Metals and Inorganics Sectorial Approach (MISA) rolling action plan

Version 24 May 2018

1. Introduction

The Metals and Inorganics Sectorial Approach (MISA) has a double objective: assessing and where necessary improving the compliance and quality of the registration dossiers in the metal and inorganic sectors (track 1) and resolving a selected number of outstanding technical challenges specific to the metal/inorganic sectors (track 2), cooperatively with ECHA.

The aim of this document is to develop a **rolling action plan for MISA for 2018-2020** to ensure that the **priorities between parallel tracks 1 and 2 are integrated and correlated** to each other. The present version of the rolling action plan focuses on the priorities planned in 2018-2019 and gives an outlook to further priorities under MISA.

The starting points to develop this rolling action plan were: the sectorial findings from the Baseline Reports completed by the industry end 2017, the 'compliance checks' and 'substance evaluation' experience on metals, and the results of the data mining exercise conducted by ECHA.
A number of actions were identified and a priority setting was applied taking into consideration their relevance for both the participating consortia and ECHA.

This rolling action plan will be reviewed regularly (once or twice a year) to ensure that it reflects the most recent progress on the identified priorities but also consideration of potential emerging issues or need for reprioritization of certain topics. This review will involve ECHA and the signatories.

The rolling plan will be annexed to the 'Framework for cooperation' summarising the main characteristics of MISA and engagement of all actors.

Participating Consortia undertake to align and integrate the key objectives and learnings from MISA, into their existing work plans, where relevant, with the appropriate priority. Such learnings from MISA can be gathered and communicated generically in a sectorial fashion. It is recommended that Consortia consider communicating their specific learnings from MISA and how they will be integrated into their workplan to ECHA.

As mentioned above, to ensure that both tracks evolve in parallel, the priorities of track 1 and track 2 must be integrated and complementary. Table 1 summarizes the high, medium, low priorities identified for the 3 coming years and how the activities on track 1 and 2 are related. These priorities were discussed on 24 January 2018 between ECHA and the metals/inorganics sector and are grouped by item (assess/improve effects data, exposure/risk characterisation, anticipation of risk

management). A more detailed action plan is described below for the high priority issues. It it is proposed to review the needs and relevance for the medium and lower priorities early 2019 and draw action plans at that time.

As a general principle, deliverables should be used to update the existing registration dossiers, where relevant, as a concrete deliverable.

Table 1. Overview of the the sectorial priorities identified for the 2018-2020 period by the participating consortia as well as the interrelation track 1 and 2

Issue category	Track 1 priorities	Track 2 priorities related to activities proposed for track 1
High Priority (2018-2019)		
1. Assess/improve dossiers on effects endpoints	Human Health: • data waiving/adaptation/read-across on repeated dose toxicity, reprotox and mutagenicity; data generation, when adaptations are inadequate, with attention to counter ion • assessment factors and justifications	• Read across/weight of evidence
	Environment: • data waiving/adaptation/read-across/ availability of TDp data and long- term toxicity with attention to the counter ion	• Read across/weight of evidence
2. Exposure assessment and Risk characterisation	Clarify assumptions and robustness of the methods and data used for workplace, consumer and Man via the Environmentassessment	• Man via the Environment
3. UVCBs	Compliance of the UVCB registration dossiers on both hazard and exposure. • Finalise discussions on SID/inquiries • Demonstrate that classification and assessment covers the variability • Ensure compliant formatting of the dossiers Address placeholders (Man via the Environment, Combined toxicity).	• UVCB and SID formatting and finalise discussions on SID and outstanding methodological aspects
4. REACH Risk Management anticipation/ environmental classification	Classification and fate modelling environment: integrate Rapid Removal for chronic environmental classification and fate modelling in a consistent way in registration dossiers	• Rapid Removal
5. REACH Risk Management anticipation	To derive informed decisions on RMMs (classification, recycling, other restrictive tools, …) for complex metal-containing materials: • Ensure that relevant information on minor constituents/impurities is available in the registration dossier,	• Management of potential SVHCs in input and output streams of metals production (including recycling) • Obtaining further clarity on how impurities and (minor) constituents are

	• Demonstrate with examples the impact of minor constituents/impurities in the input and output stream of metals production • Clarify assumptions and robustness of methods used for assessment of substances including minor constituents/impurities,.	addressed under SVHC Roadmap
6. Supply chain, uses and exposure knowledge	Clarification on the uses, use conditions and emissions/exposures	• Supply chain, uses and exposure knowledge • Materials flow analysis, and source apportionment (including diffuse sources)

Medium priority (2019-2020)		
7. Assess/improve compliance on effects endpoints	Quality and robustness of the sediments assessment	
8. Exposure assessment and Risk characterisation	Clarify combined exposure (workplace + man via the environment + consumer exposure for same substance) and confirm relevance of the SPERCs	Man via the Environment
Lower priority (2019-2020)		
9. REACH Risk Management anticipation	Stimulate industry RMOa's	
10. Reference to other regulations	Ensure reference to available information from other programmes and better recognition of REACH data/assessment	

2. Action plan

For each of the high priority issues listed in the table above, the action plan below proposes a short description of the work to be done, the proposed format and the possible deliverables, with milestones and timings. The timeline for the different priority activities is included in Annex 1.

