MISA webinar

30 August 2019

Participants: Jonathan Rickwood (Sn), Ruth Danzeisen (Co), Jelle Mertens (PM), Mariana Fernandes de Barros (Cefic), Sue Hubbard (Iron platform/Iron oxides), Chris Barrington (Iron platform and Boron), Irene Cañas Sierra (Frits/Inorganic Pigments), Alejandro Garabatos (Frits/Inorganic Pigments), Kevin Klipsch (Mo), France Capon (PM), Kerstin Heitmann (Se/Te), Eric Brasseur (Arcelor), Eirik Nordheim (Al), Karine Van de Velde (As), Kate Belska (Co), Khareen Singh (Pb), Nele Deleebeeck (MOZO, Rare Earths), Dawn Webster (RCF), Noömi Lombaert (Zn, Cd, In), Steven Verbeckmoes (Umicore), Jack de Bruijn (ECHA), Jos Mossink (ECHA), Lorenzo Zullo (EM), Hugo Waeterschoot (EM), Violaine Verougstraete (EM).

The aim of the webinar was to evaluate the progress made with the MISA programme (with emphasis on track 1: improvement of the quality and completeness of the metal registration files), by discussing the analysis of the workplans prepared by ECHA and the outcomes of the 'MISA progress' survey launched by Eurometaux in July. The slides are attached as Annexes 1 and 2.

Presentation by ECHA: A closer look at the scientific and technical developments and the workplans for dossier improvements

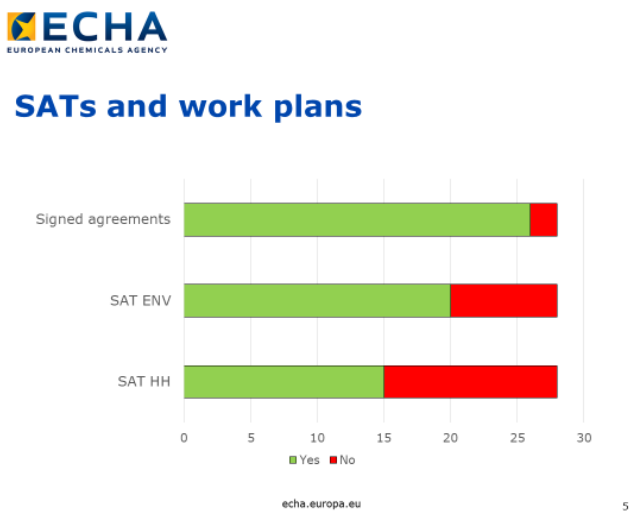
Jos Mossink (ECHA) started by explaining that the slides are based on the information extracted from the workplans submitted before and at the start of the summer, acknowledging that there have been some recent communications. Overall, MISA is on its way and a number of documents have been generated over the last year: it is thus a good moment to take stock of where we stand. It was also foreseen in the Framework for Cooperation signed by the consortia that there would be regular reports. There have also been communications about MISA to RIME, CARACAL and MSC. However, this is the first review to go more into detail, based on a set of indicators developed with Eurometaux.

Kicking off with the participation in the MISA initiative: 28 consortia/industry associations have signed up representing 35 substance groups (i.e. metal + metal compounds). More than 300 substances are included in MISA, 254 of which are explicitly mentioned in the analysed workplans. Overall, the coverage of MISA is good, but still triggers some reflections. To start with, there are some important consortia/substance groups that are still missing like Cr, Mn, …. EM and ECHA's efforts to include them have not yet proven successful. Also, participating consortia may not cover all compounds of a metal. And finally, some consortia did not include in the programme all the substances they have in their portfolio. This is regrettable in some way as these 'missing' substances could contribute to the read-across or the availability/density of data.

