

# Metals and Inorganics Sectorial Approach (MISA) - Exposure

## Webinar 1 - Life Cycle Tree

23 October 2020

### Executive summary

#### Background

The 4<sup>th</sup> 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 aiming 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.

- This 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 will be 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.

## Webinar 1: Life Cycle tree

The webinar started with two setting the scene presentations: **Jos Mossink (ECHA)** presented MISA's state of play and **Violaine Verougstraete/Hugo Waeterschoot (Eurometaux)** presented the SATs' main learnings.

The "SAT-LCT" was completed by the consortia/associations for 164 substances. Most consortia have updated these sections of their registration files recently, using Chesar and the latest version of the ECHA guidance. Only a few consortia used "use maps", raising the question how the communication flows top-down, down-top (manufacturers/importers to downstream users and end-users) are supported. This topic was therefore put on the agenda of this first webinar. One of the difficulties that was identified is the reporting of information on volumes/use, because of confidentiality issues or unavailable information or the fact that it is not a mandatory requirement.

**Andreas Ahrens (ECHA)** presented the 'overall picture' on data generation and exposure assessment, recalling the importance of communication and cooperation in the supply chain, but also to draw a clear life cycle tree as a prerequisite for exposure assessment. The ECHA Guidance R12 on life cycle is a good supporting tool for doing so and helps to report the different stages in IUCLID section 3.5 (i.e. manufacturing process, production of mixtures, industrial uses (e.g. as intermediate, catalysts, material for finally shaped metal objects, agent for treatment of article surfaces), professional activity with metal objects (e.g. sanding, cutting, welding or treatment of article surfaces with metal containing chemicals), consumer use of metal containing chemicals (e.g. in hobbies and crafts) and service life of articles (e.g. packaging; kitchen ware; jewellery; vehicles and electric/electronics; building and construction). So far, there is no dedicated reporting structure in IUCLID for recycling operations and "second life" (if different from first), however dismantling, milling, separation and other end-of-service-life operations with articles, can be reported under service life and identified with a suitable use name.

Identifying where the life cycle ends is a critical question. The assessment shall indeed cover all identified uses and (where relevant) the subsequent life cycle stages. It was clarified that in terms of assessment, the life cycle of a substance ends where: i) the substance is consumed in the manufacturing of another substance (intermediate); ii) the substance (completely) reacts on use (or in the environment), and there is evidence that the reaction products are not hazardous; and iii) the substance is recovered from end of service life of articles or production waste (as such or in form of a mixture) and is registered as another substance. The challenge is that companies processing waste (including end of service life of articles), are not downstream users under REACH, i.e. none of the information mechanisms under REACH apply.

It was recalled that each identified use (reported in the IUCLID Dossier) and its contributing activities (defined from worker and environmental perspective) should be addressed by a corresponding exposure scenario with its contributing scenarios in the CSR. Based on the conditions of use, releases and exposures of the environmental compartments and workers can be estimated (involving multiple data sets). The different use descriptor categories were briefly recalled as well.

ECHA further highlighted that the new completeness check (2021) will include a content check of the chemical safety report. The manual checks -based on standard instructions- will focus on the completeness of exposure assessment and risk characterisation.

Based on an analysis of common current shortcomings in the CSRs, practical advice was provided to help registrants to ensure they have a complete chemical safety report and include correct and understandable justifications (e.g. for waiving the exposure assessment or certain elements in it).

The following situations were discussed:

- no CSR
- mismatch between use descriptions and exposure scenarios
- use of the substance as an intermediate
- (no) hazard identified for some hazard endpoints,
- substances with high systemic hazard (but without thresholds)
- waiving of Man via the Environment or secondary poisoning assessment
- no release as justification for no exposure assessment

Andreas Ahrens concluded his presentation by mentioning the updated IUCLID validation assistant and types of support like webinars, written support material and proactive company support that are put in place to facilitate complying with the new Technical Completeness Check (TCC).

The discussion that followed the presentation highlighted:

- the importance of sufficiently substantiating the 'no release' claim when waiving exposure estimates for some or all compartments
- the need to further clarify where to report the waste stage in IUCLID when emissions make it relevant to assess
- the need to further discuss issues like natural leaching from metals not coming from production/use in the Man via the Environment assessment (webinar 3)
- the importance of reporting tonnages for individual steps in the life cycle for a thorough assessment vs. the current legal requirements and TCC that do not require their reporting (see also below). This will also be further discussed in webinar 3.

