MISA 2 workshop
Environmental Endpoint information requirements

ECHA – Helsinki – 7 February 2019

Executive Summary

The second MISA workshop, focusing on the environmental information requirements/adaptations/read-across, took place on 7 February 2019. It was attended by about 45 participants and was structured in sessions discussing the following themes: read-across, ERV and PNEC derivation and motivation from data-poor to data-rich, difficult to test substances, bioaccumulation and biomagnification assessment of data-rich and data-poor metals/secondary poisoning.

As for the first MISA workshop (i.e. on human health information requirements) that took place in October 2018, the consortia were invited to carry out -ahead of the workshop- an assessment of their registration files for the endpoints of interest, using a self-assessment tool developed by Eurometaux (SAT-ENV). The results of these self-assessments allowed to identify the themes and the questions to be addressed during the workshop and helped ECHA and industry to prepare presentations targeting the uncertainties that emerged from the completed SAT-ENVs.

The active preparation and participation in the workshops on the two first MISA priorities, as well as the submission of a work plan in follow-up of these workshops demonstrate that the agreement signed by the consortia in October 2018 is being translated into actions and thus proves their commitment. In follow-up of the human health workshop (2 October 2018), all consortia submitted workplans and 98% within the fixed, tight deadline. While the work plans vary in quality and level of detail, the overall progress made is encouraging. Additional consortia have also joined, meaning that MISA now includes 18 participating consortia and covers 321 substances.

This momentum is particularly important considering the current political climate on REACH and the requirement to enhance its implementation and the quality of the data (see e.g. REACH Review actions or the BfR studies). From this year on, ECHA will intensify its efforts to improve the compliance of registration dossiers, among other by increasing the number of compliance checks This should encourage industry to proactively review their dossiers and come up, where relevant, with concrete work plans to improve justifications for adaptations and testing proposals to cover data gaps.

The importance of transparency was recalled, both for industry (transparent workplans are key to increase the confidence in ongoing improvements) and ECHA (on the resources and actions applied in the context of the sectorial approaches). This transparency can be ensured by means of Key Performance Indicators (KPIs) that will be developed and communicated.

A detailed report of the workshop, reporting in detail the discussions held on 7 February was prepared and reviewed by ECHA/Eurometaux. This detailed report is now available for the MISA participating consortia. However, to facilitate the preparation of the work plans, but also to ensure transparency of the outcomes, a list reporting the 25 learnings and points of attention was prepared by ECHA and Eurometaux. It is reported below:

***Generic aspects*:**

1. Industry should give careful consideration to the learnings in case a non-standard approach used, as these are in principle rejected by ECHA .

2. Testing Proposals (TP) are required for all Annex IX and X studies. There are additional requirements when a standard vertebrate test requirement is involved, for:
   - The registrant: the TP must include considerations for alternative methods
   - ECHA: must conduct a third-party consultation

   Moreover, if a Registrant registered at a lower Annex and the registrant would need to conduct a new study which would fall under Annex IX/X info requirements, then a TP would need to be submitted.

3. For UVCBs the Registrant should address the contribution of all relevant (incl. minor) constituents by including IUCLID endpoint summaries from the different dossiers and referring to the study records included in the parent dossiers.

***Read-across*:**

4. The RAAF is a structured framework for assessing read-across (by ECHA) that also helps in systematic reporting of read-across assessment (by industry). If not done yet, Consortia are encouraged to consider reporting their read-across in the RAAF format to facilitate the exchange and transparency of the read-across approach. The read-across assessment provided by industry in the registration files should consider the elements given in the RAAF to ascertain that the requirements of REACH Annex XI section 1.5. “read-across and grouping of chemicals” are fulfilled.

5. Scenario 5 (category approach, release of common metal ion, no variation among category members) seems to be the most common scenario for metals and their compounds of the ENV-RAAF. It may be best for consortia to start from this scenario explaining/justifying its selection. The category and its boundaries need to be clearly described with attention for both the source and target substances to be characterised, including all of their impurities.

6. The read-across justification, including all elements (preferably following the Assessment Elements given in RAAF), should preferably be included in a single report or as an Annex of the CSR. Section 13 of IUCLID seems to be the best place to upload the report.

7. The Transformation Dissolution protocol (T/Dp) (OECD GD 29) forms the basis for the read-across on metals, soluble metal compounds and sparingly soluble metal salts (SSMCs). All T/D data, including results for all components with ecotox properties* (in the case of a multi-element compound), needs to be included/documented in the registration file as an endpoint study record, and be discussed as part of the read-across justification (*cf. the CLP/GHS, data must demonstrate that an ecotoxicity level > 1 mg/l, and the ERV should be included in the registration dossier).

8. The impact of the counter-ion (non-common compound) on the toxicity must be documented. It is noticed that this is most relevant for metals with a toxicity in the mg/l range, i.e. close to toxicity range of the most common counter-ions, and to a much lesser extent for those in the µg/l or ng/l range. A generic document describing the (lack of) effect of the counter-ion could be developed and used for this purpose, but case specific justification remains relevant for substances with a toxicity range in the mg/l and for those with organo-tails. However, the impact of non-common compounds needs to be (somehow) addressed in the read-across justification. Referring to the ubiquitous presence of a counter-ion in the environment alone is not considered a sufficient argument for low hazard.