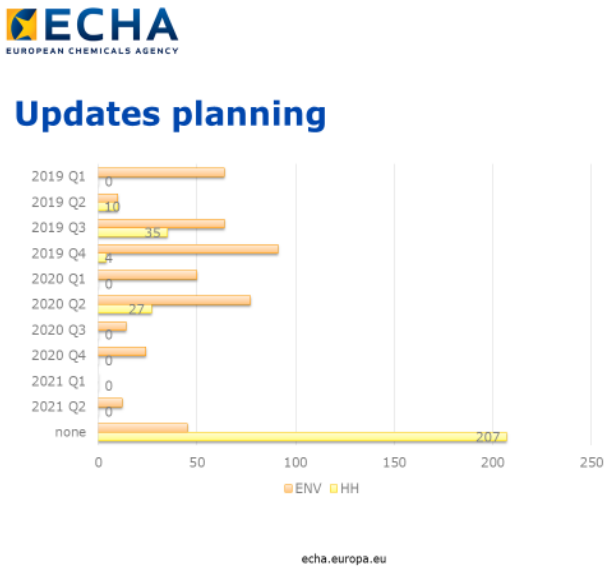
In terms of scientific and technical support, "Self-Assessment Tools" (SAT) were developed for human health, environment and UVCB. The SATs capture in detail the data provided and the waivers and are thus very helpful instruments for the consortia to have an overall picture of the content of their dossiers. The SATs have also served to identify topics for the different workshops. The workshops have represented

opportunities to raise issues, to better understand ECHA's expectations on the contents of dossiers (e.g. read-across). Workshop reports have been produced with executive summaries made available to the outside world, and have also been useful as guide for drafting the workplans The summary of key learnings from the environmental workshop in particular (MISA 2) provided good hints on what to include in the updated dossiers. In addition, there was some ad hoc support, which was used by some consortia. Important to highlight here is that the workshops and the produced materials are a very good basis to update the dossiers, as agreed in the Framework of Cooperation documents.

The slide here aside summarises the number of signed agreements and delivered SATs (to EM).



The slide below summarises the timings for updates as scheduled by the consortia (and included in the submitted workplans), making a distinction between human health and environment.



The analysis shows that there is a large number of human health workplans that do not mention a date for the updates. A request to all consortia would thus be to have a look at their workplans and include some dates. It should be noted that ECHA recently received some updates of workplans, but these were not included in this analysis.

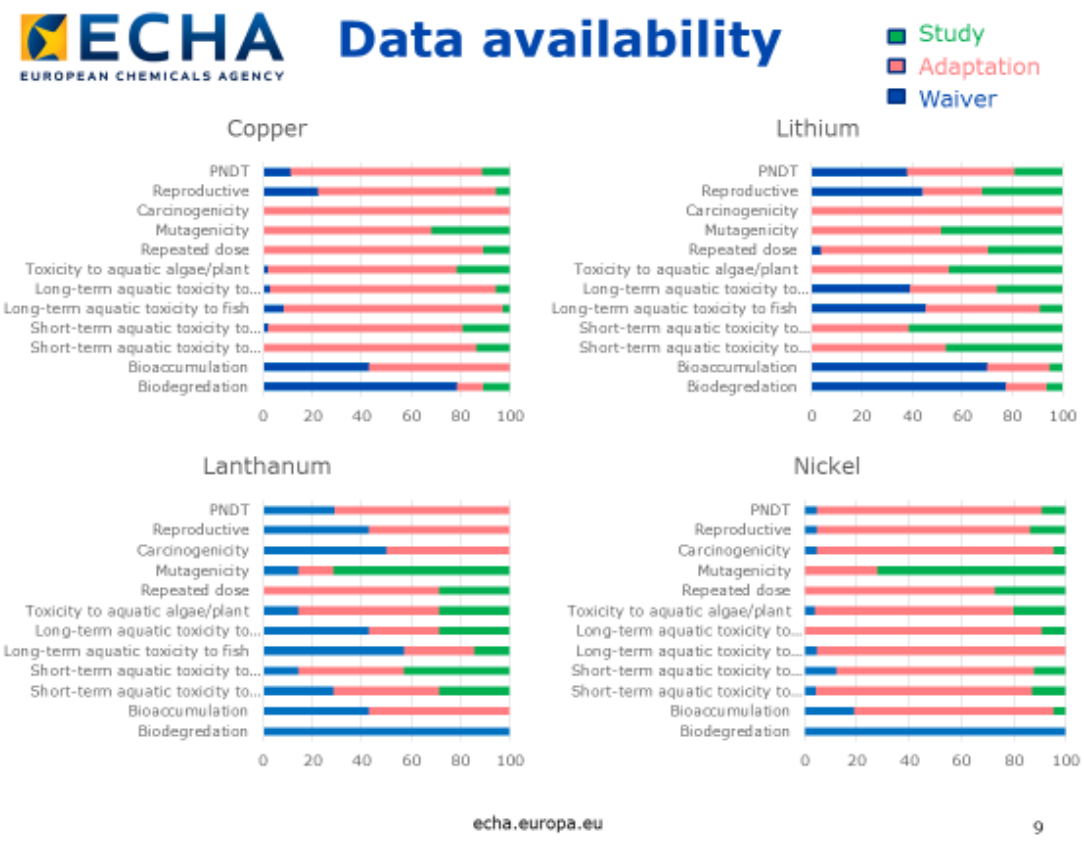
Also, a number of updates on human health are scheduled for end 2020 or up to Q2 2021, which is close to two years after the start. Based on the workplans, it is not so easy to understand the delays and why it/what is taking so long? ECHA knows that several consortia face difficulties with the TCC. They will see how to tackle that individually as there is no obvious solution to allow 'phased' updates.

