

Second Workshop on REACH Review Action 3

**Improving the workability and quality of
extended Safety Data Sheets**

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Background document for discussions

Exposure Scenario Minimum Requirements (Scoping document)

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Disclaimer:

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1. Objective and Scope

Communicating safe use advice (based on a chemical safety assessment) down the supply chain in form of exposure scenarios (attached to SDS) is one of the core novelties introduced by the REACH system. REACH Annex I describes in quite a level of detail the possible content of exposure scenarios from the scientific risk assessment perspective. The last sentence of the first paragraph in Section 5.1.1 of Annex I requires that the exposure scenario (ES) as coming from the assessment is attached to the safety data sheet (SDS). Thus the legal text does not differentiate between the ES in the chemical safety report (CSR) (for scientifically demonstrating control of risk) and the ES as attached to the SDS (for advising users of the substance regarding safe handling and exposure controls). The only legal requirement in this respect is ensuring consistency between the information in the core body of the SDS, the attached exposure scenarios and the CSR.

Annex II of REACH does not set up any requirements for exposure scenarios when becoming part of the SDS, either as attachment (for substances) or included otherwise (for mixtures). Some ECHA guidance on exposure scenarios for communication has been developed over the years (in particular see IR/CSA guidance Part D)¹ and ECHA's chemical safety assessment (CSA) tool for registrants (Chesar) provides these ES in structured harmonised format and phrases. However, the absence of explicit requirements from the communication perspective has had a number of impacts on the way REACH has been implemented so far:

- Most SDS authoring systems have not yet fully integrated the exposure scenario element, with the consequence of errors due to manual copy and paste, duplication of information and inconsistencies.
- Downstream users have difficulties to establish compliance regarding their duties under Article 37(4) and (5). They are faced with multiple exposure scenarios in a large variety of format and quality, and often cannot even identify those exposure scenarios related to their own use.
- Inspectors have difficulties to enforce the presence of compliant exposure scenarios.
- Formulators are confronted with a high diversity in terms of content and format when trying to include the ES for their raw materials into the SDS for a mixture.

To improve the workability and usefulness of exposure scenarios, ECHA (in accordance with feedback received from many stakeholders) proposes to set up a number of explicit **minimum requirements** for exposure scenarios when being part of safety data sheet systems. Such a set of minimum requirements aims to i) increase the usefulness of ES information and at the same time ii) streamline and simplify the communication of safe use through the supply chain by creating a solid basis for support via IT tools. The set of explicit minimum requirements is also likely to increase legal certainty on all sides, including enforceability.

Note: This document leaves it open whether the minimum requirements are introduced via guidance, a European Standard, modification of REACH Annex II, or changes in the articles of the legal text. Nevertheless the choice of instrument is quite important as it will enable the "follow through" by investors.

2. Relevant requirements and definitions in REACH

- REACH defines an exposure scenario as a set of conditions (including operational

¹ Guidance on Information Requirements and Chemical Safety Assessment. Part D: Framework for exposure assessment
https://echa.europa.eu/documents/10162/13632/information_requirements_part_d_en.pdf/70da6d4b-5acf-40d9-8b75-1e1c311378df , ECHA (2016)

conditions (OC) and risk management measures (RMM)) that describes how the substance is used during its life-cycle and how the registrant recommends downstream users to control exposures of humans and the environment. An exposure scenario may cover one specific process or use or several processes or uses².

- Exposure scenarios are the output of a chemical safety assessment, and actors having carried out such an assessment shall place the relevant ES in an annex to the SDS covering the identified uses.
- Annex I defines the content of the ES from the scientific perspective, however always subject to relevance in a certain assessment context. It lists exposure determinants to be considered. Thus, REACH does not define a set of mandatory information items to be contained in an exposure scenario.
- Any downstream user receiving ES with SDS supplied to him shall i) apply the OC/RMM communicated to him, and ii) include the relevant exposure scenarios when compiling his own SDS for identified uses ((Article 31 (5 and 7))
- According to Annex II the SDS (*note ECHA: assumes this applies to the core body and any inclusions/attaching of exposure scenarios*) shall enable:
 - Users to take necessary measures related to protection of human health and environment.
 - Employers to determine whether any hazardous chemical agents are present at the workplace and to assess any risk arising from their use.
- The writer of the SDS (*note ECHA: assumes this applies to the core body and any inclusions/attaching of exposure scenarios*) shall:
 - Take into account the specific needs and experience of the user audience (as far as they are known).
 - Use simple, clear and precise language.

