Lessons learnt from the first wave of CSRs received at ECHA

Tips on selected issues

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Webinar for registrants

CSA 1: Chemical Safety Assessment and Chesar

Outline

- Criteria for quality of information in the CSR
- Observations on quality deficits and tips
- Conclusions

Quality of information in the CSR

- demonstrates how the substance can be safely used during its whole lifecycle (= risks adequately controlled)
- exposure scenarios sufficiently concrete and realistic to inform downstream users how to protect human health and the environment
- transparent e.g. on model assumption, input parameters
- consistent with the Technical Dossier and consistent in itself
- complete compared to the Annex I
- if relevant, justification for omissions or deviations from ECHA guidance documents
- suitable to inform regulatory processes by ECHA and Member States, e.g.: prioritisation for substance evaluation; selection of substances for authorisation;

ECHA is aware:

- that the Chemical Safety Assessment (including exposure assessment and risk characterisation) for roughly 1 500 substances by the 2010 deadline was a very challenging task
- that given the time frame, the quality of the CSR was not the highest priority for 2010 registrants
- that for most registrants the REACH CSA is a new task that requires longer term learning and change processes
- that for ECHA developing expectations on how a CSR should look like is also a learning process
- Nevertheless, considering the objectives of REACH, the content of many CSRs that were seen so far will need improvement.

Observations and Tips

Hazard assessment

- Follow advice of ECHA Guidance on the use of assessment factors (AF) and derivation of no-effect levels (DNELs)
- Justify and document your choice and any deviations in approach
- Systematically fill the endpoint summaries in IUCLID in order to determine a consistent starting point for the exposure assessment and the risk characterisation.

PBT Assessment

- Take into account and address all available information on the substance (e.g. substance is on candidate list of SVHCs)
- If available information is inconclusive for ruling out PBT properties for at least one criterion:
  - obtain additional information, or
  - treat the substance as if it were a PBT
- Minimisation of emissions for PBT substances needs to be demonstrated

Qualitative risk characterisation

- If no DNEL is available for an identified hazard:
  - Determine the level of hazard in a qualitative way (see Table E 3-1 in ECHA's CSA Guidance part E; based on a control banding approach)
  - Select operational conditions and risk management measures corresponding to the level of hazard (and describe in ES)
  - Potentially use exposure data to demonstrate appropriate minimisation of exposure (case by case)
  - Ensure per route of exposure that both the quantitative and the qualitative assessment lead to consistent risk management measures

Use description

- Describe uses in section 3.5 of IUCLID after the safety assessment has been carried out
- Provide intuitive use names (exposure scenario titles) so that:
  - authorities can understand what happens with a substance in practice
  - DUs can easily recognise whether an ES is relevant to them
- Get harmonised use-names from downstream user organisations
- Explicitly justify the assignment of a particular use-descriptor to an activity or process.
- Describe the real market situation rather than reporting as many uses as possible.

Scope of exposure assessment

- Exposure assessment is required for all identified hazards, not only those leading to a classification
- Justification is needed if no DNEL/PNEC can be derived for a certain route of exposure or type of effect
- All uses are covered
- All life cycle stages including article service life and the waste life stage

Conditions of use

- ensure that the CSR refers to realistic conditions of use. A very low risk characterisation ratio may indicate:
  - favourable substance properties (in line with REACH objectives)
  - overly conservative risk management measures (undesirable as places burden on DUs)
- ensure that the conditions of use are made explicit in the ES with an appropriate level of detail, so that:
  - relevant and practical useful information can be provided to DUs
  - flexibility for DUs regarding technical detail of implementation is ensured
  - readers of the CSR can understand the use conditions the registrant has assumed for their assessment

Cooperation among registrants

- Member registrants describe their own uses. The CSR (or part of it) however can be jointly submitted (by the lead) or individually
- Clear confirmation is needed in each registrant's dossier:
  - which of their uses are covered in the joint CSR and which are covered in an individual CSR
  - that the exposure scenarios related to the members' own activities are implemented
  - that the relevant exposure scenarios are communicated to the customers
- Member registrants are responsible for communicating relevant exposure scenarios to their customers and to react to potential responses. ECHA advises Member registrants to read and fully understand the lead registrant's joint CSR.

Shared assessment elements

- Make use of exposure scenario information (or initial assessments) developed by sector organisations.

But:

- Such information is only a starting point for the registrants' own assessment (and not just a matter of copy and paste into the CSR)
- The specific environmental release classes (SpERCs) from the 2010 registration generally need further development;
  - to determine (generic) conditions of use leading to a certain release fraction
  - to explain how the release factors have been determined
  - to determine realistic use-amounts for i) site related assessment and ii) dispersive uses

Harmonisation and structuring of formats

- Harmonisation of CSR and ES formats is desirable. Chesar is a tool to achieve this.
- In the long run, ECHA aims to receive the CSRs in a structured data-format so that they can be processed with computational methods.

Conclusions

Summary of advice to registrants (1)

- Cooperate with DUs for realistic and useful use descriptions and exposure scenarios.
- Clearly define which processes and activities are covered per exposure scenario.
- Make conditions of use for environmental assessment more explicit.

Summary advice to registrants (2)

- Do not consider your registration dossier as a final product once submitted
  - Ensure that structures and processes are in place to update the CSR after registration
  - Pro-actively update your dossiers when new information on hazards or uses becomes available
  - Do not await the outcome of potential compliance checks - improve the quality of the dossiers through updates on your own initiative
  - Further compliance checks will be conducted and reporting on the results will improve the quality of the dossiers

Support by ECHA

- ECHA is committed to maintaining and further developing IUCLID and Chesar to support efficient CSA and harmonised CSRs and ESs for communication
- ECHA, in cooperation with industry, has initiated the *Exchange Network on Exposure Scenarios* (ENES), aiming to share experience and solutions
- ECHA publishes illustrative examples of ESs and CSRs
- ECHA expects registrants to make their CSRs a source of good quality information
- ECHA welcomes the industry initiatives to create and maintain shared resources for efficient and harmonised CSA

Thank you.

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