Metals and Inorganics Sectorial (MISA) Workshop

Wednesday 24 January 2018 – 9:00 - 17:00

Executive Summary

Introduction

The workshop co-organised by Eurometaux and ECHA aimed at bringing parties together to discuss all aspects of the MISA approach. Co-chairs Mr Guy Thiran and Mr Jack de Bruijn, respectively from Eurometaux (representing the Industry sector) and ECHA, welcomed the participants (70).

Guy Thiran (Eurometaux) recalled the importance of metals in our society, and stressed that their recyclability, to be linked to the Circular Economy, is one of metals' strengths. The hazard and possible risks of metals have been drivers over the years to further develop knowledge and assessment. Chemicals Management is key for our sector and with safe use/reuse fully part of companies' responsibilities. This is also demonstrated by the sector's active engagement in REACH 12 years ago. Eurometaux therefore supports the efforts to make sure that the REACH dossiers are of good quality and ensure risk management based on priorities (while fulfilling commitment to SAICM). However, we have experienced that approaches and methodologies for efficient management of metals/inorganics can differ from those applied 'by default', and this has led to a number of discussions on the specificities of metals/inorganics and to the development of tools and guidance documents (e.g. MERAG/HERAG). The MISA approach can help to ensure – in addition to the work on the quality and compliance of the registration dossiers- a level playing field. Eurometaux's Management Board has mandated the secretariat to work with ECHA to address the different challenges. He ended by stating that MISA is also a unique opportunity to work with other sectors (not under EM's umbrella, who are invited to join this approach). He also stressed that we need to ensure commitment in advancing on the second track (i.e. on methodological issues) that runs in parallel to the one on information gap filling. And when dealing with Risk Management Measures (RMM) we need to find the right balance with other EU environmental and Human Health (HH) policies, especially when linked to Circular Economy.

Jack de Bruijn (ECHA) reiterated that the purpose of this workshop is to work together and to find the right balance between health & safety and broader industry aspects. He recalled briefly what is at stake under REACH: from better knowledge on hazards, uses and risks to improved communication but also gradually substituting hazardous chemicals. Key drivers are registration, classification and labelling, communication and risk management, and with the burden of proof that has been shifted towards industry, registration dossiers are vital, also because they are scrutinised by authorities, the public and NGOs, who must be convinced of their assessment. The registration dossier is a starting point used to check if more information or regulatory actions are needed; and this as a continuous process. ECHA has implemented CLP & REACH and aims at reaching the 2020 goals. By 2020 they want to know for all substances above 100 tons whether they are of potential concern or not, whether more hazard information is needed, if they need to be addressed through risk management or whether they can be put aside as currently being of low priority. ECHA has set up the Integrated Regulatory Strategy (IRS) to support this. However, for a number of substances, the information needed to draw conclusions on the necessity for further work/their priority is unknown. This 'grey zone' is one of the reasons ECHA wants to work with

industry in sectorial approaches, creating as much as possible win-win situations considering the specificities of each sector (e.g. for metals, their data availability and organisation). MISA includes two tracks that should progress in parallel (on dossier quality (track 1) and methodological issues (track 2)) and is planned as a voluntary scheme, formalised by a charter and whose key words are collaboration, priority setting (as not everything can be done and solved), clear commitments, a time plan, transparency and interaction.

Parallel track 1: what can be done collectively to improve dossier/data quality, completeness & compliance?

This session aimed at presenting the findings and learning lessons from a "baseline exercise" carried out in parallel by industry and ECHA, using surveys and data-mining to define a snapshot of the situation as it stands today.

