

Metals and Inorganics Sectorial Approach (MISA) - Exposure

Webinar 2 - Workplace exposure

23 November 2020

Main learnings

Generic points

- When different forms (species) of a metal differ in their uptake on the inhalation route, the “correction” should be included in the Derived No-Effect Level (DNEL) derivation (and not at the level of exposure estimation or risk characterisation).
- Contributing Scenarios (CS) in the exposure scenarios for communication should provide clear information and avoid statements that shift the responsibility of making an assessment conclusion (“if DNEL exceeded, then take measures”) to the downstream user.
- Ensure consistency between the input parameters in modelling tools and Conditions of Use (CoU) in the contributing scenarios.
- When a contributing scenario covers multiple Process Codes (PROCs) for a modelled exposure estimate, the leading PROC used for the calculation needs to be explicit. Otherwise, the upcoming Technical Completeness Check (TCC) for CSR may fail.
- When measured data are used and the CS prescribes Respiratory Protective Equipment (RPE), it needs to be clear whether the exposure estimate accounts for the RPE reduction factor or not.

On measured data

- The measured data must fit the situation to be assessed and should represent a Reasonable Worst-Case (RWC) exposure level. In general, the number of measurements needs to be higher if there is a high variability in the exposure distribution (high GSD), if the exposure value is close to the DNEL or a high number of sites/workers is to be covered. High variability in exposure distribution may be compensated by advanced (e.g. determination of upper confidence limit) or more strict statistics (e.g. higher percentile values).
- Measured data need to be accompanied by information so that their quality (including uncertainty on exposure values inherent to the dataset) and representativity can be assessed.
- The sample number should be high enough to be representative for the number of workers/workplaces and sites to be covered.
- Measured data should refer to Similar Exposure Groups (SEG), defined by similarity in tasks/processes and materials. Exposure estimates will be derived for each SEG. The concentration should represent the concentration during task(s) reflected in the CS. Data gaps

(i.e. contributing scenarios without defined SEG) may be filled by “read-across”, if Conditions of Use are similar enough and the selection of exposure values is sufficiently conservative (to be justified in the registration dossier).

- The Eurometaux monitoring guidance (available on the MISA blog and REACH Metals Gateway) gives further hints and tricks to generate/collect data.
- What needs to be reported with the CSR:
 - Statistical indicators to enable understanding on the adequacy of the measured data for supporting the exposure estimate and the corresponding risk characterisation:
 - Number of data points
 - Characteristics of the data set: Geometric Mean (GM) and Geometric Standard Deviation (GSD) (calculated from the measurement results) and the 5th and 95th empirical percentiles (The max value can be reported but is normally not used for the assessment).
 - How the exposure estimate for the Risk Characterisation Ratio (RCR) calculation (against DNEL, Occupational Exposure Limit (OEL), other) has been derived from the exposure distribution assumptions: it is crucial to explain and transparently document the approach. Confidence intervals can help to address uncertainty.
 - In general, a high GSD triggers the need for particular justification when using the associated data-set in exposure assessment. Aligning views on the size of GSD being of concern may be part of further exchange between Eurometaux and ECHA.
 - Also
 - Conditions of use
 - Explanations on the representativity of the data set for the CS
 - Type of air sampling (static/personal). If results from static sampling are used, a justification is to be included why they are considered to be sufficiently representative for personal exposure levels (normally accepted if the results from static sampling represent a worst case, e.g. sampling conducted closer to the emission source).
 - Sampling methodology and method of analysis (including reporting of Limit of Detection (LOD) and Limit Of Quantification (LOQ)).
 - If data below LOD/LOQ are used for exposure assessment, it needs to be explained how this was done.
 - For mass-based sampling of particulates in air, it should be reported which fraction of airborne dust (according to EN 481) has been sampled.

On the assessment of impurities

- A 3-step-approach can help you determine if a separate risk assessment is required for an impurity or whether the risk is covered by the assessment for the main constituent (= substance). The application of this approach requires that some data be available, namely: the concentration of the impurity during the life cycle of the registered substance (may change from one life cycle stage to

another), hazard profile of the impurity, differences in exposure potential between main constituent and impurity (indicated by vapour pressure at operating temperature and/or melting point).

- For the hazard information on the impurity, a first screening may be based on information from ECHA's dissemination website.
- It is important to document how the decision has been taken (no separate assessment needed, separate assessment to be carried out). Separate risk assessments can be reported in IUCLID by using the assessment entity feature.

On the estimation of co-exposure for inorganic UVCBs

- Exposure assessment and risk characterisation for UVCBs need to consider simultaneous exposure to different inorganic substances. The default approach is summing up the RCRs for the contaminants present at the workplace.
- In order to utilise existing exposure datasets (which often do not cover all contaminants in the same sample), a method for taking into account the likelihood of co-exposure is needed.

Actions requiring technical follow-up

- ***Discuss on how to best report form-specific DNELs in IUCLID and/or within CSR***
- ***Discuss an adequate format for reporting/explaining the use of data below LOD/LOQ***
- ***For estimation of co-exposure for inorganic UVCBs, discuss approaches (with a transparent rationale) to address the likelihood of the simultaneous presence of different contaminants at the workplace.***