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Metals' sector experience on how the absence/presence of information has consequences for decision-making in regulatory risk management

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Outline

- Background
- Refinements of the dossiers
- Proposed way forward and cooperation

Key messages

- **R**EACH did not stop with registration!

- The R**EACH** registration dossier does play a critical role in further REACH processes (decision-making, addressing concerns…)

- The information industry added to the registration files for the purposes of the REACH registration has to be revisited/complemented to allow regulators to be able to select the most appropriate Risk Management Measure (RMM) for substances and/or address “new concerns”.

Background (1)

- REACH Registration: Industry tried to fulfil information requirements ‘as well as it could’
- When evaluating/prioritising, the regulators **only have the REACH registration file** at their disposal as well as any publicly available information (not always reliable - not always sufficient) for making an appropriate decision on:
    - the **need for risk management** or addressing an **outstanding concern**
    - the **relevance/efficiency** of **potential RMM measures**

- Example: information on uses
    - REACH registrations – industry often tried to cover every single possible use in the lead registrant’s registration dossier as a precaution (even if the use may no longer exist)
    - REACH Authorisation: need to identify/target relevant uses

Background (2)

- It has been observed -by industry and regulators- that decisions cannot always be made based on the information included in the REACH registration dossier (not sufficient)

- Up to now there was no mechanism to know upfront what information would be required. It's more of a steep learning curve.

- Although it is stipulated that all the information has to be in the registration file when making decisions on alternative concerns or RMMs, the existing REACH registration dossiers were not designed to contain all the necessary & relevant information for regulators to be able to establish the **most appropriate RMM for a substance or address concerns not covered by standard endpoints**

=> Refinement of the dossiers is recommended

Adaption/refinement of dossier files (1)

To allow the identification of the most appropriate RMM (or avoid incorrect conclusions to be drawn), the following adaptions/refinements may be required: covering information on uses, volume, exposure potential, exposure by man via the environment, physical form, regulatory efficiency and socioeconomic impacts.

- **Discard uses that are NOT relevant**
  - Uses that no longer exist (e.g. a use that has not been used in more than 10 years)

- **Map out uses** with appropriate volumes
  - Illustrating what is considered a use of the substance and what is not (what would be considered in and out of scope)

- Consider the **physical form of the substance/impact on release from e.g. article and how it changes at each step of the lifecycle** (metal-specificity?)

Adaption/refinement of dossier files (2)

- Indicate all potential **exemptions** whether **generic** or **specific** exemptions
- Preparation of **scientific justifications** for the exemption arguments (e.g. intermediates etc.)
- Refinement of existing exposure scenarios
  - E.g. needs to be clear when there is no release from the article – no exposure to the professional/consumer or the environment
- Map out the **existing EU legislation** which covers the use/uses right throughout the lifecycle
- Recently **some socioeconomic information** had to be collated and incorporated into the CSRs

Adaption/refinement of dossier files (3)

(New) concerns that could affect the RMM:

Registrants do not control all aspects of the **risk characterisation e.g.**:

- high RCRs and background due to diffuse sources (none substance related)
- new endpoints (EDc, …)
- aggregated tonnage
- …