- ***Presentation by industry of the main points requiring attention in terms of data quality***

Hugo Waeterschoot (Eurometaux) presented the findings of the "baseline reports" (BRs), whose first goal was self-reflection for the consortia (status of dossiers filed for registration) and to have a starting point to measure progress with MISA and ensure identification of collectiveness of concerns. About 170 substances were covered in the baseline exercise (about half of the package screened by ECHA), including about 100 high volume (> 100 tons) substances but also some low volumes substances and intermediate UVCBs. The substances are mostly metals but also some inorganics. The BRs examined how endpoint requirements were fulfilled (key studies, read-across, waiver), without judgment on the quality. The presentation highlighted the key findings with some explanations e.g. on the variability in the approaches that were followed (e.g. depending on availability of data or types of data). Additional findings in the baseline exercise are e.g. that a) metals are often reviewed by other legislative initiatives and where they are used/referred to deserves a check, b) although there has been interaction with downstream user associations, obtaining information, in particular when it comes to the applicability of the Exposure Scenarios is a bit of a challenge, c) tools helping with prioritisation identification of appropriate RMMs, such as material flow analysis, source apportionment and RMOa assessments are progressively picked up. A proposal of prioritisation of topics deserving further attention in MISA, based on the BRs' analysis but also on learnings from ECHA's committees, compliance checks and the COLLA exercise is summarised in the table below:

Item	Priority (timing)
Improvement/compliance on effects endpoints (high & medium): • Human Health: data waiving /adaptation/read-across on repeated dose toxicity, reprotox, mutagenicity • Human Health: Assessment factors and justification • Environment: data waiving /adaptation/read-across, availability of TDp data and long term toxicity with attention to the effect of the counter ion • Environment: robustness of sediments' assessment	 High High Medium Medium
Exposure assessment and Risk characterisation:	 High

• Clarify assumptions and robustness of the methods used for workplace, consumer and man via the environment assessment • Clarify combined exposure and confirm relevance of the SPERCs	Medium
REACH risk management anticipation: • Demonstrate that the classification covers the variability • Further develop methods like source apportionment and materials flow analysis • Stimulate industry RMOas	High Medium Low
Other regulations: • Ensure reference to available information from other programmes and better recognition of REACH data/assessments	Low
Supply chain interaction: • Ensure communication with focus on SDS quality and consistency	Medium

- ***Presentation by ECHA of the main outcomes of their data mining exercise***

Jos Mossink (ECHA) explained that the objective of their data mining exercise was to obtain a clear picture so as to support the sectorial initiative. They started by checking data availability in the dossiers, looking at the 7 key endpoints; but also on uses (equally an indication of the likelihood of exposure) and update history (what has happened to the dossiers in the last couple of years)? They made a selection of metal substances to score the data availability: from the 700-800 registrations mentioning 'metals', about 340 are high volume inorganic substances containing metals. Intermediates and joint submission members' dossiers were excluded, leaving 377 dossiers from which endpoint study records were extracted from IUCLID. They have scored data waivers, adaptation, experimental key studies or testing proposals. But while this analysis gives an overall picture, its limitations should be kept in mind: the results are about the presence of the data, not the quality or its compliance (e.g. of justifications) or whether the tested substance corresponds to the registered substance. To display the results on the endpoints etc., some grouping was done and are presented around the main element (e.g. X) with the number of substances in brackets, tonnages and a colour code. Key highlights included, for example, bioaccumulation or long term aquatic toxicity; a lot of data waivers have been used but there are also missing data. As these are important endpoints for industry. ECHA would be happy to work with the sector to add more details where needed. To be considered in the context of MISA is that a substantial amount of dossiers have not been updated in the last 3 years. To summarise, he stressed that data availability is good for some groups of metals, depending on endpoints, but that adaptations are extensively used and for some groups of metals only few studies are available. There is no assessment on whether this is justified or not, but clearly highlights that this requires some attention. Important to follow-up is to know how substances were grouped and differentiated. The suggested priorities are: i) metals with small percentages of studies, ii) read-across, iii) quality of adaptations.

The Q&A session brought up several issues such as 'grouping used around 'element' and how tonnages related to those as information requirements and how those are fulfilled will also depend on tonnage (e.g. for substances of lower tonnage bands one will find more adaptations).

- ***Presentation on added value and difficulties of the baseline exercise: what did we learn and what to improve?***

Two presentations were provided by industry on the difficulties and learnings with the industry BRs.

Jelle Mertens (EPMF) explained that 4 BRs were completed (silver metal, soluble silver substances, insoluble silver substances and refinables). For the other substances, information was collated in a single document, as a majority with the exception of some hazardous compounds, were Annex III exempted substances. Suggestions for possible improvements of the current BR template were presented (e.g. to consider lower tonnages or increase flexibility). Reference was made to another template (Opportunities for Improvement tracker) the consortium uses for internal prioritisation. He concluded by stating that the baseline reports should be considered as dynamic documents and could be used as benchmark for progress even if challenges for consortia may differ.

