



Setting the Scene

ENES 3 Workshop

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Risk Management Identification Unit



Exposure Scenario-related information for mixtures

**Setting the Scene**

- Legal requirements
- Role of ECHA
- Communicating ES information for mixtures: options and guidelines
- Other activities by ECHA

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Exposure Scenario-related information for mixtures

## REACH Requirements

- Preamble 17 (re. substances, on their own, in mixtures and in articles):  
*“Recommendations about risk management measures should systematically be conveyed through supply chains, as reasonably necessary, to prevent adverse effects on human health and the environment”*

Exposure Scenario-related information for mixtures

## REACH Requirements

- **Title IV Information in the Supply Chain**
  - **Article 31:** Requirements for Safety Data Sheets
  - **Article 32:** Duty to communication information down the supply chain for substances on their own or in mixtures for which a safety data sheet is not required
- **Title V Downstream Users**
  - **Article 37:** Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures

Exposure Scenario-related information for mixtures

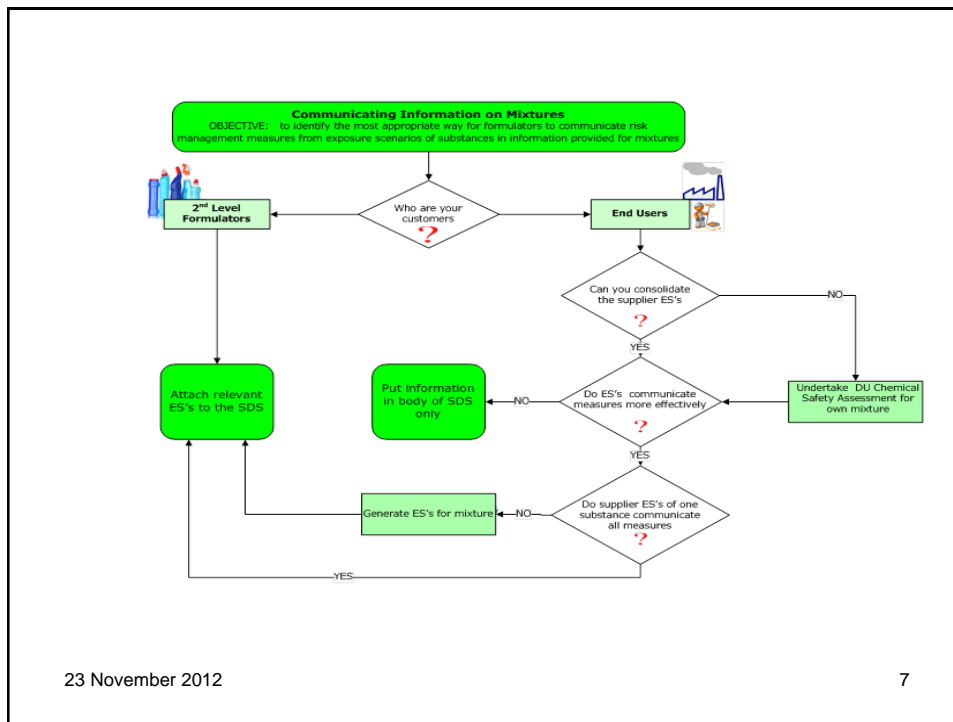
## Role of ECHA

- Promote a clear overview of the communication options so that complexity is minimised
- Develop guidelines and principles for formulators to consider when communicating exposure scenario information for mixtures
- Clarify any legal and technical questions that arise
- Promote improvements in chemical safety reports and exposure scenarios, which in turn will help information flow through the supply chain
- Promote best practice and harmonisation

Communicating ES Information for Mixtures – Guidelines and Principles

## Draft Discussion Document- Aims

- To help formulators identify the communication option that is most appropriate and straightforward
- To present guidelines for key aspects to be considered
- To present core principles applicable to more complex situations



