Outcome of Scoping Process since March

Draft Guiding Principles Building Blocks

Workshop on REACH Review Action 3
Helsinki
23 September 2019

Unit B4 Exposure and Supply Chain
Goal: Improve workability and quality of extended SDS
Follow-up to March WS
Cefic

• REACH review is a key opportunity to further clarify and standardize efficient and effective approaches.

• User targeting: Upstream assessment to generate “global ES”; customer to generate “dynamic” extSDS by selecting information for his actual processes and operational conditions.

• Minimum requirements: value of minimum requirements recognised; should complement info in main body, but not duplicate.

• Mixture methodology: Roll out what has been developed (LCID; use-map/SUMI approach); simplify and standardize where appropriate (but not one unique solution); ENES as platform.

• IT solution and digitalisation: Highlights role for improving supply chain communication (game changers). Three aspects:
  • Integrate outcomes of quantitative risk assessment into mixture SDS generation.
  • Translation of technical languages.
  • Transfer of data objects rather than unstructured information.
Comments on report from March WS

ACEA

• ES only foreseen for substances; no legal force and no benefits regarding attachment for mixtures; pictograms for instruction rather than SDS; inconsistencies with section 8.
• Not necessary to communicate DNELs/PNECs in SDS for mixture.
• No need for new methodologies for generating mixture SDS; better focus on method/tools checking plausibility in the composition/hazard sections; 80% of SDS contain mistakes.
• More emphasis on upstream communication (sector use maps) - opportunities and legal obligations; action needed where still no sector-specific use map has been developed.
• If ES/SUMI for mixture SDS unavoidable, then one harmonized structure for all attachments preferred.
• Support for structured, electronic exchange, but not only ES but full SDS.
Four overarching themes

1. More explicit definition of **information needs** at the bottom of the supply chain.
   - Discussion with SLIC’s CHEMEX community
   - 3 generic cases described in pre-reading document.

2. **Methodology** for formulators to extend the mixture SDS with ES information, DNELs and PNECs for ingredient substances.
   - Draw learnings and conclusions from two industry-led **ENES projects**
   - Develop overall **workflow** for risk management communication in the supply chain.
3. Propose **minimum requirements** for exposure scenarios.
   - Initial proposal based on current assessment practice and identified needs related to communication.

4. Harvest information on state-of-play in extSDS **authoring and processing** tools and future development needs.
   - Interview process with 7 providers of SDS authoring systems or services.
Reminder on the overall REACH process
Chemical safety assessment needs information on substance properties and conditions of use

Manufacturer

Knows the properties of the substance

Downstream user

Knows how the substance is used

- Products, processes
- Concentrations, amounts
- OC/RMM

→ Capacity to carry out the assessment
→ Allocation of assessment responsibilities
→ Exchange of information (via supply chain or other means)
Assessment Types

Similarity in methods
• Compare hazard characteristics of the substance to foreseeable extent of contact (exposure)
  • Qualitative methods
  • Quantitative methods (where thresholds exist)

Differences in scope
• Chemical Safety Assessment: per hazardous substance, all uses, whole life cycle (REACH); > 10 t/a
• Downstream user CSA: per hazardous substance, some uses, part of life cycle (REACH); > 1 t/a
• Workplace risk assessment: all hazardous substances, all uses at one site (CAD);
• Environmental risk assessment: all hazardous substances; Emissions from one site (IED);
• Product Safety Assessment: all substances in one product (various legislation)
Assessment capacity in the supply chain

Manufacturer
Knows how to carry out safety assessments

Formulator
Some know, some not

Large downstream end user
Best knows to ensure safe use, based on supplier’s hazard data
NEED: Straightforward documentation of conformity

SME downstream end user
No own risk assessment capacity
NEED: Reliable instructions to follow
Problems to be solved
Main driver(s) of REACH Review Action 3

Methodology for extending SDS for mixtures with exposure scenario, DNEL and PNEC information

• Meeting the information needs of user audiences, in the light of:
  • Worker safety under OSH (the focus for the moment)
  • Control of environmental emissions under IED
  • Product safety requirements for mixtures and articles.

