Eurometaux

Guidelines for an Industry Risk Management Options Analysis

VERSION 5 – January 2021

Consolidated versions	Date	Changes
Version 1	**25 January 2015**	

Version 2	**10 March 2015**	• Title is adapted from 'Metals Industry Risk Management Options Analysis' to 'Industry Risk Management Options Analysis'
		• Adapted copyright clause vs. use for research for non-commercial purposes as well as use by authorities
		• Adapted infographics
		• New table with strengths and weaknesses of the different RMOs
		• New annexes:
		  ○ III: Learning lessons from RMOa exercises
		  ○ IV: RMOa Identification with hypothetical substance Y
		  ○ V: Templates for the RMOa exercises

Version 3	**18 May 2017**	• New Introduction
		  ○ What is an Industry-RMOa: Purpose? - Which substances are concerned? - By whom and when should an Industry-RMOa be performed?
		  ○ Orienting principles of an Industry-RMOa and choosing between approaches
		• New Part 1 'Broad I-RMOa, a strategic review by Industry' which presents a holistic approach integrating mass flows analysis, diffuse sources assessment, circular economy considerations.
		• New Part 2 'Generic I-RMOa scheme' focussed on RMOa in the REACH context, explaining the generic I-RMOa scheme and suggesting a practical approach
		• Annex III with experience from first cases and advice has been extended and edited so as to better present the different suggestions, including the role play
		• Figures and tables were checked and edited were necessary to address inter-platform compatibility issues

Version 4	**November 2020**	• Inclusion of the Circular Economy and Climate change dimensions as additional pillars of the I-RMOa, next to the chemicals' management dimension as such • Broadening the analysis to the presence of the substances under scrutiny as impurity in other substances

		• Simplification of some concepts:
		  ○ Simple I-RMOa and Integrated I-RMOa
		  ○ More explicit modes of approaching RMO: simple, combined or integrative
		  ○ Preparation for Integration into a Website
		• Proposal of approach to reach a conclusion considering the three pillars of Chemicals Management, Climate Change and Circular Economy

Version 5	**January 2021**	• Further simplification of the modes of approaching RMO so as to avoid confusion with the concepts of Simple I-RMOa and Integrative RMOa • Inclusion of first references to Chemicals Strategy for Sustainability and concepts such as Substance of Concern, Most Harmful Chemicals, Essential Use

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EXECUTIVE SUMMARY

Risk Management Options Analysis (**RMOa**) concerns the application to chemicals management of a broadly used concept of identification, evaluation, and prioritization of risks. The conclusions of such an exercise leads to the application of resources to minimize, monitor, and control the probability or impact of those risks. Whether in a regulatory context or when considering future strategies regarding the use of a substance, it is a valuable instrument to help explore and develop risk management options (**RMO**).

As part of the **European Green Deal** and its ambition to achieve **zero-pollution for a toxic-free environment**, the European Commission has prepared a **Chemicals Strategy for Sustainability**. In that context, RMO can provide a risk management methodology able to consider the whole life cycle of substances, materials and products, including reuse and recycling.

The integrative approach of the European Green Deal with its climate ambition, industrial strategy for a clean and circular economy or circular economy action plan represents a challenge for industry to broaden its RMO approach so as to include other critical factors, in particular the climate and circular economy dimension.

This guidance document proposes an Industry-Risk Management Options analysis (I-RMOa) methodology for two main approaches:

1. The **Simple I-RMOa** which consists essentially in addressing an imminent or ongoing regulatory review of a substance for risk management under the European chemicals' management regulatory framework, i.e. REACH. The scope of the work is set by the analysis framework defined by the regulator who initiated a Regulatory Management Options analysis.

2. The **Integrated I-RMOa** which proposes several additional assessment tools for identifying and prioritising the risks, expands the range of possible risk management measures so as to i.a. cover broader environmental regulatory needs (such as Water Framework Directive e.g.). The assessment horizon is widened to include **Circular Economy** and **Climate change** objectives as two separate pillars, alongside the chemicals management assessment.

   In so doing, the Integrated I-RMOa aims at developing a holistic view of the fate of a substance and to propose measures that are consistent with the broadest range of policy priorities. It is not bound by the limitations (scope, timing, type of data and assessment tools) which the Simple I-RMOa needs to tackle.

The I-RMOa methodology aims at ensuring that the relevant information needed for a regulatory assessment becomes available whilst, at the same time, providing an integrated picture of three major Green Deal pillars i.e. Chemicals Management, Circular Economy and Climate Change.

Thanks to a transparent proportionality assessment tool, the I-RMOa strives to identify, per use, the optimal risk management measure or combination of measures. It does so through an approach that is essentially qualitative, *de facto* preparing subsequent socio-economic analyses and impact assessments. It also proposes an Ex-Post evaluation of the risk management measures that were selected.

The I-RMOa can constitute a valuable input, assisting regulators in preventing regrettable substitution, optimizing regulatory management measures in a manner that accelerates the analysis and helps shorten the time to conclusions.

PART 1: INTRODUCTION TO REGULATORS' AND INDUSTRY APPROACHES OF RMOA

INTRODUCTION

Risk Management Options analysis (RMOa) is the application to chemicals management of identification, evaluation, and prioritization of risks followed by the optimisation of resources applied to minimize, monitor, and control the probability or impact of those risks.

RMOa in chemicals management:

Risks can come from various sources including exposure to chemicals during transportation, storage, production, downstream or final use and end-of-life operations as well as accidents or natural disasters. Over the years, industry has developed its own risk-mitigation approaches, in line with regulatory prescriptions. In essence, every environmental regulatory decision may be considered as a de facto outcome of some sort of RMOa.

The practical approaches will mirror the context which is to protect public health and safety as well as the environment throughout the lifecycle of the chemicals considered.

Strategies to prevent or manage a risk include avoiding the risk or reducing the negative effect or probability of the risk. If in financial risk management, one may consider the option of transferring all or part of the risk/uncertainty to another party, in chemicals management this would be called creating a negative externality and will not be considered an option, unless the way of addressing the risk would consist in making actors along the chain aware of their responsibility of ensuring that chemicals are adequately managed throughout the supply chain.

RMOa in a broader context than chemicals management:

As part of the **European Green Deal** and its ambition to achieve **zero-pollution for a toxic-free environment**, the European Commission has prepared a **Chemicals Strategy for Sustainability**. In that context, RMO can provide a risk management methodology able to consider the whole life cycle of substances, materials and products, including reuse and recycling.

The integrative approach of the European Green Deal with its climate ambition, industrial strategy for a clean and circular economy or circular economy action plan challenges industry to broaden its RMO thinking so as to include other dimensions than the risk management of chemicals stricto sensu, in particular the critical climate and circular economy dimension.

Words of caution:

RMOa is a relatively new concept in chemicals management and thus evolving quickly with the experience that is being gathered.

At the same time, the regulatory approaches to chemicals management evolve too. The European Green Deal will set new priorities and will widen the scope of the analyses. This is, at least for a part, reflected in the integrated Industry-RMOa presented in this guidance document.

But again, this remains work in progress and this guidance will be updated regularly to keep pace with developments.

Updates will be first published on the dedicated pages of the Eurometaux website.

1. THE REGULATORS' APPROACH ON RMOA

Authorities expect from an *RMOa in chemicals management* that it helps them decide whether regulatory intervention is (further) required for a substance and identify the most appropriate instrument to address a concern. Its management of risks will be through regulatory provisions hence the use of the slightly more restrictive notion of *Regulatory* Management Options analysis.

In the EU, the concept of RMOa acquired its notoriety with the REACH Regulation although it is not foreseen or mentioned in the regulation itself. Authorities have developed an RMOa scheme as a voluntary step to establish consistency in the documenting of findings so as to facilitate a common understanding on the action to be pursued. In practice, a Member State or ECHA (at the request of the Commission) performs an analysis to conclude whether a substance is a ***'relevant substance of very high concern (SVHC)***' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that **regulatory risk management** at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision-making involving Member State Competent Authorities (MSCA) and the European Commission as defined in the REACH Regulation.

The best-known document in this approach is the "Conclusion document" which provides the outcome of the RMOA carried out by an authority. In it, that authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required, and which is the most appropriate instrument to address a concern. With this Conclusion document, the EU Commission, MSCA and stakeholders are informed of the considerations of the drafting authority. In case the conclusion document proposes further regulatory risk management measures, this shall not be considered initiating those other measures or processes. It is a working document compiled on the basis of the information available to the authority who prepared the RMOa. It may change in light of new information being made available in following discussions and official processes (such as Public Consultations e.g.). It has to be noted that it is part of a regulatory process that is defined in the articles of the REACH Regulation on the identification of an SVHC and its "eventual" prioritisation for authorisation.

A Conclusion document will present its recommendation in a standardized manner as presented in Table 1:

TABLE 1: RECOMMENDATIONS IN THE CONCLUSION DOCUMENT OF A REGULATORY MANAGEMENT OPTIONS ANALYSIS

Conclusions	Tick box
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restriction under REACH	
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	

A **Regulatory Management Options Analysis** may be significantly different from an I-RMOa that will also explore non-regulatory chemicals management approaches. The next section will be devoted to discussing the Industry-Risk Management Options Analysis.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

2. THE INDUSTRY APPROACHES ON RMOA

Risks affecting companies because of the use of a substance / or its presence as an impurity / minor constituent[2] can have consequences. Impacts can be on occupational health, the environment, the companies' economic performance, their professional reputation, or even broader in society. An Industry Risk Management Analysis (I-RMOa) assists industry in managing risks whilst addressing policy and societal concerns.

An I-RMOa is a mainly qualitative approach consisting in the stepwise identification, discussion, and prioritization of risks related to a substance, followed by the identification of all potential risk management options to prevent, eliminate, minimize, monitor, and control the probability and/or impact of these risks. Finally, the potential risk management options are analysed so as to identify the most suited risk management option in function of a set of proportionality criteria.
An I-RMOa can be performed

- **To address a regulatory initiative (a regulatory management analysis as described earlier). We will call this the *simple-I-RMOa***
- **To prepare industry/companies to address likely regulatory and societal challenges that may impact the way they operate and the substances they use in their processes. Typically, such an analysis tries to develop the broadest view of the issues at stake and** Its assessment horizon includes, next to **chemicals management**, the **Circular Economy** and **Climate Change**. These three dimensions constitute the **three pillars** of **an *integrated I-RMOa.***

Options to manage risks typically include avoidance through substitution of substances (drop in substitution) or technologies, reduction or control of the risk to levels acceptable to society through production technologies or occupational working conditions. A 'non-use scenario' may even consider the elimination of all or part of the risk through cessation or through the transfer or relocation of activities.

The involvement of downstream users is critical to define appropriate RMMs. However, this may be a challenge given that they may not be acquainted with the assessment of risk management measures and the exchange of confidential business information may constitute a hurdle for them.

In essence, this Guidance will look at how to perform:

The **simple I-RMOa:**

- **Anticipate and assist during regulatory reviews and challenges** by addressing data weaknesses in key data repositories such as the REACH Registration dossier and exploring Risk Management Options and assessing them on their merits. The outcome of such work can:
  - Identify the need for **updating** the REACH Registration dossier
  - **identify data gaps, or the need to collect data** to better understand the risks, assess progress, or identify the best RMO
  - **help structure the data** to contribute to work and discussions at different stages of the REACH process
    - Community Rolling Action Programme (CoRAP): Substances are then evaluated to better understand their properties, risks etc.

[2] Impurities are substances with no intended use that are part of the material stream. They may result equally from recycling as from the use of primary raw materials. Minor constituents are substances part of UVCBs that may or may not have an intended use. Equally they may result from recycling as from the use of primary materials. The assessment need and selection of tools for risk management for hazardous impurities and minor constituents is comparable with those of normal substances with exception of Authorisations which require an intended use.

- Public Activities Coordination tool (PACT): *Regulatory* Management Options Analysis by a Member State or ECHA in view of a decision on a risk management measure such as Candidate Listing and eventual Authorisation, Restriction or other measure (OEL e.g.)
- Identification of a Substance of Very High Concern (SVHC): the I-RMOa allows a structured and relevant input to public consultations
- Prioritisation of SVHC in view of Authorisation: relevant input to public consultations
- Restriction: relevant input to public consultations and other channels
- Authorisation: the I-RMOa allows to identify the data to gather (such as exposure) or the stakeholders t involve (Downstream Users) and will help shape and structure the further in-depth work on Analysis of Alternatives and socio-economic analysis.
- Any other regulatory measure at EU level: Regulatory measures options analyses may foresee processes under other EU legislation (such as the Directive on Carcinogens and Mutagens on the workplace (CMD), RoHS, … e.g.)

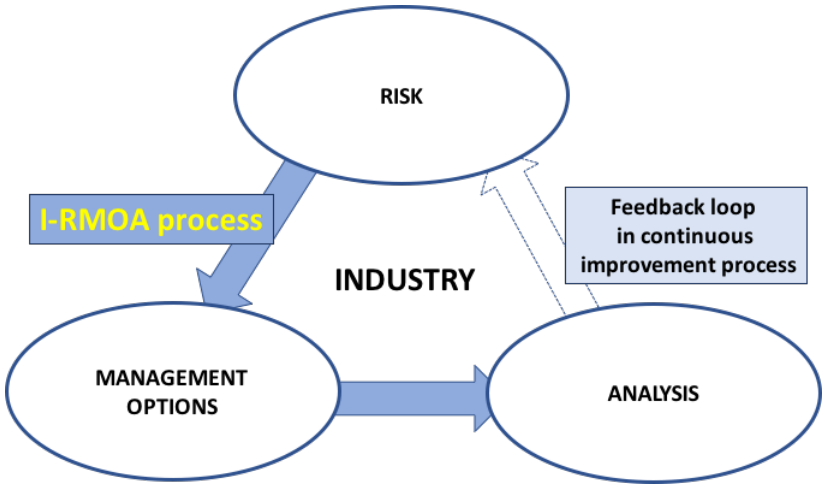
The integrated I-RMOa:

- **Follow-up on or assist in setting strategic company objectives** such as review of product portfolio in view of future investments, taking on-board new data on substance properties or exposures, etc.

- **Assist in value chain efforts to achieve measurable improvement in terms of risks** so as to help prioritize measures, identify and enter into dialogue with other stakeholders etc.

By establishing a systematic, coherent and transparent approach, the I-RMOa allows for an analysis that can be periodically reassessed, becoming a continuous process as illustrated in Figure 1.

FIGURE 1: I-RMOA AS A CONTINUOUS PROCESS



3. COMPARING THE REGULATORS' ANALYSIS VERSUS THE INDUSTRY ASSESSMENT

Table 2 compares a regulatory approach under REACH with an Industry analysis.

TABLE 2: OVERVIEW OF APPROACHES BETWEEN A REGULATORY- OR AN INDUSTRY RISK MANAGEMENT OPTIONS ANALYSIS

	Regulatory Management Options Analysis	Industry-Risk Management Options Analysis	
		Regulatory response	Regulatory-Industrial context (broader)
Purpose	• Identify a concern • Decide whether (further) regulatory measures are needed • Define the most optimal one(s)	• Provide industry data • Develop own view on the possible concerns • Suggest (more) optimal risk management options	• Identify risks that (may) need to be addressed • Identify data gaps relevant to RMOs • Define strategy related to a substance (sector or company-level)
Scope	• Substance • Its known uses • Impurities and minor constituents	• Substance • Known uses • Impurities and minor constituents	• Can be tailored to purpose (focus on specific use, specific segment of a supply chain or a wide view across supply chains impacted e.g.) • Considering the needs or constraints of other EU policies like CE and Climate
Analysis	• Need to address with new regulation? (otherwise, no action) • Which regulation might be considered? • What is the most proportionate approach? (Efficiency, efficacity, monitorability, consistency, enforceability…)	• 1 pillar analysis (up to now): chemicals management • Checks whether the concern is relevant in terms of risk • Looks for the regulatory and non-regulatory approaches possible • Discusses what would be the most proportionate option	• Up to 3 pillars analysis (Chemicals management, Circular Economy and Climate change, including energy) in function of relevancy • Complements analysis with mass balance assessments to identify possible 'hidden' priorities • Considers implications of a broader look beyond the substance as a product/article (up to impurity level) • Develop Circular Economy / Climate view
Management Options considered	• Limited to chemicals regulations or other existing EU legislation (WFD, …)	• Regulation • Alternatives or complements to regulation	• Can be tailored to purpose (focus on specific use e.g.)
Conclusions	• Regulatory conclusion to identify the relevancy and best option for risk management	• Possible alternative regulatory measure to regulatory conclusions or even voluntary measures that would be in line with the objectives with Chemicals Regulation in the EU	• Considers the pillars relevant (Chemicals management +…) • Anticipative actions (data gaps) • Remedial initiatives (company/branch level such as product stewardship etc.) • Company strategic decisions

IN SHORT

The I-RMOa and its wo main approaches

The I-RMOa aims at establishing a systematic, coherent and transparent approach of risks related to the use of substances.

I-RMOa offers a broad spectrum of possibilities of handling the identification, prioritization and management of risks which this Guidance document regroups under two categories:

- *The **simple I-RMOa:***

The **Simple I-RMOa** is very much related to an ongoing or expected regulatory management initiative. It may have a dual purpose:

- **Anticipate regulatory reviews and challenges** by addressing data weaknesses in key data repositories such as the REACH Registration dossier, exploring Risk Management Options and assessing them on their merits. The outcome of such work can:
  - Identify the need for **updating** the REACH Registration dossier
  - **identify data gaps, or the need to collect data** to better understand the risks, assess progress, or identify the best RMO, engage stakeholders etc.
  - **help structure the data** to contribute to work and discussions at different stages of the REACH process where it can i.a. provide input into a Regulatory Management Options analysis initiated at EU-level and the regulatory discussions following such an analysis.
- **Contribute during regulatory processes** by providing input during the drafting or consultation stages of a regulatory initiative.

Depending on the time available to industry, the analysis can be broadened to consider diffuse sources analysis or some life-cycle considerations to check the relevance of some regulatory measure or fine-tune it.

- *The **Integrated I-RMOa:***

When the available time allows or when a risk management measure assessment is performed independently from a pending or imminent regulatory initiative, the analysis can be much more holistic. An Integrated I-RMOa may then serve various purposes:

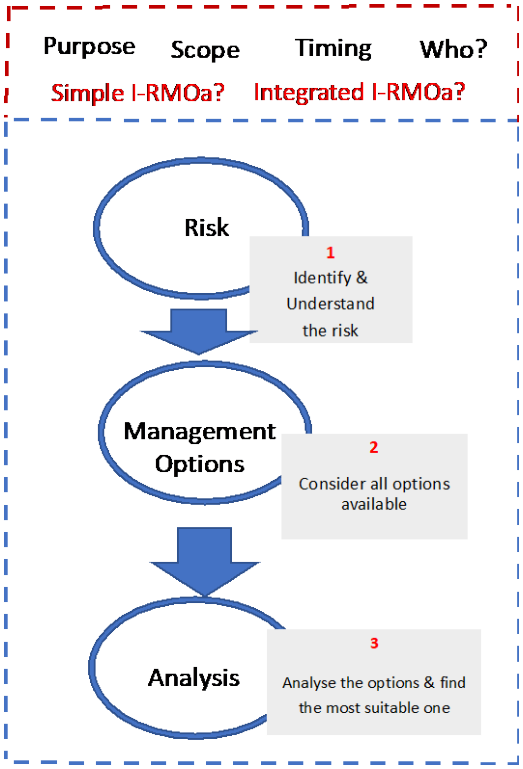
- **Develop and assess risk management measures** whose outline goes beyond the classical regulatory management (beyond 'one substance, one measure'), possibly integrating Circular Economy and Climate dimensions.
- **Respond to strategic company objectives** such as reviewing the product portfolio in view of future investments, taking on-board new data on substance properties or exposures to decide on future uses of substances in the production process, etc.
- **Assist in value chain efforts to achieve measurable improvement of risks** of as to help i.a. prioritize measures, identify and enter into dialogue with other stakeholders.

PART 2: A STEPWISE APPROACH TO I-RMOA

PREPARATORY STEPS

The chances of success of the I-RMOa may depend on the clarification, at the very beginning of several aspects, before the actual analysis starts as discussed below and illustrated in Figure 2.

FIGURE 2: THE FLOW OF AN I-RMOA



- The **purpose** of the exercise: from preparing input to an ongoing regulatory initiative to defining a substance management strategy at company or value chain level…

- The **scope** of the exercise: from having to address a substance that is under scrutiny to considering one or more substances for analysis in function of relevancy criteria.

- **Timing:** The success of the exercise will depend on matching expectations with the time constraints.

- **Deciding who should perform the I-RMOa**: individual companies, commodity organisations or substance consortia can perform I-RMOa, depending on the parameters identified earlier.

Once these basic steps performed, it will become clear what the I-RMOa approach will be: "**simple**" or "**integrated**".

The following pages will guide you through this preparatory process.

1. DEFINING THE PURPOSE

The Industry Risk Management Options Analysis (I-RMOA) can be performed to address

I. an **imminent or ongoing assessment by regulators**

II. a **variety of challenges or objectives** that may be proper to an industry branch or a company, such as an anticipative assessment of substances in companies' portfolios.

The approach in **case I**, where one responds to a regulatory initiative, leads to an analysis that is very scoped by the regulators' work, i.e. the regulatory management options under consideration. Industry will then focus on checking, refining or collecting data and on providing its take on the orientations suggested by the regulators. Deadline and formats will be mainly imposed by the regulatory process (public consultations etc.). This approach will be called **Simple I-RMOa**.

When the purpose is not to have to respond to a regulator's initiative, Industry has a broader lattitude of action and analysis. The I-RMOa can then serve many purposes and may include elements of consideration or solutions that go beyond regulatory instruments. This type of I-RMOa is designated by the expression **Integrated I-RMOa**.

identifying and addressing the risk management challenges under REACH: it may consider *other EU regulatory regimes*. Indeed, it is essentially an instrument to structure the exploration and development of risk management measures.

The I-RMOa approach presented in this guidance document contributes to focusing the minds of Industry stakeholders on a broad exploration of potential risks and risk management needs and to prioritise and structure the data collection and analysis. The approach should also help Industry to contribute credibly (when consulted) in the preparation of a regulatory RMOa and in the subsequent discussion and decision processes at EU level.

2. SETTING THE SCOPE: WHICH SUBSTANCES TO CONSIDER?

Two cases mainly can be considered: the scope is set either by a regulator's selection of a substance or by a non-regulatory entity such as an industry body or company.

The regulators' screening of substances for possible further consideration focuses mainly on the following information which will be extracted from the industry's Registration dossiers:

- Physico-chemical properties and hazard profile
- Volumes or Tonnage
- Uses, Exposure and monitoring data (environment and workplace, and if relevant consumers)
- Risk Characterisation Ratios (RCRs)
- Existing recommended risk reduction measures.

