

REPORT ENES5 break-out sessions

BREAK-OUT SESSION	H : CLP +
Presenter - SME	Ch.Boegi, St.Welz (BASF)
Moderator	A. Murray (ECHA)
Rapporteur	M-N. Blaude (BE)

Input needed

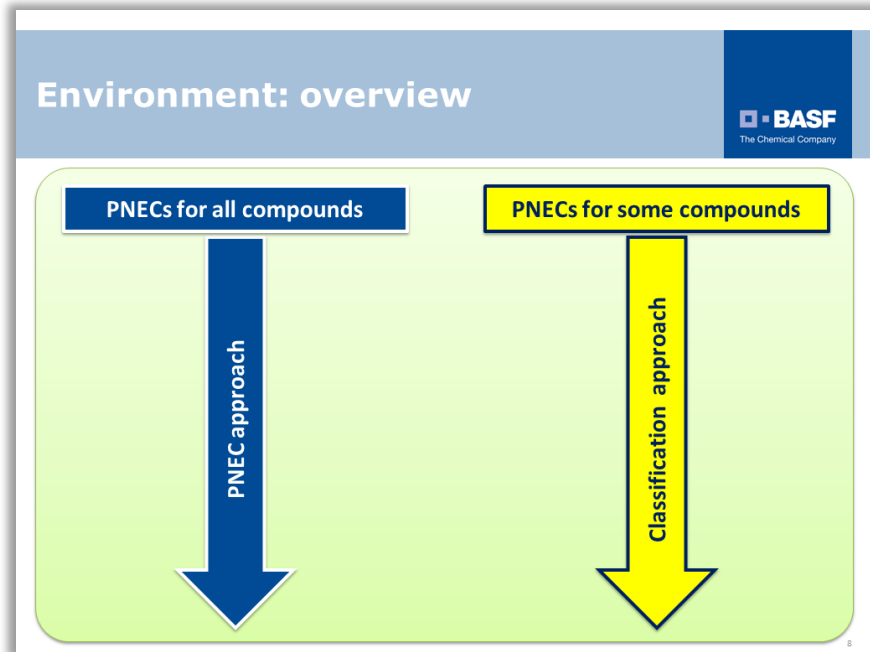
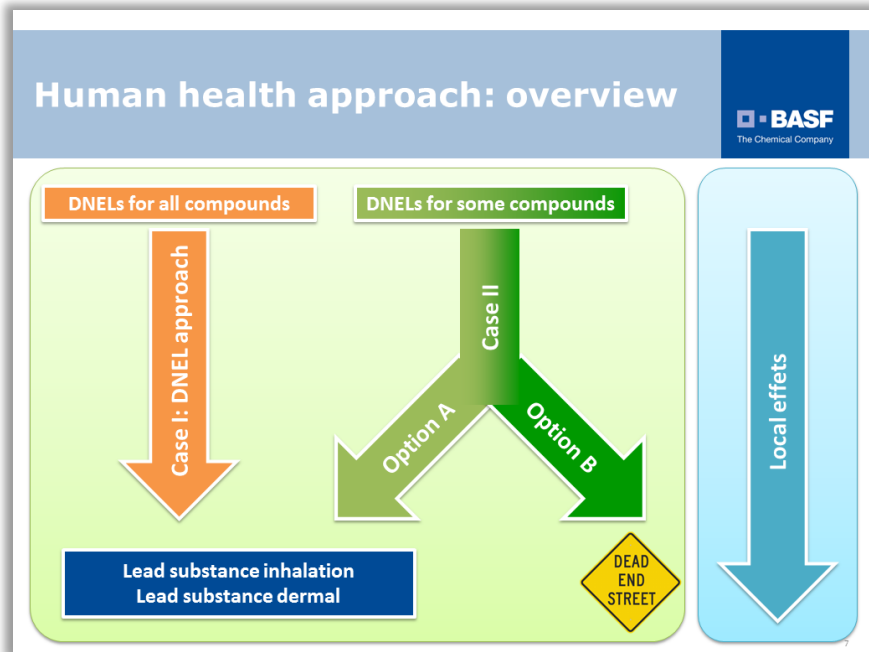
- Composition of mixture
- For relevant (= contributing to mixture classification) substances:
 - DNELs (long-term systemic), PNECs
 - Classification
 - LD₅₀ , LC₅₀ or ATE (if required)