## Communicating ES information for Mixtures – Guidelines and Principles

### Key Guidelines

1. Recommendations on risk management measures should be conveyed through supply chains, to prevent adverse effects on human health and the environment
2. RMMs for the mixture may be generated by consolidating supplier ESs or from a risk assessment
3. The risk is characterised to ensure that the likelihood of effects are avoided
4. Standardised methods and descriptors are used as far as possible
5. The information can be communicated in several ways, and the most effective method is selected
6. The information is updated as soon as new information on RMMs or hazards becomes available

Communicating ES information for Mixtures – Guidelines and Principles

## Annexing Exposure Scenarios

1. The recipient can find and understand the ESs that apply to him without difficulty
2. The information in the ES is consistent with the information in the main body of the SDS
3. Only the ESs that are relevant for the mixture and the identified uses are included.
4. The annexed ESs can be for an individual substance or for the mixture.
5. ESs are provided in local language

Communicating ES information for Mixtures – Guidelines and Principles

## Integrating information in the SDS

1. All identified uses are clearly described
2. RMMs are clearly described
3. Information from the supplier ES that can help to protect human health and the environment is not omitted

## Communicating ES information for Mixtures – Guidelines and Principles

### Consolidating Supplier ESs

1. Group supplier exposure scenarios into relevant uses or categories of use
2. Identify RMMs for all uses that are appropriate and proportionate
3. Consolidate the RMM's
4. Ensure RMMs are not incompatible
5. Effects of the mixture should be considered
6. Ensure the use is safe
7. Document the process
8. Include the information in the body of the SDS or annex as ES

## Communicating ES information for Mixtures – Guidelines and Principles

### CSA for a mixture

1. CSA for mixture may be the most resource efficient option in complex situations
2. The CSA addresses relevant uses only, and is proportionate
3. Core Principles can support the process
4. Information derived from a CSA for mixture can be included in body of SDS or annexed as ESs, as appropriate
5. The CSA for a mixture takes precedence over the individual CSA's for the individual substances
6. A combination of DU CSA for a mixture and consolidation of supplier ESs may be undertaken

## Communicating ES information for Mixtures – Guidelines and Principles

### Core Principles

- Identify the fundamental concepts that underpin all methodologies
- Allow for professional judgement and a variety of approaches
- Acknowledge that a simple 'editorial' approach will be adequate in many cases. A worst-case combination of RMMs may be appropriate, if it is not over precautionary
- Indicate whether the potential risk from mixtures should be assessed based on exposure to the mixture as a whole, or based on independent action of the substances in the mixture

## Communicating ES information for Mixtures – Guidelines and Principles

### Next Steps

- Participants of workshop have received the ECHA draft discussion document on communicating information for mixtures
- Invite feedback on aim, content and areas for clarification
- We propose using this discussion to develop guidance for downstream user (review 2013)

## Communicating ES information for Mixtures

### Role of ECHA

- Promote a clear overview of the communication options so that complexity is minimised
- Develop guidelines and principles for formulators to consider when communicating exposure scenario information for mixtures
- Clarify any legal and technical questions that arise
- Promote improvements in chemical safety reports and exposure scenarios, which in turn will help information flow through the supply chain
- Promote developments and harmonisation

## Communicating ES information for Mixtures

### ECHA actions to support accuracy and clarity of exposure scenarios

- Illustrative example CSR – now released in 2 parts with IUCLID and Chesar files
- Chesar developments
- Practical guides (DNEL setting; qualitative assessment)
- Example exposure scenarios (industrial, professional and consumer)
- Cooperation with industry sector organisations on ECom, harmonisation, promotion of standard use descriptor system
- Clarification with respect to scaling
- ENES



Communicating ES information for Mixtures

## **Expectations of ENES focus on mixtures**

- Identify key issues to resolve which will benefit majority of formulators - apply approach of exposure control
- Identify what is working well, develop and promote that
- Identify best use of ECHA resources

Thank you for your attention.