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Second Workshop on REACH Review Action 3

Improving the workability and quality of extended Safety Data Sheets

23 and 24 September 2019

European Chemicals Agency, Helsinki

Pre-reading: Safety data for chemicals - End user needs

Scoping document

Disclaimer:

It must be noted that the solutions presented in this document have not been adopted or endorsed by the European Commission or ECHA. The views summarised are the views of ECHA staff based on exchange with stakeholders. They may not in any circumstances be regarded as stating an official position of the European Commission or ECHA.

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Glossary

CAD	Chemical Agents Directive
CSA	chemical safety assessment
CSR	chemical safety report
DNEL	derived no-effect level
DU	downstream user (includes formulators and end users)
ES	exposure scenario
HSE	health, safety and environment
OC	operational condition
OEL	occupational exposure limit
OSH	occupational safety and health
REACH	Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals
STOT	Specific Target Organ Toxicity
RMM	risk management measure
SDS	safety data sheet

1. Objectives and scope

This paper considers a downstream user's needs for information to assess and take decisions on the control of exposure to hazardous substances in the workplace. The document has been prepared by ECHA as part of on-going work in support of the Commission's Review on the operation of the REACH Regulation.[1]

In the context of REACH Review Action 3, the goal is two-fold:

1. Users of chemicals, in particular OSH managers, environmental managers and product safety managers, can benefit more from the extended safety data sheet (SDS) derived from the REACH chemical safety assessment (CSA) to meet their assessment needs at company level:
    - To determine the risk management measures (RMMs) for the workers, with reference to the risk assessment under national legislation which implements the Chemical Agents Directive (CAD).[2]

2. "Downstream users" can identify clearly whether their uses and activities are inside or outside the exposure scenario (ES) communicated to them.

In addition strengthening the downstream user's (DU) response (upstream) mechanisms is required.

Scope limitation:
Users of chemicals may have other assessment needs, in particular to:
- Control industrial emissions to avoid adverse effects in the environment.
- Ensure safety of own products (mixtures, articles).

This paper covers occupational safety and health (OSH) only. Corresponding work is underway in respect of the environment but it is not covered in this paper.

This paper does not cover the assessment that a supplier of a mixture must do in accordance with REACH Annex II, when generating an extended SDS for the mixture to meet certain information needs of a chemical end user under OSH.

Context:
This paper aims to serve as an input to the discussion at the 23-24 September workshop. It is addressed to workshop participants to prepare them for discussions on the following potential workshop output(s):

- Support for a framework which defines different downstream "user audiences" and their corresponding information needs.

- Initial feedback on handling the interface between (i) the exposure scenario received and (ii) the existing exposure control practice onsite in a workplace (based on CAD assessment). Where necessary, confirmation where the framework's scenarios need to be further worked out in a follow up to the September workshop.

[1] Specifically Action 3(1): The Commission encourages more industry sectors to develop and use harmonised formats and tools that would provide more user-targeted information and simplify the preparation and use of extended Safety data Sheets as well as facilitate their electronic distribution.and the related Action 12(1): How to use REACH tools (e.g. exposure scenarios, Safety Data Sheets) to enhance the effectiveness of OSH legislation.

[2] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from risks related to chemical agents at work (as amended).

- Confirmation from the OSH community on an example, that the content of the safe use advice is moving in the right direction

The paper concentrates on the registrant's assessment for his substance(s) in accordance with REACH Annex I in meeting the information needs of an end user under certain OSH legislation, when this information is communicated in an appropriate manner in accordance with REACH Annex II. This communication includes information in the exposure scenario.

Scenarios are presented for three situations (Table 1) in which an employer carries out an assessment following the provisions of CAD. The paper draws conclusions regarding how the REACH exposure scenario, whether attached or included into a safety data sheet, can support the CAD risk assessor in the situations described.

2. How the REACH exposure scenario supports the workplace risk assessment

This paper takes as its starting point the following similarities and/or differences between the exposure assessments under REACH (see Annex 1 of REACH) and CAD:

Similarities

- The same drivers of exposure exist.
- The same stepwise method can be applied to the exposure assessment, although the role of exposure quantification is slightly different.
- Use- or activity-specific assessment is required.
- Substance degradation and reaction products need to be taken into account.

Similar and different

- Exposure quantification under CAD is only mandatory for substances with an occupational exposure limit (OEL). Exposure quantification for substances with a derived no-effect level (DNEL) depends on the Member State's requirements in its national implementing OSH legislation.

Differences

- Single substance assessment (REACH) versus multiple substances (CAD).
- Particularities or specific conditions of a single site, e.g. the work organisation, the equipment infrastructure and its design, the workplace infrastructure and its design.
- Approach to the assessment of dermal exposure (usually no quantification required under CAD).
- The DU chemical safety assessment (CSA) is mostly carried out for a single substance whereas the workplace risk assessment should integrate all "chemical agents" present at the workplace.

Whilst acknowledging that the REACH Annex I assessment can never fully replace the CAD assessment (see differences above), when comparing the two assessments, one can conclude that the (on-site) workplace risk assessment with respect to chemical exposure mirrors what the REACH registrant of a hazardous substance does for a registration.

