 95% removal effectiveness is recommended.

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

Analysis

- The effectiveness of air pollution removal of your bag filters is higher than that specified in the exposure scenario. However, the technology of RMM in place at your site differs from the technology of RMM indicated in the exposure scenario. This could be a problem if your technology leads to a release on a pathway that was not assessed by your supplier. However, for the current case, the substance is captured by bag filters which are incinerated, and thus no shift to another release pathway is expected.

Options

- Your RMM is more effective, your waste is incinerated. Due to this, no additional impacts to other release pathways such as air, soil or water are generated. 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 metal working fluids for a few key customers with substance A in concentration <25%.

Your supplier sends a set of ESs for your use (formulation) covering concentrations up to 100% and for end use in lubrication processes at high energy (e.g. metal cutting) covering concentrations up to 10%. According to this end-use ES (lubrication at low concentration), suitable gloves are needed to ensure safe use by workers.

Analysis

- The use of the substance at your site (formulation) is supported by the ES.
- The use of the majority of your metal working fluids (conc. <5%) are supported by the ES received. Make sure to include information on gloves in safety information for your customers.
- The concentration of the substance in your customized working fluid (concentration < 25%) is higher than the concentration limit (10%) in the received ES and thus your customized applications are not covered by the ES from your supplier. However, in some cases, changes in concentrations might be compensated by changes in other conditions (e.g. by reducing exposure time) via scaling.

Options

- Use at your site and use by your customers at low concentration (<5%) ***are covered by the ES*** (see Section 2.2.1 for further advice)
- Use by your customers at higher concentration (<25%):
  - if your supplier has provided scaling options, you should check if concentration in the ES (< 10%) may be exceeded by changes in other parameters (e.g. exposure time). After applying scaling you may conclude that ***your use is not covered*** and thus you must take action (see Section 2.2.2 for further advice)

Example W2 – Use indoors by professionals is not covered.

Case description

Assume your company specialises in the application of fire resistant coating 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 incorporated in one of the coating mixtures you apply which covers manual coating operations over 4 hours. Only outdoor use is covered. Nono RMM related to ventilation or respiratory protection equipment are specified.

Analysis

- Outdoor application is supported by the ES.
- Application in the workshop, could, however, generate risks to workers due to limited ventilation. This use is not covered by the ES. The reasons could be:
  - the supplier has mistakenly forgotten to provide an ES for indoor use
  - the supplier has decided to not cover indoor use

Options

- ***outdoor use is covered by the ES*** (see Section 2.2.1 for further advice)
- Regarding use at your workshop:
  - check with your supplier why indoor use has not been considered in the ES. If ES for indoor use was mistakenly forgotten, ask him to send you a new version of the ES covering indoor use. Your ***use in the workshop is covered*** in the new ES which you receive (see Section 2.2.1 for further advice)
  - If your supplier cannot include indoor use in his ES, your ***use in the workshop is not covered*** and you must take action (see Section 2.2.2 for further advice)

Example W3 – Closed system not available at customer level

Case description

Assume you are a producer of non-reactive processing aids for use by polymer converters. You use a volatile substance X as a solvent. You receive an exposure scenario from your supplier where closed systems are required as a condition to minimise exposure to workers by inhalation (corresponding to PROC3). Under these conditions, no additional RMM are required to protect workers.

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

Analysis

- Your own conditions of use are supported by the exposure scenario.
- Use by your customers might not be covered.

Options

- ***Use at your sites is covered by the exposure scenario*** (see Section 2.2.1 for further advice)
- Use by your customers:
  - notify your customers about the conditions of use (e.g. by including an exposure scenario to the SDS of your products). Your customers, in turn, have to check if their conditions of use are covered and take necessary steps.

Example W4 –Effectiveness of RMM less than ES specification

Case description

Assume you are a manufacturer of construction chemicals. In some of your formulations, you use a powdered substance A. Your supplier of substance A sends an SDS with exposure scenarios attached where LEV with 70% effectiveness is required in charging and discharging of vessels and in mixing processes, where full shift activity (duration <8hours) is assumed.

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

Analysis

- The conditions of use at your site are outside the boundaries of the exposure scenario you have received due to the relatively low effectiveness of your LEV. However, the lower effectiveness of RMM might be compensated, in some cases, by a change in other conditions of use via scaling.

