Metals and Inorganics Sectorial Approach (MISA) updated rolling action plan

Version 20 September 2019

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 provide an update of the agreed **2018-2020 rolling action plan.**

A first version of this document was made available on 24 May 2018 and annexed to the Framework of Cooperation agreements signed by the participating consortia/associations in 2018-early 2019. In the meantime, the scientific issues of three out of the six jointly defined priorities have been addressed by the organisation of workshops (MISA 1 (human health), MISA 2 (environment), Rapid Removal). The MISA 1 and MISA 2 workshops were preceeded by a self-assessment exercise and followed by the submission of a workplan to ECHA by the participating consortia.

This revised version of the rolling action plan focuses on the open deliverables and actions and on the remaining priorities planned for 2019-2020.

The starting points to update the rolling action plan were:

- the originally defined priorities in 2018 (based on the Baseline Reports completed by the industry end 2017),
- the 'compliance checks' and 'substance evaluation' experience on metals,
- the Integrated Regulatory Strategy defined by ECHA and the REACH Evaluation Action Plan
- the leranings from the first MISA workshops.

Compared to the 2018 rolling action plan, it proposes a reprioritisation and 'integration of two topics as closely related (5. risk management of hazardous constituents/impurities and 6. communication in the supply chain, see further below) .

This 2019 version of the rolling action plan will be further updated mid- and end 2020 to ensure that it reflects the progress on the identified priorities but also identifies issues that would not have been addressed by the programme . This review will involve both ECHA and the signatories.

The updated MISA rolling plan will be posted both on the ECHA website and the MISA blog (REACH metals gateway) once approved by the MISA actors (ECHA and participating consortia/associations).

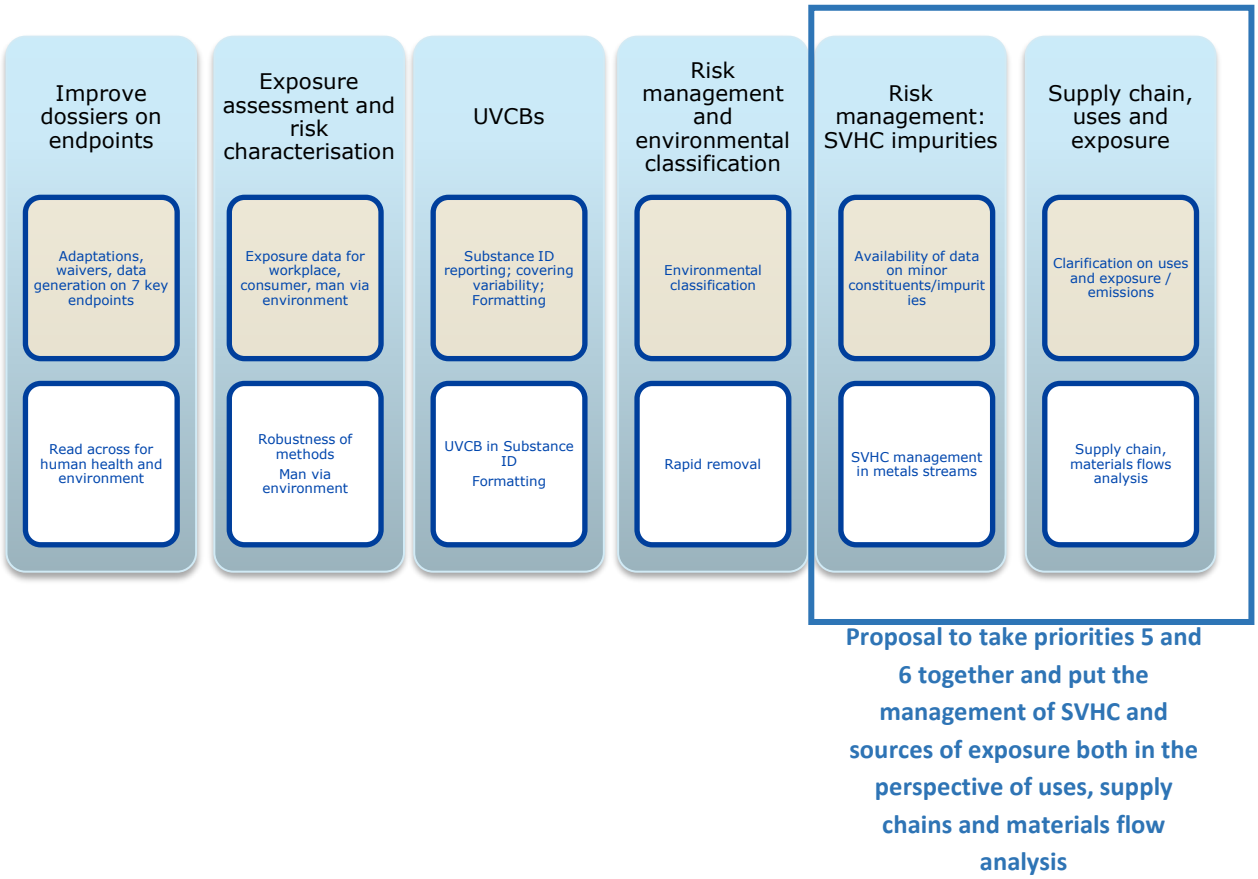
Participating consortia/associations undertake to align and integrate the key objectives and learnings from MISA, into their existing workplans, where relevant, with the appropriate priority. As a general principle, deliverables should be used to update the existing registration dossiers. Such learnings from