This process is 'automatic', thus unavoidable and **some *proactive* actions may be advisable. Industry should consider providing or complete some key data present in the Registration dossiers. The quality of the assessment following the method presented in this guidance document will to a large extent depend on the thoroughness of these proactive actions**.

When the choice of the substance is not dictated by an outside initiative such as an RMOa launched by a REACH Competent Authority e.g., it may be advisable to take some time in identifying substances that could or should be subjected to an anticipative I-RMOa.

ECHA'S VISION OF SUBSTANCES "THAT MATTER MOST"

At an ECHA-Eurometaux Workshop of 30 August 2016, Christel Musset, Director Registration at ECHA, reminded "what is at stake and expected" in REACH, and described ECHA's ideas for the period after 2018. The focus will be more on risk management of "**concerns, where it matters**" (hazard and exposure).

REACH aims at improving knowledge on hazard, uses and risks, at ameliorating communication in the supply chain, and achieving better safety and control measures. The objectives are to reduce exposure and the negative impacts of substances, and to gradually substitute hazardous substances with less hazardous ones.

ECHA's current focus is on "**substances that matter most**", namely the high tonnage registration dossiers with data gaps and with high exposure potential for workers, consumers or environment. ECHA's vision is however to move in the coming years, as illustrated in Table 3 below, to a situation where Risk Management is "in place" or "planned" and to reduce the number of substances of potential concern.

Broader EU policies ambitions that are part of the Green Deal such as the zero-pollution ambition for a toxic-free environment will no doubt influence the regulators' work plans. The Chemicals Strategy for Sustainability announces the **extension of the categories of substances likely to be covered by a regulatory management measure, beyond those substances qualifying as Substances of Very High Concern (SVHC, cf. Article 57).**

The Chemicals Strategy for Sustainability introduces the concept of **Substances of Concern (SoC)** which covers those substances that cause any chronic effect for the human health or the environment as well as substances that hamper recycling for safe and high quality secondary raw materials.

A new category of substances (Most Harmful Chemicals – MHC) focused initially on endocrine disruptors but later extended to mainlly Specific Target Organ Toxicity (STOT) and for which general bans by means of restrictions could be introduced, applicable to all their consumer uses (and later on to professional uses) except for those uses

that have been demonstrated to be essential to society (**essential use concept**).[3]

TABLE 3: POSSIBLE OUTCOMES OF SUBSTANCE SCREENING (ECHA INTENTIONS)

No regulatory action Substances for which available data suggest that no regulatory action is needed at present
Information generation required Substances for which there is at present uncertainty regarding the hazardous properties and/or the potential for release to the environment or exposure of humans; risk cannot be excluded although it cannot be established based on currently available data
Risk management required Substances for which there is risk and risk management has already been initiated or can be initiated on the basis of currently available data
Low priority substances Substances for which risk is unlikely but which need to be monitored

This ECHA vision constitutes an excellent basis for Industry when setting up its approach to a screening and assessing substances. However, this approach is subject to revision in function of changing EU priorities which will result in more substances being scrutinized for possible regulatory action within the REACH context *stricto sensu* or beyond (other EU regulatory instruments in the EHS field).

SCREENING FOR SUBSTANCES TO ASSESS

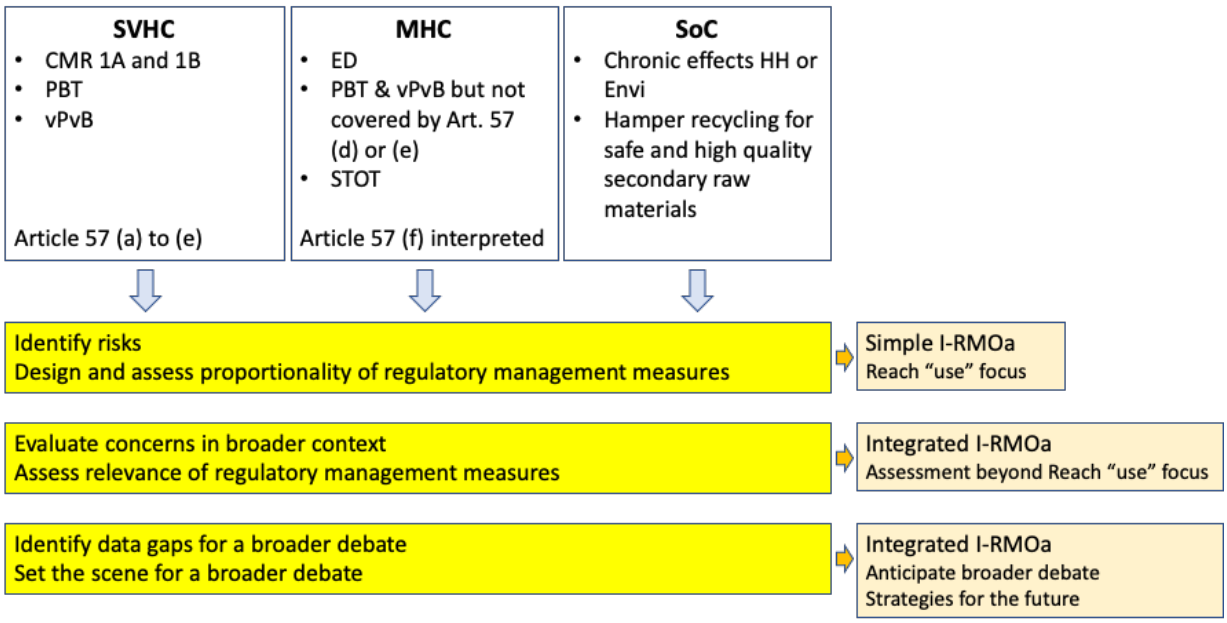
1. **Is the substance likely to be selected for further scrutiny through the ECHA screening process?**

a) *Is the substance likely to be concerned by a screening according to the SVHC Roadmap 2020 priorities?*

In the SVHC Roadmap, priority is given to substances with SVHC properties with uses within the scope of Authorisation (non-intermediate uses, in particular). For these substances – as illustrated by Figure 3 - with an SVHC profile, the Industry approach will ideally (if time permits) focus on setting the context as well as on assessing the Risk Management Options in a regulatory context. However, the tools at hand also allow to prepare for future challenges at company or at sector level.

[3] The Essential Use concept will be further defined by the European Commission in 2021. Depending on its definition, criteria and scope of use, it may make an update of this guidance document necessary.

FIGURE 3: SVHC – MHC AND SOC SELECTION VS. I-RMOA TYPES



However, ECHA's screening activities cover substance groups other than CMRs (cat 1A/1B), PBTs or vPvBs:

For Human Health:

- Sensitizers;
- Endocrine disruptors (EDs);
- Substances with Specific Target Organ Toxicity (STOT RE).

For the Environment

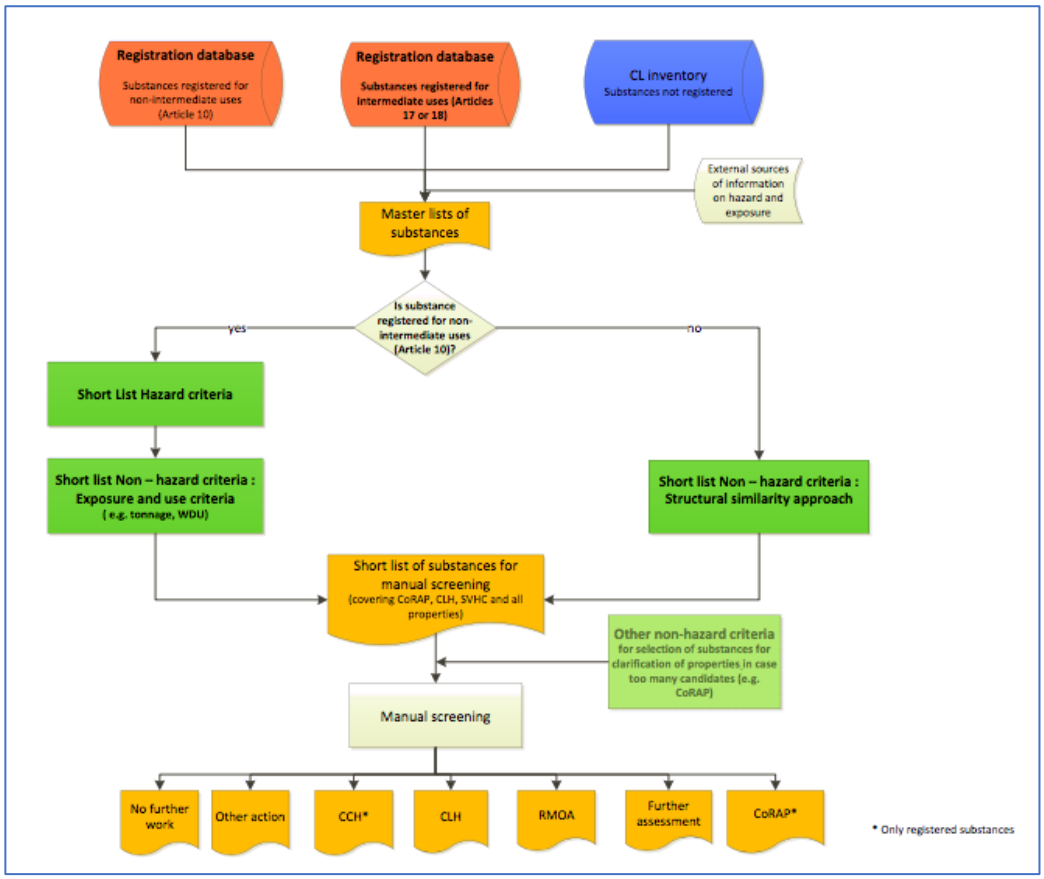
- Endocrine disruptors (EDs).

They are considered as of *equivalent concern* and some of them are included into the category to be known as of now as Most Hazardous Chemicals.
The SVHC Roadmap gives priority to substances registered for non-intermediate uses, given that intermediate uses are out of scope for authorisation. Screening and later on, RMO analyses of these registered substances are referred to as the "Core Activities" in the SVHC Roadmap implementation plan.

b) *Is the substance likely to be concerned by a screening not directly related to the "Core Activities" of the SVHC Roadmap?*

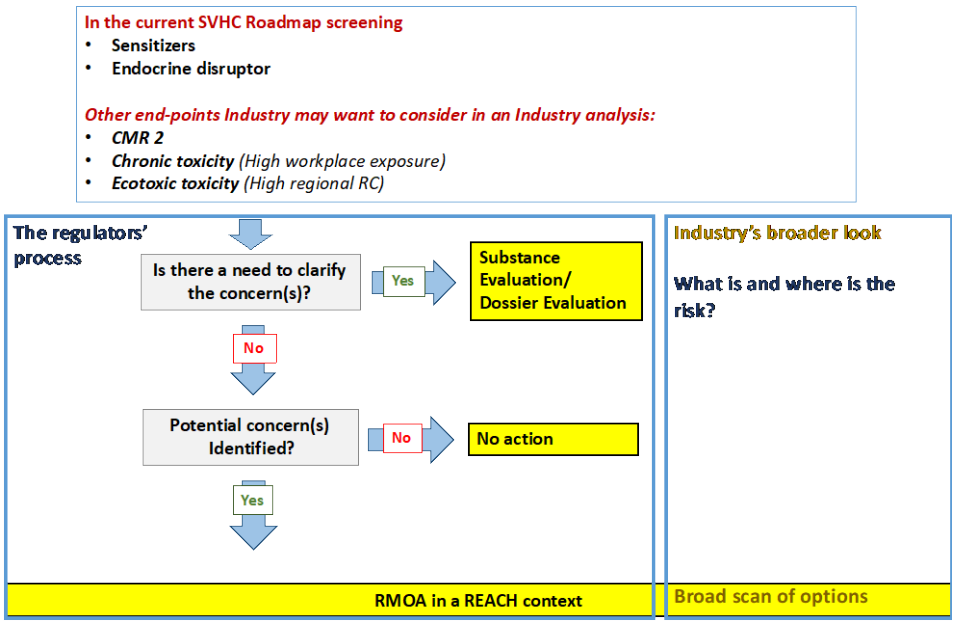
At this point, it may be relevant to refer to ECHA's Screening Definition Document released in January 2016 under the title *Scenarios to be Implemented for Searching Potential Substances of Concern for Substance Evaluation and Regulatory Risk Management.* It provides an illustration that a broad scoping of substances for Risk Management assessment, beyond the REACH Regulation criteria for SVHC selection, can make sense.
Screening scenarios are evolving – cf. with the Chemicals Strategy for Chemicals - and hence, even in the REACH context, there may be a definite case for anticipating and initiating an assessment (see Figure 4)

FIGURE 4: THE DIFFERENT SCREENING STEPS BY ECHA



The main additional hazard criterion that has been included in the Screening strategy of ECHA is **the Long Term Environmental Hazard *and* Fate**, both criteria of importance for metals and inorganics. Under the extended screening scenario and beyond (anticipation, strategy-setting) the approach might be summarized as outlined in the following illustration (Figure 5) where we see how the regulator's approach may relate to an Industry view.

FIGURE 5: DECISION CRITERIA FOR CHOOSING BETWEEN THE BROAD I-RMOA OR THE I-RMOA IN REACH CONTEXT



Recommendation:

The regulators' screening focuses mainly on the following information which will be extracted from the industry's Registration dossiers:

- Physico-chemical properties and hazard profile
- Volumes or Tonnage
- Uses, Exposure and monitoring data (environment and workplace, and if relevant consumers)
- Risk Characterisation Ratios (RCRs)
- Existing recommended risk reduction measures.

This process is 'automatic', thus unavoidable and **some *proactive* actions may be advisable. Industry should consider providing or complete some key data present in the Registration dossiers. The quality of the assessment following the method presented in this guidance document will to a large extent depend on the thoroughness of these proactive actions**.

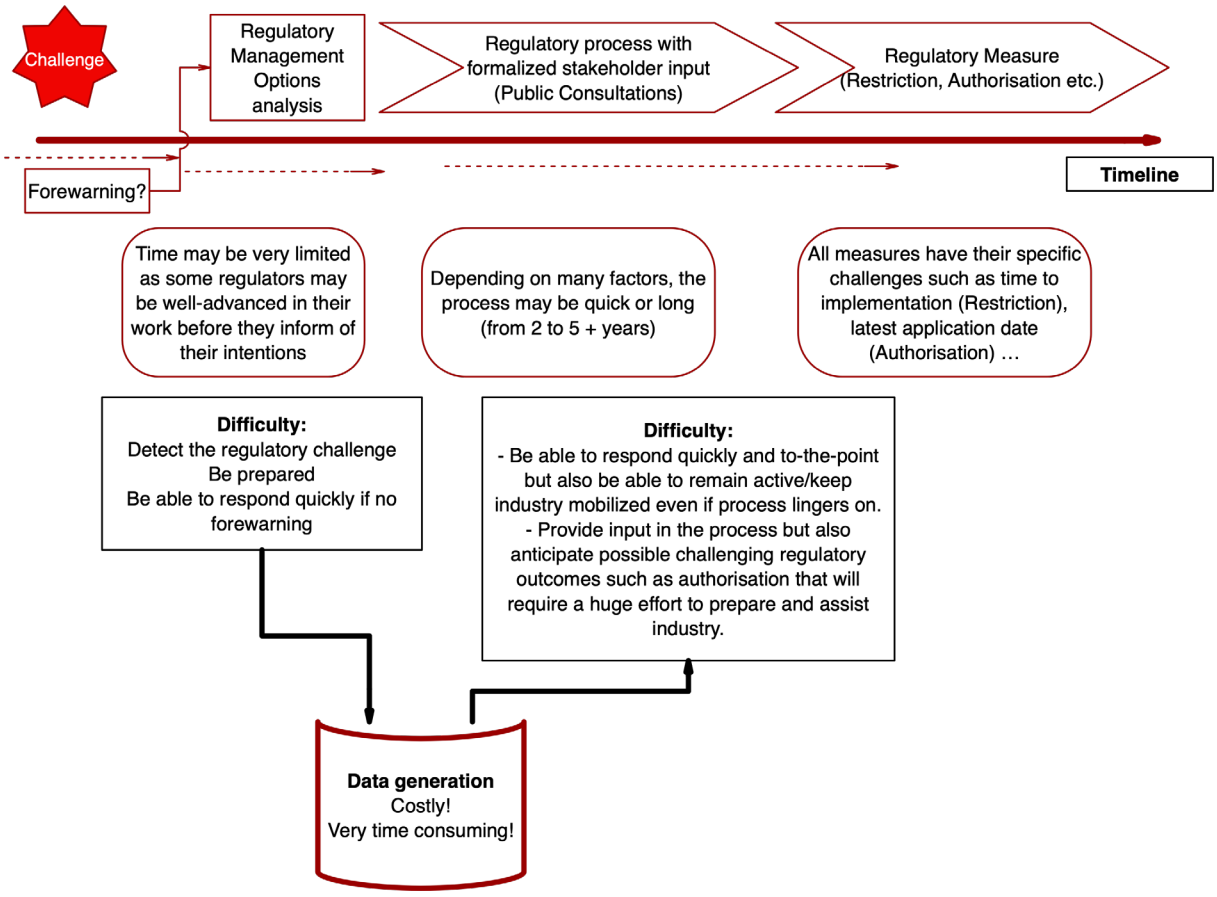
The general advice on when to get started is to conduct an RMOa screening for all substances meeting the SVHC 2020 Road Map criteria or broader (cf. Eurometaux briefings on the evolving criteria) and to get started as early as possible, so as to have enough time to develop a coherent view on how to approach the substances when they'll get scrutinized by authorities.

3. TIMING CONSIDERATIONS

An I-RMOa can be a challenging exercise in terms of time constraints and resources to mobilise. In the case of a *Simple I-RMOa*, the process may start with an ongoing or anticipated regulatory initiative that may result in a regulatory management measure addressing the use of a substance.

Once the process has been started, it will advance according to its own dynamics that are often unpredictable. Figure 6 sketches out some of the considerations one should have in mind when a regulatory challenge may be looming ahead. Once the challenge there, choices may have to be made in terms of what type of data and detail can be gathered, which may have consequences in terms of the assessment regulators will make of industry input.

FIGURE 6: TIME CONSIDERATIONS OF A SIMPLE I-RMOA



Advice: Consider an anticipation strategy (inventory of substances of potential concern, preparatory data collection or data collection strategy, use update of registration dossier to collect and provide data that may be helpful to a regulator…).

The time challenge for an Integrated I-RMOa will be different as the broader the assessment, the more time and resources will be required.

4. A LOOK AT WHO PERFORMS THE I-RMOA

As the I-RMOa, or parts of it, can be performed at different stages of regulatory processes such as the 'turbo-charged' risk management phase REACH has entered into, it may be interesting to consider what type of activities different actors may engage into during these different processes that may take several years.

We discuss here the roles which can be taken up by the different Industry actors. The REACH processes will be a key driver, but it needs to be stressed that the I-RMOa is a tool that can be resorted to independently of a particular regulatory challenge under REACH. The **scoping** of an I-RMOa will determine what exactly will be done, when and by whom i.e. companies, commodity organisations/trade associations or consortia.

A. COMPANIES

Companies which should get involved are all those directly concerned by the use of a substance likely to be scrutinized or under RMOa review.

Companies as part of a broader effort:

- Consortia will often be pivotal in raising awareness of Downstream Users and getting them involved. If consortia have an essential role in helping to set the broader picture of hazards, risks and exposures, downstream users, being the effective users of the substance, have a huge interest in considering their strategy vs. the use of the substance in question.
- The Lead Registrants and their Co-Registrants will be first in line at the stage of Evaluation (CoRAP), but Downstream Users enter into the picture as soon as the debate ventures into the uses and exposures.

Companies on their own:

- The RMOa exercise can be a tool for company planning in terms of material choices, investment or product portfolio. Companies may want to explore their options and the outcome of the exercise will inform their strategies.

The type of analysis and their objective will depend largely on where one stands in the regulatory process as illustrated in Table 4.

TABLE 4: INDICATION OF I-RMOA ACTIVITY OF A COMPANY AT DIFFERENT STAGES OF A REGULATORY PROCESS

Company	Before regulatory review or initiative	During regulatory process
Data	Anticipate - check – collect – understand the risks	Collect and share what is relevant and when relevant (cf. different stages of Public Consultations e.g.)
Risk Management Options	Identify RMOs	Communication if deemed relevant
Analysis of most proportionate RMO	Understand the strengths and weaknesses of the different RMOs and choose the most adequate	Communicate findings, if possible/relevant
Next steps	Decide and implement strategy (substitution plan, defend uses, set up communication with value chain etc.)	Act in function of strategy: - Defend uses in Authorisation/Restriction processes - Adapt substitution plan to regulatory deadlines

B. COMMODITY ORGANISATIONS

The risk management phase of REACH which will get into full speed once the 2018 Registration deadline is passed, involves dimensions such as advocacy and integration of societal pressures and acquaintance with regulatory instruments outside REACH. Industry needs may include assistance in getting the value chain organised for Authorisation. Such types of activities go beyond the usual remit of REACH Consortia, hence an important role for commodity organisations.
Table 5 provides an indicative overview of possible activities of commodity organisations in this context.

TABLE 5: INDICATION OF I-RMOA ACTIVITY OF COMMODITY ORGANISATIONS AT DIFFERENT STAGES OF A REGULATORY PROCESS

Commodity organisations	Before regulatory review or initiative	During regulatory process
Data	Anticipate - check – collect – understand the risks	Collect and share what is relevant and when relevant (cf. different stages of Public Consultations e.g.)
Risk Management Options	Help Industry identify RMOs	Communicate about this if and when useful and desirable
Analysis of most proportionate RMO	Assist Industry in understanding the strengths and weaknesses of the different RMOs and choose the most adequate one. The commodities' closer association with authorities, NGOs and civil society at large can be very valuable. Commodity organisations are also involved in scientific and advocacy activities related to other EHS policy domains, which are a valuable input in the discussion of the proportionality of RMOs	Communicate findings, if possible/relevant. Open channels for dialogue
Next steps	Implement strategy (data collection, setting up communication with value chain etc.)	Act in function of mandate which may be: - Advocacy - Organisation of Industry (communication, facilitation of exchanges in value chain, assistance in setting up of co-operation frameworks for Authorisation/Restriction etc.

C. CONSORTIA

As alluded to in the earlier paragraph on commodity organisations, Consortia have been set up with as key responsibility the production and upkeep of the REACH Registration dossier. As the Registration dossier will be the data source by excellence in the REACH risk management phase, Consortia will have a key role in the provision/collection/processing of the data that are necessary for the I-RMOa. Considerations of regulatory proportionality and advocacy are most often foreign to a Consortium's mandate hence the need for a close connection with, in particular, commodity organisations.

Table 6 provides an indicative overview of possible activities of consortia., which will be refined, as for the other actors, in the scoping phase of the I-RMOa.

