9th Meeting of the Exchange Network on Exposure Scenarios (ENES9)

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Programme item: D.3

Discussion document

Common understanding on scaling - CSR/ES Roadmap Action 4.3

1. Introduction

Exposure scenarios (ESs) are generated by registrants and describe the operational conditions (OCs) and risk management measures (RMMs) that they have identified to ensure control of risks for identified uses. When downstream users (DUs) receive ESs, they check whether their use is included in the ESs provided and whether they operate in conformity with the OCs and RMMs described in the ES.

The registrant's ES provides information on one or more sets of OC/RMM for the relevant uses. Depending on the specific situation, various other combinations of these OC/RMM could lead to equivalent levels of control at the downstream user's (DU) site.

Scaling[1] was envisaged as a concept to avoid the need to generate and communicate high numbers of contributing scenarios (that is, presenting all equivalent combinations of OC/RMM) and to provide some flexibility for the DU in confirming that they conform to the ES received.

The way in which scaling can be implemented is described in the "Guidance for downstream users"[2]. This includes the requirement that, under the scaled DU's conditions of use "the exposure levels … are equivalent or lower than under the conditions described by the supplier".

Discussions between stakeholders have been held during 2015 to explore how scaling can be more effectively implemented, while also ensuring that exposure scenarios provide realistic and relevant information both to downstream users and to authorities on the adequate control of risk. Any approach must be consistent with Article 37(4)(d) of REACH, namely that a DU "implements or recommends an exposure scenario which includes as a minimum the conditions in the exposure scenario communicated to him."

[1] Scaling is a mathematical approach whereby the conditions of use described in an exposure scenario may be modified in order to determine if the actual conditions of use on a downstream user site are still covered by the exposure scenario. Scaling applies to effects for which a quantitative risk assessment can be performed.

[2] http://echa.europa.eu/documents/10162/13634/du_en.pdf

A common understanding has emerged on how scaling can be effectively implemented and is outlined in this document, which was developed by DUCC, Cefic and ECHA with some Member State involvement. It presents the current discussions underway on scaling and the areas requiring further development. It will form the basis of further discussion with the ENES community and beyond, as relevant, in 2015 and 2016.

This discussion takes place under CSR/ES Roadmap Action area 4.3 “Understanding the formulators’ options when receiving an extended SDS”. The conclusions would also benefit end users of substances as such who might also use scaling.

2. Current Approaches

Register and communicate most realistic combinations of OC/RMM
Under the CSR/ES Roadmap, the agreed strategy for information in the supply chain is that the registrant includes the most realistic (typical) combinations of conditions of use in his dossier / CSR and communicates these to the DU. The exposure scenarios can be based on sector use maps and/or the knowledge of the registrant on how the substance is used[3]. These reflect good practice and standards that are common within the sector.

Register and communicate all possible combinations of OC/RMM
Alternatively the registrant can, in alignment with REACH, include every possible combination of OCs and RMMs that provides safe use (i.e., adequate control) and communicate all options to the downstream user.

These two approaches have been evaluated for their advantages and disadvantages:

The advantage of the first approach, based on the most realistic combinations, is that good practice is widely disseminated and implemented. Scaling is useful for DU’s when checking if their conditions of use are covered. However, some DUs may be in a situation where they may implement an OC/RMM combination that leads to a higher exposure such that their conditions of use are not covered but nevertheless, it is still safe (i.e. Risk Characterisation Ratio (RCR) <1).

The second approach, based on providing all possible combinations, reduces or even eliminates the need for scaling. The result, however, is an excessive number of contributing scenarios (CSs) in an exposure scenario. This is neither desirable nor realistic on a broad scale and is not an efficient and effective means of communication to the DU or authorities.

[3] Use maps and the CS will potentially differentiate the level of exposure control needed for different hazard characteristics or different concentrations of the substances, where these lead to different risk management measures.

3. Proposal on how scaling can be effectively implemented

A proposal for an effective implementation of scaling is outlined here. It is based on the communication of the most realistic combinations of conditions of use described above, but with additional elements to consider.

One element is to set guidelines that would limit the possible deviations from the supplier's conditions of use to those that are in line with good practice. These limitations could be specific to a CS and set by the registrant, or common to all CSs.

Another element is to provide an "upper limit" RCR in the supplier's ES, that can be used as a limit up to which scaling is supported by the registrant. This upper limit RCR is based on the assessment overall exposures of humans and/or the environment and can be seen as an extra safety margin for scaling. These evaluations should be included in the registrant's CSR and, thus, the upper limit RCR is not an arbitrary value. The upper limit RCR would be provided as a boundary of scaling together with additional scaling recommendations (e.g. "Do not remove LEV in scaling") to the DU.

