

MISA 4 Exposure – Final Webinar

Consumer Exposure, Humans via the Environment exposure, Technical Completeness Checks and overview of MISA updates

Friday, 7 May 2021

Main Learnings in brief

On consumer exposure from use of products and articles

- Overall, this area needs more attention. If hazard is identified, an exposure assessment is required for:
 - Metals (compounds) use in consumer products (mixtures)
 - Metals (compounds) forming the material matrix of articles.
 - Metals processed into or onto other material matrix forming articles (plastic, rubber, ceramics, metals)
- For setting the right priorities, a good overview on the occurrence of the metal in mixtures and articles is required. Information on the concentration of a substance in mixtures/articles and on the conditions of uses should be collected to the extent possible to carry out the assessment. A tiered approach may help to prioritise, starting with default values and refining conditions of use with e.g., interviews, surveys and literature.
- Support via modelling tools is limited for metals. The ECETOC TRA may help as a Tier 1 tool for mixtures, but not for articles. For the ConsExpo tool, fact sheet information with default values is available that could be refined for some subproducts where metals play a role as components. Both tools can be used in “free style mode” (including ECETOC TRA in Chesar), i.e., input parameters need to be defined by the assessor. However, for all these work-arounds, the evidence/parameters that are used need to be described and limitations of the tools reflected upon.
- For uses of concern, measured data may be needed, in particular with regard to migration/releases for metals in material matrices.

Key is to understand exposure routes and the conditions in which the consumer will be in contact with the substance. This understanding (and its documentation) will allow to have representative assessments.

On ‘Human via the Environment’ exposure

- The assessment is needed for hazardous substances when the tonnage is above 1000 tons/year or if the tonnage is above 100 tons/year and the substance is classified as STOT-RE1, or carcinogen or mutagen (any category) or toxic for the reproduction (categories 1A or 1B)
- Local assessment may need proper transfer factors, as i) current EUSES not suitable to model uptake via crops, milk and meat and measured ii) exposure may often include contributions from historical pollution.
- Introducing a low/fake Kow in EUSES/Chesar is not a valid workaround. The new Chesar platform under development may provide further support for the human via the environment assessments.
- Measured data should be reported with contextual information and an explanation on their representativity. The chosen statistical value used for the assessment should be duly justified.

On the Technical Completeness Check (TCC)

- Before submitting dossiers, synchronise the use description in IUCLID with the Chemical Safety Report (CSR) (or vice versa).
- Ensure that the hazard assessment in the lead dossier (differentiating or not between different compositions/forms) and the exposure assessment provided by the joint submission members match each other (except for opt-outs, where the situation is clear).
- Respect the basic rules in structuring the CSR and ensure coherence between the environmental assessment and human health assessment.
- Initiate/progress data generation or modelling for releases during service life of metal containing materials. When assuming that the release from service life is so low that no quantitative exposure assessment is needed, nevertheless the registrant needs to provide some evidence to support this assumption.
- Check/share regularly the learnings on the TCC (ECHA webinars? EM to ask regularly)

Actions requiring technical follow-up:

- **Consider possibility to develop a fact sheet on painting, coating or spraying of metal compounds (e.g., refining RIVM fact sheets covering painting and coatings including the spraying application).**
- **Consider addressing transfer factors (currently not standard information requirements) in ECHA guidance to ensure reporting in the registration dossiers and clarify main principles regarding their estimation/measurement.**
- **Clarify how to assess situations where the manufactured substance does not meet the criteria for hazard classification, but some emitted constituents or transformation products (metal species) are hazardous. How to take into account the manufacturing tonnage band?**
- **When a hazardous substance while being processed into/onto an article transforms into a non-hazardous species/form/product, how and where to demonstrate in the dossier that exposure assessment for service life is not needed?**
- **Check the need to report environmental contributing scenarios in the case of a substance that has a Derived No-Effect Level (DNEL) set for respiratory irritation in IUCLID but no other effects.**