Diving in the content of the human health workplans, most consortia plan for improvements of the read-across justifications and waivers. While ECHA acknowledges that read-across is the way forward for many metal/metal compounds and that some waivers are justified, it remains crucial to back up read-across with experimental data on source substances and to ensure that the data density is sufficient. This was also highlighted at the MISA 1 workshop. The low number of testing proposals comes as a surprise for

ECHA given they were expecting more planning for testing proposals on non-standard data to support the read-across.

For environment, the analysis shows that TDP studies have been planned, and that there are quite some efforts to improve the PNECs/ERVs. There is less done on the waivers.

Jos Mossink clarified why ECHA thinks that more could be done on the generation of experimental data by using the following slide. It shows for 4 randomly selected metals, by relevant endpoint, the importance of study data, adaptations, waivers. The length of the bar indicates the percentage of substances in the metal group. Study -data are either missing or very scarce for some endpoints.



ECHA shared their thoughts about these results:

1) Consortia could consider adding more of their portfolio substances to the MISA list, as this would allow to have more substances benefitting from what is developed, but also more broadly to improve read-across and data density. This would prevent ECHA taking decisions on individual substances at a later stage.
2) Also, several workplans are a bit 'light', focus on adaptations only or are non-committal (mentioning only for example "we will improve waivers…"). Workplans should be improved to become real workplans.

3) The proposed timelines, in particular on the HH workplans, are too long in some instances, or missing. This is even the case for less time-consuming adjustments and where deficiencies are known.

ECHA noted further that there is significant variation between workplans.

Conclusion: Overall, given the data density analysis and the existing data gaps, ECHA expects more testing proposals.

Jos Mossink reiterated that Member States and Commission are closely following this initiative. Several Member States are quite sceptical about voluntary approaches as they believe those are generally used to delay the updates of registration dossiers. The MISA community has thus to prove otherwise by showing real progress. He is not certain that at this stage they have enough in their hands to convince the more critical Member States. Also, ECHA will have to provide a quantitative review to CARACAL and RIME, showing not only scientific progress but also improvement in dossier quality and completeness. This will be done by using the set of performance indicators, including coverage, scientific and technical progress on priorities, scope of the workplans but also achieved improvements in the dossiers. These indicators will be compiled and communicated at aggregate level. ECHA will use IT tools to follow the update history of dossiers every quarter and report to consortia and Eurometaux.

The IT tools also allow ECHA to quickly get an overview of the data availability. They will also look into the workplans both at aggregate and metal group levels. At metal group level, ECHA can engage with consortia/associations to reflect and support.

Finally, ECHA will continue its regulatory strategy and screen groups of substances, open dossiers to monitor the effect of workplans and possibly use compliance checks to obtain an idea whether a metal/a metal group should be looked at in more detail. The workplans and the follow-up are taken into account in the priority setting.