3. Approach to derive Minimum requirements

The minimum requirements outlined in some detail in Appendix 1 are based on a compilation of REACH Annex I and Annex II terminology. This results from the following considerations:

- Content-wise OC/RMM ensuring control of risk (REACH Annex I terminology) means pretty much the same as precautions for safe handling and exposure controls (REACH Annex II terminology with regard to sections 7 and 8 of the SDS).
- The compilation supports consistency and prevents duplication of information when attaching or otherwise including exposure scenarios into the safety data sheet of a chemical (substance as such or mixture).

Based on the above, the following has been chosen to define a core set of exposure driving conditions that should be addressed in every exposure scenario:

- Refer to the use identifiers as laid down in ECHA's Guidance R.12 and consequently being incorporated into IUCLID. These identifiers form the backbone of communication about uses and the related safety measures up and down the supply chain. It is suggested that the title of an exposure scenario by default makes reference to the chemical product(s) or article/material type(s) covered and whether it refers to uses at industrial sites or widespread use by professionals or consumers.³
- Extract, from the occupational exposure estimation tools that industry has used so far, a set of core determinants addressed in all of the tools. We assume that this reflects the scientific consensus among exposure experts which conditions of use are relevant for exposure assessment.

² REACH Article 3 (37), modified to focus on the communication aspect to downstream users.

³ Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.12 Use description, ECHA (2015)
https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf/ea8fa5a6-6ba1-47f4-9e47-c7216e180197

- For these determinants, sets of default values are proposed as resulting from a work process with tool owners, industry associations and some Member State authorities, carried out in the framework of the ENES 3.2 project (*Consolidate the different workers' exposure tools into a common framework*). The default values are associated with phrases, which are partly sourced from the ECom phrase catalogue and partly drafted by the project group (when no suitable phrase was available).⁴
- The way of organising the information within the exposure scenario corresponds to the sector use map concept having been developed and tested over recent years in cooperation between various industry sectors and ECHA.⁵ One of the key features in this concept is that downstream sector organisations map the uses of their members and define the existing conditions of use per activity, differentiating the conditions for low, medium and high hazard chemicals. This differentiation is very similar to the control banding approach as for example applied in the COSHH system.⁶ Based on this information suppliers are expected to determine and communicate the highest safe concentration or safe amount for their substance. This principle has been confirmed in the use map testing exercise by Cefic/DUCC.
- The minimum ES requirements for consumer uses have been drafted in an analogous way based on the core input parameters for two exposure modelling tools (ECETOC TRA and ConsExpo). The exposure determinants for communication have been limited to those that are under the control of the mixture or article producer (choice of product type, concentration, amount per use resulting from use instruction or product design, safety instructions to users (if any)).
- The minimum ES requirements for environment are very limited, as the corresponding release estimation tool (a SpERC based calculation of release in EUSES) is in an early stage of development and a core set of determinants reflecting a scientific consensus does not exist yet. In particular the missing link between conditions of use as defined in BREF documents and the REACH CSA approach is an obstacle here.⁷

4. Explanation of outline tables in the Appendix

Appendix 1 contains the proposed requirements for exposure scenarios for communication in the supply chain regarding control of exposure to workers and the environment. The left column displays the headings for differentiation among title elements and the different types of conditions of use. These headings mostly refer to items laid down in Annex I or Annex II of REACH.