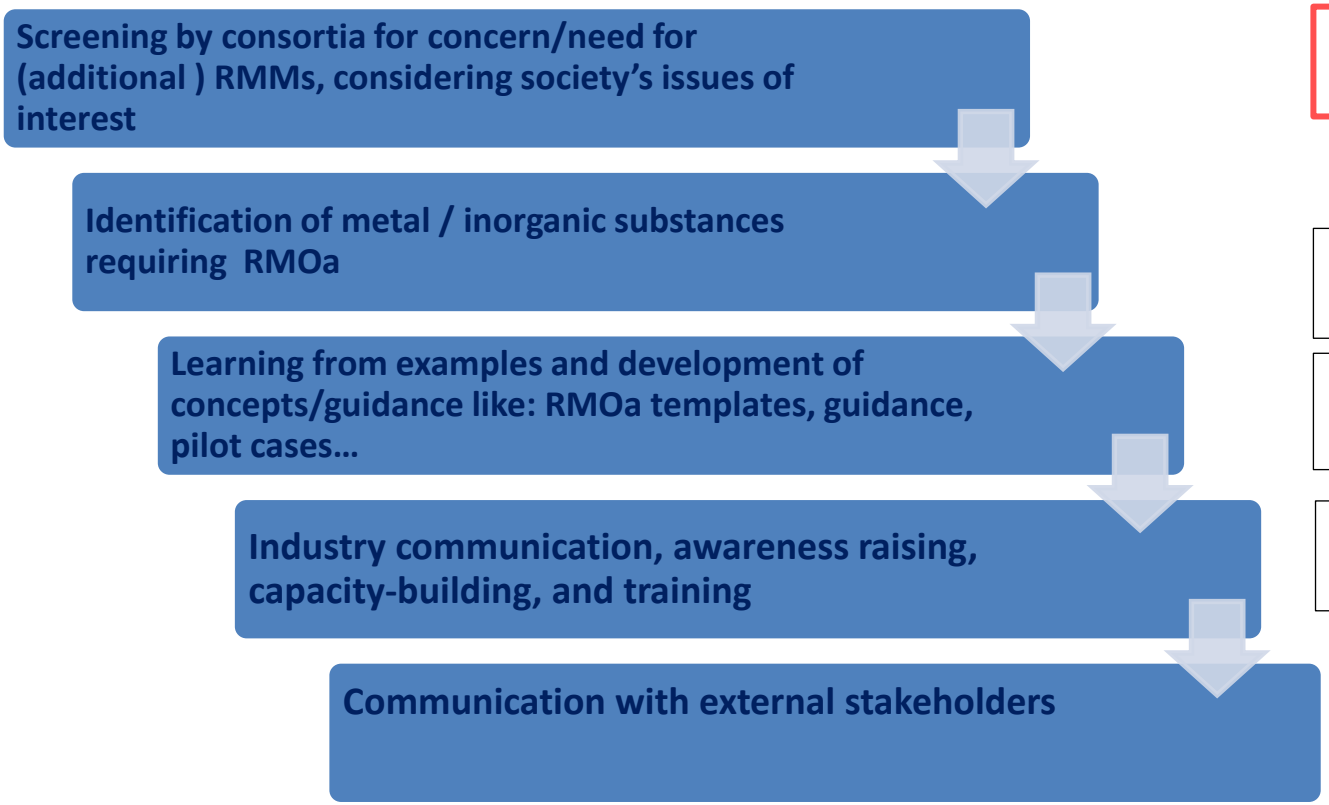
The RMOa could identify the need for clarification while a Substance Evaluation may be an appropriate tool to clarify the concern

Proposed way forward and cooperation (1)

- Better screening => better prioritisation => better RMOa of higher quality
- An RMOa (even though not mandatory for regulators) is **really critical** to the relevance and efficiency of the decision making process of the **most appropriate RMM**.
- The **comprehensiveness** and **relevance** of the RMOa can be enhanced by collaboration with industry
- **However the information in the dossier has to be in its refined state with the relevant information for a successful and most appropriate RMM to be recommended**

Proposed way forward and cooperation (2)

At metal sector level: ongoing reflection on "efficient Risk Management strategy" with discussion on following *milestones and projects*



Project 1: Registration dossier information check

Project 2: Risk Management Option analysis

Project 3: Authorisation & waste/recycling

Project 4: SEA/SIA capacity-building

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Proposed way forward and cooperation (3)

It is helpful if e.g. consortia managing the substances play a **coordinated role** with the DU sectors as soon as possible to get their support on critical information required

Education/training of DU sectors on why they need to get involved and what they need to do in support of the information requirements

Team effort – CRITICAL and KEY to the success of the most appropriate RMM being selected. Building relationships and positive collaboration with the various stakeholders

Very valuable points where most effort and time is required

To conclude, having the correct information is **KEY** to ensure relevant and efficient RMMs are selected from a societal and registrants perspective.

THANK YOU

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