To conclude, the MISA groundwork is done. There is a good participation and coverage, although the latter could be further expanded. Progress has been made on scientific and technical issues. However, the quality of workplans varies, and several need revision/updating and timelines to better reflect commitments and become real workplans. Despite this, ECHA is quite happy with the efforts made and momentum gained. This should be kept up during the 1.5 year to come.

Presentation by Eurometaux on the MISA Progress Reporting Survey

Hugo Waeterschoot presented a series of slides summarising the replies received from 18 consortia/associations (out of 28). The representativity may not be perfect as the replies probably come more from the committed consortia. Still it allows to identify some interesting aspects and participants were thanked for completing the survey.

Coverage: respondents to the survey

SM-Q n°	Consortium	N° substances
1	EPMF (Refinable, gold, Rhenium, Silver, Platinum)	89
2	ILA	25
3	I2a	10
4	As	3
5	Al	3
6	ECFIA	4
7	Nickel	13
8	Rare Earth Consortium	
9	MOZO	1
10	Frits and Inorganic pigments	38
11	Zinc	16
12	Se/Te	12
13	Cd	11
14	In	
15	Li	7
16	Iron	1
17	Boron metal	1
18	Cu	28

So in total covering **> 250 substances**

Powered by SurveyMonkey

There are some workplans that are still missing, but mainly for "new joiners" and a timing for submission has been defined. One consortium did not submit a workplan for ENV (MISA 2) due to resource constraints, low priority and harmonised classified substances. It was recalled that submitting workplans is a part of the MISA commitment.

When analysing more in-depth the scope of the submitted workplans, almost all consortia will improve their read-across justifications/motivation and waivers. This means that the workshops have stimulated an improvement of the "motivations, both for HH and ENV". Several consortia will conduct further testing and check for impact on their classifications. These are partly related to non-standard testing. The required updates and improvements are remarkably parallel between the HH & ENV endpoints

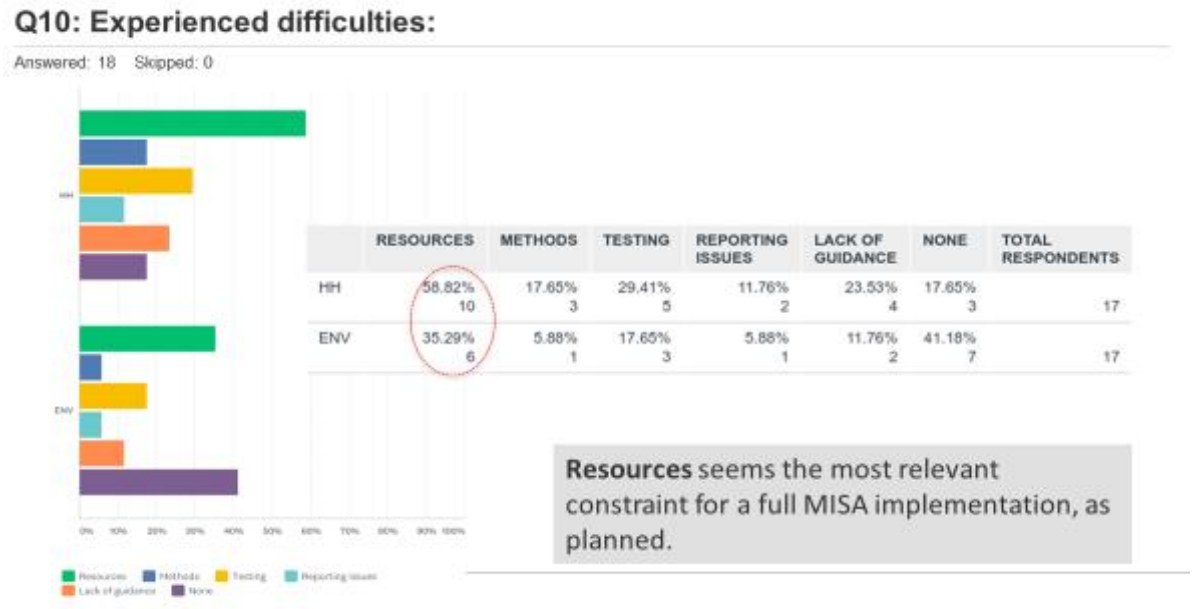
When it comes to timing, the updates on read-across and waiving schemes for environment (MISA 2) are mostly scheduled for early 2020 (9-12 months after the workplan submission), twice as fast as for HH, that will take on average 1.5 year. At least 3 of the consortia have foreseen an update of the classification and of the testing for environment (vs. 4 and 3 for human health). The difference in speed in updating between environment and health is estimated to be linked to a difference in complexity, available resources and experience with MISA.