TABLE 6: INDICATION OF I-RMOA ACTIVITY OF CONSORTIA AT DIFFERENT STAGES OF A REGULATORY PROCESS

Consortia	Before regulatory review or initiative	During regulatory process
Data	Have a system in place to anticipate data needs - check data – collect data. Assist in their interpretation.	Collect and share what is relevant and when relevant (cf. different stages of Public Consultations e.g.)
Risk Management Options	Help Industry identify RMOs	Communicate about this if and when useful and desirable
Analysis of most proportionate RMO	Assist Industry in understanding the strengths and weaknesses of the different RMOs and choose the most adequate one. The consortia's grasp of the uses along the value can provide valuable insights on where data collection and discussion efforts should be focussed	Communicate findings, if possible/relevant. Open channels for dialogue
Next steps	Fulfil regulatory obligation of keeping up to date the REACH Registration dossier (together with the Lead Registrant) and interact with the commodity organisations to open communication and data channels with the broader value chain	Act in function of strategy decided by companies, which may be: - Advocacy - Organisation of Industry (communication, facilitation of exchanges in value chain, assistance in setting up of co-operation frameworks for Authorisation/Restriction etc.

5. CHOOSING BETWEEN APPROACHES AND ORIENTING PRINCIPLES OF AN INTEGRATED I-RMOA

The difference between the two I-RMOa approaches described in the guidance resides in the ambitions of the initiators of the I-RMOa (type of assessment aimed for) and in the constraints that weigh on them.

Such constraints may be the regulatory framework, an ongoing regulatory process, the availability of data, the motivation of participants and supply chains etc. Most often, the timing constraints will weigh heavily on what can be done.

The Table 7 and .Table 8 sketch out the first decisions leading to either a more limited REACH RMO-related approach (simple I-RMOa) or a broader effort (Integrated I-RMOa):

TABLE 7: I-RMOA APPROACHES IN FUNCTION OF ASSESSMENT

DESCRIPTION OF ASSESSMENT	AIM	I-RMOA TYPE	
		Simple I-RMOa	**Integrated I-RMOa**
Collection of data for contribution to likely or ongoing RMOa's	Contribute timely data to Member States performing RMOa's	Work is focused on the main points of attention of Member States	The scope of the integrated approach will depend on the scope of the regulator's exercise and the margin of manoeuvre (time, resources, ambition)
Audit of available information in CSR and beyond	Address data relevant to RMO analysis Including the Identification of the appropriate RMO (and type of RMOa)	Under time pressure, work will be focused on the main points of attention of Member States	Check whether there is info that makes it possible and worth broadening the analysis
Critical self-reflection within sector or by companies	Identify potential need for RMM	Can be part of the risk audits that companies often perform. Effort may be done at sector level when not restrained by competition rules	Allows holistic approach (combining different analysis tools, considering various policy and society dimensions etc.)
Internal company audit	Identify remaining risks and most efficient RMM	Limited impact of individual companies on regulatory choices, but can be part of improvement processes mentioned above	Allows companies to identify RMM pathways and substance/product strategies

An Integrated I-RMOa is not performed in isolation of wider contexts and considerations. It is expected to create value to the participants as well as to other stakeholders such as authorities, through the quality of the data and the pertinence of the analysis, hence the principles in Table 8.

TABLE 8: PRINCIPLES FOR AN INTEGRATED I-RMOA

The I-RMOa should	Comment
Create value	Resources used to address the risks should be optimised (positive cost-benefit outcome) Business uncertainty should be reduced The timely (re-)orientation of business strategies can contribute to competitiveness
Become part of organizational processes	It can help Consortia set their priorities and identify the data that will have to be collected so as to be prepared, e.g., for any regulatory initiative. Can be part of the companies' management tools, including feedback systems (reporting, ex-pots assessment, adaptation)
Become part of decision-making process	A tool to help outline substance/product strategies
Systematically address knowledge challenges**, aiming at being best on best available data**	A tool for informed decision (internally) and informed discussion with stakeholders
Be adapted to the needs	A fit-for-purpose I-RMOa is defined during the scoping phase, at the initiation of the process
Be aware of biases	The objective of a systematic approach is to understand, try and limit the risks and impacts of human factors/biases
Be holistic	Consider the entire lifecycle of a substance or even the materials flow of the metal element and its compounds, and integrate considerations (the regulatory environment (CE, Climate, …) and its expected evolution, societal concerns, factors affecting competitive situation etc.)
Be transparent **and** inclusive	The analysis and its outcome will have to sustain scrutiny of biases as each stakeholder has its own approach, culture and constraints. Even for an internal assessment of risk management options, biases may constitute a risk.
Be creative**, iterative and able to integrate to** change	Can be part of an innovative search for solutions; an opportunity for strategic choices
Be re-assessed **from time to time**	The re-assessment can be either to check the validity of the data or of the I-RMOs. It can also integrate the returns from the implementation of the risk management measures

To consider before starting an I-RMOa

- The EU authorities have set out a strategy to scrutinize substances that may be of Very High Concern in the SVHC Road Map 2020.
- The SVHC Road Map should guide industry when selecting the substances which it would need to consider in an I-RMOa, when not having to respond to an immediate challenge such as the initiation of a Regulatory Management Options analysis by a Member State.
- However, one should consider the possibility to extend the criteria for selecting a substance for an I-RMOa as political pressure mounts to include in the SVHC discussion other criteria as being of “equivalent concern”.
- Companies, consortia and commodity organisations have complementary interests in an I-RMOa exercise, and their precise roles will have to be defined at the start of the exercise.
- On top of the policy agenda, the difference in depth, including types of data to be collected and assessments to be performed, and the time available will provide the decision elements for a choice between a simple I-RMOa and an Integrated I-RMOa.
  Developing an anticipative I-RMOa strategy may be of critical importance as an I-RMOa is a resource- and time-consuming exercise. One should never underestimate the challenges of addressing data gaps.

PART 3: INDUSTRY-RMOA IN PRACTICE

The I-RMOa approach as developed in Part 3 proposes to cover ground *beyond the regulatory scope of an RMO Analysis in the SVHC Roadmap 2020* context, *sensu stricto*, as there is, with the Green Deal, a need for integrating the manifold of green priorities into the Risk Management measure discussions so as to achieve a holistic and effective approach for metals and inorganics..

It will be presented as a three-pillar exercise consisting in:

- **Pillar 1:** The I-RMO analysis in the chemicals management sphere which can be split between a reactive exercise (responding to a regulatory management options analysis initiative) and a more holistic approach (pro-active or even strategy-oriented)
- **Pillar 2:** When relevant, the Circular Economy dimension is considered, and the risk management options considered under pillar I will be put to the test of circular economy priorities.
- **Pillar 3:** Also, when relevant, the Climate Change dimension will be considered and the risk management options under pillar I will be looked at from the Climate policy perspective.

The guidance will start from the REACH context while additionally suggesting new approaches that will help extend the analysis beyond what is currently considered a standard Regulatory Management Options analysis.

Pillar 1 describes the **Industry-Risk management Options analysis** from a 'purely' chemicals management point of view, although it will gradually integrate broader considerations (socio-economic mainly).

Initially focused on SVHC selection and thus *eventually* Authorisation or Restriction, the risk management policy under REACH has started opening up to other risk management options. The realisation has come that the identification of so-called 'Substances of Very High Concern" (SVHCs) (and thus at a later stage prioritisation and Authorisation) may not always be the most adequate Risk Management Option and that all relevant regulatory option should be considered earlier in the process.

Industry has the opportunity to contribute in the exploration of a broader spectrum of risk management options and this Guidance aims at facilitating this. Moreover, this Guidance has already proven useful in a broader context, beyond REACH.

And finally, the I-RMOa may also be a tool for industry to assess the quality of its data so as to prepare for regulatory reviews. It may be used as a tool by a single company to perform its own risk management assessment.

The key elements of a 'standard' I-RMOa, are to be structured along the following generic scheme. This scheme reflects a broad consensus on what is needed to make an informed decision. It is built on data should be collected as early as possible so as to 'inform' the exercise.

Of course, if the substance has been identified for assessment – has been put on the PACT list e.g. – some identification steps described hereunder can be overlooked.

1. THE SUBSTANCE

The definition of the substance to consider will depend on the regulators' selection criteria or on an industry strategic consideration as outlined in the section 2. "Setting the Scope: Which substances to consider?".
It is important to consider the regulator's views of substances that matter most (extended to the substances now also considered by the Chemicals Strategy for Sustainability) and understand the principles of substance screening.

In practice, the challenge consists in identifying in a 'neutral' way, substances for which an RMOa may be useful or required in view of the current regulatory environment and prospects of evolution. This allows to get a view on the likelihood that the substance may be considered for a regulatory assessment/RMOa.

The following checklist will help:

CHECK-LIST: SUBSTANCE SELECTION

1. **What does the Registration dossier say about the hazard profile vs. criteria in the REACH Regulation or the selection criteria of the screening system put in place at ECHA or even upcoming concerns in society?**

2. **Is the picture of hazards complete?**

    1. Do we have all relevant endpoints covered? Is the quality of the assessments satisfactory or are there still some endpoints under scrutiny? What is being done about it such as substance evaluation by a regulator or a testing proposal by Industry?

    2. What is the possible impact of remaining uncertainties?

3. **Do we have an unambiguous picture of hazards to be checked along the supply chain or will the analysis (also) cover a potential issue due to societal trends?**

4. **Is there a need or is it relevant to consider the presence of/exposure to/hazardousness of the substance in a broader context?** A more holistic view considering natural background, direct and indirect anthropologic input may help put the risks into perspective and identify the most adequate risk management option

2. UNDERSTANDING POTENTIAL RISKS THROUGH USES, VOLUMES AND EXPOSURES THROUGHOUT THE LIFE CYCLE

Once the substance that may fall under a regulatory scrutiny identified, its fate along the supply chain, actually its entire lifecycle should be mapped in view of establishing whether there is a (potential) risk

CHECK-LIST: FATE OF SUBSTANCE IN SUPPLY CHAIN AND LIFECYCLE AND IDENTIFICATION OF POTENTIAL RISK

1. **Uses**

    1) Is the Registration dossier complete in the description of uses and are these descriptions relevant for understanding exposure?

    2) Do these descriptions provide indications of the functionality of the substance?

2. **Volumes** (tonnages per Use)

    3) **Material flows (ideally)**

    For each step of the substance and product lifetime; starting from raw materials, manufacturing, down the supply chain. This will allow to illustrate how the substance enters the EU market (import and production including refining and recycling). The "first uses" can then be sketched out (for example a metal compound being used for catalyst manufacturing, surface treatment, batteries, pigments etc.) and the end uses should be identified as well. This is often where the substance is integrated into an article that will find its use in an end-use sector such as the automobile sector. Even if the end-users are not legally concerned by an Authorisation process, they may be critically impacted, hence the importance to identify them and possibly involve them in the process if and when needed. An example has been the heavy involvement of the aeronautics industry in the Authorisation process for chromium trioxide.

    4) **Specific** aspects related to the **nature/fate of the substance**

        1. What about substances entering the supply chain and industrial processes as impurities contained in natural resources (e.g. arsenic)?

        2. Is the substance present in materials that are later recovered for recycling?

    5) **Physical form of the substance, and how it may change at each step of the life cycle**: a substance may go through different physical forms (liquid, powder, massive as such or in an alloy e.g.) each of these forms having a different exposure or emission potential.

    6) Check if the substance doesn't change **speciation** during its uses or some of its uses (cf. from a metal salt to the metal during surface treatment, substance changes formula etc.). This has implications on the life-cycle assessment (cradle-to-cradle approach) as the fate of the substance would stop there.

    7) Production of **articles** (i.e. volumes involved), and potential for release of the substance from articles during use.

    8) **End-of-Life.** What is the final fate of the substance? Will the substance be recycled? Do the concerns materialise into risks that might justify a Restriction e.g.?

3. Exposure

9) Identification of **(potential) exposures/risks**.

10) **Risk characterisation for the different exposure scenarios** (Registration dossier). The Risk characterisation scenarios (RCR) should be discussed and an uncertainty analysis performed so as to refine or qualify some of the assessments (Is the RCR over conservative? What does a reality check provide as feedback? Is there a possibility that an authority carrying out the RMOa would set aside the DNEL in the dossier and recalculate the RCRs based on an alternative exposure limit value?) This introduces an analysis of the uncertainties about the existing RCRs. If on the basis of a more conservative exposure limit, the recalculated RCRs remain significantly below 1, then there should be no need for risk management. This Guidance takes into consideration the fact that authorities may want to proceed further with their analysis on the basis of the intrinsic properties of the substance.

PRACTICAL ILLUSTRATION

The possible areas of concern can be considered, according to the life cycle stages for the metal substance:

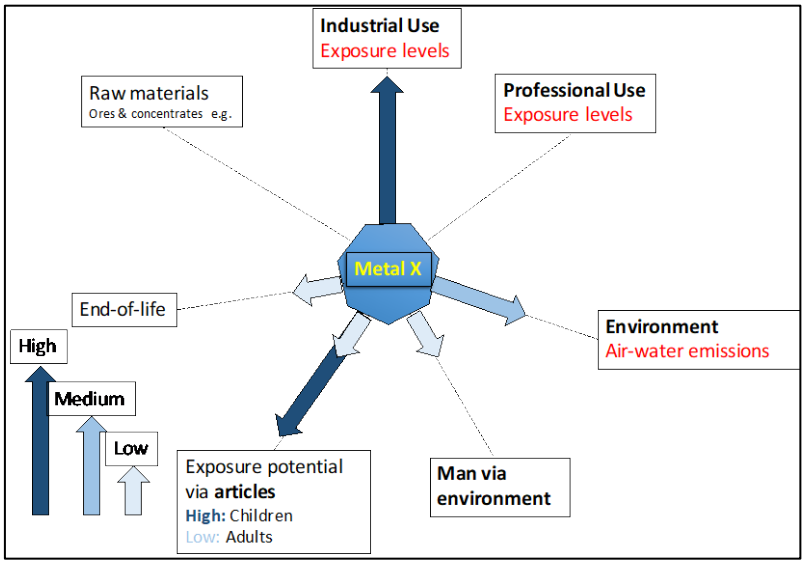
- Raw materials (e.g. ores and concentrates)
- Industrial and Professional use;
- Environment, and Man via Environment;
- Articles/consumers; and
- Recovery/recycling and end-of-life (EOL).

Approach: A first overview can be obtained by consensus between industry experts. The exercise is then to build consensus on where **all** the potential concerns may arise.

During a Eurometaux workshop, a group of industry representatives (i.e. REACH Consortia Managers and member companies) came up with a description of all potential areas of concern they were aware of for **manufacturing and use of a specific substance**. Participants were asked to rate the level of concern (from low to high). This type of group exercise has already proven to be a very useful way of focusing the minds of those who will have to support or perform the more in-depth work afterwards.

The possible areas of concern for manufacturing and use of the substance are shown in Figure 7, below, looking at its entire life cycle. In this example, potential concerns were identified and ranked per significance at occupational level (industrial and professional uses), in the environment (air and water emissions) as well as with articles that could create exposure.

FIGURE 7: EXAMPLE OF HOW TO PRESENT THE AREAS OF CONCERN IN MANUFACTURING AND USE OF A SUBSTANCE (LIFE CYCLE APPROACH)



To be more in line with the type of assessment that will be performed by a Member State or ECHA and to facilitate communication, the areas of concern may also be considered more closely to confirm whether there is a risk that should be addressed. For that purpose, the RCRs in the Registration Dossier can quickly provide precious indications (ANSES proceeded this way in its RMOas on Nickel Sulphate and Nickel Oxide). However, this may require preparatory work to conduct sensitivity and uncertainty analyses looking at the RCRs and other factors as well as a discussion on the grey zone close to a RCR close to 1 (see Table 9).

Some concerns feature higher on the scale of societal concerns than others, for example children's' health. If such a concern is encountered, it will be difficult not to take it up in the further RMOa. Societal concerns that are not immediately related to the environment or human health (such as coherence with other EU policies) may be part of the analysis but at a later stage, when the proportionality of the different Risk Management Options is discussed.

TABLE 9: RISK CHARACTERIZATION RATIOS TO IDENTIFY POTENTIAL RISK TO ADDRESS

Risk Characterisation Ratio (REACH Registration dossier)		
< 0.7	Between > 0.7 and < 1	**> 1**
Provided data are robust, concern may not have to be considered in an RMOa	Grey zone to be discussed because of its proximity to an RCR of 1	RMOa necessary to design a risk management measure

This leads to applying the following line of reasoning:

1. If the RCRs, even based on the most conservative exposure limit value that an authority may select, do remain (significantly) below 1, then in principle one may decide not to proceed further.
2. If the RCRs, or the most conservatively recalculated RCRs, are equal to 1 or higher, the RMOa exercise should continue for the relevant uses.
3. It is possible that the authority carrying out the RMOa decides to identify a risk based essentially on the intrinsic properties of the substance (hazard). It is therefore recommended that the RMOa exercise be also considered for uses where the (possibly recalculated) RCRs are below 1 as shown in the grey zone of Table 9.

3. MAPPING CURRENT MANAGEMENT ENVIRONMENT AND REGULATORY STATUS OF THE SUBSTANCE

At this stage and before risk management measures are developed, it is useful to understand whether regulators or Industry have already put in place instruments to manage the (potential) risk.

That overview of regulatory or voluntary instruments will be useful in the assessment of the need for additional measures to efficiently manage risks.

The review may highlight shortcomings in existing measures, the causes of which can be diverse: incomplete geographical coverage, divergence of scope and severity, not up to date with scientific knowledge, weak enforcement and reporting etc. It will inform the listing and discussion of any RMO.

CHECK-LIST: CURRENT MANAGEMENT ENVIRONMENT

1. **Existing regulatory framework:** What are the regulatory schemes in place at national and EU level? This will cover REACH, the Water Framework Directive, the waste framework directive and many other schemes regulating the substance, the processes in which it is used, or articles containing it.
   This overview may have to be refined later on, with the further analysis of the fate of the substance as there may be uses that will be discovered or better understood.

2. **Regulatory status of the substance** regarding the REACH regulation will be important for the further discussion of possible risk management. A substance used only as an intermediate will not qualify for authorisation and another regulatory approach may be required, such as restriction or occupational exposure limits.

3. **Non-regulatory management schemes** such as product stewardship involving the substance: Examples of such schemes are the Voluntary Emissions Control Action Programme (VECAP) which is to reduce potential emissions of flame retardants to the environment through the promotion of manufacturing best practice throughout the value chain[4]. Some of those systems are the result of an agreement between government and Industry, such as BEBAT (collection and recycling of batteries in Belgium)[5] whilst others may consist in social dialogue-type of approaches involving employee and employer associations as for example NEPSI, the European Network for Silica.

4. **Assessment of the existing regulatory and non-regulatory schemes:** Prior to designing possible new risk management measures, the existing ones should be assessed so as to establish whether they are suited to address the possible and/or remaining issues identified. This assessment of strengths and weaknesses of the existing measures will be critical in the further RMOa discussions.

[4] VECAP is run by BSEF, an international bromine production association (http://www.bsef.com/product-stewardship/)

[5] http://www.bebat.be

4. IDENTIFICATION OF RISK MANAGEMENT OPTIONS

Options will have to be considered in line with the EU policy objectives, such as protection of man and the environment, therefore favouring 'risk removal' (i.e. substitution of the problematic substance), to 'risk reduction' (exposure reduction). This hierarchy will play a role when trying to identify the most adequate RMO.

CHECK-LIST: RISK MANAGEMENT OPTIONS

1. **All potential options should be listed**, irrespective of the perception one may have of their pertinence. Assumptions on workability or acceptability may be discussed later in the exercise, but the purpose of the listing is to force those performing the RMOa to consider the views of other stakeholders as well as to explore/discover the merits of counter-intuitive approaches.
2. **All potential options should be clearly defined in scope and content,** i.e. their content (scope, basic definitions) should be clear in the minds of the assessors.

   This requires a careful approach that may encounter several difficulties:

   - There could be different ways of approaching a Restriction, either on its own or in combination with an Authorisation.
   - The option of Substitution is likely to be approached differently by a company or by a substance consortium. Experience has shown that it will be a case-by-case decision on how to proceed with this.

In practice, one may proceed in **two steps in the listing of RMOs**:

1) **First list:** Listing of the regulatory/risk management options per area of potentail concern.
2) **Second list:** Processing of the first list to produce a refined set of RMOs for the analysis

STEP 1: FIRST LIST OF RMO'S

If action is required, one should *per area of potential concern*, consider the following options (see also list in Annex I):

- Substitution (Industry initiative / mandatory through a regulatory measure)
- Existing legislation related to workplace safety and industrial settings (Occupational Exposure Limits (OEL)), the Industrial Emissions Directive (Best Available Technologies Not Entailing Excessive Costs (BATNEEC), the water Framework Directive (Environmental Quality Standards (EQS)), etc.)
- Harmonised Classification under CLP
- Substance Evaluation under REACH
- Restriction under REACH
- SVHC selection and Candidate Listing
- Authorisation under REACH
- Restriction under RoHS, etc.
- Water Framework Directive
- Other EU legislation
- **Other Risk Management Measures possible?**

One should start to identify a list of possible RMOs for the substance, per area of potential concern (see illustrative list in Annex I).

The initial exploration of the potential risk management options may lead to an opinion that an option may not be workable in the timeframe set by regulators or be extremely difficult to implement (too diverse sector, too many actors etc.). However, none of the identified options should be excluded and the participants of the exercise need to remain objective and unbiased at this point, as the next steps in the exercise will be to compare the options in terms of feasibility and other factors.

PRACTICAL ILLUSTRATION:

To assist in the listing and discussion of "potentially relevant or feasible RMOs", a graphical illustration as shown in Figure 8 below may help. In the example shown, concerns were identified (and possibly confirmed in terms of risk) in the workplace and in the man via environment endpoints. For the other areas, there may be no concerns, or these may already be addressed adequately. Figure 9 illustrates the speciation challenge when considering the fate of some substances.

FIGURE 8: EXAMPLE OF POSSIBLE RMOS IN THE CASE OF CHROMIUM VI WHERE TWO AREAS OF CONCERN WERE IDENTIFIED

The concern was qualified as of medium level, i.e. justifying a further RMO analysis. Please note that the assessment also allowed to highlight that the absence of concern in other areas was resulted from the fact that the substance had been transformed into a non-toxic form (Cr metal).