<table>
<tr><th colspan="2">1. Assess/improve the dossiers on effects endpoints</th></tr>
<tr><td>Short description:
Assess and improve dossiers on effects endpoints/ standard information requirements of REACH (repeated dose toxicity, reproductive toxicity, mutagenicity, long-term aquatic environment) with specific focus on adaptations that have been used by consortia: read-across/ weight of evidence/other adaptations.</td><td>Proposed format:
• 2 interactive workshops, on HH and ENV endpoints respectively, involving both industry and ECHA, open to Commission and interested Member States
• the workshops are prepared via a) a self-assessment tool on the targeted endpoints and adaptations completed by consortia; b) sharing of concrete examples by ECHA
• during the workshops consortia (including their consultants) and ECHA exchange on the interpretation / applicability of adaptation arguments, learn from comparing adaptation motivations and agree on the generic elements to include in the dossiers when using adaptations for the above listed endpoints
• the outcomes of the technical support work (see below) will be integrated into the discussions</td></tr>
<tr><td colspan="2">Deliverables:
• Workshop report summarising the learnings from the exercise and proposed ways forward, reviewed by all participants (including ECHA).
• This report will be provided to the participating consortia so that they can integrate learnings and update their dossiers where required, identification of data gaps and possible strategies to address those.</td></tr>
<tr><td colspan="2">Technical work to be carried out:
• Objective: support consistent, understandable, robust justifications fulfilling the legal requirements, understandable by the assessor and considering/explaining the metals specificities when relevant. Identify possible data gaps and strategies to address these, which may include testing or adaptations.
• Actions:
o Check Environmental and HH RAAF criteria and weight of evidence guidance and identify some generic principles to take to the workshops (2018 HH, before Q1 2019 for ENV)
o Define a consistent reporting of read-across and weight-of-evidence in IUCLID (2018)
o Clarify effect of counter ion (human health and environment) (2018)
o Clarify how the read-across is transferred into the classification for all metal compounds in the group, DNEL and PNEC setting (Q4 2018 HH, Q1 2019 ENV)
o Guidance on the use of bioelution results in the context of read-across and grouping (2019)</td></tr>
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Milestones and timings

- Development of "self-assessment tool" (industry) and review of its correctness by ECHA (June 2018)
- Provide a typical positive benchmark metal example (or examples of typical mistakes explaining how these could be corrected) for the metals sector (ECHA) (for Human Health endpoints: June 2018; for Environmental endpoint: November 2018)
- Consortia to complete the self-assessment tool (for Human Health endpoints: July 2018; for Environmental endpoint: August 2018)
- Technical work on read-across/weight of evidence (July-August 2018)
- Workshop on HH endpoints (October 2018) and report outlining clearly the criteria for acceptable justifications for adaptations of information requirements
- Workshop on ENV endpoints (February 2019) and report outlining clearly the criteria for acceptable justifications for adaptations of information requirements
- Update of dossiers where relevant with acceptable justifications and/or submission of testing proposals: *whilst recognising the need for a case-by-case assessment of the necessary resources, it is expected that these actions will normally be carried out within 6-9 months after the workshops*
- Guidance on the use of bioelution for read-across and grouping (2019 as dependent on timing of ECVAM for the validation of the test protocol)

2. Exposure assessment and risk characterisation supported by work on robustness of methods used for workplace (modelling data, MEASE 2), consumer and Man via the Environment (MvE) (EUSES, guidance)

Short description:

Aim is to clarify assumptions and robustness of the methods used for workplace, consumer and Man via the Environment (MvE) assessment. It is proposed to use several modes of communication (thematic workshops, webinars (MEASE),…) so as to ensure that all consortia (including their consultants) apply the most recent information to improve their exposure assessment. The metal sector will also actively support the work done by ECHA on update of EUSES

Proposed format:

- Participation in EUSES update work
- Improve existing guidance on use of monitoring data
- Provide guidance on the use of MEASE 2.0 + documentation
- Provide guidance on man via the environment assessment in line with Seminar co-hosted by ECHA, RIVM and Eurometaux in Brussels (16.01.2017)

Deliverables:

- Several guidance documents will be made available so that consortia can improve their assessments where required.
- Update of existing Metals Appendix available on ECHA website to include aspects on Man via the Environment assessment

Technical work to be carried out:

Man via the environment

- **Objective**: have better guidance to assess the potential MvE impact (to improve Restriction & Authorisation cases) whereby emissions lead to population exposure, obtain realistic estimates of Excess Risk as a result of MvE exposure and promote industry improving its MvE scenarios for metals.