The third column lists the conditions of use (exposure determinants) to be addressed in an exposure scenario (those assigned a * are considered minimum requirements). Some of the conditions of use (exposure determinants) are mentioned in Annex I or Annex II of REACH. Those not mentioned in REACH have been identified as being core conditions of use, based on the exposure modelling tools available.⁸

The fourth column assigns lists of default values (drop down menu) to most of the

⁴ ECom Package Guidance, Cefic <https://cefic.org/guidance/reach-implementation/escom-package-guidance/>

⁵ Use Maps , ECHA <https://echa.europa.eu/csr-es-roadmap/use-maps/concept>

⁶ COSHH essentials: Controlling exposure to chemicals – a simple control banding approach. HSE (01/17) <http://www.hse.gov.uk/pubns/guidance/coshh-technical-basis.pdf>

⁷ Best available techniques Reference document (BREF) developed under the IPPC Directive and the Industrial Emission Directive.

⁸ ENES Implementation plan 2018, ENES Action 3.2, page 19, ECHA https://echa.europa.eu/documents/10162/23915781/enes_implementation_plan_2018_en.pdf/40b081e7-e23d-c595-0997-52bb3623314a

determinants. These are either sourced from ECHA's Guidance R.12 and IUCLID (for the use descriptor elements) or from the worker exposure modelling tools in use.

For the conditions driving the environmental release a few determinants have been selected from the various SpERC factsheets published by industry.

5. Other minimum requirements

5.1. Table of contents

If an extended safety data sheet includes exposure scenarios for two uses or more, a table of contents is required, listing the exposure scenario titles, a page number in the Annex and providing a hyperlink.

5.2. Use identification in section 1.2 of SDS

The use identification in section 1.2 of the SDS refers to the function of the chemical. For single substances, this is the technical function of the substance within a mixture or an article.⁹ The technical function(s) listed in section 1.2 shall be consistent with the product and/or article types to which the exposure in that SDS refers.

For a mixture safety data sheet, section 1.2 defines the product category to which the mixture belongs.¹⁰

5.3. Embedded exposure scenarios

When exposure scenarios for ingredient substances are included into the SDS for a mixture, the exposure scenarios may be attached (as such or after consolidation into a single understandable section of advice on safe use) or embedded into sections 7 and 8. The requirements outlined above apply to both, embedded exposure scenarios and attached exposure scenarios.

Whether to embed or attach depends on the need to differentiate uses and/or contributing activities according to their conditions of safe use. Where an extended SDS covers various uses and/or where exposure regarding long-term systemic effects is to be controlled (and thus different activities require different control measures), usually the attachment is the more appropriate form of presenting the information.

⁹ See footnote 3. Chapter R.12 Use description, page 74, Table R.12- 15: Descriptor list for Technical functions (TF).

¹⁰ See footnote 3. Chapter R.12 Use description, page 45, Table R.12- 10: Descriptor list for Chemical Products Categories (PC).

Appendix 1

Initial draft (minimum)* requirements for Exposure Scenarios related to industrial and professional uses (including reference to existing guidance/requirements).

