

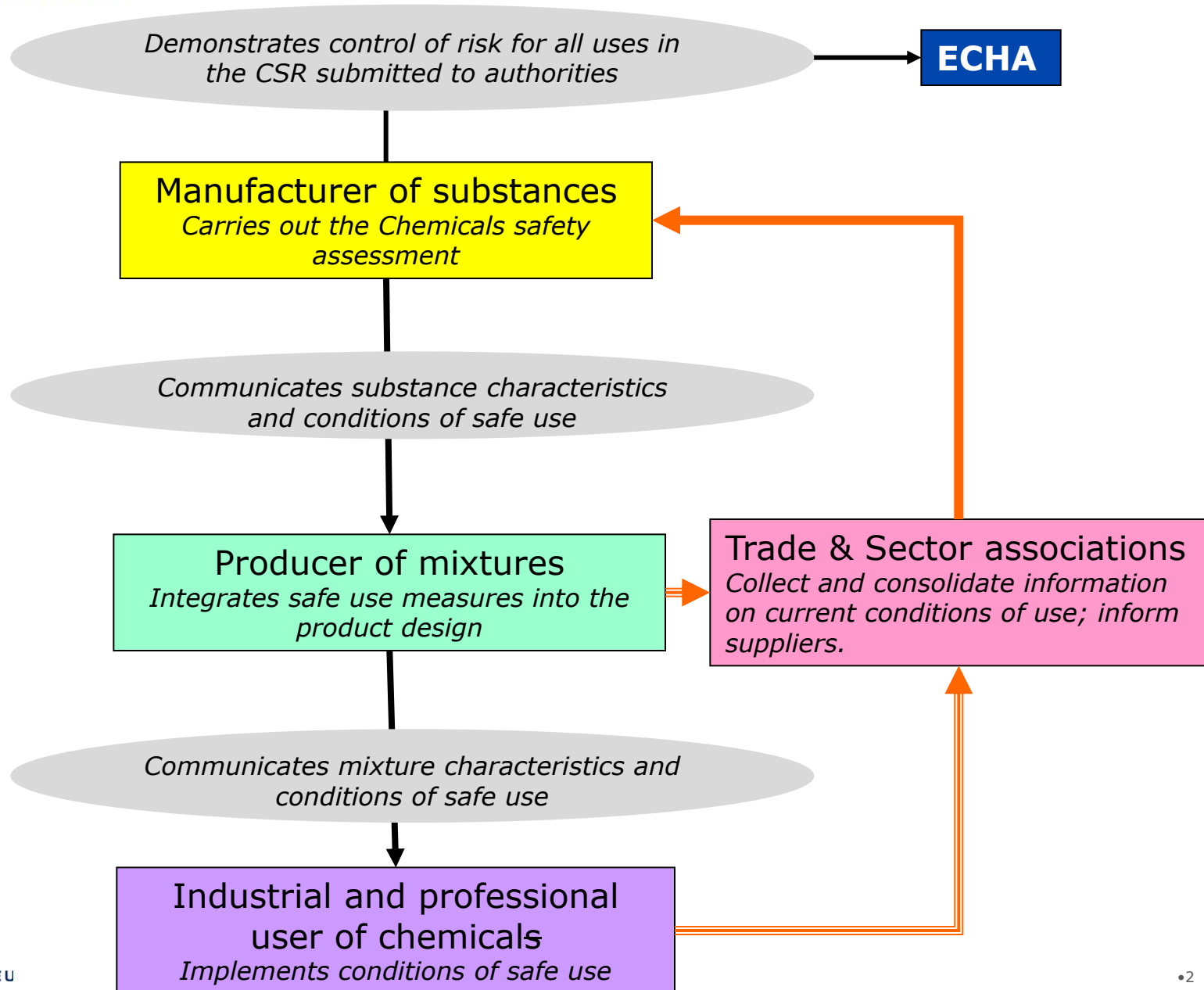
# Session 4.2 Mixtures; Reflections

ENES5

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# Current Methodologies for Mixtures – the ideal candidate

- Correctly identifies the most appropriate risk management measures (RMMs) for the entire mixture
- Clear methodology with reproducible outcome
- Potential to be automated
- Benefits from information derived from the chemical safety assessment (CSA) in REACH
- Benefits from formulator/sector/user knowledge
- Requires competence, not expertise, at formulator level

.....there may be more than one solution

# Exposure Scenario/Top down approach

*(Such as CLP+ and Critical Component (CCA))*

## Strengths

- utilises hazard/risk information from REACH/CLP process such as:
  - Classification
  - DNEL/PNEC
  - RMMs

