

- [Metals and Inorganics Sectorial Approach \(MISA\) - Exposure Webinar 2 - Workplace exposure](#)
23 November 2020

Main learnings

Background

The 4th MISA priority deals with exposure assessment. The objectives of this activity -as outlined in the rolling action plan- are to

- a) improve the quality/reliability of the exposure data in the registration dossiers (e.g. by improving the contextual information)
- b) clarify assumptions and robustness of the methods used for workplace, consumer and Man via the Environment assessment.

Initially scheduled for April 2020, due to the pandemic, the workshop aimed at discussing workplace, consumer and environmental exposure, defining together the most appropriate information to complete the dossiers, but also exchanging on metal specificities, was postponed and finally replaced by a series of webinars.

- A first webinar, recalling the importance of exposure assessment and discussing life cycle tree aspects was held on 23 October
- A second webinar discussing workplace exposure assessment was held on 23 November
- A third webinar, focusing on environmental exposure and Man via the Environment will be held on 26-27 January
- A last webinar may be organised in February to address remaining items (e.g. consumer exposure) and possible metal specificities in Chesar

To prepare these webinars, Eurometaux developed an extensive self-assessment tool (SAT), completed over the summer by the MISA consortia. The aims of the SATs are the following:

- help the registrants to survey the current status of their dossiers with the perspective to improve Chemical Safety Reports (CSRs) later on (where required)
- allow Eurometaux to identify questions/topics to be discussed jointly with ECHA during the webinars
- aim at identifying possible inconsistencies between the metal files and the ECHA guidance that would be triggered by metal specificities.

The SAT Exposure included 4 specific sections:

- **SAT-EXP 1 Use description:** will focus on the life cycle tree (LCT) developed and its quality/completeness of use descriptors (UDs) assigned based on current ECHA R.12 guidance on use description.
- **SAT-EXP 2 Environmental exposure assessment:** divided in a local and a regional section. This SAT will focus on quality/completeness of the exposure data (modelled AND monitoring data) etc. but also explore contributing emissions and approaches for use in (a correct) **regional** assessment (diffuse sources assessment used to define "allocation and importance" of sources, article release). It will also cover man via the environment.
- **SAT-EXP 3 Worker exposure assessment:** will focus on worker exposure and quality/completeness of the exposure data, addressing aspects like e.g. contextual information, assumptions behind modelling etc.
- **SAT-EXP 4 Consumer exposure assessment:** will address consumer exposure and the associated data.

Main learnings in brief

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.*