ECHA
EUROPEAN CHEMICALS AGENCY

# An illustrative example of the exposure scenarios to be annexed to the safety data sheet

## Part 1: Introductory note

**Disclaimer**

This document contains general recommendations to assist registrants and downstream users in complying with their obligations under the REACH Regulation. However, users of this document are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

**An illustrative example of exposure scenarios to be annexed to the safety data sheet**
**Part 1: Introductory Note**

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# List of acronyms

| | |
|---|---|
| AC | Article category |
| Chesar | Chemical Safety Assessment and Reporting tool |
| CSA | Chemical Safety Assessment |
| CSR | Chemical Safety Report |
| DNEL | Derived no effect level |
| DUs | Downstream Users |
| ECHA | European Chemicals Agency |
| ERC | Environmental release category |
| ES | Exposure Scenario |
| ESCom | IT project on Exposure Scenario for communication |
| ESD | Emission Scenario Document |
| EUSES | European Union System for the Evaluation of Substances |
| IUCLID | International Uniform Chemical Information Database |
| LEV | Local Exhaust Ventilation |
| OC | Operational Conditions |
| PC | Chemical product category |
| PNEC | Predicted no effect concentration |
| PROC | Process category |
| RCR | Risk characterisation ratio |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| RMM | Risk management measure |
| SDS | Safety Data Sheet |
| SpERC | Specific Environmental Release Category |
| SU | Sector of Use |
| TRA | Targeted Risk Assessment |

# 1. Introduction

Exposure scenarios (ESs) are prepared for hazardous substances and reported in a chemical safety report (CSR) under the REACH Regulation. They document the conditions of use for a substance such that the risks to human health and/or the environment are controlled. When a substance for which a CSR has been prepared is supplied to downstream users, the relevant exposure scenarios has to be included as an annex to the safety data sheet (SDS). This is commonly referred to as the extended safety data sheet.

The exposure scenarios in the CSR contain information on all the identified uses of a substance that have been assessed by the registrant. The CSR (and its exposure scenarios) needs to be kept up to date by the registrant and available; for instance, to provide information to the authorities.

The exposure scenario that is communicated down the supply chain needs to be useful and relevant for the receiving downstream users (DUs) in ensuring that he can use the substance (either a substance as such or in a mixture) safely and support him fulfilling his obligations under REACH. For that purpose, it is necessary to modify it before communicating it downstream. The key information that an exposure scenario for communication should contain is:

- The uses and types of activities that the exposure scenario covers.
- The operational conditions that were assumed by the registrant when assessing the risk.
- Advice for safe use of the substance.

This information should preferably be provided in a harmonised format, with harmonised phrases.

This publication has been prepared as one of the activities under CSR/ES Roadmap[1] and is intended to support registrants in preparing their exposure scenarios for communication. The two main challenges are to identify the information to be extracted from the CSR and forwarded in the supply chain and to select the suitable standard phrases for communication: the illustrative example has been developed in order to provide solutions and advice to these challenges.

## 1.1 STRUCTURE OF THIS PUBLICATION

The publication consists of three parts:

**Part 1**: is this Introductory Note, which gives an overview of the format for the ESs to be annexed to the safety data sheet (SDS), advice regarding the selection of standard phrases and how this was done in the illustrative example. It also includes general points to consider when preparing such exposure scenarios.

**Part 2:** is an illustrative example of exposure scenarios to be annexed to the SDS. It exemplifies how the information contained in the exposure scenarios developed for a CSR can be extracted effectively and communicated in the ES annexed to SDS. This example is derived from the "Illustrative example chemical safety report"[2] published on the ECHA website for a hypothetical substance (the so-called "ECHA substance"). Due to the nature of this substance[3], and the status of some discussions, there are some limitations on this example. Over time, with further experience and knowledge, these limitations will be addressed.

1 See the "CSR/ES Roadmap" action 1.2, http://echa.europa.eu/csr-es-roadmap

2 http://echa.europa.eu/web/guest/support/practical-examples-of-chemical-safety-reports

3 The hazard profile of the ECHA substance can be found in the CSR illustrative example, section 4.3. Overview of Substance Properties and Hazard Classification

- The human health toxicity of the substance is low. Equally, the environmental toxicity is low and for the purposes of this example is not regarded to have long term adverse effects. Thus, the example does not illustrate cases where more stringent occupational and environmental risk management measures (RMMs) are needed.

- The example does not include exposure scenarios for the service life stage and waste life stage of the substance. Furthermore, experience on how and when to communicate specific advice on waste collection and treatment is still being gained.