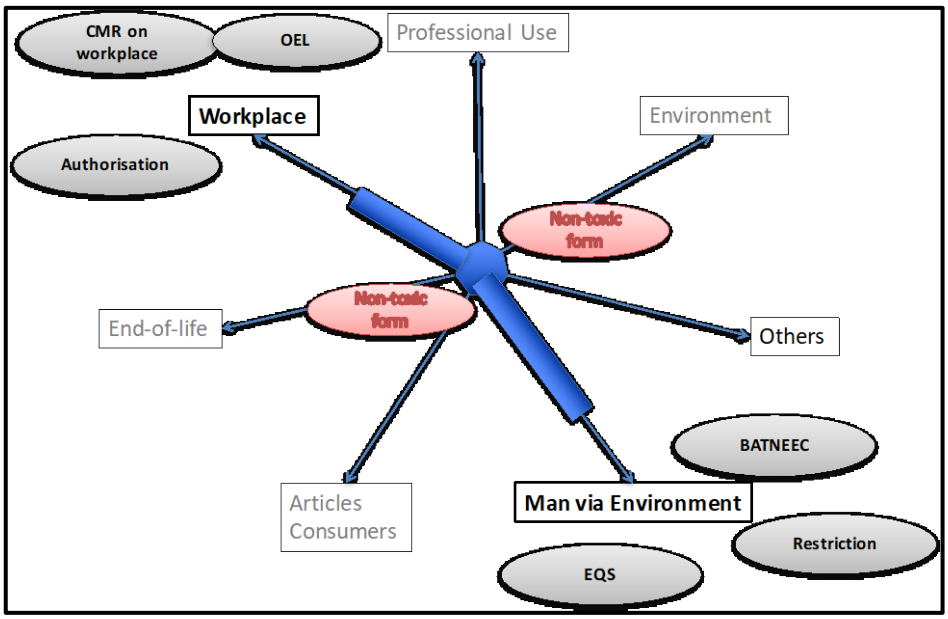
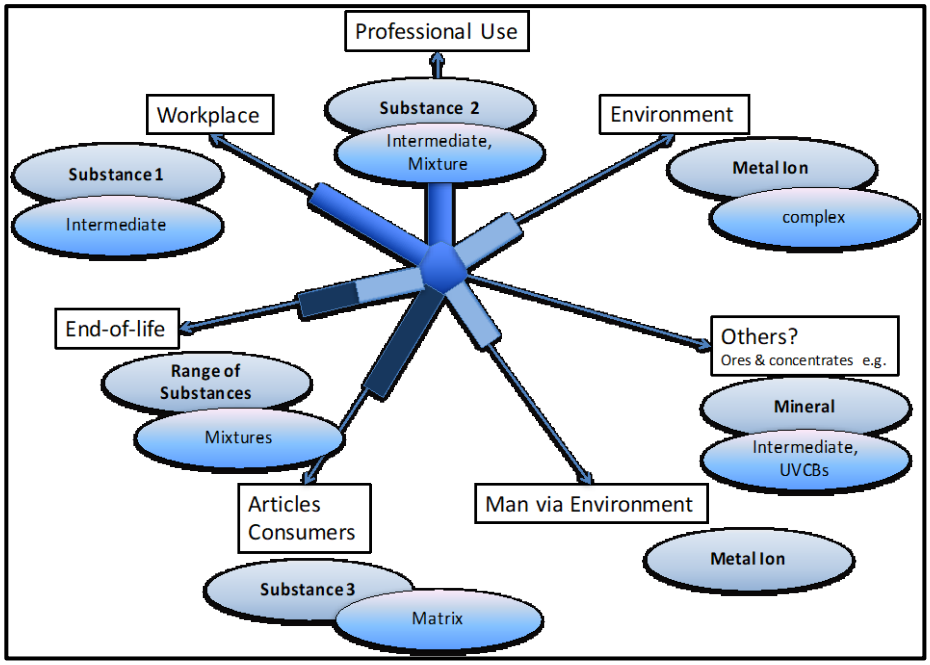


FIGURE 9: SPECIATION ANALYSIS IN CONCERN ASSESSMENT

One may encounter quite complex situations where the initial substance (called here 'substance 1') changes speciation, is found in mixtures or in matrixes. Depending on the boundaries of the analysis, the life-cycle overview may highlight potential risks not linked to 'substance 1'.



STEP 2: REFINED RMO LIST FOR DISCUSSION

Aim: Identify what might be the most efficient RMO considering substance- or sector-specific characteristics. It is important that, if Restriction is a possibility (e.g. an EU-wide risk is proven), one should also consider the possible scope and content of such a Restriction, otherwise the discussion may end up being too hypothetical.

Approach: The refinement will consider whether:

a) A **single Risk Management Measure** may suffice to address the potential risk. For example, can the issue identified be addressed with a restriction? It is considered mainly in anticipation or in response to a regulatory management initiative, this what this guidance calls a Simple I-RMOa approach. .
b) A **combination of Risk management Measures** needs to be considered. Would a single risk management measure be efficient to address the potential issue? The situation in different use sectors may be so different that e.g. a restriction with exemptions may not be desirable. A combination of measures may have to be put in place potential RMOs are equally valid for all the sub-sectors that are concerned. It is the first type of a broader look at the issues and can thus be considered a type of Integrated I-RMOa.
c) An **integrative approach to Risk Management** may be advisable. Here, the assessment goes beyond the single substance and is more holistic, thus an Integrated I-RMOa.

Discussion and illustrations:

a) **SINGLE RISK MANAGEMENT MEASURE (SIMPLE I-RMOA):**
The risk management measure can be limited to the substance (and its use(s)) and will be limited to one measure. *Typically: Restriction, Authorisation, Occupational Exposure Level.* This is the simplest approach, which will be the favoured one when there are no cross-substance issues such as the use of other SVHCs in same processes or complex issues requiring other ad-hoc measures such as a specific restriction.
Regulators may want to focus on substitution or non-use of the substance, i.e., **Authorisation or Restriction**. A Restriction may address some conditions of use or some uses whilst Authorisation would allow – at least in the eyes of the authorities- to help sort out the uses between those for which there is a case for continued use and those for which there is no case for avoiding phasing out.
However other substance-specific regulatory or technological solutions (OEL, EQS, BATNEEC) may also be considered.
An example of a simple approach where a Restriction or an Authorisation may be considered is shown in Table 10. It may reflect a case where the risk cannot be efficiently addressed by an alternative risk management measure such as an OEL.

TABLE 10: EXAMPLE OF AN RMO FOR A SIMPLE NON-INTEGRATIVE APPROACH

Use of Substance X	
Decisive criterion	*No cross-substance issues related to process and no satisfactory approach identified through other legislation*
Simple	• **Restriction** • **Authorisation**

b) **COMBINATION OF RISK MANAGEMENT MEASURES (1ST TYPE OF INTEGRATED I-RMOA):**

It is felt that a combination of risk management measures could lead to an optimal solution of challenges identified. There might be imports of the substances through articles and a Restriction could complement an Authorisation**.**

Table 11 reflects a case where the substance is present in different types of exposures and could be addressed through a mix or combination of risk management measures.

TABLE 11: EXAMPLE OF AN RMO IN A SIMPLE OR AN INTEGRATED I-RMOA

RMO	Use 1	Use 2	Use 3
Decisive criterion	*Leads to consumer exposure*	*Professional use and exposure*	*Occupational exposure in industrial settings & technological solution identified*
Simple approach	• **Restriction**	• **Restriction**	• **Restriction**
	• **Authorisation**	• **Authorisation**	• **Authorisation**
Integrated approach	• **Restriction**	• **Restriction**	• **BATNEEC OEL**

C) **INTEGRATIVE APPROACH TO RISK MANAGEMENT (FURTHER STEP OF AN INTEGRATED I-RMOA):**

The potential risk is recognized as being linked to a process that may be common to other substances and value chains, and therefore one should try to address it in an integrated way. For example, the use of a substance in ***surface treatment*** would lend itself to such an integrated approach.
One could imagine an Authorisation per substance, which would be a long and complex process and highly disturbing for the companies concerned (uncertainty - what guarantees of equality of treatment? - consistency?)

However, a creative approach may focus on acid mist, the carrier of the various substances as particulates, and the introduction of a technological solution for the entire sector (BATNEEC) could help solve the problems (see Table 12: Example of RMOs for an Integrative Approach)

TABLE 12: EXAMPLE OF RMOS FOR AN INTEGRATIVE APPROACH

RMO	Substance X		Use of Substance Y in same process	Use of Substance Z in same process
Decisive criterion	*Critical use in a process with cross-substance issues. Alternatives and /or other substances used in the process have similar hazard profile* *This approach allows to address the issue with the substance and similar substances through the process*		*Same/similar hazard profile*	*Same/similar hazard profile*
Integrated approach	**BATNEEC** ⇨			

Here again, it is important that the approach identified is justified and realistic. Industry is the best equipped to develop a set of approaches that would be more suitable than a problematic one-size-fits-all measure. One should know that this fit-for-purpose approach requires an investment in time and expertise. The pay-off may however be worth the effort.

5. DISCUSSION OF RISK MANAGEMENT OPTIONS: FITNESS TEST

A number of criteria will be discussed such as **effectiveness, practicality and regulatory consistency** in a way that can be binary (yes/no) or graduated (low/medium/high) or even scored, weighted and ranked.
It has to be taken into consideration that the EU jurisprudence employs the notion of proportionality as an overall assessment concept that covers the following three steps:

a) **Suitability**: Is the risk management measure appropriate to achieve the objective that is pursued?

b) **Necessity**: Is there no other risk management option considered suitable to achieve the objective that is less cumbersome, costly or restrictive whilst equally effective in achieving the objective?

c) **Proportionality** sensu stricto: Is the risk management option considered suitable and necessary, while not too excessive? Hereby the balance between the different interests at stake (Industry & society e.g.) needs to be considered.

Notes:

- *As will be discussed later in the Guidance, some other criteria may be added, depending on relevance and availability of data. It may, for example, be interesting to explore indirect human or environmental benefits or drawbacks. A closed system may reduce the exposure to other substances, improve productivity etc.*
- *The precautionary principle has as consequence that arbitration between uncertainties may lead to favouring the more maximalist approach…*

In practice:

Possible risk management options having been identified and defined; the next step of the analysis is to come to a conclusion (i.e., identify the best RMO) that fits with the key criteria that have been used in the RMOa's.
The potential RMOs against four key criteria. The level of expertise required at this stage may be less technical. However, policy, legal and economic considerations come into play.
Approach: The main criteria to be considered are the following:

1. **Effectiveness**
2. **Efficiency**
3. **Consistency**
4. **Broader impact (economic, human health, environmental)**

In order to be able to conclude on Overall Proportionality of the different RMOs considered.

The following pages outline this approach.

1. EFFECTIVENESS

The question is: *"Has the measure under consideration the capacity to produce the desired effect?"* One will in particular discuss its capacity to reduce possible risks in a measurable way. Effectiveness is synonym of **efficacy**. Among the aspects to be considered is the availability of **proven and affordable technology** and what is generically known about **alternatives**. Here is where the knowledge gathered in previous steps comes to use. It will be necessary for the final comparison between options to discuss the respective effectiveness (pros and cons) of each RMO considered.

Table… provides an example of a scoring of different RMOs in two types of approaches (simple and combined) as identified and presented in previous tables.

Overall effectiveness may be discussed as a combination of the following criteria:

- **Ability to reduce risk**, especially compared to the desired outcome. This will contain in itself the consideration of whether there is an alternative available.

- **Measurability** (tonnage of substance known to be used in the EU represented by companies applying for Authorisation e.g.) or **monitorability** (testing or sampling of articles or of emissions)

- **Proven technology available**. This suggested criterion is to encourage an assessment of the technologies that are needed to implement the different potential risk management measures (including the technological implications of using alternative substances) or that may constitute BATNEECs.

In the example simulated in Table 13, assessors have decided to **score the criteria from 0 to ++++**[6] depending on ability to satisfy the criterion to obtain a view of overall effectiveness by adding up the scores. Depending on the uses, the scoring may vary, and a decision must be taken on what the average is. It is important to note that the choice of the scoring system and of the criteria should be left to the assessors who can take into consideration specific dimensions related to the use of the substance. These choices should be duly documented.

[6] ANNEX III discusses scoring approaches

TABLE 13: EXAMPLE OF A COMPARISON OF THE EFFECTIVENESS OF THE DIFFERENT RMOS IN FUNCTION OF I-RMOA APPROACH

RMO	Ability to reduce risk	Measurability / Monitorability	Proven technology available	Overall effectiveness
Simple I-RMOa				
Restriction * (based on assumptions made on scope and content of Restriction)	++ (between + and +++ due to doubts on workability for some uses)	++	+	+++++
Authorisation	+ (between 0 and ++ depending on use, some being intermediates)	++ (between + and +++ depending on use)	+ (between + and ++ depending on use)	++++
Integrated I-RMOa				
Restriction * For Uses 1 and 2 (based on assumptions made on scope and content of Restriction)	+++	++	+	+++++ +
BATNEEC For Use 3	++	+	+++ (some participants claim ++++)	+++++ +

- Based on assumptions made on scope and content of Restriction

2. EFFICIENCY

The question to answer is: ***"Can the RMO be implemented in a manner that its outcome compares favourably with the efforts invested in it?"*** An efficient RMO will first have to be practicable. This criterion is more process-oriented (administrative or technical) as it compares the results of the management measure to the means needed for its implementation.

Efficiency may be considered from a variety of angles:

- **Ease to implement by Industry:** One considers if actions to be undertaken to implement the RMM are clear and implications in terms of obligations and responsibilities. Another parameter is the availability and type of tools (technology e.g.) and processes (organisation e.g.) needed to implement the RMM. The costs associated with the implementation of the different options will not be estimated, only qualitatively compared in the discussion.

- **Ease to implement by Regulators**: Under which conditions and at what cost can enforceability be assured? Here too, there will be no (tentative) quantification of the costs associated with the implementation of the different options, and they will only be qualitatively compared in the discussion.

- **Time to implementation:** If action is considered urgent by regulators, there are RMOs that have less chances of being agreed to. If a technological solution is not yet mature, the process of validating it and adopting it as a BAT may take too much time than acceptable by society.

In the following hypothetical illustration (Table 14), the authors of the RMOa may have found that a targeted Restriction would be more practical than an overall Restriction and that compared to the other options, there may be disadvantages from a policy-maker point of view with BATNEECs.

TABLE 14: EXAMPLE OF A COMPARISON OF THE PRACTICABILITY OF THE DIFFERENT RMOS IN FUNCTION OF I-RMOA APPROACH

RMO	Ease to implement by Industry	Ease to implement by Regulators	Time to implementation	**Overall efficiency**
Simple I-RMOa				
Restriction *	+ (between 0 and ++ due to doubts on workability for some uses)	++	+++	+++++ +
Authorisation	0 (between 0 and + depending on use, some being intermediates)	+++	++ (between + and ++ depending on use)	+++++
Integrated I-RMOa				
Restriction * For Uses 1 and 2	+ (between 0 and ++ depending on use, some being intermediates)	+++	+++	+++++ ++
BATNEEC For Use 3	+	+	0 (timing concern for most participants)	++

- Based on assumptions made on scope and content of Restriction

3. CONSISTENCY:

The question to address is: ***"How do the RMOs being considered perform in terms of a level playing field and regulatory coherence?"***

Table 15 illustrates four dimensions chosen for discussing consistency.

- **Regulatory consistency**: Is the RMO consistent with a level playing field across the EU? Is there a risk of distortion of competition through differences in implementation at national level?
- **Consistency with existing EU legislation**: Are there any potential regulatory overlaps with existing regulations?
- **Consistency with previous EU initiatives**: How does the conclusion of the RMOa fit with the conclusions of previous EU Risk Assessments?
- **Consistency with other EU policy objectives, especially in the field of resources preservation and efficiency (Circular Economy, Climate Change and other parts of the Green Deal)**: If, for example, the substance cannot be substituted in processes that contribute to achieving EU air quality standards, a ban may negatively affect air quality and associated public health objectives. Similarly, a measure may impact the operations of a well-functioning recycling loop and thus impact the EU Circular Economy ambitions.

TABLE 15: EXAMPLE OF A COMPARISON OF THE REGULATORY CONSISTENCY OF THE DIFFERENT RMOS IN FUNCTION OF I-RMOA APPROACH

RMO	Regulatory consistency	Consistency with existing EU legislation	Consistency with previous EU initiatives	Consistency with other EU policy objectives	**Overall consistency**
Simple I-RMOa					
Restriction *	++++	+	++	++	**+++++ ++++**
Authorisation	++	+	+	+	**+++++**
Integrated I-RMOa					
Restriction * For Uses 1 and 2	+++	+++	+++	++	**+++++ +++++ +**
BATNEEC For Use 3	0	+++	++	+++	**+++++ +++**

- Based on assumptions made on scope and content of Restriction

In the same hypothetical case, the regulatory consistency considerations might be clearly in favour of a mixed approach, for example if a previous risk assessment/EU risk reduction strategy identified uses or sectors of concern, thus justifying a more specific set of measures.

4. BROADER IMPACT

To come to an overall proportionality test, it may be good to consider the broader impacts on the value chain or on society.

Here, one may consider:

- Value chain impacts at sector-level/ company-level (SMEs and non-SMEs),
- Circular economy impacts
- Possible collateral impacts on unsuspected value chains through e.g. alloys, product impacts (loss of functionality),
- Market impacts (impacts on market shares, trade balance),
- Monitoring costs and administrative consequences.

Table 16 provides an example of how to look at broader impacts but those performing an RMOa may decide on another set of criteria. The hypothetical case described in Annex IV shows an example of how the broader impacts can be considered with a more in-depth analysis of impacts at company level and value chain level. The Annex IV case splits the consideration of the economic impacts from the analysis of the human health and environmental considerations. The templates in Annex V also consider them separately. The choice is left to those performing the exercise and will depend on the substance.

TABLE 16: EXAMPLE OF A COMPARISON OF THE BROADER IMPACT OF THE DIFFERENT RMOS IN FUNCTION OF I-RMOA APPROACH

RMO	Value chain impact				Societal impact		Overall broader impacts
	Neutrality vs. supply disruption	Neutrality vs. sustainability of SME business	Neutrality in terms of Impact on investments	Neutrality in terms of cost to value chain	Socio-economic benefits	Additional Human health and/or environmental benefits?	
Simple I-RMOa							
Restriction *	+	+	++	+	0	+	+++++ +
Authorisation	+	0	0	+	+	0	+++
Integrated I-RMOa							
Restriction * For Uses 1 and 2	++	++	++	++	0	+	+++++ ++++
BATNEEC For Use 3	+++	++	++	0	0	++	+++++ ++++

- Based on assumptions made on scope and content of Restriction

Annex II provides further detail on some of these impacts (value chain disruption, societal impacts etc.).

6. SYNTHESIS: THE RISK MANAGEMENT OPTIONS THAT COULD BE CONSIDERED AND CONCLUSION ON THE MOST ADEQUATE OPTION

The outcome of the different scorings can be presented in an overall proportionality synthesis table as the one shown in Table 17.

TABLE 17: EXAMPLE OF SYNTHESIS TABLE

RMO	Effectiveness	Efficiency	Consistency	Broader impacts	Overall proportionality
Simple I-RMOa					
Restriction *	5+	6+	9+	6+	**26+**
Authorisation	4+	5+	9+	3+	**21+**
Integrated I-RMOa					
Restriction * For Uses 1 and 2	6+	7+	11+	9+	**33+**
BATNEEC For Use 3	6+	2+	8+	9+	**27+**

- Based on assumptions made on scope and content of Restriction

The synthesis of the exercise, the basis for internal communication and decisions or outreach, will basically highlight:

- The **potential risks** in the context defined by the scope (can range from REACH registration dossier uses to more holistic view of the presence and fate of the substance)
- The **potential RMOs** and the discussion of their **relevance and proportionality**
- The **conclusions** drawn and **recommendations**
- **Possibly, and depending on scope and context, the report may contain several add-ons such as**
  - **Alternatives per (Identified) Use**

    The Analysis of Alternatives (**AoA**) starts with describing the functional contribution of a substance to a process or an article so as to be clear on what is expected from an alternative. At the RMOa phase, the AoA may be more generic in the identification and discussion of alternatives than in the case of individual applications for an Authorisation, but it should reflect the state-of-the-art to avoid future challenges such as during public consultations. Following issues will come up during the AoA:

    1. Identification of key functional requirements may force to split the analysis into different functionality groups.
    2. Among the questions to address:
       a. Drivers for substitution: potential exposure, cost (relative prices), and market pressure.
       b. Drivers for continued use: could be the cost of the alternative (unit price, performance-related cost), technical considerations related to functionality, process complexity or the production of additional impurities/waste and market conditions (technical specifications or consumer preference)
       c. Likelihood of an alternative becoming available: ongoing trials (from most likely to yield success to 'plan B alternatives', at a less mature stage) and timeframe
       d. Other criteria such as
          - Hazard profile of the alternative (an issue for metals because alternatives have often similar hazard profiles)

- Operational constraints linked to the process e.g.
- Sustainability criteria (resource availability or depletion, energy and carbon leakage)
- Life cycle (displacement of problem to a later stage?)
- Key economic elements (e.g. cost of the alternative substance, process implications, etc.)

e. Credibility: An AoA should stand the test of a peer review.

The Analysis of Alternatives may bring to light that the use of the substance has already been limited to processes or products that are difficult to substitute, i.e. that the markets have already made an 'arbitration'.

- **Socio-Economic Assessment per Use**

  In the context of REACH, socio-economic assessments (SEA) are conducted applying quantitative methods to both describe economic events and trends and to bring various impacts (e.g. health, environmental, social or societal as well as economic) of an RMOa under a common denominator (i.e. Euros).

1. *Key determinant in the analysis:* The key aspect of a SEA is the identification of the critical elements or pivotal factors that trigger the socio-economic consequences.
   It is important to be cautious with the key arguments that one may consider bringing forward regarding the absence of alternatives.
   Let's imagine a substance used as a pigment providing a specific colour: *How to put a value on a colour*, e.g. when that is the key functionality provided by a substance? The Analysis of Alternatives may have indicated that no alternatives were available to provide exactly the same colour but will this conclusion be acceptable from a political point of view? Regulators tend to believe that the market and consumers will adapt to the loss of a particular colour shade unless it has proven a particular efficiency (road marking, signalling, safety lights etc.) that provides a societal benefit. The SEA should therefore critically take up the conclusions of the AoA.

2. *Market impacts:* On top of economic and technical feasibility, the SEA may identify consumer preferences that will drive the market response (price elasticity, opt for imports if the articles affected are not available anymore) or loss of competitiveness, etc. These aspects are particularly interesting to explore when alternatives have already been made available to consumers for some time.

3. *Employment effects*: Can the SEA identify a serious risk of net loss of jobs and plant closures in the EU?"

SEA refinement at the RMO stage will vary according to the RMO type, for example:

- Indicative OEL: requires few if any socio-economic arguments
- Binding OEL: involves examination of compliance costs
- Restriction: socio-economic impact, preferably via a Cost-Benefit Analysis
- Authorisation: socio-economic impact via a Cost-Benefit analysis based on likely scope and duration of Authorisation

A broader perspective - societal rather than socio-economic - may be brought in at this stage:

The criterion of sustainability may be most relevant to explore, especially in the EU where there are several regulatory initiatives and policy targets aimed at stimulating economic growth and job creation, or to protect the environment. In this guidance, **climate change** and **circular economy** will be considered especially.

