Common understanding on scaling
CSR/ES Roadmap Action 4.3

ENES9

5-6 November 2015

Brussels

By Andreas Ahrens (ECHA)

on behalf of

Industry-ECHA-Member State Working Group

Reminder on background

- Based on their Chemical Safety Assessment (CSA), registrants generate exposure scenarios (ES), and communicate them down the supply chain.
- Downstream users (DU) check whether they operate in conformity with the conditions of use described in the ES.
- A contributing scenario (CS) consists of one set of Operational Conditions and Risk Management Measures (OC & RMM) suitable to achieve control of risk (safe use), e.g.
  - Concentration of substance
  - Conditions of use driving the fugacity of substance
  - Duration of exposure
  - Ventilation conditions
  - Personal protective equipment
  - Administrative controls
- Various combinations of values for these OC/RMM could lead to safe use at the DU's site.

History and recent developments

- Discussions on scaling are ongoing since a while (Environmental topic at ENES2, presentation of DU ES Conformity tool at ENES5, first ECHA/Industry meeting Jan 2012)
- Current DU Guidance addresses aspects of scaling
- More recent ECHA/Industry meetings included technical discussions (e.g. environment)
- Consultations resulted in “Common understanding” document shared as pre-reading document for ENES9
- Presentations provides status update and perspectives for joint development of the scaling concept

Purpose of scaling

- Scaling is a concept
  - to avoid generation and communication of high numbers of contributing scenarios (presenting all equivalent combinations of OC/RMM) and
  - to provide some flexibility for the DU in confirming that they work inside the boundaries of the ES received.

NOTE: In line with other CSR/ES Roadmap activities, scaling is not meant as a permanent method to "repair" unrealistic exposure scenarios under the responsibility of the single downstream user.

Core elements of the concept

Registrants communicate

- the most realistic/typical combinations of OC/RMM describing good practice
- guidelines/rules defining the possible deviation from the supplier's conditions. These rules could be
  - ➢ common across registrants
  - ➢ set by the single registrant and may be
    - ✓ specific to contributing scenarios, e.g. advice NOT to remove a certain RMM
    - ✓ include an "upper limit" RCR up to which scaling is supported by the registrant

Advantages

- promotes that the DU receives information that is considered good practice in his sector of use
- limits the number of contributing scenarios 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
- establishes rules regarding the “allowed” deviations from the ES received
- ensures that the CS specific boundaries for scaling (including upper limit RCR) are included/referred to in the ES communicated by the registrant
- provides REACH authorities with information on the most typical conditions of use and the applicability domain of scaling around these conditions

Updating exposure scenarios

- Existing exposure scenarios may need to be updated in response to
  - new information on substance properties becoming available
  - downstream users requesting an update
  - registrant's own initiative
- Update to be made
  - in the extended safety data sheet
  - in the registrants CSR
- Some planning needed to do this batch-wise and according to priorities.
- REACH leaves some flexibility regarding timing, and timing to be agreed by the parties involved

Next Steps *and Tentative Timelines*

If the scaling concept is generally accepted, the following steps are proposed:

- Agree on scope and rules of scaling in order to draft a technical guide and test version of the DU ES Conformity Tool (including associated user manual) – *by end Q1/2016*
- Initiate testing* by volunteer testers (Industry and Authorities) – *by end Q2/2016*
- Collect feedback – *by end Q2 2016*
- Revise documents and adjust tool, as needed – *before ENES Nov 2016*
- Identify communication options to support concept and tool – *by end Q4/2016*

** NOTE: Some testing has been already performed in parallel to development of the concept and the tool to its current state*

Contributors / Working Group

- ECHA: Andreas Ahrens, Bridget Ginnity.
- DUCC: Sylvie Lemoine, Thorsten Wind, Thomas May, Thomas Wolf.
- Cefic: Frank Schnöder, Jean-Christophe Dewart.
- BAuA: Eva Lechtenberg-Auffarth.