Data quality in CSR

Use, exposure and risk information

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02.02.2012

Lead registrant workshop
Helsinki

Why emphasis on Chemical Safety Report?

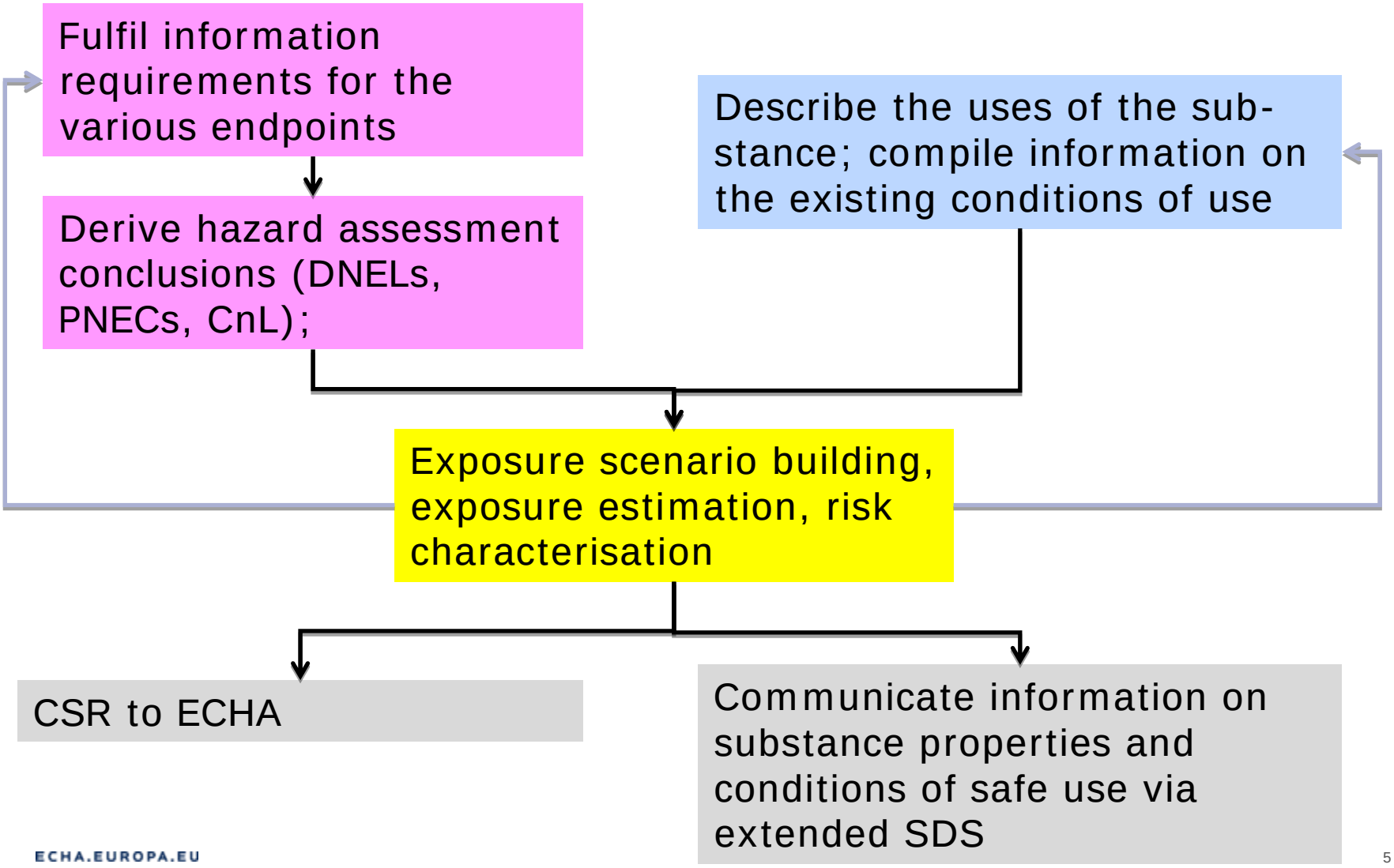
- CSRs document how the substance can be safely used (= risks adequately controlled), based on a transparent assessment.
- Their quality is essential for delivering the objectives of REACH. They are a key source of information:
  - for communicating to downstream users (to enable better protection of human health and environment)
  - for ECHA and Member States for regulatory processes under REACH.
- The CSR is not “just an attachment”. An incomplete or inconsistent CSR may lead to non-compliance of the registration dossiers.