An I-RMOa is a systematic process of chemicals management which can be summarized as follows:

- 1st : Setting the Scene
  Substance to discuss is given by a regulatory process or needs to be selected in function of a set of criteria - Areas of possible concern are mapped – Significance of concern is defined - Need for Risk Management is established
- 2nd : Identifying RMOs
  All possible Risk Management Options are listed and defined
- 3rd : Fitness test of RMOs
  RMOs are discussed and most proportionate is/are identified

The practical approach described in the guidance is based on a set of steps that help narrow down the analysis. Once risks are identified and described one can consider a broad set of risk management measures which may be a combination of measures, in function of the uses. Among the many advantages of the approach presented, one can mention that it allows:

- **Screening for all potential concerns**
  The screening means the identification and investigation of substance specific information to make a preliminary assessment on whether there are concerns, or potentially remaining concerns, that may need to be addressed by means of risk management measures. This screening may go beyond the notion of 'concern' as considered in the context of the REACH Regulation (SVHC).
- **Putting the potential concerns in context**
  A series of analyses are at hand (described in Annexes) to assess the relevance of the potential concerns, through e.g. a source analysis, a tool that may be particularly useful in the case of naturally occurring substances.
- **Identifying the data needed for selecting RMMs**
  This may be specific to the regulatory environment (EU-REACH, chemicals management legislation in other jurisdictions, …). The outcome may be also the setting of a pathway for collecting these data.
- **Discovering and comparing all potentially relevant RMMs**
  The comparison may look at RMMs in terms of efficiency and overall proportionality; may highlight stumbling blocks (time constraints, credibility issues etc.)
- **Presenting an industry view on possible risk management approaches or decide on measures to implement (company analysis)**

The Circular Economy Assessment is closely related to the Materials Mass Flow Assessment. It focusses on whether the lifecycle includes a closure of loop and what its characteristics and significance are.

The recycling dimension is complex to analyse in two ways:

a) it includes the main materials' recovery and often also minor substances added during the manufacturing processes as well as potentially unwanted materials like impurities
b) it requires an understanding where the substances referred to in point a) will end up and if uses could create a potential for risk

The Circular Economy assessment is of high relevance as it may help identify management measures (regulatory or not) that may benefit both Industry and Society (address risks related to exposure to substance, preservation of resources, protection against the release of impurities which may be substances that are undesirable from a risk to man or environment, economic or technical point of view).

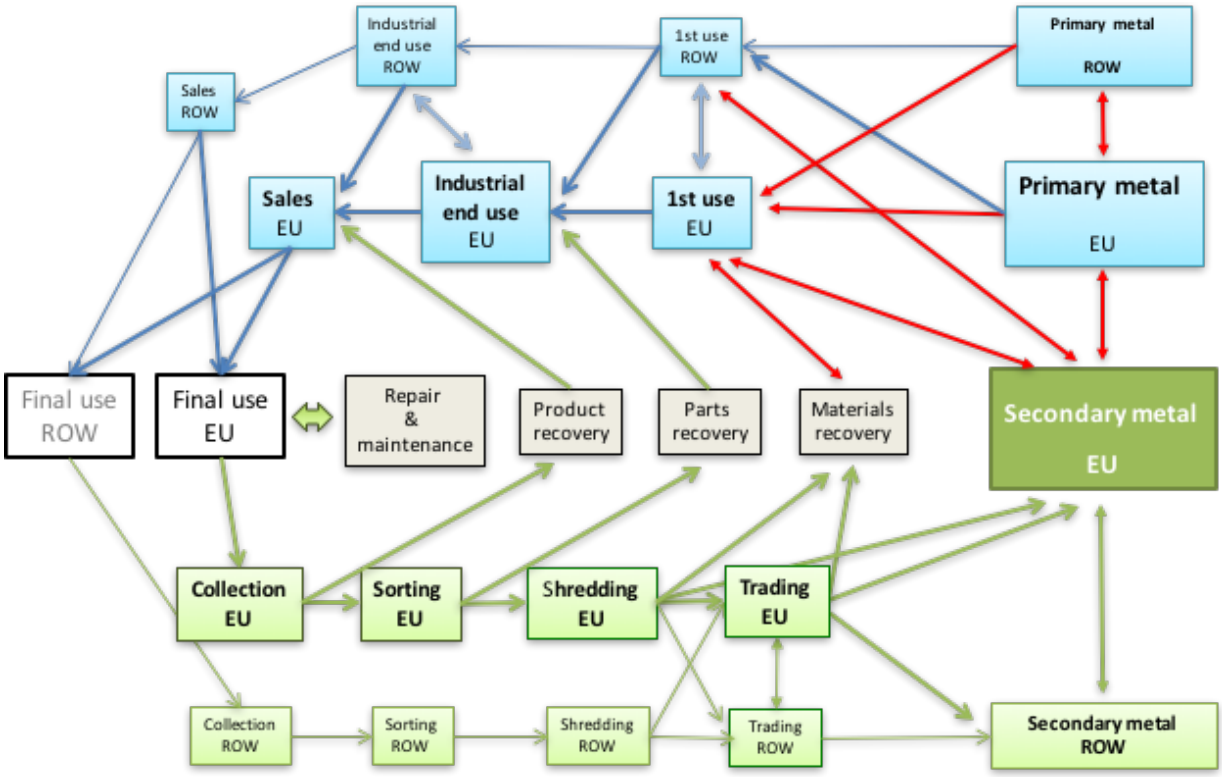
1. OUTLINE OF THE ANALYSIS

The suggested Circular Economy approach considers the lifecycle of an element and its compounds from a materials flow perspective. Such a perspective is complex and may be represented like a spiderweb as presented in Figure 10. The ambition is to optimize the overall materials flow from manufacturing over user steps, end-of life until recycling. This approach, particularly suited for an integrative I-RMOa approach, allows a discussion of measures that may go beyond the strict risk management of an individual substance or use. It applies a cradle-to-cradle approach rather than a cradle-to-grave, thus considering closing the materials loop.

When that is relevant, the analysis *de facto* considers the substance as a resource. It presupposes that the availability of materials for the economy cannot be considered as granted any more due to increased global competition to access finite resources: losses of materials are losses for the economy.

Figure 10 provides a generic scheme with the different dimensions of a circular economy, seen from a metal's perspective. The scheme can be refined per metal to take into account the characteristics of the supply chain.

FIGURE 10: THE CIRCULAR ECONOMY DIMENSION IN A METALS CONTEXT



For an EU primary and/or secondary metal manufacturer or user, the Circular Economy dimension is of the utmost importance as its company objectives match to a large extent those of the Circular Economy package.

Companies indeed aim at optimising their operations in a way that coincides with the Circular economy objectives as shown by the following elements **at production level:**

- ***Optimisation of yields and of energy consumption***
  This has several dimensions such as:
  - Optimisation of **extraction**/manufacturing of metals (base metals, precious metals, minor metals e.g.) and optimisation of **recovery** of metals from new scrap (DU manufacturing waste) and old scrap (EOL, materials becoming available from the 'stock of metals' accumulated as articles in society);

- Minimisation of **waste** and ensuring, e.g., that final slags can be of such a quality they can have a useful further life (building industry, infrastructure) rather than ending in landfill sites;
- Minimisation of **unwanted elements** in input materials (impurities) and optimal processing (concentration in by-products or in waste material or managed re-circulation)

○ ***Operational optimisation*** may mean

- Optimisation of **material mixes** (primary & secondary materials) in the metallurgical process loops;
- Specialisation in the processing of materials (by-products, often UVCBs) that others cannot treat in a resource -efficient manner (too small quantities, too complex process etc.). This is also a way to ensure a better performance in circular economy terms.

The circular economy dimensions along the supply chain may include the following functionalities (see Table 18)

1) **Industrial Ecology:** Eco-efficiency, industrial symbiosis, technically, economically and environmentally sustainable loops… The materialisation of all these concepts requires a regulatory framework that allows durable supply chain commitments, that favour economies of scale, long-term planning comfort. These are based on and grow out of what is technically and economically favourable to all parties, in a context where the interests of society at large are fully considered.

2) **Economy of functionality:** The migration towards service-based relationships may potentially contribute to a sustainable economy. Recycling of products that are not sold and remain property of their manufacturer can greatly facilitate the establishment of efficient recycling loops.

3) **Repair and maintenance:** This is classically considered as part of the overall Circular Economy system, but actually more an issue at the consumer-end of the supply chain, facilitated by adapted (eco-) design. However, the quality of the articles will depend on the quality of their components, which relates to upstream in the supply chain, up to the alloy manufacturers.

4) **Reuse:** This concept can be seen broadly from community-scale initiatives to the organised reuse of electric vehicle batteries for home energy storage.

5) **Recycling:** Ultimately, the efficiency of the end-of-life stage will determine whether a virtuous circular economy loop could be established at local, regional, national or EU level.

TABLE 18: CIRCULAR ECONOMY DIMENSION ALONG THE SUPPLY CHAIN

	Industrial Ecology (1)	Economy of Functionality (2)	Repair (3)	Reuse (4)	Recycling (5)
Refiners	X				X
Alloy/ compound manufacturers	X				X
Semi-manufacturers/ chemical processers	X				X
DUs/OEMs	X	X	X		X
Final product manufacturers	X	X	X	X	X
Consumers			X	X	X
Collectors etc.	X				X

As can be seen in the table above, the most critical elements in terms of circular economy for those metal industries at the high end of the supply chain will be **recycling and industrial ecology** and a number of key questions will have to be considered in an I-RMOA:

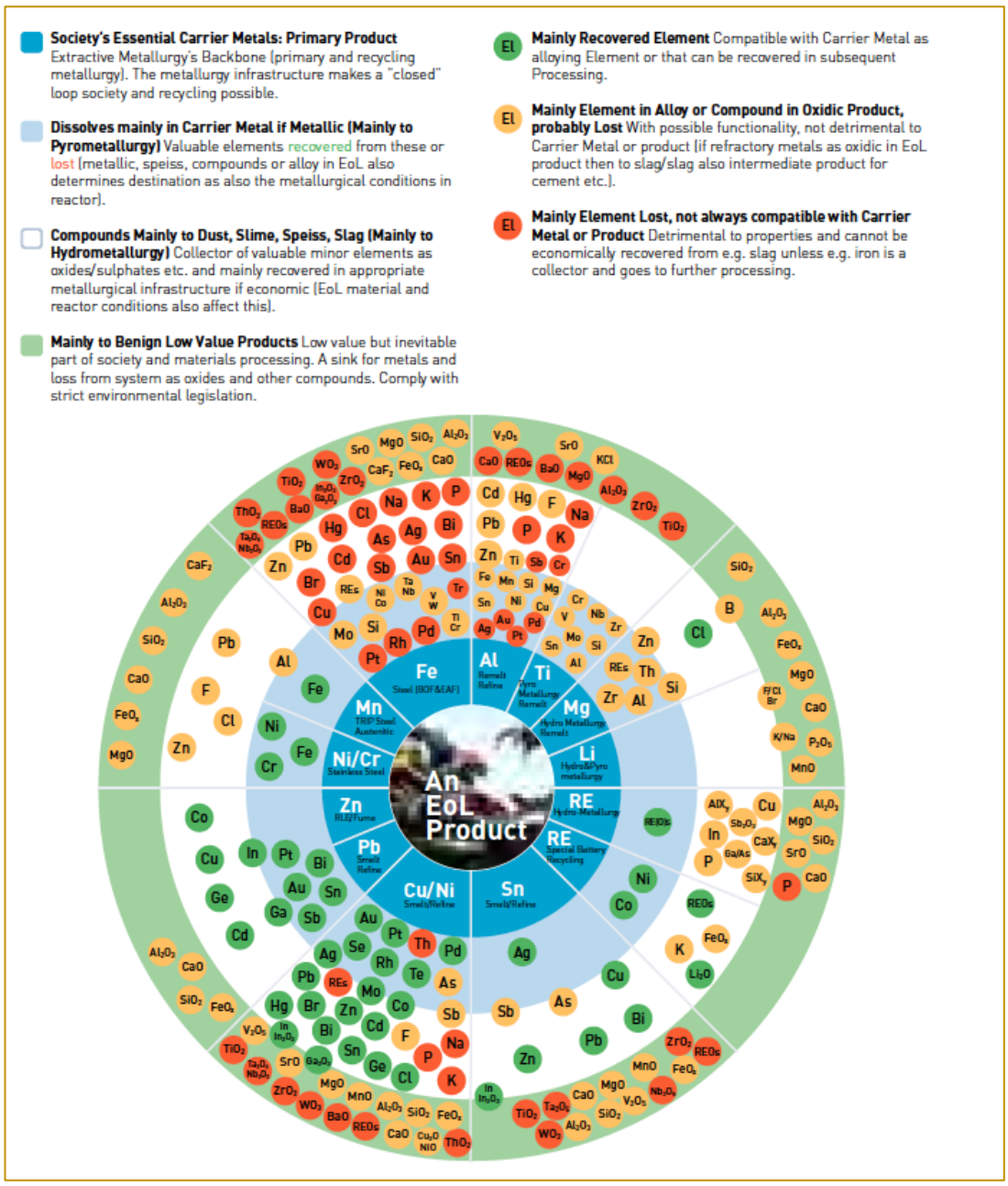
- How to ensure a steady/reliable flow of secondary materials?
- Will the future regulatory Risk Management Measure impact the flow of secondary materials?
- Will the regulatory measures allow the current diversity of materials to continue to be collected and processed in the EU?
- If the materials mix is to change, what will be the implications?
- What about elements appearing in streams where they might have a detrimental effect as a consequence of forced material choice (substitute) or phasing out (becoming unwanted element)?
- Will the measure(s) impact the viability of the existing industrial ecology, such as complex non-ferrous metals refining circuits?

Metal supply chains are not closed loops per metal: there is a strong link between them as shown "Metal Wheel" of the 2013 UNEP report "Metal Recycling – Opportunities, Limits, Infrastructure" where the authors depict the destination of different elements in base-metal minerals as a function of interlinked metallurgical process technology (Figure 11)

Each of the slices represents the complete infrastructure for base- or carrier metal refining and constitutes a factor in any discussion on the circular economy impacts of regulation.

The authors of the UNEP report indicate that the "*complexity of consumer product mineralogy requires an industrial ecological network of many metallurgical production infrastructure to maximize recovery of all elements in end-of-life products*." (Reuter and van Schaik, 2012a&b; Ullmann's Encyclopaedia, 2005 as quoted in UNEP report)"

FIGURE 11:UNEP METAL WHEEL



From Metal Recycling – Opportunities, Limits, Infrastructure (UNEP – report 2b of the Global Metal Flows Working Group of the International Resource Panel of UNEP – 2013), page 30

SPECIAL POINT OF ATTENTION:

Unwanted materials as impurities or minor constituents of UVCB's?

With a growing diversity of primary and secondary material sources, a continuous increasing number of substances used in articles, the industry has to face the exposure potential and risk management of unwanted hazardous materials like some unwanted impurities and minor constituents.

Impurities, metals that have no functional role in the 'parent' metal containing them, and minor constituents, raise other types of questions and discussions on possible trade-offs:

- *If hazardous, can they be separated safely and given a safe use on their own?*
- *If not, can they be kept safely in the 'parent' substance/material and recirculate with them without risk (dilution effect)? (recuperation as a material)*
- *If the hazards and risks differ from the mother material, impurities or the minor constituents may need to be handled in a specific I-RMOa*
- *Or requiring specific risk management in case they need to be removed as a waste or as a filler in other materials such as slags*

The discussion on the management of impurities in hazardous elements becomes increasingly relevant for industry and society require data on what the releases and risks may be as discussed in the next points. However, the I-RMOa concepts as developed for main substances apply in an equal way to impurities.

2. PRESENTATION FOR THE I-RMOA DISCUSSION

The relevance to Circular Economy policies may be discussed by situating the substance under scrutiny in a scale of relevance as shown in Table 19 below:

TABLE 19: RELEVANCY DISCUSSION IN RELATION TO THE CIRCULAR ECONOMY POLICY

Relevancy Category related to the Circular Economy dimension	**Very Relevant (negative)**	**Relevant (negative)**	**Neutral**	**Relevant (positive)**	**Very relevant (positive)**
Definition	• The substance is not or barely recycled or recyclable at end-of-life. • There are very significant known drawbacks to the substance and its use in terms of the Circular Economy.	• The substance is poorly recycled or poorly recyclable. • There are known drawbacks to the substance and its use in terms of Circular Economy.	• One cannot identify a direct or indirect contribution to the Circular Economy of the substance. • The Circular Economy dimension is not relevant	• Is recycled / can be recycled • Used in or researched for applications that allow recycling. • May display properties that make its use relevant from Circularity perspective • Considered a candidate for (improved) recycling efforts • Recycled material does not achieve same performance as the primary product • There may be economic constraints to recycling (energy input and cost e.g.)	• A high percentage of the substance is recycled at end-of-life. • May display properties/potential that make its use very relevant or even critical from a Circular Economy point of view.
Explanation and examples	The use of the substance goes counter to the spirit of the Circular Economy. Example: *Relevant to the discussion*: specific uses in which the substance is lost for what would be more 'circular' uses. *(e.g. ZnO in tyres where it remains an issue in recycled uses)*	Substance and/or use constitute a challenge in terms of the Circular Economy (technically or economically difficult to collect and recycle) Example: *Circular Economy Difficulties:* An alloying element that technically disrupts (poisons) established recycling circuits (e.g. Bismuth blocks the recycling of Copper)	Used in such a way that it is difficult to identify a circular economy dimension. Example: a substance used as an intermediate in chemical processes, a fertiliser, a molecule used in over-the-counter drugs, substances such as oxygen for which the concept of circular economy is not relevant (at least not on the Earth surface).	The substance is recyclable and there are recycling circuits established for it. Example: some plastics recycled in lower tier applications or metals that are recycled but cannot be used to the same quality level as the primary material	One or more of the following conditions are met: • Highly valuable • High recycling performance • Strategic resource for the EU economy and its availability depends on recycling performance • Very significant benefit in terms of resource use (including energy) to achieve circularity • … Example: Recycled base and minor metals that can be introduced in equivalent uses as primary use

Once the relevance established, the Circular Economy dimension will influence the proportionality discussion according to the relevancy category as illustrated in Table 20 here:

TABLE 20: TYPES OF RISK MANAGEMENT MEASURES IN FUNCTION OF CIRCULAR ECONOMY RELEVANCY

Relevancy Category related to the Circular Economy dimension	**Very Relevant (negative)**	**Relevant (negative)**	**Neutral**	**Relevant (positive)**	**Very relevant (positive)**
Impact on RMO selection and analysis	< ---------- Growing pressure towards avoidance, substitution to correct the lack of contribution to the Circular Economy ----------> Growing relevancy to place the Circular Economy as one of the RMO-defining elements				
Type of measures	Targeted Restriction(s)/possibly authorisation to phase-out uses	Push for more restrictive/corrective measures which may be restriction/authorisation)	Unlikely to impact proportionality discussion and focus will be on other aspects (toxicity etc.) In some instances, an OEL will be considered neutral in terms of Circular Economy	Measures that would aim at striking a balance between addressing risks and exploring potential for greater contribution to the Circular Economy	Use-specific approaches (combined and integrative approaches) Such as, in some cases: BAT, OELs, EQS, … Targeted Restriction (selected uses) Industry initiatives

The above-mentioned relevancy discussion may be critical for the selection of potential Risk Management Options in the final proportionality analysis. In that analysis, the Circular Economy dimension plays an important role as the overall proportionality of the selection and weighting of RMOs. The assessment of the Circular Economy impact can be tested using the following set of 3 Circular criteria: "**reusability/recyclability**", "**preservation of functionality of the concerned substance allowing utilisation for the same use**" and "**Longevity of use**". An assessment of the RMOs regarding their performance in terms of these 3 criteria leads to a qualitative proportionality scoring such as --, -, 0, +, ++.

Table 21 provides an illustration on how such a scoring can be applied for a substance that has been considered **negatively relevant** because of wide-dispersive professional uses that are the source of human health concerns and the production of articles that are technically and economically difficult to collect and recycle.

TABLE 21: EXAMPLE OF PROPORTIONALITY SCORING OF THE CIRCULAR ECONOMY DIMENSION OF A SET OF POTENTIAL RMOS

Scoring of the Circular Economy dimension	Preservation of resource: Reusable/ Recyclable	Preservation of properties / functionalities (Same use possible ?)	Circularity over time: Longevity of use	Relevancy and proportionality from Circular Economy point of view
RMO 1 Authorisation aiming at total phase-out	**0**	**0**	**0**	**0** *The scoring group considered that considering the poor relevancy of the substance in terms of Circular Economy, a phasing-out would not impact its Circular Economy performance*
RMO 2 Restriction aiming at limiting the uses to those where not only the human health risks could be addressed but recyclability could be improved	**+**	**+**	**0**	**++** *The scoring group expected that the focus on recyclable uses would allow a more efficient collection and improved recycling processes leading to a better-performing recycled substance*
RMO 3 OEL	**0**	**0**	**0**	**0** *The scoring group considered that the OEL would not influence the 3 criteria considered for the analysis and thus not the Circular Economy performance of the substance.*

The objective of discussing the Climate dimension of the substance is

a) To assess whether the Climate dimension – linking to the various Climate policy aspects – will be relevant to discussing the RMOs.
b) To discuss, when that dimension is relevant, the relative performance in terms of Climate policy of the RMOs considered.
c) To include Climate aspects in the RMOa proportionality assessment.

Even if the RMOa consist in a scanning of the fate of the substance throughout its life cycle, it does not equate to a Life-Cycle Assessment (LCA) looking at the overall resource and energy performance. Indeed, in an RMOa we look at these aspects relatively to alternative substances and technologies. The discussion of the Climate dimension will thus be qualitative at this stage whereby the assessment will have to be justified, acknowledging that it is difficult to set the boundary of the discussion.

Another critical aspect is to consider the Climate (energy consumption and/or CO2 emission) impact over the substance life cycle. Indeed, a substance may be energy-intensive in its production but may contribute to sustainability if it provides durability to articles and or allows the energy to be recuperated during the recycling phase. In essence it is the energy / functional use from the life cycle perspective of the substance that counts. The detail of this discussion goes beyond the scope of an RMOa and is in the remit of an LCA as mentioned earlier. Alternatively, in an RMOa assessment different options can be qualitatively compared to their positive or negative contributions to climate aspects during manufacturing/use/EOL and recycling.

The relevancy to Climate change policies may be discussed by situating the substance under scrutiny in a scale of relevance as shown in **FOUT! ONGELDIGE BLADWIJZERVERWIJZING.**.