- **Actions:**
    - Participate in update to EUSES model (ECHA) (2018-2019)
    - Work on other actions agreed at ECHA/RIVM/EM 2017 seminar, focusing on those specific for metals and in particular on those required to improve the Applications for Authorisation (2019)
    - Draft metal-guidance aiming at improving MvE assessment on metal specific aspects (2019)

Workplace - environment

- **Objective:** ensure data can be reported in the most appropriate way and are accepted as accompanied by enough supporting information (when e.g. modelled data)
- **Milestones, deliverable and timing:**
    1. Work on understanding/reliability of MEASE 2.0: webinar + documentation (2018)
    2. Discuss use of Chesar for combined assessment
    3. Work on robustness/coverage of SPERCs (ongoing under ENES Roadmap 2018-2020)

Milestones and timings:

- Develop documentation/understanding/reliability MEASE 2.0 (communication material, link with Chesar); participate actively in SPERCs work under ENES Roadmap (quality criteria, review fact sheets), identify solution on combined assessment for metal dossiers in Chesar
- Participate in update to EUSES model (ECHA) (2018-2019)
- Work on other actions agreed at ECHA/RIVM/EM 2017 seminar (2019)
- Draft metal-guidance aiming at improving MvE assessment on metal specific aspects (2019)
- Update of dossiers where relevant (indicate scheduled updates in Consortia workplans plans by Q3 2019)

3. UVCBs	
Short description: Several metal consortia have upgraded their UVCB dossiers from intermediates under SCC to full Annex X dossiers in 2014. Also, UVCB dossiers have been developed in some inorganic sectors. A risk assessment approach has been developed, assuming that the toxicity of UVCB is driven by the toxicity of the constituents. The followed approach resulted however in several formatting issues (e.g. to have a workable IUCLID, only the summaries of the data on constituents were included which may be perceived as 'incomplete dossiers'). The formatting issues have a direct impact on the way UVCB data are disseminated on the ECHA website. The link between the SID section and the assessment is complex due to the nature of the UVCB and should be further clarified (this will also facilitate management of inquiries). Finally, the dossiers contain placeholders to be addressed e.g. on combined toxicity and man via the environment as methodologies needed to be developed.	**Proposed format:** • Starting from existing dossiers and work out solutions for reporting of data, link SID-uses-assessment-risk management • Discuss proposed solutions with SID/Computational and Evaluation units • Include agreed ways forward in existing UVCB guidance to industry

Deliverables:

- Improved UVCB dossiers fulfilling data requirements and clear, understandable risk assessment approach
- Improved data on ECHA dissemination website

Technical work to be carried out:

- **Objective:** have compliant UVCB dossiers
- **Actions:**
    - Finalizing discussions on **SID** and description of impact of variability on classification
    - Working on **formatting** of the dossiers in IUCLID to ensure compliance of data including on adaptations (use of the assessment entity, identification of solutions for data reporting/sharing/updating on constituents
    - Finalise approach on **combined toxicity** and prepare guidance
    - Improve placeholder on **Man via the Environment**
    - Ensure alignment of proposed improvements with discussions on methodology held at MSC
    - Discuss with **dissemination unit** to ensure compatibility of format with dissemination requirements

Milestones and timings:

- Finalise technical work and discussion with ECHA on proposed solutions:
    - Discussion end of summer 2018 with relevant units in ECHA unit on proposed ways forward
    - Share updated industry guidance before December 2018
    - Organise discussion back-to-back with MSC subgroup on UVCBs on outstanding issues in industry guidance
    - Finalise industry guidance (February 2019)
- Include in Consortia workplans scheduled updates by end summer 2019

4. Risk Management anticipation/ environmental classification and fate modelling

Short description:

The CLP and GHS ruling for metals include the assessment of the Rapid Removal from the water column. The way to assess this criterion for metals has however not yet been concluded.