Options

- If your supplier has provided scaling options, check if lower effectiveness of your LEV may be compensated, via scaling, by other conditions which may be applicable at your sites (e.g. lower duration of activity/use)
  - After applying scaling, perhaps you conclude that ***your conditions of use are not covered***, thus you must take action (see Section 2.2.2 for further advice). You may also decide to perform your own CSA to demonstrate that risks at your sites are controlled. Your monitoring results may support this assessment.
  - You can alternatively, upgrade your LEV system to reach the required level of effectiveness.

Example W5 - Absence of risk management measures at customer level

Case description

Assume you are a producer of oil based metal working fluids 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 an exposure scenario for industrial end-use where LEV with over 90% effectiveness is required to limit respiratory exposure. You have LEV at your sites matching the required effectiveness. Based on your knowledge about the metal processing sector, you are aware that a significant number of metal processing companies have either no LEV systems or LEVs of lower effectiveness.

Analysis

- Use at your sites is supported by the exposure scenario.
- Use by your customers could not be covered, however in some cases lower LEV effectiveness can be compensated with changes in other conditions.

Options.

- Use at your site ***is covered by the exposure scenario*** (see section 2.2.1 for further advice).
- It is likely that the use of a number of your customers ***will not be covered*** by the exposure scenario if you simply forward the information that you have received from your supplier. If your customers have LEV with lower effectiveness, this condition could be compensated by change in other conditions of use via scaling. If scaling options are provided in the ES, forward this information to your customers. If LEV is not available, the **exposure scenario does not cover** the use. Possible actions include development of a new exposure scenario or implementing technical/engineering solutions.

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 exposure scenarios.

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 an exposure scenario where specific training requirements are indicated (such as periodic training on substance properties and handling procedures).

Training and certification programs for workers are in place at your sites and at your industrial customer sites, which fulfil the requirements of the exposure scenario. However, your paints are also used by workers in small scale car body repair shops where training programs cannot be checked.

Analysis

- At industrial workplaces, implementation of training is 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 are needed to guarantee safe use.

Options

- Industrial use: ***is covered by the exposure scenario*** (see Section 2.2.1)
- Professional use ***could be not covered***. 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 label and appropriate, additional supporting material (e.g. leaflets) could be sufficient to ensure the safe use of the substance.

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 agents, you use substance X as a degreaser. The concentration of substance X is up to 25%. Your supplier of substance X sends an exposure scenario covering concentration of the substance up to 5% in consumer goods.

Analysis

- The concentration of substance X in your cleaning agents is significantly higher than the concentration indicated in the exposure scenario.

Options

Consumer use of your products is ***not covered by the exposure scenario.*** Reduce the concentration of substance X in your cleaning agents to match the concentration indicated in the exposure scenario or you will 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 multipurpose cleaning products. You use a volatile substance A in your cleaning products. Your supplier of substance A sends an exposure scenario covering consumer use of the substance in cleaning products. In the scenario, it is indicated that containers for consumer use should be equipped with dispensers to limit the substance quantity used to less than 10mg/event to reduce exposure by inhalation. Your containers do not have dispensers, making it more likely that the dose/event would be exceeded.

Analysis

- The specific quantity per application indicated by the supplier is a fundamental parameter for the assessment of consumer exposure. A mechanism for ensuring that the correct quantity is used is required.

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. dispenser, single unit dose, no spraying) or the design of your cleaning products (such as tablets, gels or foam) to match the quantity per event reported 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 usually applied in garages, wet rooms or basements. You use a substance Y in your formulations.

You receive an exposure scenario from your supplier of substance Y, covering use of substance Y by consumers. It indicates that very good natural ventilation (open windows) or forced ventilation is required during use.

Analysis

- Absence of good ventilation (no windows and no forced ventilation available) must be assumed in some situations when your coatings are used. 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 in a well ventilated area”).
- ***Indoor use is not covered by the exposure scenario***. If indoor use of your coatings is intended, 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 product to reduce the risks associated with evaporation.

NOTE: If the hazardous properties of substance Y might lead to high risks for consumers, investigate the feasibility of removing substance Y from consumer goods, 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 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 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 use of gloves may result in poorer manipulation of the micro-amounts of adhesives, giving rise to 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 unsuitable 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 conditions do not exactly match the conditions in the exposure scenario. However, it may be possible to demonstrate that the downstream user conditions provide for safe use of the substance using an approach termed “scaling”.

This approach, which replaces the need for a (CSA), is further described further here.