Frank Van Assche (IZA) presented the feedback for zinc substances that are data-rich. The assessment under the Existing Substances Regulation was used as starting point for the 12 inorganic zinc substances (>1000 tons) they registered under REACH. Read-across based on the zinc ion toxicity and solubility was used for grouping. This grouping was applied for the BRs as well with however some specificities (e.g. toxicity profiles/classification, regulatory coverage, downstream uses and length of supply chain) indicated in the comments fields, which means that the content of these fields should be accessible to have a good idea of the grouping. These specificities may lead to a splitting of the BRs depending on a case by case basis. At this stage, the BR template is very general and some suggestions were made like the need to be able to combine monitoring and modelling data for exposure.

The Q&A session discussed the next steps of the baseline exercise. ECHA explained that the idea was to have an overall picture of the dossiers' quality, done in cooperation with industry and to be used to determine what should be improved in the coming years. It was stressed that the analysis should allow to discriminate dossiers on a substance covered by the participating consortia versus others to know where actions can be taken. It was commented that grouping substances in the BRs can affect the detail level of data given and although it was agreed that proceeding substance by substance in the context of benchmarking would be more efficient, resources should be considered as well.

Parallel track 2: technical issues of key importance for metals/inorganics

This session aimed at discussing the findings and learnings on potential priorities and work planning for the technical issues to tackle within the sectorial approach.

- ***Presentation by ECHA on Read-Across Adaptations with focus on metals and most frequent deficiencies identified***

Kimmo Louekari (ECHA) indicated that read-across and grouping are extensively used in the metals REACH dossiers as one of the adaptations set out in Annex XI 1.5. Both the REACH Regulation and ECHA guidance provide the background. Substances with properties that are likely

to be similar or follow a regular pattern as a result of a structural similarity can be grouped, but this means that one needs to demonstrate that similar chemistry leads to similar toxicity. This aspect of prediction is often forgotten in the justifications for the read-across. Kimmo's presentation reviewed the elements that ECHA needs to see when opening the dossiers, such as structural similarity, toxicokinetics, evidence of similar properties (e.g. in a data matrix, covering physico-chemical properties and lower tier (eco)toxicity studies or 'bridging' studies) and the reasoning or hypothesis used to predict the unknown. He also presented the most common shortcomings like incomplete identification of the source substance, a missing read-across hypothesis, absence of supporting information on the key aspects of the approach, insufficient documentation of the quality of the source data and not well identified applicability domain. For some metal/inorganic dossiers, the justification document may be missing and there is not always a clear hypothesis or it is limited to the 'soluble metal ion causes toxicity'. Documentation should refer to the low toxicity of the counter ion or to the lower biological ranges. When it comes to transformation/dissolution studies, these are acknowledged as key to the hypothesis for environmental read-across but data can be absent or the validity is not clear, affecting conclusions and interpretations. He also discussed the bioelution test, currently undergoing its validation by ECVAM. The objective is to have an OECD test guideline for oral exposure, however a test for the other routes of exposure may be needed as well. Bioelution tests may be better predictors of the ion release than water solubility but they cannot totally predict how much becomes systemically available. A slide summarised bioelution results for cobalt metal and compounds used in the context of the CLH. Such results might have an effect on potential categories to be proposed if e.g. there was a trend, allowing to make subcategories to generate information. With regard to the environment, read-across for aquatic toxicity is relatively often done to cover information requirements for both short term and long term aquatic testing, classification and labelling, identification of PNEC, exposure assessment and risk. Issues again can be the lack of data or the explanation of the 'prediction'. The latter should include information on the behaviour of a substance in aquatic environment (i.e. transformation/dissolution data on target AND source), information on bioavailability (including e.g. detoxification, speciation) in aquatic environment and the impact it has on the possibility to predict, as well as an analysis of the impact of bioaccumulation potential on aquatic toxicity. He concluded his presentation by giving some standard recommendations ('recipe') on how to best support a read-across argumentation.