- The example includes contributing scenarios for contained (closed) paint application processes; however, the possibilities of the ECETOC TRA and the ESCom phrase catalogue are limited in this respect. At present, it is not possible to describe and assess containment conditions in a process/task-specific way, except for synthesis and formulation.

This illustrative example serves to provide solutions and advice on how to extract information from a chemical safety report and how to report it in the exposure scenario; it thereby supports the demands for more clarity and harmonisation in the way information is communicated in the supply chain.

**Part 3**: is the Chesar 2.3[4] file from which the exposure scenarios in the example have been generated. Chesar is ECHA's tool for developing chemical safety assessments and was used to prepare the illustrative example CSR and the exposure scenarios for communication.

In addition, annotated templates of exposure scenarios for communication for an industrial use, a professional use and for consumers are published together this example and are available on the ECHA website [5].

4 http://chesar.echa.europa.eu/

5 http://echa.europa.eu/support/practical-examples-of-exposure-scenarios

# 2. General advice when preparing an exposure scenario to be annexed to the safety data sheet

Some general tips to consider when generating the ES for communication are as follows:

- Include a table of contents (ToC) before the actual ES for communication that are annexed to the safety data sheet. This table of contents provides an overview of the exposure scenarios contained in the extended safety data sheet. This ToC should consist of ES short titles (see section 3.1.1 below). Rules on how to generate the ES short titles are under discussion in the context of the CSR/ES Roadmap and will be soon available on the Roadmap ECHA website[6] .
- Group or arrange the ESs in a logical order, e.g. according to life cycle stages including the main user groups, or to the market sector.
- Prepare only those ESs and contributing scenarios[7] within an exposure scenario for communication that are really needed. For example, there is no need to communicate the ES for the registrant's manufacturing or own use.
- Limit the information in the ES to that which is practically relevant to the addressee (DUs). It is generally not necessary to convey conditions which do not constrain the use of the substance or cannot be controlled by the DUs.
- The ES should be neither excessively descriptive nor too general or vague. Seek a dialogue with downstream user organisations to strike the right balance. Risk management measures should be meaningful and appropriate.
- Clearly differentiate in the ES between the conditions of use that the downstream user is required to implement (and on which the assessment was based) and those conditions that are additional good practice advice.
- Ensure that the information is consistent within the different parts of the ES itself and between the ES and the main body of the safety data sheet, particularly sections 7 and 8 of the safety data sheet.
- Use a harmonised format (such as the ES format published by ECHA) and ESCom standard phrases (see section 3) as much as possible.

6 http://echa.europa.eu/csr-es-roadmap

7 A contributing scenario is a set of conditions referring to a specific activity/task within a use.
See also Chesar Manual 2, Chapter 3, https://chesar.echa.europa.eu/web/chesar/support/manuals-tutorials

# 3. Harmonised communication for exposure scenarios

Industry sector organisations, IT providers and ECHA are working together to standardise the communication for exposure scenarios as part of the CSA/ES Roadmap[8] . The cooperation relates to the format of the exposure scenario, the use of standard phrases in building the exposure scenario and the electronic communication of the information. The aim is to facilitate the supply chain communication mechanisms required under REACH.

Standardisation relating to exposure scenarios brings several advantages:

- It enables automation of the generation of the extended safety data sheets.
- It facilitates the process of translating the information into different languages.
- It minimises the potential for misunderstandings or conveying incorrect information.
- It provides consistency for the recipients.

This illustrative example is based on the harmonised format agreed between industry sector organisations and ECHA. The format is described in section 3.1, together with some considerations on how to identify the information to communicate. Due to the advantages described above, ECHA strongly recommends the use of the standards.

The standard phrases used in the illustrative example are based on the ESCom Standard Phrase Catalogue[9] wherever possible. Further considerations related to the selection and development of standard phrases are discussed in section 3.2.

An IT standard (termed the ESCom XML) has been developed to enable the electronic communication of exposure scenario information and the standard phrases contained in the ESCom standard phrase catalogue.

This example illustrates the layout of the ES for communication when generated by Chesar (see section 4).

## 3.1 FORMAT AND CONTENT OF EXPOSURE SCENARIOS

The agreed format of the exposure scenario consists of 4 sections:

1. Title section

2. Conditions of use affecting exposure

3. Exposure estimation and reference to its source

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

An outline of the content of each section, with reference to the illustrative example, is presented below.

8 See the "CSR/ES Roadmap" action 4.2, http://echa.europa.eu/csr-es-roadmap

9 Current version 1.4: http://www.cefic.org/Documents/IndustrySupport/REACH-Implementation/Guidance-and-Tools/ESCom/ESCom-phrase-catalogue-V1.4.xlsx , Consult the Cefic web pages for any update (http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/ ).