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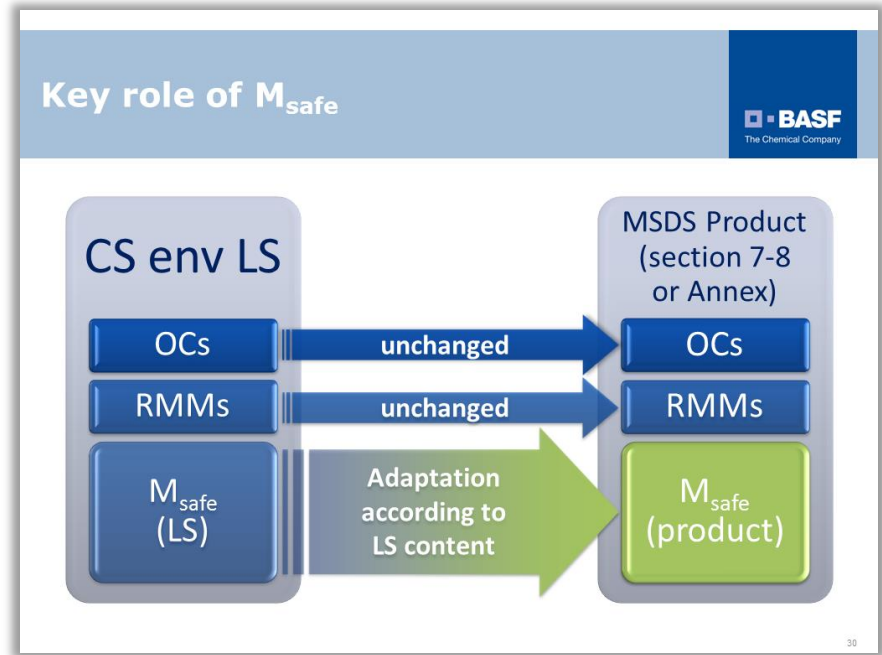
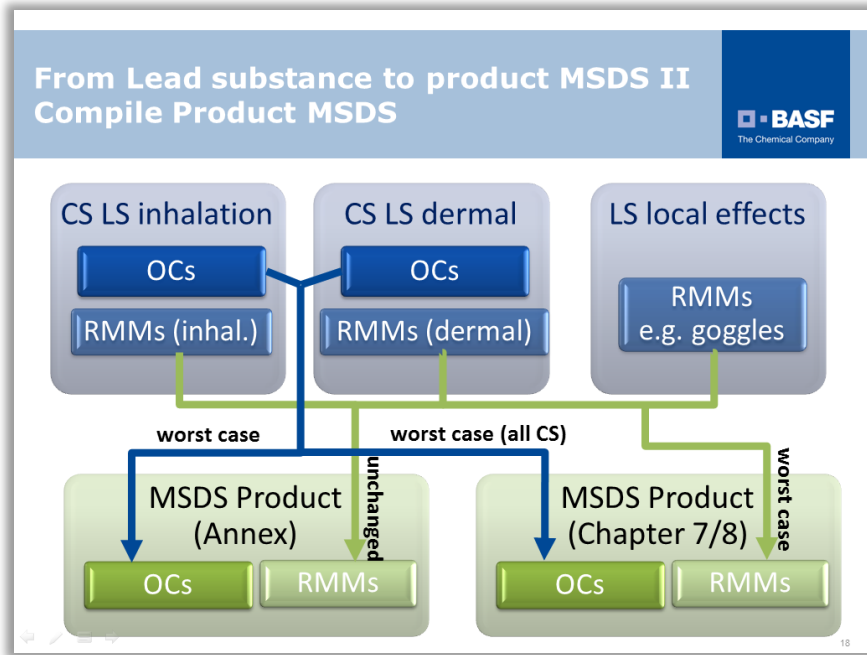
Basic principles (I)



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Basic principles (II)