Several questions were posed during the Q&A session to both further clarify the potential weaknesses of the metals justifications (i.e. mainly the quality of the supporting data) and ask for further details on the acceptance of e.g. not yet validated toxicokinetics models or bioelution. It was commented that read-across is also at the heart of the COLLA approach. The issue of the counter ion is a common question for most metals and it was suggested to build a common database for the counter ion ecotoxicity that could be referred to.

- ***Presentation by Eurometaux on learnings and milestone planning for track 2 priorities as derived from the Baseline Reports and REACH experience***

Violaine Verougstraete (Eurometaux) reminded that understanding effects and overall exposure and uses of metals is a critical step in defining the potential risk and the risk management measures. MISA proposes a forum to resolve 'main outstanding issues' that impact the efficiency and relevance of chemicals management for metals/inorganics. Criteria have been defined with the consortia to qualify an issue as being of relevance to the track 2 programme. The slides presented the list of identified issues, based on the workshop held with ECHA in 2016, the baseline

reports and on recent discussions with authorities (e.g. risk management of impurities or the thresholds for carcinogenicity). To be able to prioritise and agree on common work, it is proposed that the technical issues should ideally relate to identified track 1 priorities and to work in integrated tiers (Tier 1: compile knowledge, experience and data, identify a proposed way forward; Tier 2: exchange with authorities on the proposed solution and agree on the type of deliverable; Tier 3: update registration dossiers where relevant). To save resources, it is important to make the best use of existing/planned work at different levels (e.g. HeTAP or ETAP). It will also be important to involve authorities to ensure support and increase knowledge and capacity-building. The main outstanding issues, which are read-across, UVCBs, thresholds for carcinogenicity, man via the environment, management of impurities, materials flow analysis and source apportionment, T25 and potency and rapid removal were briefly described with a proposal of priority.

Several questions posed in follow-up related to the resources to be injected in track 2 and MISA's governance, thus introducing the next session. Further clarifications were asked on the issue of impurities, thresholds so as to better understand the aim and scope of the work to be done. It was also concluded that involving authorities like Member States will be essential to further facilitate capacity-building on metal specificities.

Discussion: definition and agreement on priorities, urgency (for the work plan) and related resources for tracks 1 and 2

This session started by recalling that the main aim is to achieve clarity as it is needed for the mapping of the chemicals universe, improve quality and compliance on a priority basis. Eurometaux proposed to start by collectively focusing on the following issues/endpoints:

- Read-across
- Reprotoxicity endpoint (PNDT, PNDT second species, EOGRTS)
- Long term aquatic toxicity
- Impurities management
- Man via the Environment

ECHA confirmed that their priorities include read-across but also UVCBs. The importance of impurities was acknowledged and ECHA will further engage on this.

Two models could be used to perform the MISA work, either relying on combined learning (joint metal efforts and common priority endpoints) or self-learning by consortia on their specific relevant endpoints with exchange of experience at the end as kind of validation. Both approaches have pros and cons that were presented. The role of Eurometaux would be different as well in both models. The attendees were invited to express their preference for the type of model and their (dis)agreement on the proposed priorities using colour cards. The majority of the responses were in favour for an alternative model, combining joint work around common topics and consortia remaining in the lead for work/interaction on specific issues.

Sectorial approach management aspects

The last session of the day was organised as a panel discussion comprising three questions:

- *A charter to formalise commitment to the MISA: what should this charter include in terms of content?*

The charter should clarify that ECHA and industry want to work together and address transparency, in a simple format. ECHA reiterated their commitment to the MISA programme, but they need clarity on what can be done on both sides, in the coming years. MISA is voluntary but signing the charter means an active engagement. Wording, aspects of timing and resources shall be further considered to improve the draft that was made available to the participants in their meeting files. The importance to have other bodies on board when it comes to peer-review of e.g. technical issues was reiterated. The charter should also consider the type of management model that will be applied (e.g. a generic charter referring to common priorities accompanied by individual commitments with respect to actions and timelines foreseen to improve the compliance and quality of the registration dossiers). Evaluation of resource needs and setting priorities will be essential. The aspects of free-riders and dossiers not falling under the umbrella of the EM consortia was re-discussed as well: it was agreed that having other sectors mobilised would allow a good progress on the dossiers' quality, but here as well timing and resources need to be considered.