8.1 Introduction to Scaling

In an exposure scenario, the supplier defines one combination of conditions of use that provides for the safe use of the supplier’s substance with respect to humans and the environment.

If the exposure scenario is based on a quantitative CSA, safe use of a substance is assumed when the estimated exposure is below the Derived No-Effect Limits (DNELs) and Predicted No-Effect Concentrations (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 exposure is estimated using measured data or mathematical models, based on specified operational conditions, types and effectiveness of risk management measures. These conditions of use are communicated by registrants to downstream users through the relevant exposure scenarios attached to the SDS.

The conditions of use specified in the exposure scenario represent the minimum requirements that a downstream user should implement in order to achieve the level of exposure that has been assumed by the registrant for a particular use of the substance.

In practice, conditions of use at downstream user sites are likely to differ in some way from those specified 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.**

Additional information on scaling and practical examples on scaling are available in the following ECHA guidance documents:

Guidance for Downstream Users
http://echa.europa.eu/documents/10162/17226/du_en.pdf.

Guidance on Information Requirements and Chemical safety assessment:

Exposure scenario Format (in part D and in part F)
http://www.echa.europa.eu/documents/10162/13632/information_requirements_esformat_en.pdf
Extending the Safety Data Sheet (Part G)
http://www.echa.europa.eu/documents/10162/13632/information_requirements_part_g_en.pdf

9. DOWNSTREAM USER CHEMICAL SAFETY ASSESSMENT

Section 2.3 outlines the possible actions to take if your conditions of use are not covered. One option is to undertake a Chemical Safety Assessment (CSA) within 12 months of receiving an extended SDS with a registration number. Although you can ask your supplier to undertake this assessment, you may prefer to do it yourself[11].

A downstream user CSA is not as complex as a CSA carried out by a registrant. It needs to address only those uses that are not covered in the received exposure scenarios. There is no requirement to undertake a hazard assessment, if you consider that the hazard assessment reported in the SDS is appropriate. The general provisions for downstream user CSRs are presented in Annex XII of the REACH Regulation. The format of the CSRs should follow that set out in Annex I of the REACH Regulation (sections 9 and 10 only, if appropriate).

You are likely to have site-based risk assessments and measurements to draw upon, which were undertaken in accordance with the Chemicals Agents Directive, Industrial Emissions Directive or other relevant EU-EHS legislation. The CSA could be based on one or more of the following:

1. Chemical risk assessments already undertaken at your site for the activity / process category of interest

2. Personal exposure or environmental emission measurements undertaken for the activity / process category of interest or similar tasks

3. Exposure estimation using an appropriate tool[12] such as:

   a. Ecetoc TRA
   b. Stoffenmanager
   c. Advanced Reach Tool (ART)
   d. EUSES
   e. ConsExpo

4. Determination of appropriate control measures using control band based tools such as:

   a. COSHH Essentials (from UK Health and Safety Executive)
   b. EMKG (from BAuA, the German Federal Institute for Occupational Safety and Health)

5. Generic CSA's undertaken by your sector organisation as part of the development of generic exposure scenarios.

Keep in mind that the key objective of this in-house assessment is to establish whether your conditions of use are safe, and whether they pose a risk to human health or the environment. If the assessment establishes that they are not safe, then changes to your conditions of use must be implemented. You must provide relevant information on safe use to your customers.

[11] Check first whether you are exempt from the requirement to undertake a CSR as described in section 2.2.2
[12] These tools are publically available, free of charge. The tools vary in their level of sophistication and applicability. Some are conservative screening models, others incorporate greater specification of parameters, giving a more robust estimation for certain scenarios.

If you generate your own (CSR), you do not have to submit it to the authorities, but you do have to keep it up-to-date and make it available upon request.

In addition, you are required to report to ECHA according to Article 38 of the REACH Regulation, as described in section 2.2.3.

10. DOWNSTREAM USERS QUESTIONS AND ANSWERS

Common questions which may be posed regarding exposure scenarios and how to handle them are answered here. A more comprehensive range of questions and answers on downstream user reports and issues related to exposure scenarios are responded to on the ECHA website at: http://echa.europa.eu/web/guest/support/faq/questions-and-answers-on-downstream-user-reports

Q1 I haven't received exposure scenarios. Why not?

Q2 My use/conditions of use are not covered and I've contacted my supplier. What can I expect them to do?

Q3 I have more than one supplier for a substance and their exposure scenarios for the same substance are different. What should I do?