9. For metals including an organic-tail (organo-metals or organo-metal-salts), please document the dissociation and the fate/toxicity of the organic fraction. Guidance (including the best terminology to be used) on this item is provided in the OECD guidance n° 212[1]. The scheme on slide n° 56 (see MISA slides) may also be a helpful tool in this respect.

10. The valence and speciation of metal(loids) will impact the release rate and consequently the expression of toxicity. A good documentation of the differences caused by the valence and speciation is therefore needed. The speciation as a function of pH may require further attention for specific metals (e.g. Al, …).

ERV-PNEC derivation:

11. For data-rich metals, it may be best to include in the registration file a separate table of the data that was not considered for hazard and risk assessment because of lower quality (e.g. Klimisch score 3 and 4) or lack of relevance. The Registrant should explain and justify the quality and relevance criteria

[1] http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2015)2&doclanguage=en

used, especially paying attention when substance-specific criteria were utilised, so that ECHA can check the transparency/validity of the assessment made.

12. Apply the agreed metal ERV/PNEC derivation concepts for data-rich metals (geomeans, normalisation, SSDs, Assessment Factors (AFs),…) correctly. If you deviate from the metal's guidance, provide clear justification why you did so and what the impact is.

13. Ensure a solid, correctly developed and reported T/D data set for all metals (7 and 28 days) and SSMCs (24 hours, 7 and 28 days). Include the results for all components with ecotox properties* of a multi-element compound.

14. For classification/ERV derivation: the Registrant should explain and discuss the pH dependency of the release rate (by conducting the T/D test at different pHs, as per the guidance) and of the ecotoxicity data.

15. For PNEC derivation: Describe the uncertainty "covered" and "remaining" in the motivation for the choice of the relevant Assessment Factor(s). This issue is relevant for "data-poor" as well as for "data-rich" files. Deviation from standard AFs would need a clear and transparent explanation.

16. The value of the Equilibrium Partitioning (EP) method for Sediments and Soil toxicity assessment, is mainly for screening purposes. Preferably, for metals the assessment should be best conducted using direct testing rather than modelling

Bioaccumulation and secondary poisoning assessment:

17. For metals and inorganic metal compounds, there is no standard bioaccumulation screening possibility based on physicochemical properties, as the octanol water partitioning (Log Kow) is not applicable for metals and metal compounds. Bioconcentration Factor (BCF) and Bioaccumulation Factor (BAF) data are therefore to be used but must be assessed with care.

18. Given that for metals the BCF is generally inversely related to the exposure level, the selection of BCF data or the running of new studies, are generally best conducted as close as possible to the No Observed Effect Concentration (NOEC) value.

19. The lowest Assessment Factor (AF=30) for derivation of the $PNEC_{oral}$ for secondary poisoning characterisation, may lead, even for data-rich metals, to a risk scenario for this pathway that requires refinement processes, as shown in the nickel case. A deviation from "the standard approach" needs to be clearly explained and justified.

Difficult to test substances and generic testing recommendations:

20. The Water Accommodated Fraction (WAF) method (see REACH and OECD guidance on difficult to test substances), should NOT be used for metals. The reason is that this method often uses nominal loadings and lacks the pH and surface relationships necessary to estimate the potential hazard.

21. Direct aquatic ecotoxicity testing of metals and SSMCs is in principle not recommended. However, if used or needed (e.g. for complex materials like UVCBs) then it should be conducted based on the dissolved fraction(s) of the T/D medium, at the appropriate pH (pH that dilutes the most).

22. To estimate the correct speciation of 'difficult to test metals' in the water phase, phase diagrams + the factors, controlling speciation, should be reported. Such information would help in defining in which chemical forms certain metals may occur under environmental conditions and to preliminarily assess whether they have the potential for expressing toxicity under (standard) environmental conditions.

23. Experience shows that for 'difficult to test metals' (Al, In, Sb, …) depending on the pH, the total metal concentration in water can be more relevant to assess the toxicity than the soluble fraction. However, this needs proper justification in the registration file stating why this is the case, given it is deviating from the standard assessment rule of metals.

24. Further laboratory work/testing: ensure that equilibrium is reached before starting the (ecotox) testing, which for soil and sediment experiments may sometimes take a long while (sometimes months). If equilibrium cannot be obtained within a practical timescale for ecotoxicity testing, the implications for hazard and risk assessment must be properly described and if possible corrected (e.g. lab-field factor for soil). Any correction of the results from the ecotoxicity testing should be properly explained and justified.

25. Spiking solids or sediments with metals is a critical step and requires careful attention on how this is done/was conducted to ensure that the data sets are valid for REACH. Please describe how this was done at least for the key studies.

Consortia were invited to prepare and submit a workplan to ECHA (using either the Excel format prepared by Eurometaux or others) by 29 March 2019.