- *How to measure progress over the three years and how will priorities be re-evaluated?*

It is proposed to clearly identify the starting point, to have an agreement on priorities and write down where we want to be at the end of years 1, 2 and 3. At the end of e.g. year 1, priorities will need to be re-evaluated and some feedback will need to be given to authorities. Being concrete and transparent will help to build trust in the approach. Horizontal (sectorial) reporting could be envisaged, which does not exclude individual progress as well. A structure should be set up for the governance and the follow-up: this could be a group composed of Eurometaux/consortia/ECHA (and possibly external parties). A 'win' industry would like to see more clearly is that, provided some progress can be shown, the lower priority for regulatory action could appear more concretely.

- *How to involve other stakeholders? How to ensure transparency on the approach?*

The group agreed that involving other stakeholders and in particular the Member States will be key and there are several solutions for doing so. Some support from ECHA will be needed to motivate sectors/metals not falling under EM's 'umbrella'. Stakeholders' involvement will be further discussed. Having the information (partly or totally) included in the BRs and a draft charter before Easter will help ECHA justify the resources needed to be invested in MISA. The group further discussed the format in which this information could be handed over. Other actions on transparency were discussed, like sending a letter by Guy Thiran to the other inorganic sectors. Before moving to the next steps, priorities should clearly be agreed upon.

Conclusions and next steps

Guy Thiran (Eurometaux) concluded by recalling that the quality of the REACH data is of upmost importance and that therefore MISA, which is about improving availability and quality of data and the reasoning behind offers an important potential. As important are the consistency and rigour on how these data will be used and prioritised by authorities. This is critical for the coherence and credibility of the EU chemicals management policy and the links with other EU policies. The discussions illustrated that the baseline reports and data mining are a source of valuable information even if the template can be further improved. MISA shall be considered as a sort of investment, with long term benefits, but a balance needs to be made between benefits and costs. Important questions to pose in this context are whether we want to sacrifice the long-term benefits

to the short-term constraints? What if we do not do it? Experience has shown that it is better to engage in discussions, with a good feedback and communication. This requires building a win-win situation with deliverables for both tracks 1 and 2 in parallel and a governance structure. Transparency on commitment, time and deliverables from both industry and ECHA is essential vs. other stakeholders. ECHA's degree of commitment is limited and different than what industry can provide, and defining the best resources is another equation to solve. He concluded by saying that we are on a journey where we should keep in mind that the best is the enemy of the good, meaning that we will not solve everything but maintaining a broader and longer perspective is fundamental.

Jack de Bruijn (ECHA) confirmed that a long-term investment is necessary. It seems clear from the discussions and presentations that the situation is not the same for all of the metals/inorganics and the question is how to tackle the metals/inorganics that have remained silent up to now. ECHA prefers to hear first from industry if improvement is needed, before moving to compliance actions. The 'win' aspects seem rather clear but further features like the monitoring of the exercise on both industry's and ECHA's sides, but also for the outside world should still be fixed. He thanked the participants for their willingness to discuss, and hopes that together we were able to deal with a lot of the industry's concerns as we seem to have made quite a bit of progress.

Violaine Verougstraete (Eurometaux) proposed the following next steps:

1. Agree on a format for the information included in the 'baseline report' that could be communicated more widely and fulfil the needs for transparency and justification of resources invested on both sides
2. Agree and formalise the priorities to include in the rolling plan, annexed to the charter
3. Work on the draft charter so that it can support the principles of MISA, stress the voluntary and cooperative nature of the approach aiming at improving the quality and compliance of dossiers and risk management. It should be simple, refer to the two tracks and be clear on the steps we want to take, as well as how progress and priorities can be evaluated
4. Communication aspects to demonstrate the commitment towards the outside world and engage other substances to join

Further discussions with ECHA are needed. To make progress it is proposed to use the MISA steering committee as well as the REACH Forum meeting of 21 March to take half a day to discuss these aspects further and create a win-win situation. She thanked all the speakers and participants for their active input and help.