MISA can be gathered and communicated generically in a sectorial fashion (e.g. reports of the workshops, MISA blog). It is recommended that consortia/associations consider communicating their specific learnings from MISA and how they will be integrated into their workplan they submit after each activity to ECHA (via the MISA functional mailbox).

To ensure that both tracks evolve in parallel, the priorities of track 1 and track 2 must remain integrated and complementary. Table 1a summarises the 6 high priorities that were identified for 2018-2020 and how the activities on track 1 and 2 are related to those priorities.
These priorities are also summarised in Figure 1a. A status update and/or more detailed action plan is described below for these high priority issues. A number of medium and low priority items had also been identified in January 2018 during an ECHA-industry workshop (Table 1b). It is proposed to review the needs and relevance of these priorities mid-2020,and draw action plans at that time if still relevant.

Member States and Commission are informed about the progress and results of the rolling action plan on a regular basis by means of progress reports to CARACAL and RIME+. Representatives of Member States and Commission have and may participate in workshops. MISA workshop summaries are made publicly available on the REACH Metals Gateway (https://www.reach-metals.eu/metals-and-inorganics-sectoral-approach-misa) and the ECHA Website (https://echa.europa.eu/misa).

Figure 1a & Table 1a. Overview of the the MISA sectorial high priorities identified for 2018-2020 as well as the inter-relation between tracks 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 Environment assessment	• 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 finalising 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/minor constituents and impurities	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, • 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.	• Management of potential SVHCs in input and output streams of metals production (including recycling) • Obtaining further clarity on how impurities and (minor) constituents are addressed under the REACH Management schemes
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 (MFA), and source apportionment (including diffuse sources)

Proposal to take priorities 5 and 6 together and put the management of SVHC and sources of exposure both in the perspective of uses, supply chains and materials flow analysis

Table 1b. Overview of the the sectorial medium and low priorities identified for the 2018-2020 period

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 RMOas	
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 here below proposes a short status update and/or a short description of the work to be done, the proposed format and the possible deliverables, with milestones and timings.

Colour legend

= completed = ongoing = to be done

1. Assess/improve the dossiers on effects endpoints	
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.	**Proposed format and status update:** • **two** interactive workshops, on HH and ENV endpoints respectively, involving both industry and ECHA, open to Commission and interested Member States were held on 2 October 2018 and 7 February 2019 • the workshops were prepared via a) a self-assessment tool on the targeted endpoints and adaptations completed by consortia and b) sharing of concrete examples by ECHA • during the workshops consortia (including their consultants) and ECHA exchanged on the interpretation/applicability of adaptation

	arguments, learned from comparing adaptation motivations, and agreed on the generic elements to include in the dossiers when using adaptations for the endpoints of relevance • the outcomes of the technical support work (see below) will be integrated into the discussions • consortia defined the needs for updating their dossiers by improving justifications and motivations and/or (planning for) submitting testing plans. Workplans were submitted to ECHA.

