ECHA perspectives on SCEDs

Agenda point 5.2

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Overview

- ECHA perspectives on SCEDs
- ECHA suggestions
- SCEDs in Chesar

ECHA perspectives on SCEDs

General perspectives on SCEDs

- ECHA welcomes the industry initiative to develop SCEDs
- ECHA understands SCEDs as product-specific building blocks for the CSA under REACH
  - to help registrants in carrying out their exposure assessments for consumers' uses
  - providing transparency in the assumptions made (default values) for the assessment
- SCEDs are likely to facilitate harmonisation and efficient communication through the supply chain regarding conditions of safe use of consumers products

Feedback on the current state of development

- Industry sectors have made an effort to:
  - develop a common structure for the SCEDs
  - provide transparency in the derivation of the values for the different determinants of exposure
  - provide explanatory information on the SCED concept
- The current SCED concept is in line with the principles agreed in ECHA guidance
- A lot of progress has been made, but some issues are still to be solved

ECHA suggestions to the SCED group

Adapt TRA equations to SCEDs (1)

- SCEDs originally designed for being used in TRA
- SCEDs contain information that cannot be used within the current TRA. As a consequence each user has to:
    - adapt TRA (modify the equations and/or enable overwriting of defaults), or
    - use other tools
- ECHA's concern: development of various sector-specific adaptations of the TRA leading to:
    - variety of exposure estimation for the same substance in the same product type (impact on transparency)
    - "picking" SCED determinants instead of using the SCED information in a coherent manner (impact on reliability)

Adapt TRA equations to SCEDs (2)

- SCEDs to contain a fixed set of determinants of exposure to be used in "standardised adapted TRA" equations

- Impact of the various determinants on exposure estimation to be clearly explained in the SCED guidance

- Making available an updated TRA tool should be discussed

Refine the SCED template

In the SCED template

- Add current TRA inputs not yet listed (spray application, adult/child use)
- Add new parameters:
  - inhalation factor. Meaning to be properly explained.
  - differentiation between indoor and outdoor uses (impact on ventilation and room size)
- Remove from current SCED template:
  - inhalation rate: difficult to justify why to change the inhalation rate of consumers

Clarify relation between TRA defaults and SCEDs

- Provide advice to registrants (SCED users) for product types where a i) TRA input data-set and ii) a SCED input data set are available in parallel (existing sub-categories)

Develop standard justification

- The various values for the exposure determinants need sufficient justification. Guidance, examples and standard justifications would be helpful in particular for:

    - the concept of the transfer factors, leading to exposure reduction is to be well explained

    - when a route is considered "non relevant"

Clarify the assessment for infrequent uses

- In addition the assessment approach for "infrequent uses" (less than once a day) is to be clarified:
  - how to derive exposure estimates for
  - comparison with which DNEL?

Further develop SCED identifiers

- A clear identification of SCEDs is needed
- This may consist of:
  - the SCED name (and code? like in SPERCs)
  - the relation with existing Product (sub)-Category
  - the form of the product (e.g. powdered, spray, low viscosity liquid, high viscosity liquid)
  - the coverage of the SCED e.g. in relation to the substance properties (e.g. volatility range)

SCEDs in Chesar

ECETOC TRA for Consumer in Chesar

- ECETOC TRA for Consumer is a tool plugged in Chesar 2.2
- It allows the assessor to:
  - generate an exposure assessment for consumer uses of the Products and Articles (sub)-categories supported by TRA
  - generate exposure scenarios for consumers' uses in the CSR and for communication

SCEDs in Chesar (1)

- ECHA is willing to further develop Chesar to enable the use of SCEDs in the chemical safety assessment

- Implementation concept (as for SpERCs):
  - Chesar enables the generation of the SCEDs in a Chesar compatible format (XML)
  - industry sectors to create the relevant file with Chesar and make them available in their website (potential link from Chesar website)
  - Chesar users to import the appropriate SCEDs in their Chesar library for being used in their assessments

SCEDs in Chesar (2)

- When selecting a SCED for the assessment, Chesar would support:
  - the exposure estimation by the (extended?) TRA algorithm
  - the generation of the ES in the CSR describing the conditions of use as in the SCED
  - the generation of an ES for communication based on available standard phrases [Note that the availability of phrases for the short title of the ES need to reflect properly the sub category covered by the SCED]

Next steps and open questions

- Setting a working group ECHA- Industry to define
    - the SCED data format
    - the functionalities to be supported by Chesar
- Decide whether to implement an "extended" TRA to better support the use of the SCEDs
    - according to the annex TR 114 of ECETOC report (IP remains to ECETOC)

We are ready to start!

Thank you!

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