2.1 Exposure assessment tools

CAD does not prescribe the tool(s) to be applied by an employer to carry out the workplace risk assessment. Over the many years since CAD came into force (2001), Member States and industry sectors have elaborated and provided support to employers (e.g. standards, practical guides and tools) to assist them in undertaking a workplace assessment. Assessment approaches might be quantitative, especially when a substance

has a national occupational exposure limit (OEL) for inhalation, or qualitative in nature, such as control banding approaches. Alternatively, task- or process- or industry-specific guidance can be applied directly to the working situation.

In contrast, the exposure scenario is frequently generated by the REACH registrant utilising an exposure estimation modelling tool, the most commonly applied being ECETOC TRA. However, the basic/core information parameters are not dissimilar to those required for the CAD assessor. These can be summarised as follows:

- Substance identity; physical form; chemical-physical properties.
- Hazard information (driving scope of exposure assessment).
- Differentiate according to activity of worker (task/process).
- Relevant route(s) of exposure.
- Amount/concentration, duration and frequency.
- Risk management measures and their effectiveness (engineering controls and personal protective equipment).

2.2 User audience and information needs[3]

Given the hypothesis mentioned above that the REACH exposure scenario documents an equivalent range of information (corresponding to the hazard identified) such as the task(s), who is exposed and how, and how adequate control can be achieved with control measures in place, how then can such an exposure scenario support employers in completing their CAD workplace assessment?

A number of scenarios can be envisaged and this paper will elaborate further on the following situations of a company with the following characteristics:

- Large companies with own risk assessment capacity.
- Small/Micro companies without own risk assessment capacity, and:
  - Following the instructions provided by the supplier, sector organisation or authorities i.e. no separate or additional assessment beyond checking whether the instructions are followed.
- Whether national authorities request exposure quantification against a REACH-based DNEL or not.

Table 1 beneath expands on the factors relevant to each situation and provides a starting framework, which attempts to reflect the diversity of situations in the supply chain and in different Member States.

[3] The term "user audience" is taken from REACH Annex II Part A section 0.2.3: "The safety data sheet shall be prepared by a competent person who shall take into account the specific needs and knowledge of the **user audience**, as far as they are known."

Table 1. Utilisation of REACH exposure scenario in the CAD assessment for different workplace situations: a potential framework

Factors considered	Situation		
	User audience 1	***User audience 2***	***User audience 3***
	Company with full assessment capacity carries out quantitative assessment against OEL or DNEL.	*Company with full assessment capacity carries out qualitative assessment (except for substances with OEL).*	*Company benefits from supplier's assess-ment, and checks only applicability to their activity.*
Potential role of exposure scenario communicated with SDS (attached or otherwise included).	No, or an informal, source of potential improvement of on-site assessment. **Confirms** (without inspection) that foreseen hazards have been accounted for and "adequate control" is achieved.	**Complements** the existing qualitative assessment for non-OEL substances.	**Facilitates (or acts as)** the core part of end user's CAD assessment.
Processing of received exposure scenario.	Confirm presence of exposure scenario covering own uses. High level check for equivalence i.e. conformity with own uses; document any significant difference, and potentially inform supplier.	Confirm presence of exposure scenario covering own uses. In-depth equivalence check of measures (focusing on STOT classified substances and/or low DNEL substances); document significant differences (and inform supplier?)	Check whether own activities are addressed; follow supplier's recommendation.
Consequence of significant mismatch of exposure scenario with own site-based assessment	Notification to ECHA that use not covered, but that CAD assessment exists. Upstream communication if exposure scenario conditions inappropriate. [REACH Art.31(9)]. Improve, amend on-site OSH if relevant. Ensure that CAD assessment documentation basically matches DU CSR principles (REACH Annex XII).	Notification to ECHA that use not covered, but that CAD assessment exists. Upstream communication if exposure scenario conditions inappropriate. [REACH Art.31(9)]. Improve, amend on-site OSH if relevant. Ensure that CAD assessment documentation basically matches DU CSR principles (REACH Annex XII).	n.a. No own assessment, but if an exposure scenario cannot be found that fits, they should contact their supplier (or another supplier).
Particular quality requirements needed for exposure scenario.	Applicability domain of exposure scenario fully transparent to CAD assessor. Generic exposure scenario with abstract language on conditions of use (no technical details) to simplify matching with existing CAD assessment.	Applicability domain of exposure scenario fully transparent to CAD assessor. Generic exposure scenario but sufficiently specifying engineering controls resulting from the supplier's quantitative assessment.	Applicability domain of exposure scenario fully transparent to CAD assessor. OC/RMM expressed in technical language of the sector. No generic ES with abstract language. DU sector organisation promotes consistency across suppliers.[4]

[4] Note: The sector use map plays a pivotal role in connecting the DU sector -> registrant -> DU end user and the standard required for adequate control of exposure.

2.3 Practical implications of the framework

The following are some practical implications of the approach set out in section 2.2 and Table 1, on which further discussion will take place at the September workshop.

- Downstream user REACH CSR is still required for uses not covered at all in the extended SDS received.

- Are criteria required for a "light" documentation approach for the exposure scenario conformity check for **user audience 1**?

- For **user audience 2**, a method or simple comparison tool for an *equivalence assessment* to be developed.

- For **user audience 3**, any existing agreed practice/advice from authorities and/or sectors needs to be referred to in use maps.
  (In the absence of a sector use map, the fall-back position could be where the company follows previously agreed advice, this is then regarded as a surrogate for a DU CSR.)