Output generated

- Lead substance(s) identified
- "Proposal" of set of OCs and RMMs ensuring safe use of the mixture based on LS information
- May be cross-checked with current version of mixture SDS for plausibility
- Proposal can be refined if deemed appropriate (justification recommended)

Main points discussed: General

- validity of DNELs and classification (but same problem for any method)
- Problem of DNEL lower because non confident (larger assessment factor): not always the best lead substance
- Problem when difference between result of the RMM saying it is safe and CLP classification if data are lacking (but same problem for any method)
- Future: consider endocrine disruptors, eqlc
- No perfect method for all mixtures , need OCs & RMM for the mixture, not focalized too much on lead substance
- Lead substance approach gives efficiency gains, compared to substance by substance



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Main points discussed: Specific

- Consider volatility (vapour pressure or saturated vapour concentration): to differentiate volatile and non volatile substances: because for many kinds of uses, only the volatile substance is important for inhalation exposure
- Environment: differentiate volatile & non volatile substances? Different fates of the substances.
- Need to see benefit/effort to add volatility in a pilot study before increasing complexity of the method



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Main points discussed : Specific

- If output seems too stringent, check if more realistic measures are appropriate for the mixture based on current practice
- Why not additivity for health assessment? It is used for these endpoints where it is relevant according to CLP (local effects).
- Inhalation: differentiate substances with LC50 vapour from substances with LC50 mist: only relevant for surrogate approach (option B)



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General Pros

- Not sector dependent
- Comparison DPD+ / CLP+ : same output in all cases so far, probably some differences will appear when running further examples using the PNEC approach
- High degree of automation

Applicability domain/ limitations

- Can be broadly applied in an ideal world (DNELs available, when no need of expert judgment,...)
- Can be performed by those currently writing SDS
- In depth expertise/expert judgment only needed in some difficult/extreme cases: still to be evaluated
- Use of expert judgment if good reason to reject output (inappropriate lead substance): sound justification needed



