

# ECHA - Industry Follow up discussion on Scaling

## Exchange Network on Exposure Scenarios (ENES8)

20 May 2015

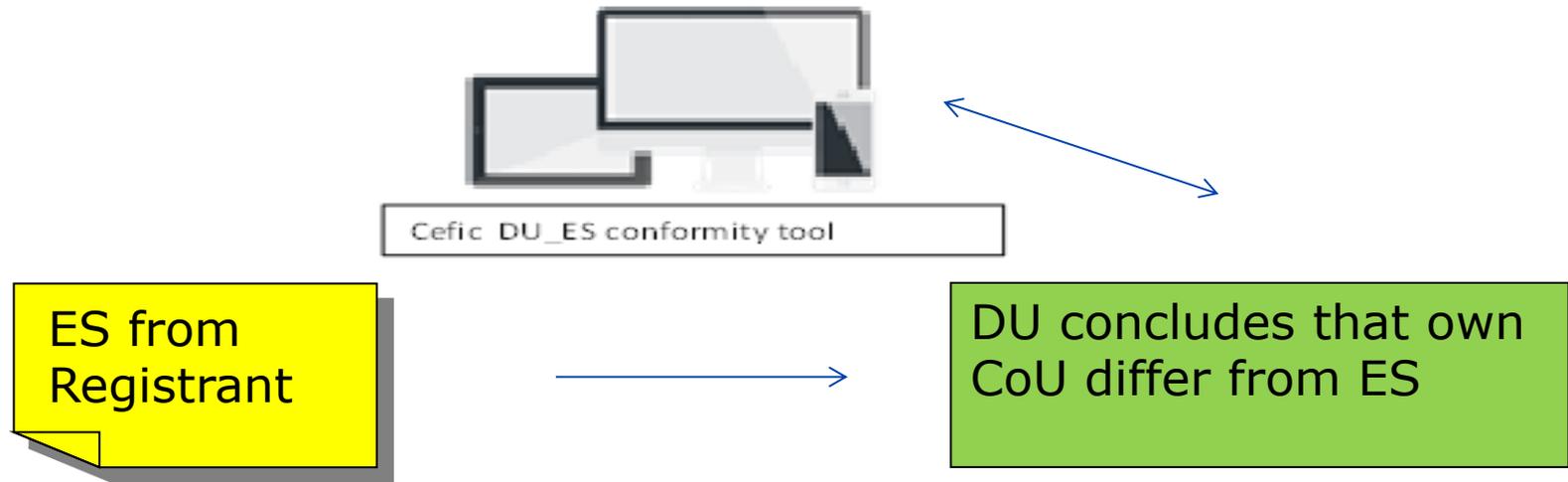
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# Agenda of 20.04. Meeting

- Clarification of Cefic approach to scaling
- Potential input by DUCC on typical business cases related to scaling
- Discussion of identified points
  1. Updating registration dossiers after adapting ES to DU conditions: issues and temporary solutions
  2. Advising downstream users on scaling options
  3. Exploring whether comparing exposure control strategies rather than RCRs could reduce scaling burden on downstream users.
  4. Establishing whether dilution can be applied for “local” scaling without invalidating the registrant’s assessment.
- Conclusions and next steps

# Cefic ES Conformity Tool



- Registrant sends ES with reference to Cefic DU conformity tool
- The tool includes (for all and/or individual CS)
  - Parameters that can/can't be modified
  - Upper limit RCR (not to be exceeded via scaling).
  - Other scaling advice

- DU downloads CEFIC TOOL to check own conditions of use
- Follows scaling instructions
- Establishes whether or not he works in conformity within scaling boundaries
- DU can use the tool to prepare DU CSR (if needed)

## Scaling or update of ES

- Scaling is a method for DU to demonstrate conformity with the conditions of use described in the ES received.
- It provides flexibility to DUs in combining values for the exposure reduction factors of the TRA (if ES essentially supports the use, however minor variation needed)
- However, if the ESs for a substance largely fail to realistically address the conditions of use, an update by the registrant (or alternatively a DU CSR) may be needed.
- Reminder: Several initiatives under the CSA/ES roadmap aim to make better quality information available.
- The timing for the update of the registration dossier, the SDS, and the communicated conditions of safe use may need some flexibility for temporary solutions.

## Communication of scaling advice

- DUs would download the DU ES Conformity tool from the Cefic website
- Three potential ways for DUs to put suppliers' information into the ES Conformity tool:
  - Input information communicated by M/I for manual input by DUs into tool
  - Input information communicated by M/I to DU via Excel spreadsheet for easy cut/paste into tool to avoid discrepancy on original exposure assessment
  - Xml solution (in the long term) as part of a SHE system file at company level.
- For an interim period this communication may take place in parallel to the SDS system.

## Equivalent exposure control strategies

- Combination of engineering controls with duration (1-8 hours) and concentration is a typical scaling feature.
- Identification of equivalent exposure control strategies could:
  - reduce emphasis on strictly meeting an RCR (in the area of  $RCR < 1$ )
  - reduce need to apply scaling by downstream users
- Should this approach be further explored potentially leading to a set of rules?
  - Changes within engineering controls, but no removal of engineering controls via scaling.
  - Short term tasks to be addressed by dedicated scenarios from the beginning.

# Environmental scaling by dilution

- Reminder
  - The local release rate is driven by the daily tonnage used onsite and the release factor.
  - The local PEC includes a contribution released in the region (to take account of multiple sources of release).
- CEFIC SpERC group clarified that environmental scaling is meant to compensate higher site tonnage by higher river water volume. Release factors not to be modified.
- Consequently the total amount of substance released into the environment would not change via scaling. => One major concern removed.
- Applicability domain (in terms of substance properties) for this more limited scaling approach still to be clarified.

## Next steps (1)

- Draft a **common vision** (understanding) on the long term process to go from today's situation to a situation where realistic /helpful ES are communicated to Dus, and are also documented in updated registration dossiers.
  - *ECHA to draft initial outline for comment and addition by meeting participants. June 2015*
- Further consider the concept of ES update by supplier as an alternative to the Cefic "advanced" scaling approach (to reduce the occasions for DUs to do scaling);
  - *Industry to consider concept.*
- Explore feasibility of **decoupling** SDS update from CSR update timelines.
  - *ECHA to discuss with Member States*
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## Next steps (2)

- Explore feasibility of “equivalence of control strategy”; can it be extended to the environment and consumers? Could it be integrated in the ES conformity tool and/or reflected in use maps/SWEDs/GES?
  - *ECETOC TRA Group to consider. ECHA to consider further.*
- Complete “sensitivity analysis’ regarding scaling by local dilution
  - *CEFIC - ECHA to liaise*
- Communicate outcome with CSR/ES Roadmap-ENES coordination group/MS etc.
  - *ECHA (before ENES8)*

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