

# Outcome of Scoping Process since March

## Draft Guiding Principles Building Blocks

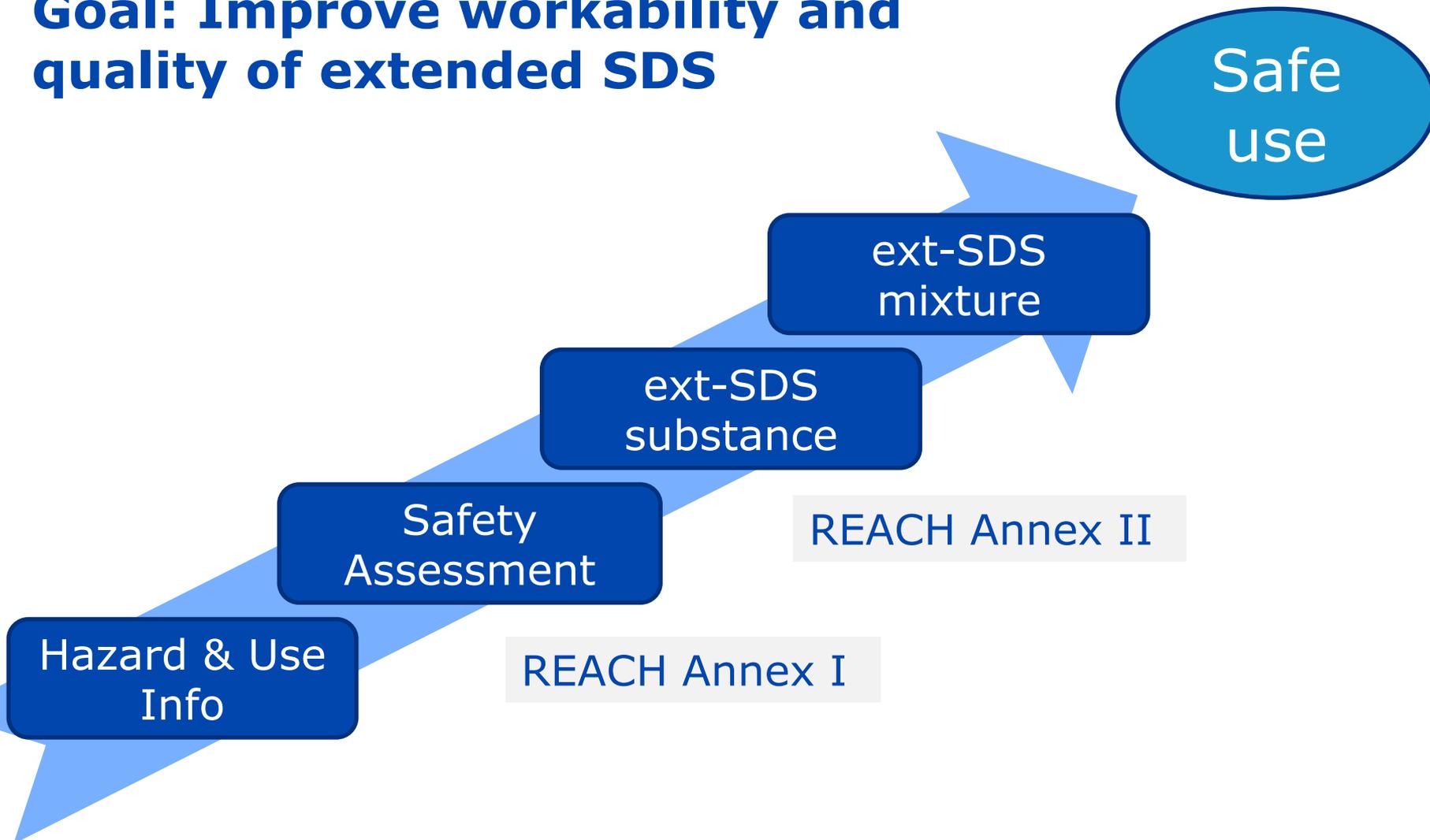
**Workshop on  
REACH Review Action 3  
Helsinki**

**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.

## 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.

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)

## 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



## 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.

- 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**



- 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.

- 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].

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?**