Deliverables:

Workshop report summarising the learnings from the exercise and proposed ways forward, reviewed by all participants (including ECHA) + Executive summary including key learnings, posted on the ECHA website and MISA blog. The executive summaries have been made publicly available	**COMPLETED**
Self-Assessment tools on each participating substance and workplans submitted timely to ECHA	**COMPLETED**

Proposed additional deliverable:

MISA- 2B environmental & human health 'stock-taking' workshop in winter 2019 - 2020 to evaluate progress made with the updates, the alignment with metals guidance and learnings from environmental information requirements & classification/human health Information requirements/compliance checks reviews	**ONGOING (date to be confirmed)**

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/inorganics specificities when relevant. Identify possible data gaps and strategies to address these, which may include testing or adaptations. Update self-classifications and their motivations.

- **Actions:**

Check Environmental and Human Health RAAF criteria and weight of evidence guidance and identify some generic principles to take to the workshops	**COMPLETED**
Define a consistent reporting of read-across and weight of evidence in IUCLID	**ONGOING**
Clarify effect of counter ion (human health and environment) in a document that can be attached to the registration dossiers	**ONGOING**
Clarify how the read-across is transferred into the classification for all metal/inorganic compounds in the group, DNEL and PNEC setting	**ONGOING**
Guidance on the use of bioelution (i.e. assessing release of the metal ion) results in the context of read-across and grouping	**ONGOING**

Milestones and timings for this activity

- 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: September 2018; for Environmental endpoint: January 2019)
- Consortia to complete the self-assessment tool (SAT) (for Human Health endpoints: September 2018; for Environmental endpoint: January 2019)
- Summarise key learnings from the SATs to identify the key issues for debate at the MISA 1 and 2 workshops
- Technical work on read-across/weight of evidence (July-August 2018)
- Workshop on Human Health endpoints (MISA 1, October 2018) and report outlining clearly the criteria for acceptable justifications for adaptations of information requirements
- Workshop on ENV endpoints (MISA 2, February 2019) and report outlining clearly the criteria for acceptable justifications for adaptations of information requirements
- Draft work plans and update of dossiers where relevant with acceptable justifications and/or submission of testing proposals
- Guidance on the use of bioelution for read-across and grouping (2019)
- Taking stock workshop on ENV/HH endpoints: discuss progress made with the updates, the alignment with metals guidance and learnings from compliance checks cases and classification cases (date tbc)

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:

Aims are to a) improve the quality/reliability of the exposure data in the registration dossiers (e.g. by improving the contextual information), and b) clarify assumptions and robustness of the methods used for workplace, consumer and Man via the Environment 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 potential EUSES update work
- Improve existing guidance on use of monitoring data
- Provide guidance on the use of MEASE 2.0 + documentation
- Workshop Q1 2020 to discuss 'exposure-related quality/ robustness issues of data sets,' and coherent use of models.
- Provide guidance on Man via the Environment assessment in line with Seminar co-hosted by ECHA, RIVM and Eurometaux in Brussels (2017)

Deliverables:

Several guidance documents will be made available so that consortia can improve their assessments where required.	**ONGOING**
Proposal to update the existing Metals Appendix available on ECHA's website to include aspects on Man via the Environment assessment	**ONGOING**

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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 potential update to EUSES model (ECHA) (2018-2020)	**ONGOING**
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)	**ONGOING**
Draft metal-guidance aiming at improving MvE assessment on metal specific aspects (2020)	**TO BE DONE**

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)

- **Actions:**

Work on understanding/reliability of MEASE 2.0: webinar + documentation (2020)	**ONGOING**
Work on robustness/coverage of SPERCs (ongoing under ENES Roadmap 2018-2020)	**ONGOING**