Contributing solution strategies:

➢ Sector use maps and “normalisation” (=> slide xyz) of registrant’s CSA output
➢ Minimum requirements for an exposure scenarios
➢ Requirements for SDS authoring/processing systems to handle the exposure scenario information.
Problems to be solved

• Formulators receive exposure scenarios:
  • Unmanageable numbers and diversity,
  • Language unsuitable for communication to user audience(s),
  • Text documents (often copied directly from the registrant’s REACH CSR).

• Consequences:
  • Forward the “mess” to the next level in the supply chain, or
  • Ignore it and thus flow of information stops (incompliance), or
  • Manually sort it out.

• No clear concept yet how DNELs/PNECs for ingredient substances are taken into account when deriving the SDS for a mixture

• No common understanding yet how REACH exposure scenarios feed the information needs of the managers responsible for compliance under CAD and IED onsite.
Guiding principles towards solution

confirmed by experience in ENES projects
Guiding principles (1)

• Role of exposure scenarios information in the SDS: Based on REACH CSA, and aims to:
  • Provide use- and activity-specific advice on preventive measures and exposure controls
  • Are based on a quantitative exposure assessment (where relevant)
• ES information continues to exist/apply in the SDS for mixture, either in an embedded or in an attached form.
• Attaching the exposure scenario information to the SDS usually better supports communication and processing.
• For end-use mixtures, one consolidated section of safe use advice for the mixture as a whole is desirable.
Guiding principles (2)

• Good quality exposure scenarios can facilitate the determination of preventive measures and exposure control at the workplace. Companies without own risk assessment capacity would benefit in particular.

• For companies with own workplace risk assessment capacity, documentation of conformity with REACH duties should be made straightforward.

• The sector use map approach, including the “normalisation” of registrant’s assessments, is likely to improve the workability and quality of the extended SDS.

• Formulators should base their safe-use advice for customers on a CSA method.
  • Make direct use of CSA outputs (= exposure scenarios) carried out by a supplier up the chain, or
  • Do own CSA (including additive risk across ingredient substances, where it applies).
Building blocks towards solution
Overview on building blocks

- Sector Use maps
  - DU sector maps; SUMI libraries [Broaden availability]
  - Registrant’s use maps (GES type) [Consider Adaptation]
- ESCom [Consider better resourcing]
  - Phrase catalogue
  - Xml exchange standard
- Chesar for registrants
- Formulator’s tools [integrate into tool box]
  - SUMI selection (based on sector use maps)
  - Lead Component Identification (LCID) + Consolidation rules
  - Exposure estimation and risk characterisation (CSA)
- Extended SDS authoring and processing tools
- DU Conformity check tool
ES Minimum Requirements
Goals

• Increase the usefulness of the exposure scenario information

• Streamline and simplify the communication through the supply chain by creating a solid basis for support via IT tools
  ➢ Make mixture methodology work

• Increase legal certainty on all sides, consistency and enforceability.

Approach

• Emphasis placed on use descriptor systems (Guidance R.12, IUCLID, OECD); make product category (PC) or Sector of use (SoU) a mandatory identifier for all uses.

• Include references to sector use maps as the source of information.

• Take harmonised core conditions of use from worker exposure estimation tools as the basis => more concrete descriptions of engineering controls! [ENES 3.2 project]

• For environment still conceptual work required [initial minimalistic proposal by ECHA].
Conclusions

To be discussed during the workshop:

• Target the supply chain communication system to those who need safe use instructions the most.

• Overall workflow forming the framework for the methodology for extending the SDS for mixtures.

• Minimum requirements to i) synchronise actors (=> workability) and to ensure coherence of ES information with assessment requirements for OSH and environment.

• For the tools required, develop a path for implementation and use in the IT supported SDS infrastructure.

Any immediate questions for clarification?