Also, interesting to note is that for the lower tonnages, further environmental testing for soil and sediment may be expected due to the next steps of the tiered assessment scheme.

A point of attention is that there is no classification update foreseen for compounds of an element that changes its harmonised classification. This may not have been mentioned in the survey as it is considered that it is automatically done, but this deserves a check by the consortia.

The implementation of the human health workplans seems to be more delayed than the environmental plans (20% workplans vs. 40% on environment and human health respectively).

The survey included a question on the difficulties experienced by the consortia to implement the workplans. *Human resources* are the main issue, as well as some *methodological aspects*. Some difficulties are related to *testing*. It seems interesting to compare this list of "difficulties" with the analysis done by ECHA on the workplans.



	RESOURCES	METHODS	TESTING	REPORTING ISSUES	LACK OF GUIDANCE	NONE	TOTAL RESPONDENTS
HH	58.82% 10	17.65% 3	29.41% 5	11.76% 2	23.53% 4	17.65% 3	17
ENV	35.29% 6	5.88% 1	17.65% 3	5.88% 1	11.76% 2	41.18% 7	17

- Some consortia go for "combined updates", aligning HH and ENV updates for an issue in one go. This may in first instance been seen as a delay, but it is not.
- "*Synchronising updates with ongoing TPs and Testing decisions*" is difficult given the slow progress with TP approvals …leading to postponement of running programmes
- The "*lead environmental classification"* issue and its way of handling data-rich datasets now acts as "a hurdle/barrier". Registrants do not know anymore what kind of data handling for data-rich substances is acceptable or in line with REACH. Some consortia said they are now lost.
- The "*lack of resolution of the Rapid Removal issue"* is perceived as a lack of guidance and a barrier
- *Methods and reporting issue*s caused delays (to be further clarified with consortia). For example where to put the RAAF evidence in the dossiers or UVCB related questions were mentioned.
- Some guidance difficulties were identified as well (e.g. counterions guidance, bioelution for grouping, etc.)
- The delay in the workplan submission for some consortia has been caused by the publication of Substance Evaluation decisions after the workplans were submitted, which consumed extensive resources.
- Some consortia also had to go through an *update to IUCLID 6* when introducing updates. which is a resource-consuming exercise for data-rich substances,
- The financial planning for MISA obligations/consequences was often not available for 2019 given already defined mid-2018, hence providing some delays.

Participants to the survey could also communicate some observations: several consortia indicated they are **updating their workplans** 1 or 2x a year depending on progress and new insights (learnings from testing or new guidance). Overall, MISA stretches Consortia's human resources beyond what they had scheduled.

In the bilateral discussions Eurometaux had with several consortia after the survey, it appeared that on the methodological aspects, concerns do not seem related to existing guidance but rather to *the complexity of their "own" case*. Some indicated that **human health updates are also delayed** including improvements to the substance ID section.

Finally, 1/3 respondents said that they would update the list of substances (new in MISA, extension to lower tonnages, UVCBs. Two larger consortia had a closure of SID debates and will split files).

To conclude, the learnings are mostly in line with the expectations:

- The execution of the environmental workplan is better on track than the human health one
- Several consortia are still assessing the need/relevancy for testing
- Some identified barriers are causing the delay, allowing for some remediation

Finally, Eurometaux concluded that the Survey Monkey is a good and time-efficient approach to **report progress and define difficulties**: *what is on track, what is delayed and what is the main reason for the delay*. Surveys also allow to collect information on progress barriers (e.g. lacking guidance, where to report, …) or uncertainties (data-rich data assessment challenged by RAC, bioelution for grouping,…).

The outcomes can be used as a starting point for defining the interpretation of the KPIs.