ECHA's presentation was followed by industry presentations on the following topics:

- i) An example of life cycle tree for a metal was presented by **Daniel Vetter (EBRC, on behalf of Eurometaux)** who highlighted that the Chesar tool was helpful to synchronise the use descriptions and group uses, considering the number of applications and scenarios. He went more in detail on some of the considerations to be made during generation (cleaning and maintenance tasks with PROC 28 processes, the assignment of appropriate Environmental Release Categories (ERCs) such as ERC 2 and/or ERC 3 for Exposure Scenario (ES) formulation and the multiple Process Codes (PROCs) issue). He then gave the example of welding where the end-use of the metal (in welding consumables) and article service life stage of the metal (welded metal parts) occur at the same time and exposure depends on the techniques used. The appropriate risk management (e.g. personal protective equipment to be used, including respiratory protective equipment (RPE) will be defined depending on the welding technique, itself depending on the uses (consumers, professional and industrial).

- ii) **Carol Mackie (Copper Compounds Consortium)** explained how they collected information from downstream users in an iterative way and how they were able to address some of the commercial and confidentiality complications of the data gathering with the help of a traffic light system. The latter helped to draw the consortium members attention to the requirements and the consequences of data gaps. It was commented that such a tool serves the same purpose as the DU sector use maps.
- iii) **Daniel Vetter (EBRC)** highlighted other methods to receive up-to-date data information from downstream users, i.e.
- the “use mapping” -with the existing use description for nickel metal (in 2015)- served as basis for the improvement of the LCT as suggested in the current ECHA R12 Guidance. It was based on feedback provided by industry, the Generic Exposure Scenarios (GES) were completely revised, and specific ESS were included in the registration dossiers instead.
  - survey on use description and conditions of use with the development of questionnaires to gather recent information on use description, together with relevant information on conditions of use per contributing scenario
  - development of data submission form for gathering new monitoring data.
- iv) **Federica Iaccino (Eurometaux)** briefly presented the work done on the Mass Flow Analysis (MFA). The aim was to assess whether the MFA could help to improve the overall understanding on high volumes metals manufactured/imported in the EU, to understand the feasibility of volumes’ tracking by using MFA as a workable alternative to tonnages/use in the supply chain and to define to which extent it is possible to derive a flow scheme about metals’ use in the EU. A template was put together (MFA. xls) and some best practices to develop a MFA could be defined. The learning lessons showed that the degree of success is driven by companies’ participation & time invested in communication/follow-up of questionnaires and the ‘simplicity’ of the supply chain and the uses/transformation covered. The conclusion at this stage is that the MFA allows to provide differentiation between major and minor uses, but it remains difficult to retrieve final volumes (%) covering the entire supply chain.
- v) This was completed by a presentation by **Jelle Mertens (EPMF)** on the silver case. A MFA exercise was launched pro-actively to respond to specific requests from authorities but also to prepare the IUCLID update and advocacy. The main learnings from this exercise were that it was difficult and time-consuming, especially without regulatory pressure. The willingness to participate in information gathering often depends on the position in the ‘industrial chain’, with manufacturers/consortium members being easier to motivate than traders and downstream users. Confidentiality issues regarding tonnage information, uses render the MFA challenging, especially for niche substances. Also, there is the potential double-counting issue (when a compound is used to make a next one). The exercise also allowed to draw some learnings on the roles of non-REACH uses, intermediate uses and the comparability of the “real tonnage” vs. reported total tonnage band on ECHA website.
- vi) **Maxime Eliat-Eliat (ARCHE Consulting representing EPMF)** gave a presentation on service life after transformation with a change in hazard pattern, referring to the example of tetrachloroauric acid (TCA) used in electrochemical and galvanic plating. Whilst TCA is classified for several endpoints, gold is not classified. TCA cannot be regarded as an intermediate as the metal electrodeposition is an integrated step in the process for the

production of an article, meaning that ERC 6a cannot be assigned. Assigning ERC 5 implies a further service life for the TCA; however, the articles do not contain TCA, but gold in metallic form. The questions are therefore whether a) ECHA expects that for the service life of article step conditions of use are defined and exposure estimates are derived?, b) How can the wrong interpretation be prevented for the service life of article by consumers when consumers aren't actually exposed to TCA?, c) is there a more straightforward solution for reporting in the CSR (currently manual edits are needed)?, d) Is it possible to mention that further service life assessment after plating is not relevant in Chesar? The issues were acknowledged by ECHA who will further discuss this with the ECHA Chesar team.

The webinar was concluded with the following **actions identified for follow-up**:

- *Low concentration of substance in article service life stage (impact on use reporting and CSR)*
- *Hazard changes between industrial use and article service life (impact on use reporting and CSR)*
- *Cover dismantling and recovery operations in IUCLID and CSR. Determine when its relevant. And if relevant, how to do it*