TABLE 22: SUBSTANCE RELEVANCY IN RELATION TO CLIMATE POLICIES

Relevancy Category related to the Climate dimension	**Very Relevant (negative)**	**Relevant (negative)**	**Neutral**	**Relevant (positive)**	**Very relevant (positive)**
Definition	There are very significant known drawbacks to the substance and its use in terms of resource conservation, energy use and or climate change. It can be said to directly or indirectly impact in a negative way on the Climate challenges. (e.g. disbanding the use of borates as a flux material increases the temperature of the melt in metal processes)	There are known drawbacks to the substance and its use in terms of resource conservation and energy use. It can be said to directly or indirectly impact in a negative way on the Climate challenges.	One cannot identify a direct or indirect contribution or potential contribution of any significance in terms of addressing the Climate challenges	The substance is used in or is researched for applications that are directly or indirectly related to addressing the Climate challenges. The substance may display properties that make its use very relevant in terms of energy conservation etc. (e.g. metals used in energy carriers but for which the manufacturing energy is not recuperated)	The substance is used in or researched for applications that are known to address the Climate challenges. (e.g. metals used in energy carriers that allow for recuperating the manufacturing energy during recycling)

Explanation and examples	The substance and its use constitute a significant challenge in terms of the Climate objectives (energy intensity, energy efficiency, overall emissions, sustainability, durability etc.). Its use negatively impacts the Climate. Example: Fluorinated gasses (hence the EU F-gas regulations)	The substance and its use constitute a challenge in terms of the Climate challenges (energy intensity, energy efficiency, overall emissions, sustain-ability, durability etc.). It is of no use in addressing the Climate challenges. Example: Substance used for a short life, throw-away packaging without any recycling of the energy A substance that can be recycled but requires more energy than for primary use	The substance is not used in energy production/storage/transport etc. There is no significant difference in its energy-performance (consumption etc.) compared to its known alternatives. Example: a molecule used in pharmaceuticals	Energy transport systems (cables etc.) A Substance that, compared to its alternatives allows significant savings in energy use (thus also emissions) Example: a metal used for energy transport or a solvent/flux that allows fibre/metal production at lower temperatures	Clean/renewable energy production and storage (solar, wind etc.). Example: windmill components, constituents of rechargeable (and storage) battery systems of outstanding energy performance and the substance is/can be recycled to recover most of the energy to produce it.

Once the relevancy established, the Climate dimension will influence the proportionality discussion according to the relevancy category as illustrated in Table 23 hereunder:

TABLE 23: SUBSTANCE RELEVANCY AND PROPORTIONALITY IN RELATION TO CLIMATE POLICIES

Relevancy Category related to the Climate dimension	**Very Relevant (negative)**	**Relevant (negative)**	**Neutral**	**Relevant (positive)**	**Very relevant (positive)**
Impact on RMO selection and analysis	< ---------- Growing pressure towards substitution (authorisation, restriction) ----------> Growing pressure to address human health and/or environmental issues without jeopardising use of the substance				
Type of measures	Push for more restrictive measures (restriction/authorisation)	Push for more restrictive measures (restriction/authorisation)	Unlikely to impact proportionality discussion and focus will be on other aspects (toxicity etc.)	Will impact proportionality discussion and influence the choice of measures (less push for restrictive measures/overall substitution)	Use-specific approaches (combined and integrative approaches) Such as: BAT OELs, EQS Targeted Restriction (selected uses) Industry initiatives

The above-mentioned relevancy discussion may be critical for the selection of potential Risk Management Options for the final proportionality analysis. In that analysis, the Climate dimension can play an important role as the overall proportionality of the RMOs can also be tested for their impact on a suggested set of 3 Climate criteria that are "**impact on energy cost during manufacturing**", "**impact on energy use at use phase (energy consumption per functional use)**" and "**recuperation (or not) of the intrinsic energy during recycling**".

A qualitative assessment of the RMOs regarding their performance in terms of the 3 criteria mentioned above may lead to a proportionality scoring such as --, -, 0, +, ++. Table 24 provides an illustration of such a scoring. The hypothetical case in Table 7 is one of a substance with human health concerns at manufacturing stage and in professional uses which in the Climate relevancy discussion has been considered **positively relevant (substance used in energy transport)**.

TABLE 24: EXAMPLE OF PROPORTIONALITY SCORING OF THE CLIMATE DIMENSION OF A SET OF POTENTIAL RMOS

	Impact on energy cost during manufacturing	Impact on energy use at use phase (energy consumption per functional use)	Recuperation (or not) of the intrinsic energy during recycling	Relevancy and proportionality from Climate point of view
RMO 1 Authorisation aiming at total phase-out with only known substitute being less energy-efficient	**-**	**-**	**--**	**- - - -** *The scoring group considered that a forced substitution with less energy-efficient substance would lead to an overall negative Climate impact*
RMO 2 OEL	**-**	**0**	**0**	**-** *The scoring group considered that the OEL would impact on the Climate performance at manufacturing stage due to the need for the installation of additional equipment to collect and treat gases*

OVERALL CONCLUSION OF THE INTEGRATED I-RMOA

The conclusions of a 'purely' chemicals management-oriented analysis have been discussed in the section on Pillar 1.

This section will explore the way to reach conclusions when Pillar II (Circular Economy) and/or Pillar III (Climate Change) are added to Pillar 2 (Chemicals Management *sensu stricto*).

Several situations are possible:

- The analysis covered two pillars: Pillar 1 and Pillar 2 or Pillar 3)
    - The conclusions of the separate pillar analyses are convergent
    - The conclusions reached in the separate pillars diverge or there are options that are too closely ranked for an easy conclusion
- The analysis covered the three pillars

1. PRESENTATION OF OUTCOMES OF THE ANALYSIS IN THE PILLARS

This section will explore the way to reach conclusions when Pillar II (Circular Economy) and/or Pillar III (Climate Change) are added to the I-RMO analysis.
For the purpose of illustrating the approach, a fictitious case and scoring is considered for a set of possible 4 types of RMOs. So as to avoid any interference of individual opinions on a practical example, the RMOs are not described.
The discussion will start with putting together the conclusions of the analysis of the three pillars, starting with Pillar I (Chemicals management):

PILLAR I: The outcome of the RMO discussion and the scoring (in this case a scoring between -2 and +2) is represented in Table 25:

TABLE 25: PILLAR I PROPORTIONALITY SYNTHESIS

Pillar I: Chemicals Management					
	Effectiveness	Efficiency	Consistency	Broader Impacts	**Conclusion Pillar I**
RMO 1	1	1	1	1	**4**
RMO 2	-1	1	1	-2	**-1**
RMO 3 (combination)	2	1	1	0	**4**
RMO 4 (combination)	1	2	2	1	**6**

Discussion: In this case, the first conclusion will be that RMO 2 is not considered as being proportionate. RMO 4 scored best but the other options are very close so that they all three may qualify for further discussion or a more quantitative SEA/impact assessment.

PILLAR II: The conclusion of the Pillar II discussion can be presented as shown in Table 26.

TABLE 26: PILLAR II PROPORTIONALITY SYNTHESIS

Pillar II: Circular Economy				
	Reusable /recyclable	Preservation of properties / functionalities	Longevity of use	**Conclusion Pillar II**
RMO 1	1	1	0	**2**
RMO 2	-2	-2	0	**-4**
RMO 3 (combination)	1	1	0	**2**
RMO 4 (combination)	1	1	0	**2**

Discussion: In this case, the conclusions of Pillar I are confirmed or even strengthened for RMO 2 but do not provide a conclusion regarding the three other options.

If the analysis consisted only of Pillars I and II, the overall conclusion would not be much influenced by Pillar II and RMO 4 would probably be selected as the most adequate/proportionate risk management option, pending possible confirmation as discussed above.

PILLAR III: The conclusion of the Pillar II discussion can be presented as shown in Table 27.

TABLE 27: PILLAR III PROPORTIONALITY SYNTHESIS

Pillar III: Climate Change				
	Impact on energy cost during manufacturing	Impact on energy use at use phase	Recuperation of intrinsic energy during recycling	**Conclusion Pillar III**
RMO 1	0	1	1	**2**
RMO 2	0	0	0	**0**
RMO 3 (combination)	-1	0	-1	**-2**
RMO 4 (combination)	-1	0	0	**-1**

Discussion: In this case, RMO 1 comes out as the most favourable one in terms of Climate Change objectives.
RMO 3 which would have been further considered in a classical chemicals' management RMOa would now be difficult to consider further considering its negative scoring for the Climate Change dimension.
If the analysis consisted only of Pillars I and III, the Pillar III conclusion would tip the overall balance in favour of RMO 1.

PILLARS I, II & III: The synthesis of the scorings of the 3 pillars is presented in Table 28 below:

TABLE 28: SYNTHESIS OF SCORING OF 3 PILLARS

Overall Conclusion of the 3 Pillars				
	Pillar I	Pillar II	Pillar III	**Overall**
RMO 1	4	2	2	**8**
RMO 2	-1	-4	0	**-5**
RMO 3 (combination)	4	2	-2	**4**
RMO 4 (combination)	6	2	-1	**7**

Discussion: RMO 1 and RMO 4 lead the scoring whilst RMO 2 and RMO 3 are disqualified. The final choice seems now between RMO 1 and RMO 4

A multiple pillar analysis offers the following advantages:

- It introduces nuances to the analysis and forces the assessors to consider nuancing their views.
- It broadens the context of the analysis, introducing new elements to consider
- By possibly modifying the ranking of RMOs along the process, it may call for a refinement of the analysis
- It calls on new expertise to be involved (energy, life cycle, recycling etc.) which adds value to the exercise. Multi disciplinarity increases the chances of optimisation of risk management through creativity and out-of-the-box thinking
- It strengthens the case for ex-post re-assessment of the RMO decision and implementation.

Possible drawbacks of a multiple pillar RMOa one needs to keep as points of attention may be:

- The method explained here can be biased by pure mathematical reasons such as the number of criteria selected in a pillar (Here four criteria in Pillar I vs. three in the two other pillars)
- Scoring criteria must be rigorously defined and scoring must be explained so as to reduce the risk of biases (cf. aversion for authorisation e.g.). Experience has proven that an as objective as possible presentation of the RMOs helps their discussion and scoring.
- The closer the scoring the greater the advantages of presenting the strengths and weaknesses of the options that are considered the most suitable for political/strategic decision taking. The greater the chances also that an SEA may help decide between the options.

2. DISCUSSION OF OUTCOME

The outcome of the three-pillar analysis may be complex to present to the ultimate decision-takers and may require a synthesis table presenting the findings in a SWOT-type of reasoning. This may allow a better understanding of the compromises a decision ultimately may have to make compared to what might be considered an ideal solution.

In some cases, the outcome may be so clear that no further discussion is needed but the RMOa outcome is mainly a decision aid for regulatory or industry strategies. The outcome of the analysis could be summarised in a table considering the positive and negative impacts as hypothetically illustrated in Table 29.

TABLE 29: SUMMARY OF ANALYSIS OF 3 PILLAR ANALYSIS

	Pillar I: Chemicals Management		Pillar II: Circular Economy		Pillar III: Climate Change	
	Strength Opportunity	Weakness Threat	Strength Opportunity	Weakness Threat	Strength Opportunity	Weakness Threat
	Options considered overall suitable for addressing the risk(s) identified					
RMO 1	Effective because Efficient because… Consistent because… Positive broader impacts expected because…		Positive impact in terms of recyclability… Properties preserved…		Neutral in terms of energy use during production because… Positive impact on energy use at use phase because… Positive impact in terms of recuperation of intrinsic energy during recycling because…	
RMO 4 (combination)	Effective because Very efficient because… Very consistent because … Positive broader impacts because…		Positive impact in terms of recyclability… Properties preserved…			Negative impact on energy cost during production because…
	Options not considered overall suitable for addressing the risk(s) identified					

RMO 2	Efficient because… Consistent because…	Not effective because… Negative broader impacts on…		Implementation would seriously hamper recyclability of… because of… Properties would not be preserved under the following conditions…	Climate neutral impact	
RMO 3 (combination)	Very effective because… Efficient because… Consistent because No broader impacts because…		Recyclability promoted because Functionality preserved because…			Negative impact on energy cost during production because… No recuperation of intrinsic energy during recycling because…

ANNEXES

CONTENT

ANNEX I - THE BROAD I-RMOA TOOLS SET

1.1. INTRODUCTION TO THE TOOL SET

The I-RMOa may be ambitious in its scoping and correspond to different necessities. It may be aimed at addressing a regulatory challenge in view of anticipating and contributing in a regulatory RMOa exercise or providing input in a Public Consultation. It may also aim at screening the product portfolio of a company, covering all products and substances used by the company or it may be an exploratory exercise to identify future challenges.

The Broad I-RMOa will ideally cover identification/investigative work carried out before the substance gets is taken up in a regulatory risk management process. It allows to identify the contributions to emissions/exposure that would require management in function of the regulatory scheme or concept applied (REACH context, Not-to-Exceed concept aiming at continuous improvement of emissions, air or water quality legislation, waste etc.).

The information provided in the REACH registration dossiers and C&L Inventory is the starting point for identifying potential substances of concern and 'uses' of concern. Other regulatory and monitoring information from external sources and predictive methods may also be used with the strategic ambition to map and understand the contributors to emissions/exposure.

The following pages will show tools allowing a Broad I-RMOa to quickly help identify RMM pathways that are relevant to Industry and Society by a combination of support tools, especially, the **ASSESSMENT OF THE FOLLOWING DIMENSIONS:**

- **LIFE CYCLE** (SCAN)
- **SUBSTANCE/MATERIALS MASS FLOW,**
- **SOURCES AND RELEASES, INCLUDING DIFFUSE SOURCES AND THEIR SIGNIFICANCE**
- **CIRCULAR ECONOMY**
- **CLIMATE**

A mode of presentation or synthesis of the assessment will also be proposed in the following pages.

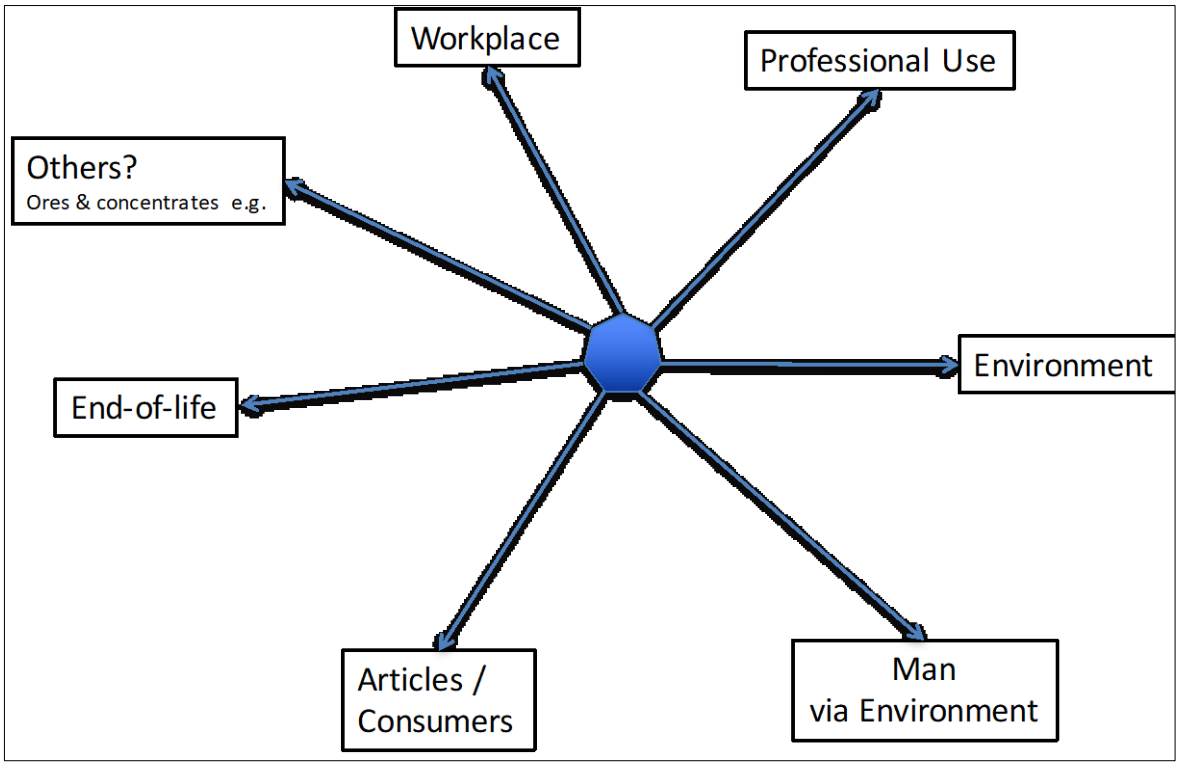
1.2. I-RMOA TOOLS SET

1.2.1. LIFE-CYCLE SCAN: WHERE IS THE SUBSTANCE PRESENT AND WHAT ARE THE IMPLICATIONS?

As illustrated In Figure 12, the e broad I-RMOa will start with a life-cycle scan of the substance. All possible life-stages and exposure possibilities of the substance are identified and documented.

It may be that the downstream uses lead to the manufacturing of articles where the substance is not present anymore, as such. For example, a metal compound may end up on or in articles (metal surface layer or metal in glass) or may have been transformed into another compound (battery).

FIGURE 12: LIFE-CYCLE SCAN OF THE SUBSTANCE



1.2.2. MATERIALS MASS FLOW ASSESSMENT

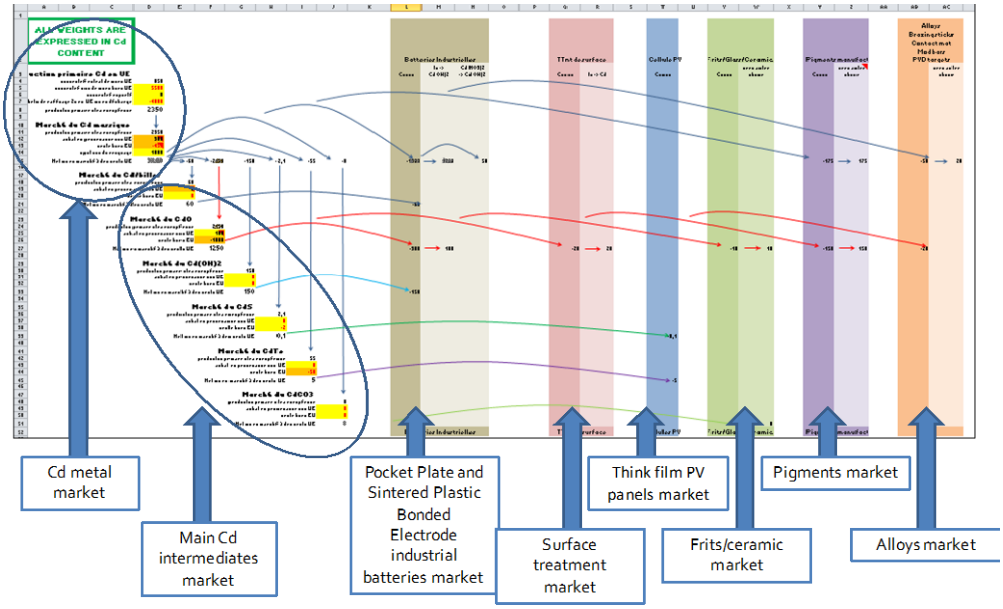
This can be a valuable support tool for the assessment. It provides an overview of the pathways for substance use and industrial processes (cf. Environmental risk or impacts assessments, links with LCA). It will identify under which form/speciation the substance – a metal element or its compound - is present and if/ when it is transformed into another form/speciation. It can further provide information on where the substance may be released from the supply chain as an ***emission*** or as a ***loss of resource to the economy***. Including Materials Flow assessment (mapping and release) therefore allows combining and integrating REACH with broader considerations such as Circular Economy.

This assessment may also help clarify and refine the intermediate use or the article status of the substance as it may, *through an understanding of the processes*, help clarify what the potential risks (and solutions) might be. This may, for example, lead to imagine a risk management focus that is not immediately targeted at the substance (e.g. acid mist suppression in plating).

A detailed illustration of such a material mass flow assessment is provided in Figure 13 where a materials flow diagram for Cadmium and its compounds is sketched out. This is an effort to reconcile the 'business segments / markets' point of view common to Industry with the REACH approach focussing on 'uses'.

FIGURE 13: MATERIALS MASS FLOW ASSESSMENT DIAGRAM FOR CADMIUM AND ITS COMPOUNDS

Cadmium and compounds



The knowledge of the markets and of the processes will allow to know if, e.g. Cd is transformed into CdO by a specialty compound manufacturer (hence a market), or if the downstream user (battery manufacturer, for example) uses Cd (Cd market) to transform it into CdO (no CdO market).This may lead to the production of a typical mass flow diagram where the different business segments (i.e. markets) can compared to each other in terms of tonnage and, if relevant for the analysis, status vs. REACH Authorisation (intermediate or not).

FIGURE 14 illustrates how the mass flow assessment can lead to make an inventory of the ways through which parts of the material are 'lost' through e.g. emissions.

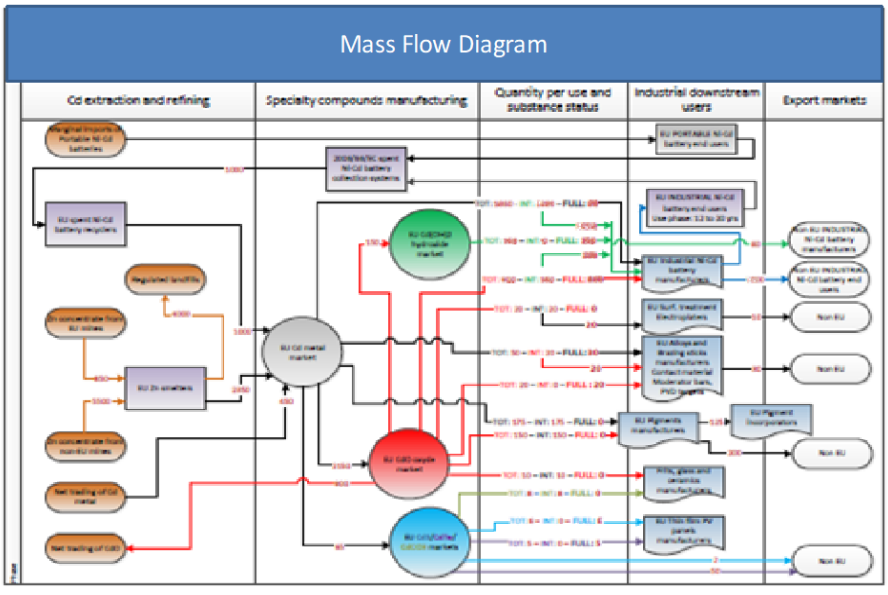
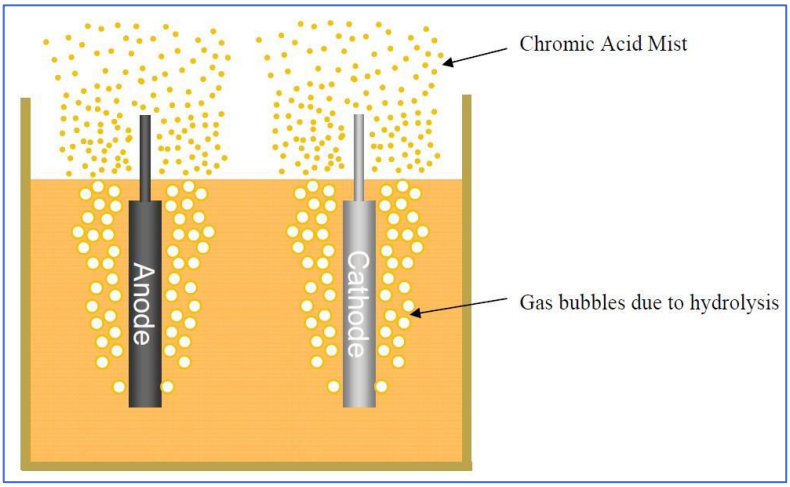


FIGURE 14: ASSESSMENT OF MATERIAL LOSSES FOR CADMIUM AND ITS COMPOUNDS

Hexavalent chromium and contributing factors to exposure

A review of electroplating processes during which one develops understanding of where the Cr (VI) units go can be performed along or in parallel to a mass flow analysis of chromium VI. It can lead to identifying generic factors that contribute to hexavalent chromium exposure in the workplace.