Minimum content requirement per single exposure scenario (General)	Existing "requirement" based on	Minimum content requirement per single exposure scenario (title identifiers and exposure determinants)	Default values <i>Note: Most of the qualitative values are already further defined in ECHA or industry guidance or in the proposed set of harmonised conditions of use developed under ENES action 3.2. A few value sets however may need some fine-tuning</i>	Existing "requirement" or other reference
<i>An exposure scenario can only cover one life cycle stage of a substance. The selected life-cycle stage determines which of the title identifiers and exposure determinants are relevant.</i>				
Exposure scenario title briefly describing the identified use covered	Annex VI, 3.5 Annex I,	Life cycle stage*	Formulation or re-packing Use at industrial site Widespread use by professional workers Article use [service life (worker at industrial site)] Article use [Service life (professional worker)]	R.12/IUCLID
		Product categories*	Multi-select; see descriptor list Guidance R.12	R.12/ IUCLID
		Article categories*	Multi-select; see descriptor list Guidance R.12	R.12/IUCLID
		Sector of use	Multi-select; see descriptor list Guidance R.12	R.12/IUCLID
		Additional information		
<i>The block below covers the requirements per contributing scenario within the exposure scenario. One exposure scenario includes two or more contributing scenarios. For the same activity two or more contributing scenarios may be defined, to determine the maximum safe concentration (or site amount) under certain risk management conditions.</i>				
Contributing scenario name briefly describing the activity/process covered	Annex I	Contributing activity name briefly describing the workers' activity/process covered*	Catalogue of sector specific names/titles if available (SWED titles in sector use-maps)	./.
		Type of process and related workers activity (PROC)*	see descriptor list Guidance R.12	R.12/IUCLID
		Risk management level [Control band] the OC/RMM refer to (<i>if such levels have been defined by sector</i>)	[1=low][2=medium][3=high]	./.
		Other information helping to understand the applicability of the contributing scenario	<i>To be worked out; potentially SWED code, highest safe concentration;</i>	./.

Minimum content requirement per single exposure scenario (General)	Existing "requirement" based on	Minimum content requirement per single exposure scenario (title identifiers and exposure determinants)	Default values <i>Note: Most of the qualitative values are already further defined in ECHA or industry guidance or in the proposed set of harmonised conditions of use developed under ENES action 3.2. A few value sets however may need some fine-tuning</i>	Existing "requirement" or other reference
Operational conditions (to which precautions and exposure controls apply)	Annex I	Physical form of chemical*	[Gaseous][Liquified gas][Liquid][Solid object][Granules, pellets, flakes][Solid suspended or dissolved in a liquid][Paste, slurry][Molten metal]	Annex I Values: IUCLID
		Dustiness of solid product during handling* (for solids only)	[low: granules, flakes, pellets][medium: coarse dust][high: fine and extremely fine dust]	Deter: Expotools Values: Expotools
		Duration of exposure per day*	[numval]	Annex I Values: Expotools
		Frequency of use	[Daily/frequent][Infrequently]	Annex I Values: Expotools
		Temperature of process*	[Ambient][Elevated]	ExpoTools
		Elevated temperature	<i>Specify upper bound</i>	
		Place of use*	[indoor][outdoor]	Deter: Expotools Values: Expotools
Risk Management Measures Recommend precautions for safe handling	Annex I Annex II	Specify (degree) of containment*	[no] [Low: Process contained with a loose lid or cover, not air tight. The enclosure is not opened during the activity] [Medium: Process contained. Transfer is enclosed with the receiving vessel being docked or sealed to the source vessel. The enclosure is not opened during the activity]. [High: Substance contained within a sealed and enclosed system. Material transfer entirely enclosed with high containment valves. The enclosure is not opened during the activity].	Annex 1, Annex II, 7.1 Values: Expotools
		Specify Measures to prevent dust and aerosol generation*	<i>To be worked out; e.g. submerged loading, wetting, vacuum transfer, airless spraying, ...;</i>	Annex II, 7.1

Minimum content requirement per single exposure scenario (General)	Existing "requirement" based on	Minimum content requirement per single exposure scenario (title identifiers and exposure determinants)	Default values <i>Note: Most of the qualitative values are already further defined in ECHA or industry guidance or in the proposed set of harmonised conditions of use developed under ENES action 3.2. A few value sets however may need some fine-tuning</i>	Existing "requirement" or other reference
Risk Management Measures Recommend appropriate engineering controls	Annex I Annex II,8.2.1	Specify extent of general room ventilation*	[Good standard of general ventilation; not less than 3 to 5 air changes per hour] [Good standard of controlled ventilation; 5 to 10 air changes per hour] [Specialised room ventilation of more than 10 air changes per hour] [Specialised room ventilation of more than 30 air changes per hour] [Downward laminar flow booth]	Deter: Expotools Values: Expotools
		Down ward laminar flow booth or spray room	[yes][no]	Deter: Expotools Values: Expotools
		Specify local exhaust ventilation*	[no] [Efficiency of at least 50% such as canopy hood, movable capturing hood, or other LEV systems] [Efficiency of at least 80% such as specialized receiving hoods] [Efficiency of at least 90 % such as capturing hood or on tool extraction] [Efficiency of at least 99 % such as fume cupboard]	Deter: Expotools Values: Expotools
Risk Management Measures Recommended Personal Protective Equipment	Annex I Annex II	Specify in detail eye/face protection*		Annex II, 8.2.2
		Specify in detail hand protection*	<i>To be worked out</i>	Annex II, 8.2.2
		Specify in detail other skin protection*	<i>To be worked out</i>	Annex II, 8.2.2
		Specify in detail Respiratory protection*	<i>List of APFs; to be worked out</i>	Annex II, 8.2.2
Other conditions of use				
Maximum safe		Provide highest concentration of	<numval>	Annex VI, 3.4

Minimum content requirement per single exposure scenario (General)	Existing "requirement" based on	Minimum content requirement per single exposure scenario (title identifiers and exposure determinants)	Default values <i>Note: Most of the qualitative values are already further defined in ECHA or industry guidance or in the proposed set of harmonised conditions of use developed under ENES action 3.2. A few value sets however may need some fine-tuning</i>	Existing "requirement" or other reference
concentration		substance resulting from application of OC/RMM* (CONC _{safe}) defined in this contributing scenario*		
Exposure estimates and RCR	Annex 1	8h average inhalation (daily) 8h average dermal (daily) 15 min peak inhalation	<numval> <numval> <numval>	
Exposure estimation method applied				
Environment part				
Contributing scenario name briefly describing the activity/process covered	Annex I	Contributing scenario name briefly describing the activity/process from the perspective of environmental releases*	Catalogue of sector specific names/titles (SPERCs in Sector use maps)	./.
		Category of release pattern (ERC)*	see descriptor list Guidance R.12	R.12/IUCLID
		Risk management level [Control band] the OC/RMM refer to (<i>if such levels have been defined by sector</i>)	[1=low][2=medium][3=high]	./.
		Other information helping to understand the applicability of the contributing scenario	<i>To be worked out; potentially SpERC code, highest safe amount per day;</i>	./.
Operational conditions to which the precautions and exposure controls apply	Annex I	Extent of water contact*	[no water contact][water contact only for equipment cleaning][water based process]	./.
Precautions for safe handling	Annex I Annex II	Degree/type of containment; closed system;*	<i>To be worked out;</i>	./.
Release/exposure controls	Annex II	Specify/exemplify types of suitable onsite controls to be applied for exhaust gas treatment; with required efficiency;*	<i>To be worked out;</i>	./.
		Specify/exemplify types of suitable	<i>To be worked out;</i>	./.

Minimum content requirement per single exposure scenario (General)	Existing "requirement" based on	Minimum content requirement per single exposure scenario (title identifiers and exposure determinants)	Default values <i>Note: Most of the qualitative values are already further defined in ECHA or industry guidance or in the proposed set of harmonised conditions of use developed under ENES action 3.2. A few value sets however may need some fine-tuning</i>	Existing "requirement" or other reference
		onsite controls to be applied for waste water treatment; with required efficiency;*		
		Indicate whether baths and other water-based residues are to be disposed of as waste.*	<i>To be worked out;</i>	./.
		Emission factors (fraction from used amount) assumed to be emitted.	% to air % to water % to waste	Deter: Expotools Values: Expotools
Highest safe amount per site under the conditions of use described.		Provide highest daily amount of substance per site resulting from application of OC/RMM* (Msafe) defined in this contributing scenario	<numval>	Deter: Expotools Values: Expotools
Exposure estimates and RCR	Annex 1	Predicted environmental concentrations and RCR	<numval> <numval> <numval>	Deter: Expotools Values: Expotools
Exposure estimation method applied				