### 3.1.1 Title section

The title section includes a "short title" and a "title".

The "short title" gives a brief description of the scope of the ES and can be used to build the table of contents for the exposure scenarios that are annexed to the safety data sheet. It is composed of at least two identifiers:

- Life cycle stage: such as formulation, use at industrial site, professional use
- Market sector information: such as Product Category (PC) Sector of Use (SU) or the Article Category (AC).

It may include an optional additional third identifier such as technical process or level of containment. These optional elements are not included in any of the short titles in the ES for communication example here (Part 2) as they are still under development by industry.

Principles on how to build structured short titles have been agreed at ENES 6[10] and guidelines will soon be available on the Roadmap ECHA website.

The "title" includes the Exposure Scenario name. It also presents a list of all applicable tasks/activities (termed 'contributing scenarios' (CS) [11]) covered by the ES. The names and assigned use descriptors[12] (Environmental release category ERC, Process category PROC, Product Category PC, Article Category AC) of each contributing scenario are reported here.

The "short title" and "title" should be consistent. In most cases, the "short title" will be a structured summary of the information provided in the title section.

### 3.1.2 Conditions of use affecting exposure

This section is the core of the ES as it presents the Operational Conditions (OCs) and Risk Management Measures (RMMs) recommended for each contributing scenario.

Only those conditions of use that are practically relevant for a DU to ensure safe use are reported. This means that not all of the conditions of use that are reported in the ES in the CSR are transferred to the ES for communication. Factors that affect the relevance for the ES for communication include:

1. Whether the condition constrains the use of the substance. However, it has to be taken into account that, in some cases, even though conditions do not constrain the use, it is still useful to communicate them e.g. assumptions by the registrant during the assessment, or even making explicit that no restriction applies.

2. Whether DUs have control over the conditions of use; this is particularly important for ES addressed to end-users.

3. Whether the condition is important to enable the DUs understand the assumptions that the registrant has made on how the substance is used.

10 http://echa.europa.eu/view-article/-/journal_content/title/sixth-meeting-of-the-echa-stakeholder-exchange-network-on-exposure-scenarios-enes-6

11 A contributing scenario is a set of conditions referring to a specific activity/task within a use.
See also Chesar Manual 2, Chapter 3, https://chesar.echa.europa.eu/web/chesar/support/manuals-tutorials

12 See Guidance on use descriptors:
http://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

Illustrations of how these factors were applied in the example (Part 2) are:

Re. 1 Information such as "the substance cannot be used for more than 1 hour/day" is always reported in the ES.

Information on conditions that are "absent" was generally not included. For example, if the use of local exhaust ventilation (LEV) was not required in the chemical safety assessment, "no LEV" was not included in the ES for communication.

Re. 2 The exposure scenarios ES3 and ES4 in the illustrative example are intended for professional and consumer uses of the substance respectively. End-users have no control over the environmental conditions of use that are specified for the abovementioned uses since their uses are considered as wide dispersive uses. Consequently, the environmental conditions of use related to a Sewage Treatment Plant (STP), such as flow rates, application of sludge to agricultural soil, etc., were not reported in the environmental contributing scenarios in the ES for communication.

Re. 3 The exposure scenario ES 4 covers the consumer use of a coating. Consumers do not receive SDS nor ES. The ES for consumer uses are addressed to formulators so that they can use the information in the design of the products for consumers. For example, in these cases, the information on the concentration, amount and release area were included. A formulator can check and compare these conditions of use with the design of his product and the related technical instructions.

### 3.1.3 Exposure estimation

Section 3 of the exposure scenario for communication reports the methodology that has been applied to develop the emission estimation, the estimated level of exposure and the risk characterisation ratio for all the relevant protection targets (environment) and route/type of effects (human health). Alternative ways of completing section 3 are also possible, such as reporting the risk characterisation ratio only; in such case, the expected exposure can be calculated by the recipient of the SDS by means of the DNEL/PNEC reported in section 8.1.4 of the SDS.

This section is relevant to formulators and end-users of substances, if they are undertaking a more detailed review of the ES.

### 3.1.4 Guidance to Downstream Users to evaluate whether they work inside the boundaries set by the ES

Section 4 includes advice to the downstream users on how they can verify that their use is covered. One typical situation when such advice may be needed relates to the variability in the conditions of use ensuring control of risk. Various combinations of concentration and exposure time for example can lead to the same risk characterisation ratio. Same applies for the combination of daily use amount on site and environmental risk management measures. Usually the registrant will communicate one of such combination in his ES, but the DU may work with a combination different from that in the ES. In such situation a method termed "scaling" can be applied. This section is not mandatory; it can be used by the registrant if he wishes to provide information on scaling; if so, the section must include, as a minimum:

- Scaling method
- Scalable parameters
- Boundaries of scaling

This section is helpful for recipients when they are checking if their use is covered and it would typically direct them to a website calculator provided by the supplier.