One of them is **mist generation during plating where** hydrogen bubbles burst when they reach the surface, causing small droplets of the electrolyte solution, which contains Cr(VI), to go into the air.



(illustration from pfonline.com)

This has become a major area of investigation and improvement overall of working conditions with the development of mist suppressants**,** leading to an overall improvement of the exposure situation of workers.

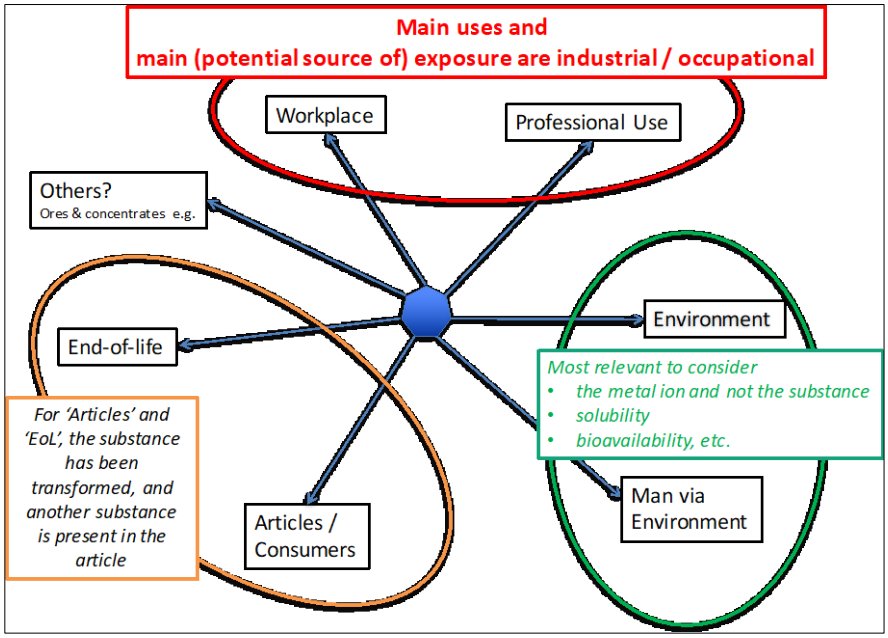
Other factors are more company-specific than specific to the industrial process considered generically (rack insertion/removal or work practices) and companies may have to assess them individually.

1.2.3. EXPOSURE – RELEASES, INCLUDING DIFFUSE SOURCES AND THEIR SIGNIFICANCE

1.2.3.1. PICTURING RELEASES AND EXPOSURE

In the example case illustrated here in Figure 15, the 'uses' that are relevant, including in terms of REACH Authorisation, are industrial and occupational.

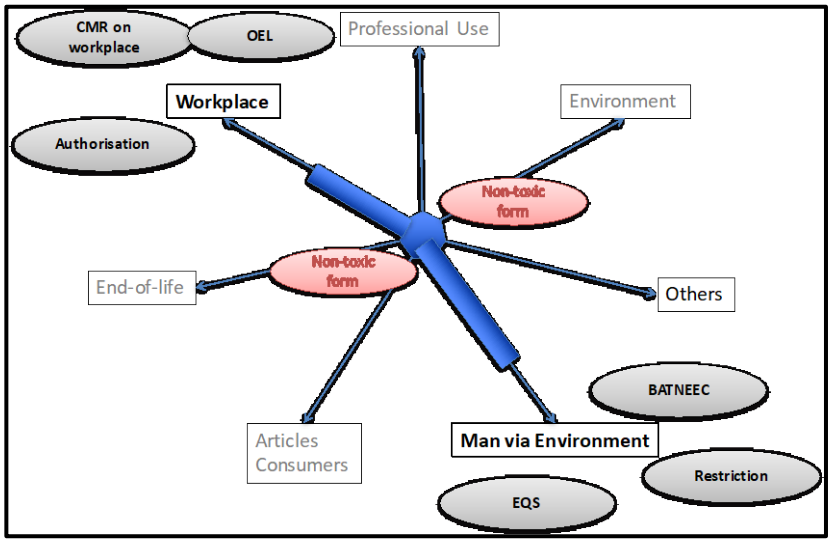
FIGURE 15: SYNTHETIC PRESENTATION OF THE RELEASE AND EXPOSURE CONCLUSIONS



The information available in the substance CSR can be used to make sure the latest data is made available for the assessment. Releases to the Environment and its Man via Environment corollary should consider the metal ion rather than the substance as such.

The life stages following the production and use of a substance involve use of articles where the substance (a compound in the illustration) has changed speciation and has been transformed into another compound or into the metal (possibly into a non-toxic form!), opening the debate of grouping assessments e.g..

FIGURE 16: CONCLUSIONS AFTER FURTHER REFINEMENT RELATED TO FATE IN THE ENVIRONMENT



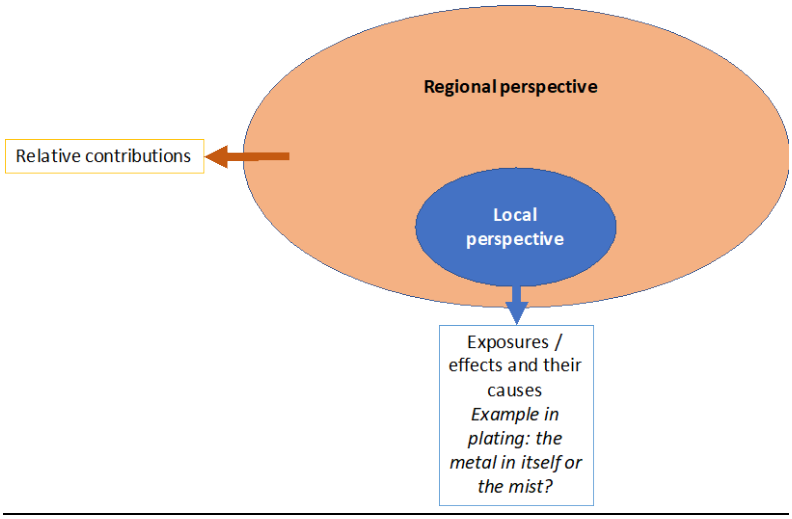
In the illustrative case, the life-cycle scan showed that the main sources of exposure or potential exposure were occupational, in industrial and professional settings. The analysis of the environmental dimension (environment and Man via the environment) led to consider the relevant parameters (metal ion, solubility, bioavailability, …) whilst at the later stages of the product/article, the assessors stumbled on the fact that the substance under scrutiny is not present as such any more .

The conclusion of the analysis can be presented schematically as shown in Figure 16 above.

As the European Environmental Agency states "*Diffuse pollution can be caused by a variety of activities that have no specific point of discharge. Agriculture is a key source of **diffuse pollution**, but urban land, forestry, atmospheric deposition and rural dwellings can also be important sources. By its very nature, the management of diffuse pollution is complex and requires the careful analysis and understanding of various natural and anthropogenic processes*."

A form of 'holistic materials flow analysis' will help map the emissions and be useful 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 helps develop a potentially different take on the issues that matter most (see Figure 17)

FIGURE 17: THE CHANGE OF PERSPECTIVE WITH A DIFFUSE SOURCES ASSESSMENT



The Diffuse Sources assessment may thus lead to the development of a strategic view on the issues related to the substance, helping to identify pathways for an efficient, significant and cost-effective reduction of emissions/exposure.

Note that this does *often not necessitate* new data collections, although the more 'intuitive' conclusions may require, at a later stage, additional refinements (costs, technologies and impact assessments etc.)

Two examples to demonstrate the importance of the Diffuse Sources Analysis for informing the need for an adequate Risk Management options, are provided here:

Example 1: CADMIUM

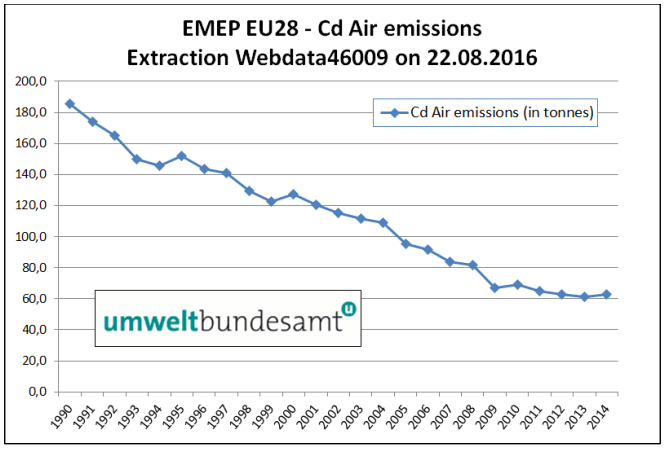
Soil:
Natural and anthropogenic point and diffuse sources which contribute to the levels of cadmium found in soil and sediments are e.g. mine/smelter wastes, commercial fertilizers derived from phosphate ores or sewage sludge, municipal waste landfills)

Water:
Cadmium enters the aquatic environment from numerous diffuse sources such as agricultural and urban run-off, atmospheric fall-out) and point sources, both natural and anthropogenic.
Cadmium is released to the aquatic environment from a range of anthropogenic sources, including non-ferrous metal mining and smelting, surface treatment operations, phosphate fertilizers, sewage treatment plants, a hazardous waste sites and other landfills.

Regarding the industrial emissions, the Water Framework Directive 2000/60/EC has set the objective of cessation or phasing-out of discharges, emissions and losses of cadmium by 2020.

Air:
Cadmium is emitted to the atmosphere from both natural and anthropogenic sources. The most important natural source of cadmium is weathering and erosion of cadmium-bearing rocks, but other sources include volcanoes, sea spray, and forest fires.
The main anthropogenic sources are non-ferrous metal production and fossil fuel combustion, followed by ferrous metal production, waste incineration, and cement production. Many sources are available to evaluate the importance and the historic evolution of air emissions (cf. Figure 18)

FIGURE 18: CADMIUM AIR EMISSIONS 1990 – 2014 (EMEP- EU 28)



In the case of cadmium, the 'Environmental' sources assessments would highlight that, considering tonnages and wide-dispersity of usage, the phosphate fertilisers are the biggest anthropogenic source of input of cadmium to the environment. Simultaneously other sources of cadmium in soils have been declining over the years: deposition from air emissions has been constantly decreasing, due to efficient pollution control measures and changes in energy mixes. Other sources are getting under control such as non-industrial Ni-Cd batteries, whilst some sources as e.g. artist paints are extremely marginal contributors.

This conclusion will be reinforced by the added consideration of the 'Man via Environment' issues where for the human health-relevant pathways identified, the major sources are

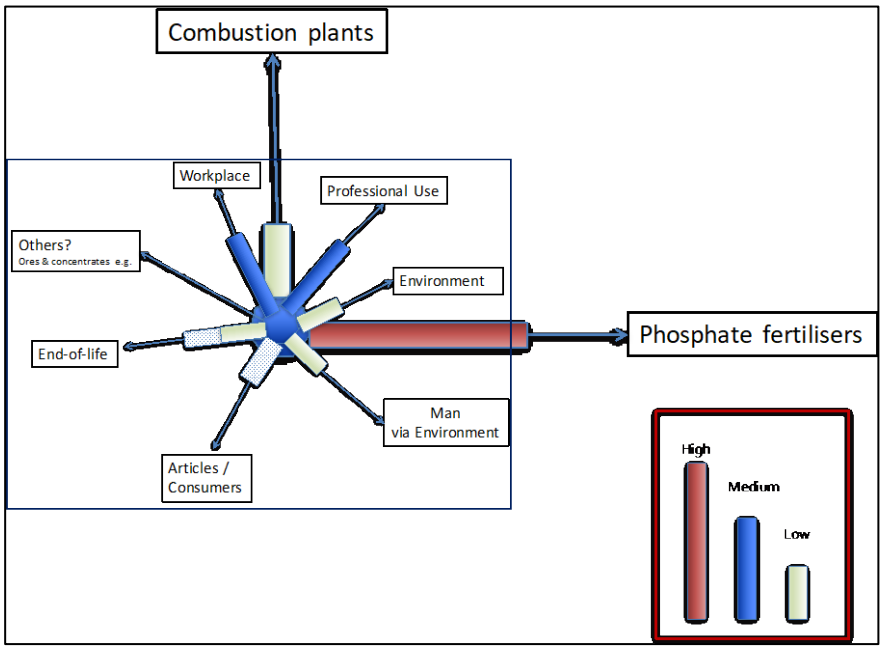
Food Intake: 95th percentile = 1.6µg/d and
Smoking: 20 cigs => 2.0µg/d

Whilst uptake due Drinking water (0.06 to 0.10µg/d), Inhalation (0.025 to 0.045µg/d) and *Soil and dust ingestion (0.035µg/d) are limited, including near industrial point sources.*

> *A **strategic pathway** that could be derived from such an assessment which goes beyond the life-cycle of an individual manufactured cadmium compound would therefore possibly be to try and focus efforts and resources on an integrated strategy regarding phosphate fertilisers. This may include the selection of cadmium-poor source materials (rocks), decadmiation, phosphate recovery etc. Additionally, policy measures directed at smoking habits of the population could further contribute to a significant reduction of uptake.*

Figure 19 shows that an Industry assessment that would have considered both mass flows and diffuse sources analysis may lead to a interesting conclusions. Starting from an assessment that would have focussed on 'direct' anthropogenic sources (diffuse and point sources), one identifies another significant source whose persistence would 'dilute' the effect of any measure that may be initially considered.

FIGURE 19: INTEGRATION OF MASS FLOW AND DIFFUSE SOURCES ANALYSES FOR CADMIUM INTO AN INITIAL ASSESSMENT OF CONCERNS (HYPOTHETICAL EXAMPLE)



The societal debate on tobacco usage and availability is left aside because out of the remit of the cadmium value chain.

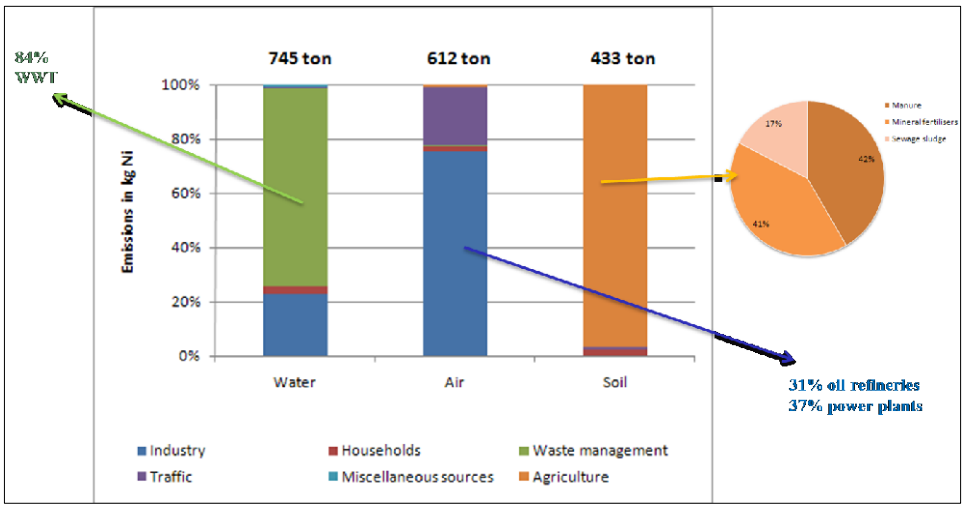
Example 2: OTHER METALS

A diffuse sources analysis may lead to an entirely different picture for policymaking and may shed a different light on the real benefits and proportionality of risk management options that may be considered.

As shown in

Figure 20 , a diffuse sources analysis of nickel shows that, for the sake of efficiency, traditional risk management measures may have to be considered as only a part of an integrated strategy that would include innovation, energy mix policies etc.

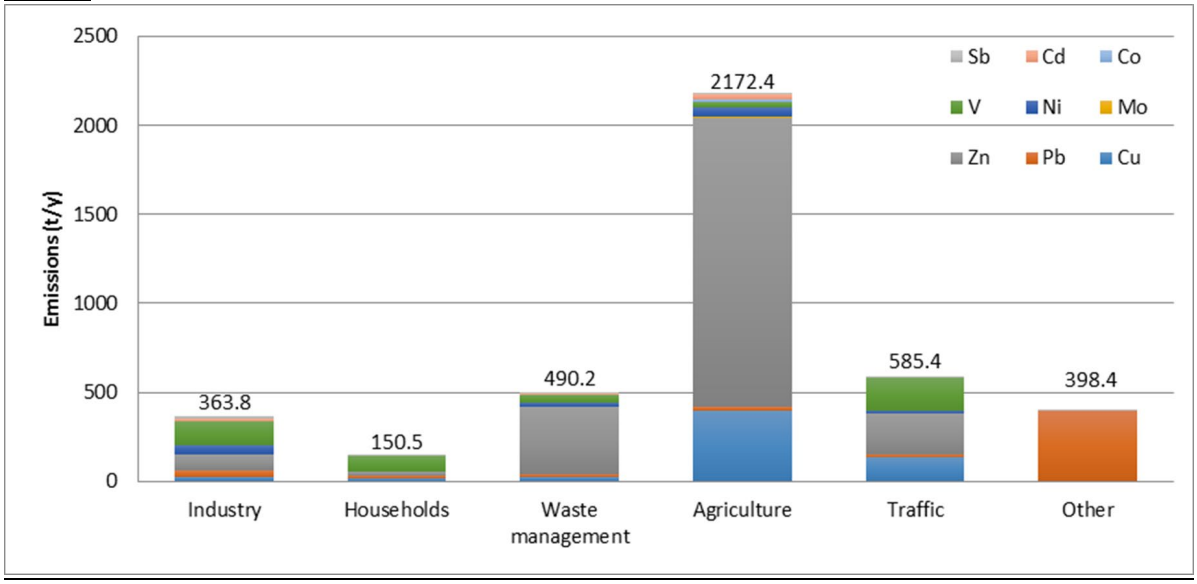
FIGURE 20: DIFFUSE SOURCES OF NICKEL IN WATER, AIR AND SOIL



As another illustration, Figure 21 provides an overview of the total regional emissions by source for 9 metals in the EU. Emission patterns for metals are surprising and should encourage I-RMOa authors to explore this dimension to the benefit of society.

FIGURE 21: TOTAL REGIONAL EMISSIONS OF 9 METALS BY SOURCE (EU)

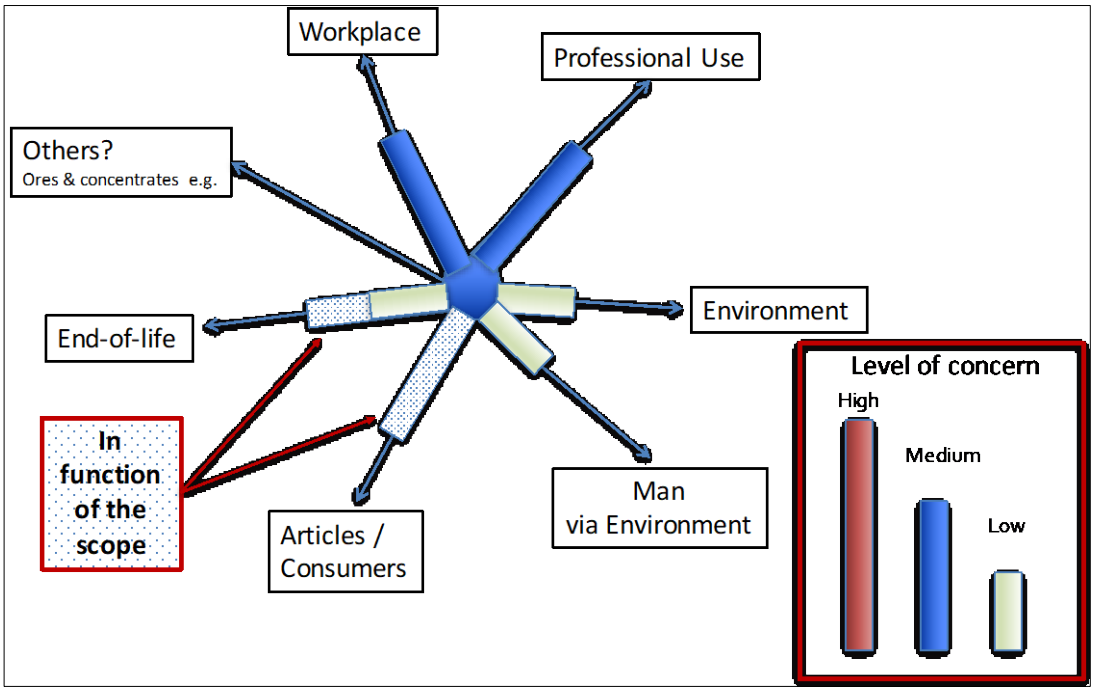
FIGURE 1



1.2.3.2. ESTIMATING THE LEVEL OF CONCERN

In function of the scope of the analysis, this step helps in getting a grasp of the broader scene and put the different issues in perspective as illustrated in Figure 22

FIGURE 22: RATING OF THE LEVEL OF CONCERN



In the example discussed earlier, one considered the worker exposure situation (RCRs, OEL values) as the relevant dimension to discuss.

But, depending on the scope set by those initiating the I-RMOa, one may venture into the fate of the articles (use and end-of-life) with their releases (wear) and losses to the environment (non-recycled fraction). The difficulty here may be that the substance under scrutiny may have changed speciation.