Q4 We supply the substance in mixtures. What should we inform customers of and how?

Q5 How can I be responsible for how my customers use my mixtures?

Q1 I haven't received exposure scenarios. Why not?

You may not have received exposure scenarios attached to the SDS for the hazardous substances you purchase. There can be valid reasons for this, which include:

- the substance has not yet been registered (low tonnage band)
- a Chemical Safety Report (CSR) is not required for the substance[13]
- the substance was registered as a transported intermediate
- the substance is not hazardous and the SDS is provided on a voluntary basis
- the relevant information on Operational Conditions and Risk Management Measures is incorporated in the main body of the SDS
- your supplier has not yet updated the SDS
- for a mixture, the substance concentration in the mixture is below the cut-off concentration for which an exposure scenario is required.

If you think that none of these reasons apply and that an exposure scenario should have been provided, contact your supplier.

Q2 My use/conditions of use are not covered and I've contacted my supplier. What can I expect them to do?

Your supplier can undertake several actions:

- identify if your use is actually covered in the exposure scenario and inform you about it

[13] A CSR is required for substances registered in quantities over 10t/y. If the substance meets the criteria to be classified as hazardous, an exposure assessment and exposure scenario (sections 9 and 10) should be included in the CSR.

- if the use is advised against, inform you why. Your supplier also has to update their registration dossier and include the “use advised against” in Section 3.7 of annex VI of the registration dossier, if this was not done at the time of registration.
- assess your use/conditions of use and send you an updated exposure scenario (this involves an update of the CSR).

Communication along the supply chain can be time-consuming. You may experience delays in finding the right contact person, and further delays in getting an adequate response. There could be several reasons: your supply chain is long and complex; your substances are mostly imported from non-EU countries; your supplier does not have in-house expertise or has limited experience of REACH. If communication along the supply chain is difficult, your industry association may be able to help you.

When you notify your supplier, they are obliged to assess your use before the next supply. However, if the next supply is within one month of the notification, the supplier has one month to comply with these obligations.

Q3 I have more than one supplier for a substance and their exposure scenarios for the same substance are different. What should I do?

It would normally be expected that exposure scenarios relating to human exposure are similar. There may be valid reasons for the differences in exposure scenarios for the environment. For example, different suppliers may supply different overall quantities, and so the assumptions made in considering the environmental exposure would differ.

Check if you comply with the most restrictive requirements. If not, but you comply with another exposure scenario and consider that it ensures safe use, contact your suppliers to highlight this and to reach a satisfactory resolution.

Q4 We supply a registered substance in mixtures. What information should we provide our customers and how should we provide it?

If you supply mixtures which include one or more registered substances and if an SDS is required for the mixture, you, in turn, have to provide your customers with information on the hazards of the mixture and the conditions of safe use including appropriate risk management advice.

The main approaches to incorporate additional information on the substances are outlined below:

a. integrate information to provide for safe use of the substances into the core sections of the SDS.

b. develop exposure scenarios for your mixtures (using exposure scenarios received for the registered substances and/or downstream user CSA as the starting point). These replace the exposure scenarios provided by your supplier.

c. attach the exposure scenarios that you have received for the individual substances that are relevant to your customers. A summary and cross reference should be included in the core sections of the SDS.

The appropriate approach will depend on the properties and foreseen uses of your mixtures. See section 3.23 of “Guidance on the compilation of data sheets” for further information at: http://echa.europa.eu/documents/10162/13643/sds_en.pdf:

Q5 How can I be responsible for how my customers use my mixtures?

You are responsible for ensuring that, for your own use, the operational conditions and the risk management measures match the requirements of the exposure scenario and the SDS.

Regarding customer use, REACH does not require you to verify the actual conditions of use of your customer. Focus on the foreseeable conditions of use that are directly related to the particular technical purposes of your mixtures as indicated in Section 1.2 of the SDS. Ensure that customers are informed of the hazards and conditions of safe use (see question 4 above).

For example, if you produce paints, it is reasonable to expect that industrial paint may be sprayed, or to know that your mixtures are designed for indoor or outdoor use. It is not reasonable to know about aspects such as shift duration, ventilation systems, waste water treatment etc. at your customer sites, or be able to obtain this information.

It is the customer's responsibility to verify whether their conditions of use are covered by the SDS (and the exposure scenario, if required) they receive from you. They must take action if their use or conditions of use are not covered.

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 is 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"[14]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)

[14] 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)

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