Milestones and timings for this activity:

- Develop documentation/understanding/reliability MEASE 2.0 (communication material, link with Chesar and outcome of ENES' action 3.2 on Consolidate the different workers exposure tools into a common framework) (2020)
- Participate actively in SPERCs work under ENES Roadmap (quality criteria, review fact sheets
- Participate in potential update to EUSES model (ECHA) (2018-2020)
- Organise MISA 4 workshop on workplace and environment exposure-related aspects, exact scope to be defined (February 2020):
- Work on other actions agreed at ECHA/RIVM/EM 2017 seminar on Man via the Environment(2020)
- Draft metal-guidance aiming at improving Man via the Environment assessment on metal specific aspects (2020)
- Update of dossiers where relevant (2020)

3. UVCBs

Short description:	**Proposed format/status update:**
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 a UVCB is driven by the toxicity of the constituents. The followed approach resulted however in several formatting issues (e.g. to have	• Starting from existing examples/dossiers and work out solutions for reporting of data, link SID-uses-assessment-risk management • Discuss proposed solutions with SID/Computational/Dissemination **and** Evaluation units

a workable IUCLID, only the summaries of the data on constituents were included which are 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.	• Include agreed ways forward in existing UVCB guidance to industry

Deliverables:

Publication of MISA Industry guide on metals and inorganics UVCB assessment under REACH + recommendations on how to report	**ONGOING**
Improved UVCB dossiers fulfilling data requirements and clear, understandable risk assessment approach	**ONGOING**
Improved data on ECHA dissemination website	**ONGOING**

Technical work to be carried out:

- **Objective:** compliant inorganic UVCB dossiers

- **Actions:**

Finalising discussions on **SID** and description of impact of variability on classification	**ONGOING**
Working on **formatting** the dossiers in IUCLID to ensure compliance of data including on adaptations (e.g. use of the assessment entity, identification of solutions for data reporting/sharing/updating on constituents	**ONGOING**
Finalise approach on **combined toxicity** (constituent based hazard assessment) and prepare industry guide on inorganic UVCBs (metal sector)	**ONGOING**
Improve placeholder on **Man via the Environment**	**COMPLETED**
Ensure alignment of proposed improvements with discussions on methodology held at MSC and CARACAL and RIME+ (*tbc)*	**TO BE DONE?**
Discuss with **dissemination unit** to ensure compatibility of format with dissemination requirements	**TO BE DONE**

Milestones and timings:

- Finalise technical work and discussion with ECHA on proposed solutions:
  - Discussion autumn 2018 with relevant units in ECHA on proposed ways forward
  - Share updated industry guidance on SID in December 2018
  - Organise discussion back-to-back with MSC subgroup on UVCBs on outstanding issues in industry guidance: tbc
  - Develop some examples of assessment from SID to reporting and have an internal industry discussion (August 2019) -discussion with ECHA (September 2019)
  - Organise workshop to present examples and agree on possible ways forward for updates (5 November 2019)
- Finalise industry guide: (Q1 2020)

- Develop self-assessment tool (SAT iUVCB) to prepare the workshop scheduled for 5 November 2019 (summer 2019)
- MISA 3 Workshop November 2019
- Draft work plans and update of dossiers where relevant (2020)

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/status update:

- Industry communication to ECHA: status update on knowledge level with Rapid Removal scheme and tools (December 2018)
- Workshop with Member States, ECHA, and industry to discuss the testing method based on the Transformation Dissolution protocol held on 8 February 2019
- Workshop held with Member States, ECHA, and industry back-to-back with RAC meeting on 11 June 2019 on the applicability of the Rapid Removal concept for environmental hazard classification

Deliverables:

Workshop reports with the Member States on the Rapid Removal concept and application for metals (8 February and 11 June 2019)	**COMPLETED**
Agreement on way forward to consider Rapid Removal (from testing protocol to use of results)	**2020**

Technical work to be carried out for this activity:

- **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. This was submitted ahead of the two workshops	**COMPLETED**
Updating the registration files according the CLP legal text and metal specific guidance when becoming available.	**2020**

Milestones and timings:

- Collect existing data and relevant new information to be discussed during a workshop and for submission to ECHA
- Discussion with ECHA/Member States and review process with proposals for guidance

- Integrate Rapid Removal for chronic environmental classification and fate modelling in a consistent way in registration dossier if there is an agreed way forward or at least include clear explanations/justifications of how it is used
- Prepare paper with workshop findings for discussion on the applicability of the rapid removal concept in CARACAL (ECHA)
- Adapt guidance according to outcome of CARACAL discussion (ECHA)
- Updating the registration files according the CLP legal text and metal specific guidance when becoming available.

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/associations 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 guide on analysis of regulatory options) 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 (link with CARACAL discussions on SIS/SIM) Management of hazardous constituents/impurities also relies on good insight/knowledge in supply chains and use patterns and recycling schemes. As activity 6 is focusing on the latter aspects, it is proposed to combine and work simultaneously on activities 5 and 6 and ensure coherence of learnings, tools.	**Proposed format:** • Gather examples of potential SVHCs in input and output streams of metals production (including recycling)[1] • Development of an exemplified risk assessment/management strategy recognising REACH and Circular Economy objectives, and share/present it to ECHA and Member States in a workshop -refinement of the industry strategy in line with comments made
Deliverables: Workshop summarising the findings and identified action needs, reviewed by all participants (including ECHA and Member States) — **2020**	

[1] This can be extended to inorganics based on specific input

Industry guide on analysis of regulatory options to help the sector to reflect on best further options to promote sustainable substitution and control the risk when relevant	**2020**
Presentation workshop outcomes to RIME	**2021**
This report will be provided to the participating consortia/associations so that they can integrate learnings and update their dossiers where required- identification of data gaps and possible strategies to address those.	**2021**

Technical work to be carried out

- **Objective**: develop and launch a risk assessment/management approach for substances (minor constituents and impurities) in materials present in the metals sector, which could help in the selection of potential RMM and ensure compliance with Circular Economy principles

- **Actions:**

Draft the risk assessment approach and prepare the workshop discussions (including a legal analysis of CARACAL paper on SIS/SIM)	**2021**

Milestones and timings for this activity:

- Develop risk assessment strategy and develop some examples: (2019)
- Develop industry guide on analysis of regulatory options to promote internal data gathering and tool selection for effective risk management: (mid 2020)
- Workshop and report: (end 2020)
- Sharing outcomes with RIME: (after 2019)

6. Supply chain, uses and exposure/emissions knowledge (proposal to review/update timings and milestones where necessary in this table early 2019)

Short description:	**Proposed format:**
Good knowledge on uses allows to identify sources of exposures/emissions to focus on when to launch/perform 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	• Develop template for Materials Flow Analysis (MFA) and apply to a couple of metal/inorganic examples • Update of data on uses, tonnages (including tonnage per use) • 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. It is proposed to combine this with the discussion of the impurities/minor constituents -see above

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. Management of minor constituents/impurities relies on good insight in supply chains and use patterns. Therefore priorities 5 and 6 will be combined and worked on simultaneously.	

Deliverables:

Template for MFA + explanatory note -exemplified with impurities/minor constituents	**2020**
Publication and updated data on diffuse sources that could be included in the dossiers	**2020**

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 in the context of impurities/minor constituents (see activity 5)	**2019**
Preparation of a couple for well developed examples with some recommendations on how to prepare MFA	**2020**
Update data and existing draft publication on diffuse sources (2019-2020)	**2019-2020**
Define how this can be reported in IUCLID and possibly use maps	**2020**

Milestones and timings for this activity:

- Develop the MFA examples and resulting recommendations : (2019)
- Workshop with Member States, ECHA, industry on MFA: (tbc)
- Update data on diffuse source and publication: (2019-2020)
- Include the scheduled updates in consortia workplans (tbc)