

MISA 4 – Exposure

Webinar 3 – Environmental exposure 26 -27 January 2021

Main learnings

- Any proper registration file should recognise that:
 - A proper exposure assessment has validity and should preferably anticipate needs beyond REACH compliance requirements (e.g., CSS/ZPAP).
 - If there is a classification for one of the endpoints, then there is a need for exposure assessment. The scope of exposure assessment depends on the effects seen in the testing.
 - Contributing scenarios and release estimates for the environmental are always required in case a DNEL or a PNEC could be derived from the available effects data¹.
 - Reliable and representative monitoring data always prevail modelled evidence especially for regional data.
 - Metal specificities in exposure models like EUSES, should be adjusted, so as to ensure relevant assessments for metals.

Some basic principles

- A complete set of exposure information is required when risk characterization is based on measured exposure (as for modelled exposure): condition of use, resulting releases, resulting exposure. Ensure that this principle is understood and met for CSR updates.
- Back calculations from a set RCR-target to “safe volumes” are not recommended and may not work any longer considering the implementation of the MAF.
- Please use relevant metal SpERCs instead of ERCs when available.
- “No releases” statements always require justification/motivation, usually an exposure scenario describes the conditions under which “no release” occurs.
- Report occupational and environmental assessment for a use in the same exposure scenario, and preferably use *one environmental contributing scenario per use*.
- It is strongly recommended, certainly for complex dossiers, to include all exposure scenarios, estimates and risk characterisation together in chapter 9 of the CSR -including all the explanations- and to include the information on the aggregate exposure (across uses) and risk in chapter 10.
- Documenting a basic understanding of “the metal mass flows” (across the metal substances), from manufacture into the different areas of use and recycling, is most helpful to understand substances’ uses and volumes, recycling and the potential releases (or “leaks”) and exposure from the materials cycle.
- The LoQ should be at least 2 times lower than the PNEC to consider measured exposure data sets to be relevant for risk characterization. If this condition is met and if samples are

¹ DNEL and PNECs can/should be only derived if adverse effects have been observed (i.e. so no DNEL/PNEC based on highest dose tested without relevant effects seen)

below the detection limit, they should be included in the PEC calculations and not be discarded, as this might otherwise not provide a clear view on the potential for risk.

Widespread Use

- Municipal STP effluent data allow to over-write modelled, aggregated release and exposure estimates for widespread uses (professional uses, consumer uses and article service life) with data. They are therefore a recommended source to improve and verify the WSU assessment for metals.
- It is recommended to update municipal STP metal releases as those have evolved over the last 10 years.

Regional

- For metals, representative measured regional data are inclusive for REACH and non-REACH emission sources, and therefore preferred over modelled data.
- The combination of modelling and monitoring estimates allows for source allocation and proper exposure management.
- Promote a common regional background concentration method across CSRs for various registrations (and metals if feasible). The method needs to be described and the reporting in the CSR to be illustrated.
- Contributions from non-REACH sources can often be dominant for metals. An inventory of “emission sources” contributing to the regional scenario can define the relative importance of non-REACH sources and should be part of any main metal dossier.

Supply change communication

- Exemplify safe use information to be communicated downstream (an example SDS would be useful)
- Ensure that exposure-driving conditions are addressed in the safety data sheets and understood by the downstream users.

Man via the Environment (MvE) (see last exposure webinar)

- Observation: Model calculations can really overestimate the MvE assessment of metals (see Cr case). The use of local and regional specific data (number of inhabitants, use of local crops or market based information, air ambient monitoring data, ...) is often needed to reach a realistic scenario for metals.

Increase general understanding on the scope and potential impact of Mixture Assessment Factor (MAF).

- Define a **clear updating strategy** which will be different for local than for the regional assessment.
 - In principle, **local updates** should be performed when volumes have changed, new uses appear or new technologies or RMMs are applied.
 - **Regional updates** should preferably be conducted at a medium-term regular interval to capture changes in collective emissions.

The broader picture

- When making the effort to update your local assessment, it is better to anticipate upcoming developments (e.g., the MAF and Zero Pollution Action Plan (ZPAP)) and move towards more

accuracy if possible, by replacing modelled data by relevant and representative monitoring data (e.g. release estimations of point sources, receiving environment monitoring, etc.).

- It may make sense for Consortia/Associations to tackle some exposure assessment aspects collectively. In particular: STP releases (balance emissions, sludge), EU-wide regional monitoring data on water, certain product groups or article life where there are several metals included (added or as impurities)

Actions requiring technical follow-up

- **Requirements for quality and representativity of data with regard to use/ES, sampling and analytics, Limit of Detection, statistical indicators for documenting measured environmental concentrations in the CSR to be spelled out (see analogue action for occupational exposure)**
- **Method (including exemplification) for using measured data from municipal STP in the CSR under REACH including example in CHESAR.**
- **Method for determining regional background concentration and source analysis**