Still it shall be noted that not all MISA consortia participated. We need to ensure higher participation to increase representativity. Some low volumes and newcomers follow a different time scheme.

Discussion

- Some explanations were provided on the number of workplans without clear timings. When it comes to the tiered testing strategies, it has been difficult to include timings as ECHA acts a bit as a black box when it comes to the Testing proposals administration time.
- Some of the consortia are "bogged down" by the new nanomaterials' requirements and the disproportionate workload to fulfil the nano requirements.
- Important to note as well it that some of the MISA consortia do not cover all substances of a same metal, some compounds are dealt by groups which may not be interested in improving dossiers (minimum diligence). In addition, some metal/metal compounds like Cr are spread over different groups, with different dynamics. To be able to address this, metal consortia need to know the substances for which timings are missing. Can ECHA give an indication which metals have such issues? ECHA replied by reminding that they can only see what is written in the workplans and/or updates and this was the information used for their analysis. When they were referring to incomplete coverage, they also had in mind some consortia under the EM umbrella who included only a limited

number of substances as test cases in MISA. ECHA stressed that consortia should keep in mind the overall perspective: ECHA will look at all substances over the next 7-8 years and it would be a pity to have separate evaluations for compounds of substances for which some conclusions and testing issues would have been addressed in MISA. ECHA has some difficulties to understand why all compounds of metals in the portfolio are not covered in one go. It is thus better to reflect in all openness and on what we could do in the coming months

- The example of 3 groups of substances currently in CORAP was mentioned. Should the CORAP aspects be reflected under MISA (as a tag)? *It was replied that the testing schemes as submitted under Substance Evaluation could be referred to in the workplans.*

Some other questions arrived in writing due to time constraints. The included answers were therefore not raised in the call but as a follow-up on the written questions.

- *A question for latecomers (but probably also relevant for others): if you come to the conclusion that you need to complete your dataset of the key source substance in your category with some higher tier tests, the working plan will include the 'inclusion of test proposals' + reference to these test proposals in the dossiers of the target substances. But the update of the dossiers with the new testing information and adjustment of the read-across justifications will come post-2021 (which is the current endpoint of MISA). Will there be a MISA '2' to indicate updates post-2021 and to allow ECHA to further monitor upcoming changes in the dossiers?*
  Reply: while MISA is indeed running until the end of 2020, the generic planning for later updates can be included in the MISA workplan. The work plan should include the planning of the studies. We would assume that the planning of the studies is carefully done as to maximize the usability for read across

- *When we signed up to the MISA programme the implication was that ECHA would 'screen' check all our substances participating in the programme by end 2020. I see that in the updated Rolling Action plan 2021 is now listed for some deliverables and actions. Has the timing for the MISA programme changed?*
  Reply: MISA is indeed a programme that runs until the end of 2020. Some generic actions generated before the end of the workplan will however not have been finalised by the end of 2020 and will continue until they are resolved (e.g. guidance development).

- *Just a comment in response to scepticism by Member States about MISA: surely, rather than being an excuse to delay dossier updates, MISA has spurred many of us into action! In terms of timescale, as was mentioned by Hugo, some of us have limited internal resources and rely on external consultants who are all very busy these days!*
  Reply: absolutely, MISA has spurred activity significantly which we would like to make clear in the identified KPIs. This activity + the outcomes (improved dossiers) would allow to convince more critical Member States

- *Will the responses of these questions be circulated to all participants? Thanks. Reply: yes*

Conclusion and follow ups

The presentations by ECHA and Eurometaux provided the attendees with reflection on the progress process review allowing all to know where we stand. Points for further action/reflection are the extension of the MISA scope in terms of number of substances, the review of the workplans on timing and the mapping of outstanding barriers to identify how those can be addressed.

Comments on the updated Rolling Action Plan (version 27 August) can be submitted before 5 September. It will subsequently be published.

ECHA will further report the progress with MISA to Member States and Commission and reflect about reporting modalities and KPIs.

Survey Monkeys to collect information on the progress on the MISA implementation and the difficulties observed, will be organised at regular intervals (6 months?) (or in alternance with stock-taking workshops).

The webinar was closed after 1h15.