## Drawbacks

- Often based on single substance (per route)
- Lead substance (if identified) can differ, depending on selection criteria
- Registrant RMMs may not be optimal for the use/sector
- Judgement whether overly precautionary may be subjective
- Is dependant on quality of exposure scenario (ES) information for all substances

*These are just some of the many strengths and drawbacks identified in ENES discussions*

## Controls based / bottom up approach

*(Such as Detergents and Lubricants approaches)*

### Strengths

- RMMs are appropriate to use and sector
- Terminology and control measures are familiar to downstream users

### Drawbacks

- Does not fully utilise hazard/risk information from registrant chemical safety assessment (CSA) (although similar type of assessment may be undertaken at sector level)
- Risk of inconsistencies between information at registrant and downstream user level
- Needs well organised supply chain with capable industry associations

*These are just some of the many strengths and drawbacks identified in ENES discussions*

## Can we take the best of both approaches?

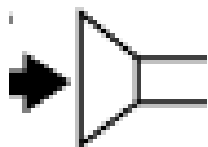
### Top Down Strengths

- utilises hazard/risk information from REACH/CLP process such as:
  - Classification
  - DNEL/PNEC
  - RMMs

### Bottom Up Strengths

- RMMs are appropriate to use and sector
- Terminology and control measures are familiar to downstream users

# Information on RMM in exposure scenario (worker)



Local Exhaust Ventilation (LEV) 90%



Personal Protective Equipment (PPE) 80%

Information provided:

- The level of control
- The type of risk management measure

## The level of control

- The effectiveness of the risk management measures is a good descriptor of the amount of control needed, if the exposure estimate and risk characterisation are of good quality, and based on a consistent and harmonised methodology across various activities/processes.
- Is the total effectiveness the most useful information for the formulator?  
(for example: total effectiveness: 98% (80% + 90%))
- How useful to the downstream user is the detailed specification on the risk management measure by the registrant?



## The type of risk management measures

- The usefulness of the risk management measures specified depends on the registrant knowledge of the use of substance, and the mixtures they may be in
- Is it better when the actual risk management measures for mixtures are identified and specified at formulator or end user level (either by sectors or companies)?
- This identification and specification of RMM could be based on exposure scenario / formulator knowledge/ sector advice /Control banding advice etc.
- Does specification of RMM at DU level promote controls beyond LEV/PPE recommendations? Are other typical engineering controls that could be employed with the mixture more likely to be included?

# Information on RCR in the Exposure Scenario

- $RCR = \text{exposure estimate} / \text{DNEL (PNEC)}$   
This is a measure of how essential the RMM is.
- $RCR < 1$  – Risk is controlled
- $RCR \ll 1$  – RMMs (if applied) may be too precautionary
- $RCR > 1$  – Risk is not controlled
- The RCR may help to determine if the target level of control is appropriate.
- If the effectiveness is initially selected on the most stringent basis, this could be objectively reviewed based on the RCR
- This would eliminate need to identify lead substances
- Can we use the RCR more?

## Can the RCR be of help in mixtures?

- Components may have additive effects (e.g. organic solvents)
- Many approaches look at this possibility afterwards – but some expertise is required
- Is it better to assume initially that the effects are additive? This is a precautionary approach and requires less expertise
- Could a combined RCR be used in some way?
- If the combined RCR indicates the risk may not be controlled, evaluate if the assumption that effects are additive. Change the assumption if this can be justified
- Would this reduce the requirement for “expert judgement” at formulator level and enhance reproducibility of selection of RMMs

## Looking forward...

- Effective communication in the supply chain is essential for a fundamental and sustainable solution to ensure the safe use of chemicals in mixtures
- To achieve this longer term solution, formulators/sector organisations need to inform registrants of the actual, specific conditions of use.
- Registrants need to incorporate this information in their chemical safety assessment and communicate it in exposure scenarios
- In the meantime, we need to continue the ENES work to find workable methods to deal with the current situation

# Reflections on how to build on the work so far (1)

- The effectiveness of the RMM (determined by the registrant) can be useful information on the level of control that is required
- The knowledge and experience of downstream users is essential to ensure appropriate RMMs are specified
- A possible merging of approaches is if the actual RMMs are identified and selected by the formulator, based on the effectiveness established by the registrant
- The RMMs could be based on the exposure scenarios / formulator knowledge/ sector advice /control banding etc.

## Reflections on how to build on the work so far (2)

- It may be feasible to use the RCR as an indicator of whether the RMMs for the mixture are too precautionary or not precautionary enough.
- If so, this may be a suitable alternative approach to identifying a lead substance
- The risk from mixtures may be better controlled if the effects of substances are assumed additive by default. It can then be justified (if necessary) if additivity does not apply.
- A combined RCR for the mixture might be a useful indicator of whether the risk is controlled.

Thank you!

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