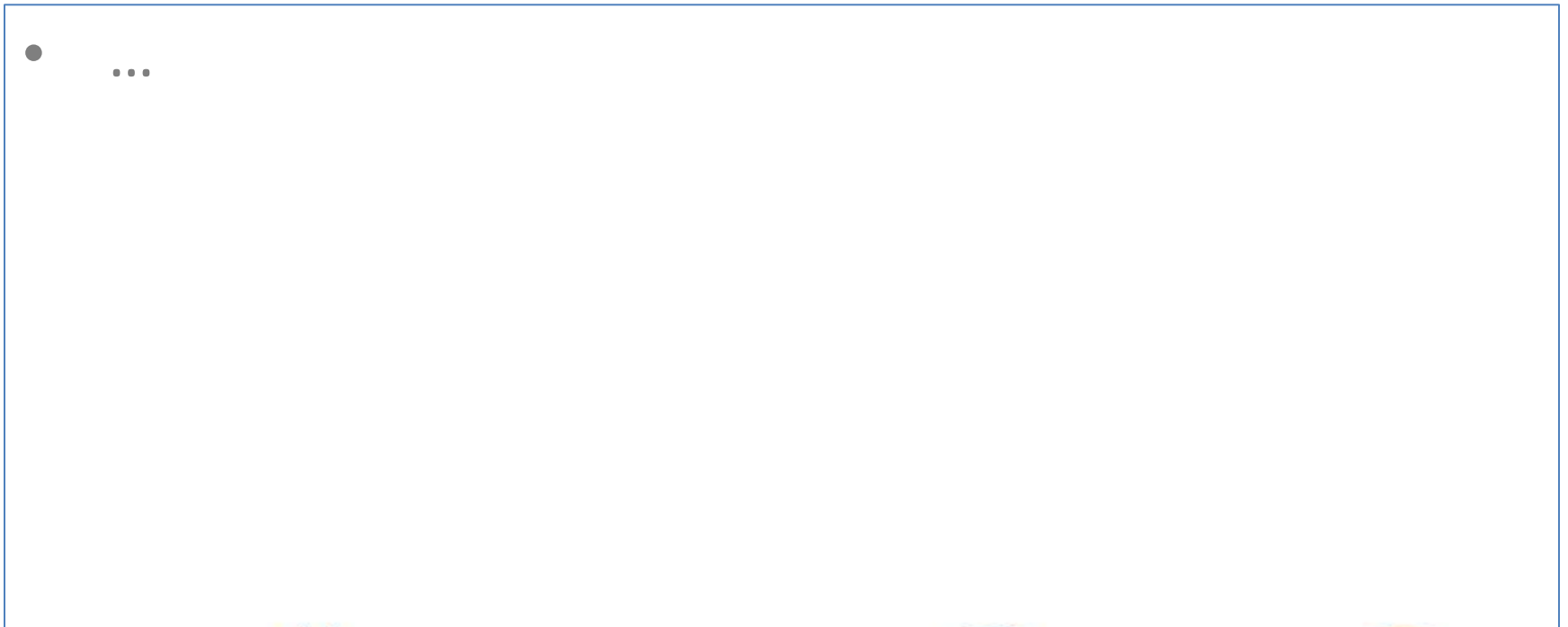
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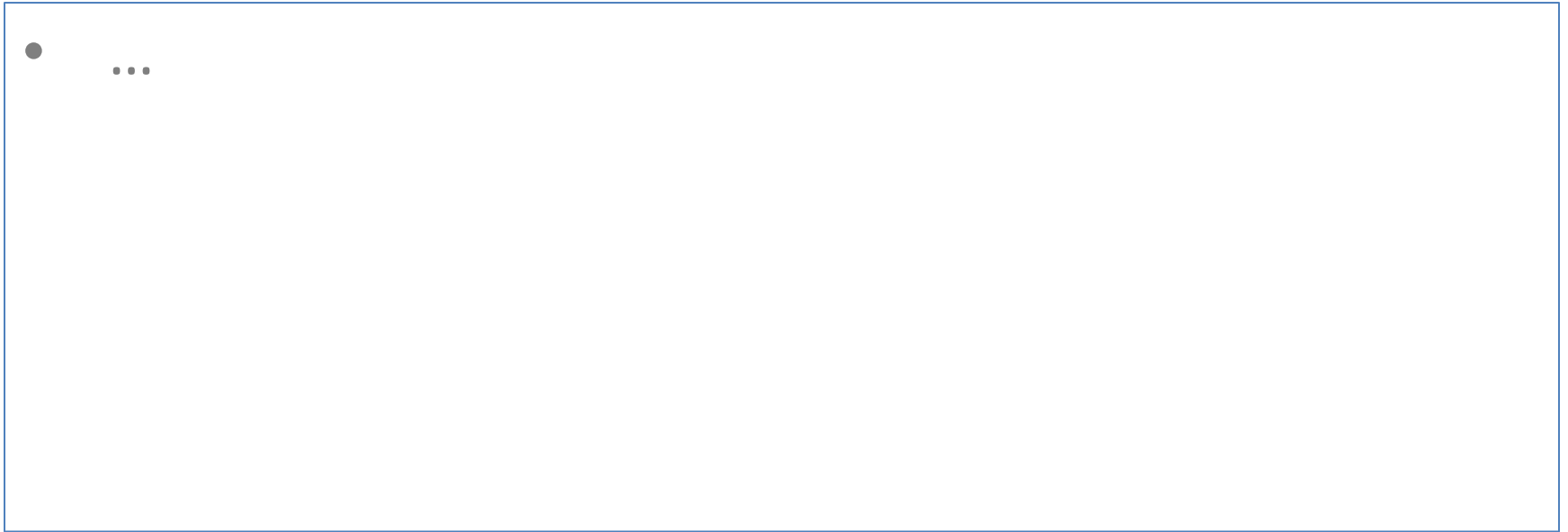
Minimum required training

- Expertise?: mathematic: result without too much expert judgment : if happy with the result: OK, if not: it requires expertise (so , case by case)

Time required to develop the Safe use information



Required actions to develop the method to operational status



General Conclusions and recommendations from the group

- Depending on the feedback of the method : any feedback welcomed to further improve the method
- See for the examples presented: OCC & RMM and see what comes out for the mixture
- If real examples : send SDS of mixtures to try them in the system

Proposed follow-up action	Who should take the lead



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