Section 4 has not been completed in this illustrative example as it is still under development at the time of publication.

More information on how to verify if you are working in the boundaries set by the exposure scenario and details on scaling is provided in the Guidance for downstream users[13] and the Practical Guide 13[14] .

## 3.2 STANDARD PHRASES IN THE ESCOM CATALOGUE

The ESCom Standard Phrase Catalogue was used extensively in developing the example. Version 1.4 was used, the version available at the time of publication.

Existing standard phrases were selected as much as possible, whenever they were consistent with the information in the illustrative example CSR. Suitable standard phrases were typically available for the use names and for the phrases that relate to the conditions of use based on the exposure estimation tools such as ECETOC TRA.

Nevertheless, it was not always possible to identify a suitable standard phrase in the catalogue. Situations where this occurred in the illustrative example include:

- For transfer activities, such as those reported in the example at the formulation, industrial end use and professional end use stages (see exposure scenarios ES1, ES2 and ES3 respectively) where only the PROC definition was available in the phrase catalogue. These phrases (related to PROC 8 and PROC 9) were considered too long to be effectively understood by a downstream user. As a consequence, a new set of shorter phrases is proposed in the example. This has been done for the purposes of clarity in the example; under normal circumstances, new phrases have to be submitted for review by the ESCom Phrases Group for consideration and eventual inclusion in the catalogue.
- Some sentences or words in the phrases that are available in the phrase catalogue are not aligned/ consistent with terminology in the REACH Regulation, e.g. formulation of preparation instead of formulation of mixture. Therefore, phrases aligned to the REACH terminology are presented which are currently not in the ESCom catalogue.
- For the environment, the conditions of use linked to the specific exposure assessment (such as related to Specific Environmental Release Categories, SPERCs) are often expressed using phrases that are not currently available in the ESCom standard phrase catalogue (see for example ES 2 in the example). Therefore phrases were used which are currently not in the ESCom catalogue.

In general, when a suitable phrase could not be identified in the ESCom Standard Phrase catalogue, a phrase which is currently not in the ESCom catalogue has been used for exemplification purposes for the relevant identified use. Where this occurs, the phrase was made as general as possible, so that it can be used in other contexts. They may qualify to become standard phrases in the future. In the illustrative example, any phrase that does not come from the ESCom standard phrase catalogue has been written in Italic in the ES for communication (see Part 2).

The ESCom Standard Phrase catalogue will be regularly updated, taking into account new proposals from sectors and/or tools owners, so that its usability will further improve in the future.

If you generate "new phrases" that are not already included in the ESCom Standard Phrase Catalogue, first

13 http://echa.europa.eu/documents/10162/13634/du_en.pdf

14 http://echa.europa.eu/documents/10162/13655/du_practical_guide_13_en.pdf

check whether similar phrase is already available in the catalogue; if not, try to be as generic as possible so that the phrase can applicable to other cases. Involve sector organisations or co-registrants when generating new phrases; finally, follow the rules for building phrases as set in the phrase guidance document, and consider to submit them as new phrase proposal to the eSDScom website[15].

At the moment, the ESCom phrases are only provided in the English language. Translations are currently part of the commercial activities of the IT providers.

15 http://www.esdscom.eu

# 4. Generation of exposure scenarios using Chesar

The ES for communication has been generated using ECHA's Chesar 2.3 tool from an existing chemical safety assessment (previously published as the Illustrative example CSR Example[16] ).

The benefits of using Chesar include:

- It ensures consistency between the ES for CSR (submitted to ECHA as part of the registration dossier) and the ES for communication (supplied to downstream users as an annex to the safety data sheet).
- It enables the upload of the ESCom Standard Phrase catalogue and the search for suitable phrases using key words or metadata.
- It contains standard phrases associated with the Tier I determinants (conditions of use associated with Tier I models such as ECETOC TRA and EUSES), so that they will be automatically included in the ES for communication.
- It makes a pre-selection (see paragraph 2.1.2) of those conditions that merit reporting in the ES for communication, while permitting the user to deviate from the proposed pre-selection.
- It facilitates the printing out of the ES in a standardised format[17] in paper form.

16 http://echa.europa.eu/web/guest/support/practical-examples-of-chemical-safety-reports

17 See Chesar 2 User Manual – Part 5, https://chesar.echa.europa.eu/web/chesar/support/manuals-tutorials

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