Advantages of proposed approach

The advantages of this proposed approach are that it:

- promotes the provision of information to the DU on the conditions of use that are considered good practice in a sector of use
- limits the number of contributing scenarios provided to the DU to those that are likely to be relevant for the majority of users
- provides flexibility to the DU to establish conformity even when his conditions of use give rise to higher exposure than in the supplier ES
- establishes guidelines regarding the deviations that are permissible from the conditions of use described in the received ES
- ensures that the CS specific boundaries for scaling (including upper limit RCR) are included in the ES communicated by the registrant, thereby reducing the need for further communication
- provides REACH authorities with information on the most typical conditions of use and the applicability domain of scaling around these conditions, indicating the boundaries of conformity.

4. Aspects to be further developed

Guidelines on limitations and advice on applicability

Some guidelines and common boundaries can be identified and agreed among stakeholders when scaling may not be applied. Examples include, but are not limited to:

- Use of personal protective equipment (PPE) only, in place of engineering controls should not be justifiable by scaling, particularly when it is inconsistent with the

hierarchy of controls (Chemical Agents Directive)[4]. If wearing PPE is a more realistic option due to the type of downstream use and is sufficient for protection, these situations are best addressed by a separate ES or CS and incorporated in use maps if appropriate.

- If the substance is very hazardous, it may be more appropriate to provide the DU with specific conditions of use in the CS and limit the opportunities for scaling.

It may be helpful also to identify those situations where scaling *is* a suitable option. These include, but are not limited to:

- Modifying the concentration of the substance in the product against exposure time (duration or frequency).
- Modifying the level of control, typically against changes in concentration and/or exposure time.

Environmental aspects

The scaling discussion has focussed largely on human health aspects, but it is also important to address more clearly the technical aspects of scaling related to environmental CSs.

One example is compensating a higher (daily) site tonnage and the subsequent local release with a higher river flow rate so that the predicted local environmental concentrations remain unchanged. This situation should be permissible within scaling because this does not have an effect of regulatory relevance on the background concentrations. For other environmental scaling parameters, the appropriateness of the scaling calculations as well as the validity domain need to be evaluated and examples should be identified.

How a downstream user conducts scaling in practice

At present, there is minimal practical support for a DU to conduct scaling. A recalculation/scaling tool is under development by Cefic for ECETOC TRA-based exposure assessments, called the ES Conformity Tool. In the future, it may be possible for registrants to communicate scaling advice on relevant parameters, the upper limit RCR (where used) and the boundaries in a way that can be readily transferred into the recalculation/scaling tools useful to both DUs for calculations and authorities for documentation.

Where and how scaling advice is provided

The “Guidance for downstream users” makes a number of suggestions to providing scaling advice (such as the determinants that can be changed and the upper limit for the RCR) in Section 4 of the ES. It is under discussion how this advice can best be provided and whether it is sufficient if Section 4 simply provides a reference (e.g., to a website or a guidance document) to where such advice can be obtained. Considerations include:

[4] This prioritises engineering controls and collective protection measures over personal protective equipment (Directive 98/24/EC).

- Development of commonly agreed guidance on scaling, with procedures and rules for scaling.
- Required input.
- Supporting tools aligned with the guidance.

Updating exposure scenarios and timing considerations

Existing CSRs may lack considerations and/or justifications for advice to the DU to implement scaling as proposed here. This is an issue in particular when the registrant ES includes overly precautionary RMMs. Consequently, registrants may need to update their dossiers with ESs reflecting current practice and include considerations and/or justifications on how to provide more flexibility to DUs for scaling but still lead to adequate control of risk.

Updating the registration dossier in an efficient manner is challenging for industry. A pragmatic proposal is that the updates be done batch-wise, within a reasonable timeframe. Thus, not all updates to an ES are immediately transferred into an update of the registration dossier submitted to ECHA. The timing for updates of the registration dossier is not clearly specified in REACH, although it is a requirement that the CSR be available and up-to-date. Consequently, this timing proposal needs discussion and agreement by various parties involved.

Next Steps

If this concept is generally accepted, further discussion is needed to establish commonly agreed boundaries and guidelines (Q1-Q3 2016). It is expected that proposed boundaries and guidelines could be tested on actual exposure scenarios to help clarify if they are necessary and appropriate.

The other aspects that are addressed earlier in this section – environmental aspects, tool development, provision of scaling advice and timing considerations - also need to be developed and agreed.

The impact of any agreed changes on guidance would have to be considered, with regard to both registrants and downstream users.