ECHA is aware

- that the chemical safety assessment (including exposure assessment and risk characterisation) for roughly 1500 sub-stances 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 a longer term learning and change processes
- that for ECHA developing expectations how a CSR should look like is as well a learning process

The Chemicals Safety Assessment Workflow and Tools

Assessment Workflow



Tools (1)

IUCLID (mandatory; by ECHA)

- Currently: All information on substance identity and properties; endpoint summaries including hazard conclusions (to be carried forward into the CSR)
- Brief general description of identified uses
- Future: Include key information from exposure assessment and risk characterisation (extract from CSR text-file)

Chesar (non mandatory; by ECHA)

- Workflow support for use description, exposure assessment and risk characterisation
- Database, import/export of assessment elements
- Generation of CSR and exposure scenario for communication

Tools (2)

EScom (non mandatory; by industry)

- Data exchange standard for the communication of exposure scenario information down the supply chain
- Standard phrase catalogue for communication of information contents

Shared assessment elements (non mandatory; by industry)

- Maps of relevant uses for different downstream sectors
- Generic condition of use for specified processes or activities (+ corresponding initial release/exposure estimates); e.g.
    - Generic Exposure Scenarios (ES)
    - Specific Environmental Release Categories (SpERCs)

Observations and Tips

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 (undesirable as placing burdens on downstream users)
- ensure that the conditions of use are made explicit in the ES with an appropriate level, so that
  - relevant and practical useful information can be provided to downstream users
  - nevertheless flexibility for DU regarding technical detail of implementation is ensured

Use description

- Describe uses in section 3.5 of IUCLID after the safety assessment has been carried out (to ensure consistency with the [joint] CSR)
- Provide intuitive use names (exposure scenario titles) so that DU can easily recognise whether an ES is relevant to him. Get harmonised use names from downstream user organisations.
- The use description should reflect a real market situation.
- Ensure consistency when assigning the use descriptors (should be done by person with basic knowledge in exposure assessment).

Shared assessment elements (GES)

- Make use of GES developed in cooperation with DU sector organisation as a starting point; Note: GES to be updated based on experience from 2010 registration
- Develop additional GES where gaps occur
- More specific ES (even customer specific) may be needed depending on the substance properties and condition of use

Shared assessment elements (SpERC)

- SpERCs from 2010 need further development;
- Particular challenges:
  - Determine (generic) conditions of use leading to a certain release fraction
  - Determine realistic use-amounts for i) site related assessment and ii) dispersive uses

Shared assessment elements (SCED)

- Specific consumer exposure determinants (new development)
- Tools for assessment of substances in consumer products are available (TRA and Consexpo)
- But DU organisation need to fill gaps (e.g. DIY construction chemicals) or to refine overly conservative assumptions

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 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 the quantitative and the qualitative assessment lead to consistent risk management

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 (or at least key information from the CSRs) in structured data-format so that is can be processed with computational methods

Cooperation among registrants

- Member registrants describe their own uses. The CSR (or part of it) however can be submitted jointly (by the lead) or individually. For rules, see ECHA's Data Submission Manual 19.
- Clear confirmation is needed in each registrant's dossier
  - which of his 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
- Make arrangements for update situations

Long-term perspective

- Ensure that structures and processes are in place to update the CSR after registration
  - New uses and conditions of use (e.g. response communicated up the chain after registration)
  - New information on hazards
  - Improvement of quality - repair quality deficits in 2010 and 2013 (?) dossier
  - Response to ECHA requests following from compliance checks

Conclusions

Summary of advice for registrants

- Cooperate with downstream users 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.
- Ensure that structures and processes are in place to update the CSR after registration

Support by ECHA

- ECHA is committed to maintain and further develop IUCLID and Chesar to support efficient CSA and harmonised CSR and ES 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 exposure scenarios and Chemical Safety Reports
- 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