



# ENES 3 Summary and Conclusions

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# Day 1 - Mixtures

## Mixture-SDS requirements

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- Although REACH regulates substances, REACH-driven legal duties apply to mixtures
  - to convey risk management measures to prevent adverse effects
  - to ensure SDS content is up-to-date
  - not necessarily in the form of a 'Mixture Exposure Scenario (ES)'
- Existing mixture SDS are a good starting point, but insufficient from a REACH perspective
  - Occupational Safety and Health requirements are essential and complementary to REACH
- Not all mixture SDS require communication of ES-related information e.g. non-classified mixtures, but a systematic approach to mixture risk assessment (RA) is advisable nonetheless for all mixtures

## Formulators' challenges

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- Formulators are a crucial REACH-interface, but their task in relation to mixture assessment and deadline management is very complex
- Risk Assessment of mixtures would benefit from a structured and systematic approach
- Expertise needs to be built
- Formulators would benefit from automation (medium- to long-term) in software systems to efficiently process the substance information received

## Mixture SDS – needs from recipients

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- Formulators and end-users have different needs with regard to ES-related information for mixtures
- Formulators (e.g. Formulator 1 to Formulator 2): ES-like format preferred in general at Formulator 2 level
- End-users (e.g. Formulator 2 to End-user): 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

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- 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

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- 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)

## Case studies – learning points

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- Applicability of the presented approaches to other sectors is possible in principle: it has to be assessed on a sector-by-sector basis (see feedback from break-out groups regarding pre-conditions, sector characteristics and limitations)
- Can 'genericity' be derived from these examples?
- Further work is needed
  - DPD+ to be further developed: environment, 'CLP+', special substances (non-threshold CMR, irritant/corrosive), special attention to additivity/synergistic/antagonistic effects, comparison with other methods (CCA), more examples ⇒ Industry to take the lead and address shortcomings identified by all stakeholders
  - Higher-level guidance, e.g. ECHA's proposed *Guidelines and Principles* paper on mixtures, to be further developed and 'tested' against the case studies
  - Can a common format be designed for communicating mixture risk assessment information in SDS?



## Day 2

# Progress on actions identified at ENES 2

## Progress since ENES 2

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- eSDS annex harmonised Table of Content: need to finalise format (proposal presented, awaiting feedback)
- Realistic assessments and RMM: progress achieved, more work needed
  - SpERCs: new guidance published, documentation of existing SpERCs to be updated, more sectors to develop SpERCs, sectors to develop Chesar SpERC files
  - SCEDs (Specific Consumer Exposure Determinants): harmonised sets of refined parameters for 'ECETOC TRA consumers v3', useful to demonstrate safe use at Tier-1 level. Awareness raising and acceptability to be worked on
- Harmonised formats for ES: available, to be further promoted
- ES Content Essentials: further progress needed
- Communication in the supply chain
  - DU use mappings based on DUCC format are useful, are used and save time

## Scaling

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- 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

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- 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

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- **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**