



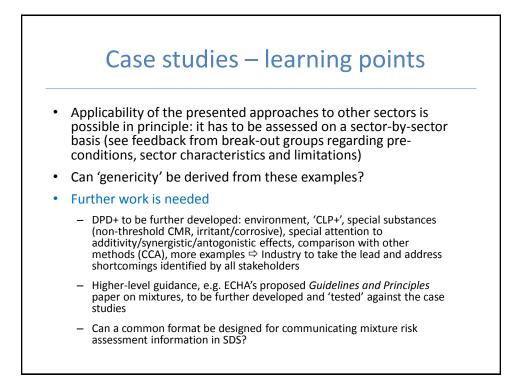
- Formulators and end-users have different needs with regard to ES-related information for mixtures
- <u>Formulators (e.g. Formulator 1 to Formulator 2)</u>: ES-like format preferred in general at Formulator 2 level
- <u>End-users (e.g. Formulator 2 to End-user)</u>: concise, targeted, understandable, consolidated and RMM-focused information
 - Provided in the SDS main body or as an annex

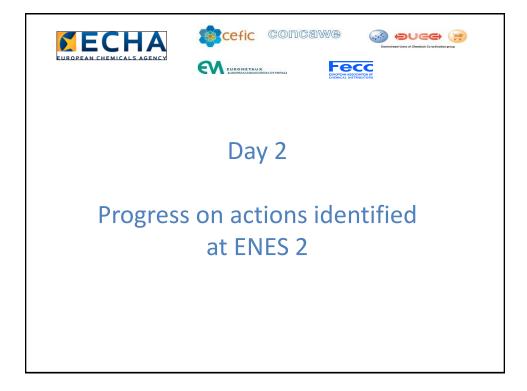
Learning points on methodologies to handle mixtures

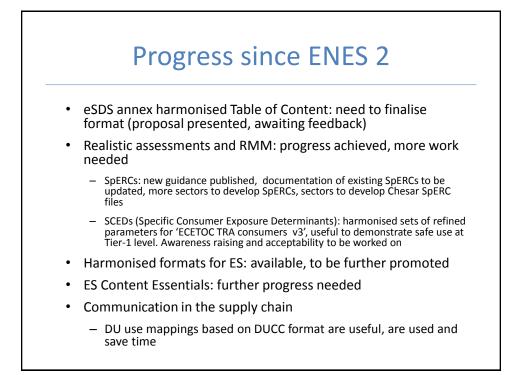
- There is no 'one-size-fits-all' solution for all mixtures
- Different methods to consolidate/aggregate substance information for mixtures + different outputs exist ⇒ ECHA's proposed decision tree for communicating information on mixtures:
 - ES of substance (annex);
 - ES of mixture (annex); or
 - Simple information in the main body of the SDS.
- Consistency between ES-related information (RMM from risk assessment) and SDS main body (REACH Annex II, section 8, P-statements of CLP) to be ensured

Case studies (end-use mixtures) – learning points

- Often consist of risk assessment of mixtures at DU level
- Case Study Commonality: group mixtures into categories, prioritise and focus on 'risk-driving substances'
- Two main approaches (so far discussed for workers, human health; applicability for environment to be explored)
 - 'top-down' (1 case): start from substance ES, aggregate into a mixture ES, then extrapolate to other mixtures that have a similar use/risk pattern
 - 'bottom-up' (3 cases) : start by clustering mixtures by use/OC/RMM patterns, identify the boundaries of each group ('risk envelope'), check whether incoming substance ES fits within the risk envelope: DNEL-based (DuPont) or concentration+classification-based (ATIEL). 'Bottom-up' approach more efficient if done at association level.
- The output, as communicated, can take different forms (ES or in SDS)







Scaling

- Some elements agreed (definitions, communication of scaling instructions by Manufacturer/Importer (M/I))
- · Other points to be resolved
 - RCR level communicated by M/I
 - Measured data to demonstrate safe use
 - Examples, further clarification of principles would help
- Scaling: a tool for DU, driven by the registrant
- Scaling: not a substitute for unclear/incomplete OC/RMM information from M/I
- DU CSA to be 'demystified'

Looking to the future: ECHA's CSA/ES Roadmap

- · Multi-stakeholder process for roadmap development
- An action plan to improve generation and communication of good quality CSR/ES information
 - Gaps and Solutions-focused
- Discussion document shared by ECHA: to be finalised by mid-Jan 2013, for further consultation
- Will serve as a single document with
 - An overview of who is doing what
 - Identification of gaps
 - Monitor progress on solutions development

It takes time to get good quality data and tools, but it is worth the effort

Next steps

- Good practices established in ENES should be made more understandable, implemented, and further promoted
- Mixture assessment requires more work: Working group on mixtures to develop guidance and extract learnings/genericity based on worked-out examples
- More sectors to share experience and become engaged
- ENES participants invited to send feedback (ECHA *Guidelines and Principles* paper on mixtures, eSDS annex Table of Content, scaling)
- ENES participants to actively contribute, act as multipliers, and further disseminate ENES conclusions
- ENES seen as positive by authorities and industry
- ENES to remain active between meetings
- ENES4: to be further defined