

Discussion Group C – Report

**How to generate exposure scenarios for mixtures?
Current status and the way forward.**

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Discussion Scope

- Exposure scenarios information in the SDSs for mixtures for end-uses based on exposure scenarios for the single substances.
- Generic exposure scenarios for a certain types of mixtures (GES approach) vs other approaches, and how to develop them
- Note: mixtures sold as raw materials (i.e. leading to mixtures in mixtures) is a topic for future discussion

Significant uncertainties on DU duties related to mixtures?

- Terminology “ES for mixtures” does not exist as such in the legal text: ES concept relates to substances only, as such or in mixtures (or articles)
- Legal text does not prescribe how to transmit ES information in mixture SDS:
 - Practical options based on interpretation of the legal text: Annex or main body of SDS (section 8)
 - Annex vs main body of the SDS?
 - End-use: likely that integration into main body is better for the final user, unlike intermediary mixtures
 - Choice also depends on the amount of information that needs to be communicated (long -> annex)
- Does the 12-months deadline apply for updating SDS of mixtures? Not specifically mentioned in legal text
 - Note: it is complex due to substance/supplier specificity

Significant uncertainties on DU duties related to mixtures?

- Art 31.7 is the main legal reference.
- However, the legal text is not cristal-clear:
 - ES information triggers DU duties, regardless of where it is located (annex or main body). If info is in the main body, need to flag which information is ES/REACH related
- If several substances in a mixture, a mechanism needs to be found to reflect the substance information in the mixture SDS, but
 - Is substance traceability needed all through supply chain?
 - Is simple advice enough to end-users (e.g. bodyshops)? (note: some end-users mix or dilute the raw material supplied)

Approaches available to support the communication of exposure scenario information in mixture SDSs

- Known approaches: Lead substances selection / GES approach / possibly others (not discussed)
- DPD+
 - Starts with classification of mixture
 - Lead substance to be assessed per endpoint: “hazard class precedence” not foreseen. Similarly acting substances need to be summed up (additive endpoint).
 - What happens once the Lead Substance(s) is(are) identified? RMM/OC considerations typically follow selection of lead substance (see industry guidance)
 - Limitations of DPD+? e.g. metal alloys: DPD+ was not enough; more info than classification was needed (DNELs/PNECs/RMM/OC), but concept of grouping of alloys is applied.

Approaches available to support the communication of exposure scenario information in mixture SDSs

- GES: Consistency within supply chain is possible, more difficult across supply chains
- Once having applied DPD+ to many mixtures, you may be able to group mixtures as a result (not very far from the GES approach)
- For a limited number of substances in mixture: option is to forward ES of lead substance(s), without losing important information;
- For complex mixtures with many substances, GES could be a good alternative
- Whether the ES is generic or specific, condensing information into simple advice is always possible, where needed
- **PROPOSED F/U ACTION: understand process steps and output following lead substance identification via e.g. DPD+**

Information elements and the processes to define a GES for mixtures?

- **GES for mixtures:** consists in condensing many mixtures that have a common use into representative ones, for which one typical ES applies: the applicability domain of a GES is defined by a given set of OC/RMM, specific hazards/classifications
- GES: requires good supply chain cooperation (knowledge of composition of products and classification by all players), works only for short and specific supply chains
- Need to map OC/RMMs on one side and hazards/classifications of mixtures on the other side
 - ATIEL: started with conditions of use before looking at hazards/classification.
 - A.I.S.E. pilot: Hazard of mixtures as starting point + application types.
- Separate assessment for health and environment when 'mapping' mixtures

Information elements and the processes to define a GES for mixtures? Challenges?

- GES also contains concentration substance in the typical mixture
- GES method for mixtures relies on existing (pre-REACH) information on substances, since not all substance ES are available yet, e.g. 2013/2018 substances
 - it is still possible to describe the levels of controls for these substances ('OEL: proxy for DNELs').
 - Note: unlikely that formulators in the middle of the supply chain can use GES, unless they are part of the specific supply chain
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- **PROPOSED F/U ACTION : understand pros and cons/ applicability of GES and DPD+ using practical examples**

How would these GESs support the formulator in processing incoming substance ES information into SDS information for the whole mixture?

- Formulator of end-use mixture: checks incoming substance ES against mixture GES (i.e. the 'pre-cooked ES' for mixture), can conclude he works within the conditions of use
 - If it does not fit within the GES boundaries, a separate evaluation is needed for the mixtures
- Formulator of end-use mixture: can also use the 'representative' ES generated by GES method to update his SDS for mixtures
 - Question of where it resides (annex vs main body): company decision (ATIEL).
 - Format of a GES: looks like standard ES (same sections), although not all information triggers duties (not all REACH-driven).
- **PROPOSED F/U ACTION : look at more difficult cases (mixtures purchased) and mixtures of mixtures in context of GES**

Time horizon for processes and tools to be in place?

- THIS WILL TAKE TIME ! Not possible to tell how long
 - Note: 18 mths for full GES method for lubricants
- DPD+ understanding is needed as soon as possible (applies regardless of GES or else): examples to be looked at.
- **Assess how to follow-up on above actions: ROADMAP?**