Proposed format:

- Workshop with Member States, ECHA, (OECD) and industry to agree on assessment and testing method based on the Transformation Dissolution protocol
- Drafting of targeted guidance and submission of protocol to UN

Deliverables:

- Agreed way forward to consider Rapid Removal (from testing protocol to use of results)

Technical work to be carried out:

- **Objective:** develop Rapid Removal concept/tool/assessment method for use in the CLP classification of metals and inorganic compounds.
- **Actions:** compile knowledge in a package to be submitted and rediscussed with authorities

Milestones and timings:

- Collect existing data and relevant new information to be discussed during a workshop and for submission to ECHA April (2018)
- Discussion with ECHA/Member States and Review process with proposals for guidance (Q1 2019, see possibilities to organise it in February 2019)
- Integrate Rapid Removal for chronic environmental classification and fate modelling in a consistent way in registration dossier (2019)

5. Risk Management anticipation: Potential SVHCs as minor constituents or impurities in materials for recycling and refining (proposal to review/update timings and milestones where necessary this table early 2019)

Short description:

Metal recycling materials and primary metals often include hazardous minor constituents/impurities. These hazardous minor constituents/impurities may cause risks (e.g. from a REACH and Circular Economy perspective). Aim is to collect examples of how minor constituents/impurities could impact input and output streams, get insights into how Consortia in the sector have so far reflected on this issue in registration dossiers (composition, exposure assessment and risk characterisation) and identify potential for improvements in reporting. The discussion could also address what information beyond the REACH requirements would be useful to gather to enable the selection of appropriate risk management measures in an industry RMOa or in preparation of an RMOA by authorities. Clarity on how the above impurities and (minor) constituents should be assessed under the SVHC Roadmap is also sought for the purpose of having relevant information available.

Proposed format:

- Gather examples of potential SVHCs in input and output streams of metals production (including recycling)
- Workshop (with industry, Member States ECHA) reviewing best cases aiming for assessing the examples and conclude on how to balance REACH and Circular Economy concerns for RMM conducting relevant RMOa work on this subject.

Deliverables:

- Workshop report summarising the findings and identified action needs, reviewed by all participants (including ECHA and Member States)
- Presentation outcomes workshop to RIME?
- This report will be provided to the participating consortia so that they can integrate learnings and update their dossiers where required, identification of data gaps and possible strategies to address those.

Technical work to be carried out

- **Objective**: develop and launch an assessment approach for substances (minor constituents and impurities) in substances, which could help in the selection of potential RMM and ensure to comply with Circular Economy principles

- **Actions:**
    - Template to report best cases and prepare the workshop discussions

Milestones and timings

- Collect best cases examples (2019)
- Workshop and report (end 2019)
- Sharing outcomes with RIME (after 2019)

6. Supply chain, uses and exposure/emissions knowledge (proposal to review/update timings and milestones where necessary this table early 2019)	
Short description: Good knowledge on uses allows to identify sources of exposures/emissions to focus on when launching/performing risk management (and/or prioritise efforts). While REACH allows to identify a series of uses (or uses advised against), for metals/inorganics and thus the related exposures, it should be acknowledged that there may be significant sources of emissions that fall outside its boundaries. Natural sources shall be considered as well. Materials flow analysis' may help map the uses and emissions and be beneficial in identifying the relative importance of the various sources compared to the overall emission pattern which, in the case of naturally occurring substances will include natural and anthropogenic sources. It is important in this respect to consider the actual contributions of the sources to environmental exposure at local and regional level. Materials flow analysis and diffuse sources/source apportionment provide information that may help pointing to where risk management should be targeted and would be more efficient. The mapping of emission sources is also useful to compare monitoring data with modelled data.	**Proposed format:** • Develop template for Materials Flow analysis and apply to a couple of metals examples • Workshop with workshop with industry, ECHA and Member States to discuss the pros and limitations of the MFA approach and identify way to report it in IUCLID
Deliverables: • Template for MFA + explanatory note • Publication and updated data on diffuse sources that could be included in the dossiers	
Technical work to be carried out **Objective:** develop an objective assessment of the selective exposure contributions and importance of different uses at consumer and regional scale with the aim to improve the consumer and regional assessments and define best options for Risk Management where relevant **Actions:** • Review of materials' flow analysis case studies in metals' sector and development of template (2018) • Draft explanatory note on good practice materials' flow data collection (2018-Q1 2019)	

- Update data and existing draft publication on diffuse sources (2018)
- Define how this can be reported in IUCLID

Milestones and timings:

- Develop the MFA template and explanatory note on MFA (2018)
- Workshop with Member States, ECHA, industry on MFA (tbc)
- Update data on diffuse source and publication (tbc)
- Include in Consortia workplans scheduled updates (tbc)

Annex 1: Overall timeline: