Scaling
Task group proposal

ENES 3

21 November 2012
Brussels

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Background

- ECHA-Industry meeting on Scaling - January 2011
  - Applicability of scaling
  - Development of scaling options: State of the art
- Development of Practical Guide for Downstream users on exposure scenarios in 2011-2012
  - Scaling examples proposed by industry
  - Areas of further discussion identified
  - Practical Guide published in June 2012 without scaling examples
- Scaling also a topic in ENES1 and ENES2
- Task group established in August 2012 (agreed at ENES2)

Task group on scaling

- Seven members (MSCA-DUCC-Cefic-ECHA)
  - Two teleconferences /One meeting in Helsinki

Terms of reference

- Review of ECHA's advice on scaling
- Review the feedbacks received on the Practical guide examples
- Identify common views and needs for further discussion
- Propose practical solutions on scaling/alternatives to scaling
- Elaborate a document for ENES3 discussion

Scaling: Common views

What is scaling

- A way to demonstrate that a DU operates within the conditions of the supplier's exposure scenario
- Mathematical approach
- Applicable only to quantitative parameters
- Applicable only if supplier has used modelling tools in exposure estimation
- Scaling instructions have to be based on the same tool that supplier used (or a tool based on the same or more conservative logic)

Scaling **is not** the way for DUs to deal with unrealistic or over-conservative conditions of use in the exposure scenarios → communication back to supplier needed in this case

Communicating scaling options

- Communication of scaling options in the exposure scenario is a **supplier's responsibility**, not a **DU's choice**.
- Communication will typically include at least
  - The method
  - The parameters that can be scaled **AND**
  - The allowed range for scalable parameters (input to scaling)

  OR
  - The exposure level which cannot be exceeded after scaling is applied

Scaling method

- Mathematical formula
- Web interface
- Same tool as used by the supplier
  - If scaling with the same tool than supplier, also the version, release etc. has to be he same (or compatible)

Scaling and RMM

- Scaling can be used to justify that a RMM is not required if equivalent/lower level of exposure can be compensated by other parameters (= Effectiveness of RMM is set to zero in scaling formula)
- Scaling cannot be used to justify different RMM than those recommended in the ES (e.g. PPE to replace LEV)
- DU can implement more stringent RMM
  - Respect for the hierarchy of RMMs (from other ESH legislation)
  - This does not require DU CSR
  - This **is not** scaling

Scaling: Point(s) for further discussion

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Increasing exposure level/RCR when scaling

- ECHA, MS: Not a scaling option. DU CSR is required
- Industry: Too restrictive interpretation of 37(4)(d) of REACH
- Further discussion needed to identify and develop practical approaches to support
  - Registrants in defining scaling conditions
  - Communication in supply chains
  - DUs' CSR

Related issues

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Use of measured data

- Not scaling
- A method to demonstrate effectiveness of an RMM
- Comparing measured data with DNEL/PNEC can show that for his conditions of use RCR is the same or lower than the one commuicated in the exposure scenario
- Quality and representativeness of the measured data needs to be proved

Downstream user chemical safety report

- Might be the most reasonable option for a downstream user
- The hurdles – real or perceived – have to be identified and analysed in order to make the option more widely understood and accepted

Conclusions

- Scaling is
  - …a mathematical method
  - …where the supplier determines the boundaries in his scaling advice
  - …and provides downstream user with a tool to perform scaling
- Fundamentally different views on increasing the RCR/exposure level by scaling
- Measured data can be used to validate that downstream user operates under the conditions of the exposure scenario
- Hurdles to DU CSR need to be analysed and removed


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