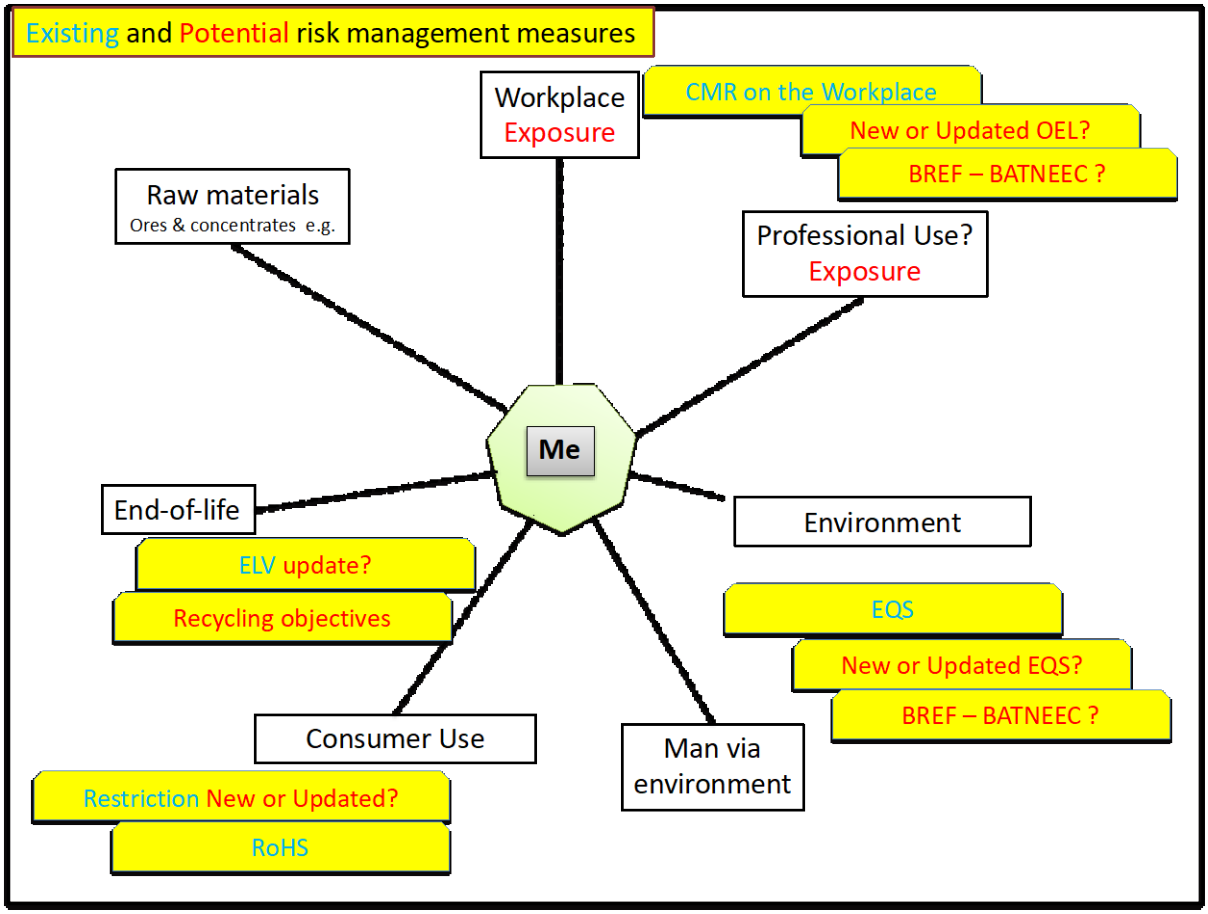
The assessment of sources of exposure / release from a life-cycle perspective (cf. mass balance, diffuse sources) can provide a view on point sources and some diffuse sources (be they under a different speciation). that may be significant or even the most relevant ones (agriculture, unintended sources of exposure).

1.2.4. PRESENTATION OF THE EXISTING REGULATORY RISK MANAGEMENT MEASURES OR WHAT COULD THEY BE?

An inventory is established of the existing regulations and management tools whilst possible alternative approaches are identified (Figure 23). The assessment will be refined by consider the scope (geography, activities) and efficacy (values up to date, enforcement etc.) of the existing measures.

Depending on the scoping of the exercise and on the level of sensitivity of the issues (public perceptions, political pressures, etc.), the discussion may go beyond the use of the substance to consider the fate of the articles for which the releases may be assessed (intentional or normal use and wear?).

FIGURE 23: EXISTING REGULATORY AND POTENTIAL RISK MANAGEMENT MEASURES



ANNEX II – TYPES OF OUTCOMES OF AN I-RMOA

Depending on its objectives, the Broad I-RMOa may lead to different types of conclusions and actions:

- **Proactive approach, independent from an immediate regulatory initiative**:
  - Identification of areas for improvement in terms of exposure/emissions locally (point sources) or alternative approaches (consider a path to substitution, tackling other indirect/unintentional sources).

    Examples:
    - *Acid mist suppressants reduce exposure to all the metals present in the plating bath. They are an illustration of the fact that an industrial process-focussed approach can offer cross-substance benefits.*
    - *User industries may, based on their understanding of the availability of a suitable alternative, decide to discontinue some uses. The use of lead stabilisers for potable water piping has been voluntarily discontinued end 2005 by the pipe producers members of the European association TEPPFA and under the PVC Industry Voluntary Commitment, sales of lead stabilisers were reduced in stages with a phase-out deadline set for 2015.*
    - *If the I-RMOa is performed by a company, the outcome may be*
      - *immediate remedial measures or a phased investment plan to reduce, adequately control or eliminate the concern*
      - *R&D in view of technical improvements or substitution,*
      - *product portfolio choices*
      - *a decision to seek a rapprochement with other industries (to form an industrial ecology cluster, having in mind Circular Ecology objectives or develop other initiatives or ventures)*
      - *…*

  - Improved understanding of the relative contributions of the different sources with a better view of where efforts should be focussed on.
    If some issues can be dealt with technically or via 'topical' regulations, other remediation approaches may require broader societal debates and efforts over a longer period (awareness raising, consensus forming, implementation and its technical and socio-economic compromises, trade dimensions etc.) but they may be worth trying in view of their significance in terms of contribution to the concern.

    Example: Cadmium sources un related to the cadmium industry may require solutions not related to the 'use' of the substance. These unintended releases should be addressed in their specific context.

- **Proactive approach with a view of facilitating Risk Management Options analysis by regulators (REACH or others):**
  - Identify data needed for a better understanding of the substance's fate
    - Volumes of uses and volumes of the different sources
    - Status (intermediate or not) and function
    - Changes in speciation
    - Exposures
    - End-of-Life
      - Volumes
      - Constraints to closing the loops (Circular Economy point of view)

Examples:

- *The extent of a possible concern may be unknown or monitoring data may be insufficient to understand the exposures from a risk management point of view. The decision may thus be taken to set up epidemiological studies and targeted monitoring campaigns.*
- *Engage with value chain (downstream users) to collect data and develop common understanding of the issues*

- **Develop understanding of all potential or likely RMOs that regulators may consider and assess them**
  - Participants may have found inspiration in the Role Play described in Annex IV of this Guidance to 'integrate' the thinking of the other stakeholders (regulators, other user sectors, various segments of civil society). Looking at the issue from different angles may help develop solutions that may seem counterintuitive.

  Examples

  - *Understanding the timing constraints (delivery objectives) on regulators, stimulates the development of early Analyses of Alternatives or of industry initiatives so as calls on suppliers of solutions.*
  - *A better understanding of the decision elements of the other segments in Industry may help in setting up a dialogue, up to now inexistent, to explore and discuss the various possible RMOs.*

- **Develop understanding of and document the interactions of likely RMMs with other policy objectives related to access to raw materials (Critical Raw Materials, Circular Economy), new energy paradigms (renewables, decentralisation, storage), the transportation and public transit and other sustainability concerns (durability etc.).**
  - The Broad I-RMOa allows a holistic view of the issues at hand – may have started from a hazard classification of a substance – and outlining the parameters of a risk management approach.

  Examples

  - *The sustainability and resilience of our energy systems rely – for reasons of resource and technology availability and independence - on the accessibility of diverse materials. Looking beyond the hypes, the assessment may provide an objective view on the contribution of a substance.*
  - *Anticipated market developments such as growing e-mobility or increased demand for durable materials may create a different picture on the future role of a substance.*

- **A critical look at the issues, may identify the relevant socio-economic information that may usefully contribute to an RMOa initiated by a regulator and start a data collection program.**

A synthesis of knowledge developed on the cadmium value chain which included mass flow assessments and diffuse sources analysis could be the one provided in the following Table 30, which is an illustration of a very synthetic summary of key elements.

TABLE 30: EXAMPLE OF POSSIBLE CONCLUSION IN THE CADMIUM INDUSTRY

	Air emissions	Water releases	Waste generation	Worker protection	Man via Environment (Local)	Man via Environment (General population)
Cd manufacturers (Zn smelters) Specialty chemicals (CdX) manufacturers Article manufacturers	Cd industry represents: 4,3% of all industrial air emissions but only 7,5% of all air emissions in EU 28	A priority hazardous substance: phase out and cessation of Cd releases required by EU WFD directive (2020)	Cd containing waste are regulated as hazardous waste	Industry initiative built on the conclusion of the Cd/CdO risk assessment ensures Cd exposure is being reduced below SCOEL proposals	Major source of uptake by general population is through food and smoking. Major source of Cd addition to agricultural soil is through (Cd containing) phosphate fertilizers. Studies show that Cd concentration in soil in now following a downward trend	
Additional consideration: Cd using industrial sites are regulated under SEVESO III Directive						

One notices that this synthesis does not need an avalanche of quantitative data. It sets the scene for further discussions based on verifiable statements. From there on, an Industry (or segments of it or companies) can develop their strategy in terms of where the points of attention should be and engage with authorities and other stakeholder

ANNEX III - LIST OF RMOS AND THEIR STRENGTHS AND WEAKNESSES

This is a ***non-exhaustive list of existing Chemicals Management Legislation*** as there might be product- or substance-specific regulations that are relevant to the analysis e.g.

- Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation 1272/2008)
- REACH Regulation (1907/2006) with a particular focus on Authorisation and Restriction
- Transport of dangerous goods (Directive 2008/68)
- Import and export of dangerous chemicals (re. Rotterdam Convention (Regulation 649/2012))
- Biocidal Products (Regulation 528/2012)
- Plant protection (Regulation 1107/2009)
- Consumer protection regulation such as Toys Safety Directive (2009/48)
- Occupational Safety and Health Legislation:
    - Risks related to Chemicals at Work (Directive 98/24) and Directives on indicative occupational exposure limit values (Directive 2009/161)
    - Carcinogens or Mutagens at work (Directive 2004/37) (UPDATE TO LATEST VERSION)
- Environmental legislation
    - Waste management
        - Basel Convention on transboundary movements of hazardous wastes and their disposal (Council decisions 93/98 and 97/640)
        - End-of-Life Vehicles (Directive 2000/53 and amending acts)
        - Batteries and accumulators and waste batteries and accumulators (Directive 2006/66 and amending acts)
        - Waste electrical and electronic equipment
            - Waste electrical and electronic equipment WEEE Directive 2002/96 and amending acts)
            - Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive 2011/65)
    - Water
        - Water Framework Directive (Directive 2000/60)
        - Environmental Quality Standards (Directive 2008/105) – priority substances
        - Quality of water intended for human consumption (Directive 98/83)
    - Air
        - Ambient Air Quality (Directive 2008/50)
        - Arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons (Directive 2004/107)
    - Industrial Emissions
        - Industrial Emissions Directive (2010/75)
        - Waste Incineration Directive (200/76)

Policies to consider in the assessment of the pros and cons of the different RMOs:

- Sustainable Consumption and Production and Sustainable Industrial Policy (SCP/SIP) Action Plan (Communication SEC (2008) 2110 & 2111)
- Roadmap to a Resource Efficient Europe
- Integrated Product Policy (Green Paper COM 2001/68)
- Thematic Strategy on the Sustainable Use of Natural Resources (Communication COM 670/2005)
- Substance-specific strategies such as for mercury (export ban Regulation 1102/2008) and storage as waste (Directive 2011/97)

- Circular Economy Package adopted on 2 December 2015 which among other objectives and measures, includes ambitious waste management and recycling targets by 2030 and the promotion of re-use and industrial symbiosis.

Table 31 provides a schematic and incomplete overview of strengths and weaknesses of the different RMOs.

It will be regularly updated based on feed-back of practitioners.

TABLE 31: STRENGTHS AND WEAKNESSES AND POTENTIAL POLICY TARGET CONFLICTS OF POSSIBLE RMOS

RMO	Strengths	Weaknesses	Potential target conflicts (with other EU policies	Notes
SVHC selection	- fast process - Allows to send a message to the market that the use of the substance should be reconsidered and alternatives be envisaged	- As such, no immediate beneficial effect because no direct impact on emissions/exposure - Risk of stigmatisation of substance and uses that may appear later (during Authorisation process) to be of high societal benefit	- May discourage use of substances for R&D purposes in the EU, thus diverting innovation investments and knowledge development away from the EU - No consideration of sustainability elements	(1)
Substitution (voluntary)	Although NOT an RMO foreseen in the Regulation, a voluntary industry initiative: possibly complementing a regulatory initiative may be considered - The measure would be taking into consideration industrial constraints (timing etc.) - Potential to generate goodwill in the larger community - Reduced business uncertainty	- There are no legal means to force companies to join such a voluntary initiative - Guarantees of delivery may be burdensome (extensive reporting from Industry vs. administrative enforcement/controls) - Estimated to be medium to long term to identify and implement substitutes	- Risk seems a priori limited - Sustainability considerations need to be considered (impact on CE, Climate, …) given presently not done.	(2)
Use advised against in the registration file	- Quick measure	- Only a success if all manufacturers/users and importers respect this measure	- Check conformity with competition rules - Ensure sustainability considerations are included	
Authorisation	- Strong instrument to push for substitution and/or to make sure that uses that are technically and economically 'fit' for phasing-out are effectively banned - Allows Industry to make its case: society is informed on state of the art and on the real use of substances	- Complex dossier preparation, including discussions in the value chains between actors with different stakes and understanding of the issue - Business uncertainty: Uncertainty of the decision process Review times may be difficult to match with business planning (long-term contracts, investments)	- Business uncertainty may - weaken the competitiveness of EU value chains - divert flows of critical raw materials from EU to other production areas in the world - Sub-optimal substitution (even regrettable substitution) may reduce appeal of EU products, lead to off-shoring production or impact on recycling chain efficiency and profitability	

		- Consistency concerns for processes using different SVHCs - Resource-intensive (Industry but also reviewers and assessors) - Intermediate uses are not covered which reduces potential Human Health and Environmental benefits - Long term measure to implement (> 5ys)	- Difficulty to factor in the sustainable use of natural resources or natural elements	
Restriction	- Based on an established risk that justifies an EU-wide measure - Clarity of the rules which apply to all - scoping can be made specific to a single use or type of articles based on risk concerns - allows a wide variety of suited measures (restrict concentrations, OELs, training, banning, …)	- Complex to prepare for a Regulator (scoping, technical aspects, alternatives, socio-economic dimension) - Enforcement can be challenging (testing of imported articles e.g.) - Does not cover isolated on-site intermediates which may reduce effectiveness in terms e.g. of Human Health protection (workers) - Medium term measure to implement	- Difficulty to factor in the sustainable use of natural resources or natural elements	
Binding-OEL	- Allows to address all occupational exposures (irrespective of the regulatory status of the substance, i.e. intermediate or not) - Business certainty once implemented	- Potential disparity of implementation at national level (depending on whether indicative or binding) - Science is evolving and OELs may be difficult to establish and agree on. - Potentially conservative assessment factors in setting the OEL may have a huge impact on companies due to the lack of SEA considerations		
EQS (Water Framework Directive)	- Allows a holistic assessment and approach of the concerns (surface, ground and coastal waters with management of water bodies based on river basins or catchments and interlinks with Industrial emissions Directive etc.)	- Slow in adopting new understandings on e.g. bio-availability of elements in the water bodies - slow process (> 5y)		
BAT (Industrial Emissions Directive)	- Based on Industry expertise and on in-depth understanding of technical and economic feasibility	- Lengthy process which makes it inadequate to address issues that are considered urgent to address - slow process > 5y)		

Notes:

- **(1):** Opinions are divided on whether SVHC selection could be considered an RMM in and of itself.

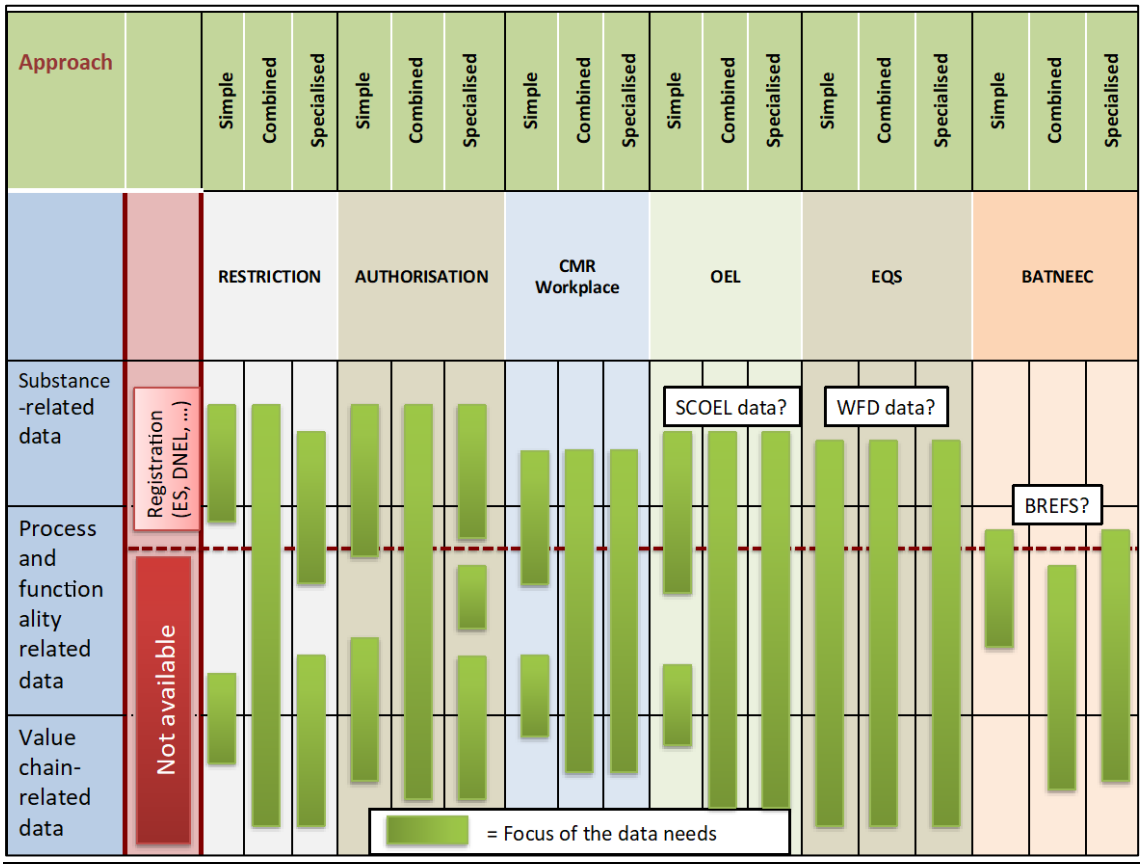
- **(2):** NEW! An interesting development, where regulators consider and discuss the pros and cons of a voluntary initiative, can be witnessed with the discussion on a Proposal for a Restriction on Diisocyanates under discussion (submitted in February 2017). The text foresees a restriction unless other measures are implemented such as a training program for workers.
  This would be a precedent if the text of the Restriction were to confirm that a ban can be avoided when "the employer or self-employed worker ensures that measures and trainings are taken prior to the use of the substance…"

- Overall speed of the process were considered as "fast" when the measure can be handled in 1 year, "Medium" in case this requires 2-4 years and "Long-Slow" if it takes more than 4 years.

ANNEX IV - DATA COLLECTION REQUIREMENTS ACCORDING TO RMO

Registration dossiers constitute the main starting point for ECHA and the MS. Therefore, Industry should also start with the Registration dossier of the substance of concern, and conduct a review of the hazard properties, as well as of the current exposure scenarios. However, depending on the RMO, additional information will also be required, which will need to be collected through separate studies (e.g. use-volumes, supply chains, alternatives, socio-economics, etc.). This additional work will require considerable time/effort, and additional costs, illustrations of this are provided in **Fout! Verwijzingsbron niet gevonden.** and **Fout! Verwijzingsbron niet gevonden.** whose purpose are only to illustrate that there is no RMO that can be discussed based on REACH Registration dossiers only.

TABLE 32: POSSIBLE DATA GAPS IN FUNCTION OF THE DATA TAKEN UP IN THE REACH REGISTRATION DOSSIER



The above Table 32 *(where the term 'specialised' is used for the 'integrative' approach*) is an illustration of the fact that some options are more demanding in terms of data than others but also and foremost it serves to highlight that information on process and functionality-related data and value chain-related data, is not readily available, especially to regulators, as not contained in registration dossiers

The Industry RMOa exercise may thus serve to collect and process data that could be shared with regulators when they decide to initiate their own RMOa or during public hearings and consultations. Table 33presents a view of what type of data may be needed to collect on top of what is available in the Registration dossier.

TABLE 33: ILLUSTRATION OF KEY DATA NEEDS FOR THREE RMOS

Some data needs (generic) — = Not in Registration dossier

	REACH Registration Dossier	Accuracy	Uncertainty	Restriction	EQS (WFD data?)	BATNEEC (BREFS?)
Substance-related data	• Human Toxicity	DNELS?	DNELS?	+	+	
	• Regulations			+	+	
	• Environmental Toxicity	DNELS?	DNELS?	+	++	
	• Regulations			+		
Process and functionality related data	• Volumes (overall)	Reality?		+	+	+
	• Exposure (generic)			+	+	+
	• Process and product regulations			+	+	+
	• Volumes per use / peocess			+	+	+
	• Functionality per use/process			+	-	-
	• Alternatives per use/process			+ plus tox profil	-	-
Value chain-related data	• # legal entities / plants			+	Regional Population	+
	• # Workers exposed and dependent on substance use			+		
	• Market (volumes, trade)			+		-
	• Price elasticity			+		-
	• Cross-value chain interrelations			+		-
	• Life-cycle dimensions (sustainability issues, recycling dynamics)			+	+	+
	• Costs current vs. alternatives/ non-use situation			+	-	-
	• Costs current vs. new technology			If combined/ integrated approach	+	+

ANNEX V - LEARNING LESSONS FROM RMOA EXERCISES AND PRACTICAL ADVICE, INCLUDING ROLE PLAY

This section will be updated regularly as learning lessons come in from different I-RMOa exercises performed by Industry.

1. ISSUE IDENTIFICATION

2. It has proven useful to **first hold an internal (commodity/consortium) preparatory exercise** to go through the Industry tasks and check-list (see PARTS 1 and 2).

3. It is very important that in the early phase of the RMOa exercise, **the participants consider how a regulator may look on the issue**!

   What will a regulator base his assessment of the concern on?

   - Own data
   - Registration dossier and what are the points that may 'stick' (calculation of exposure and of DNELs e.g.) views on RCRs
   - NGO reports and academic research
   - Free accessible data on the Internet

   Confronting that point of view with the Industry view may lead to uncover risks of misunderstandings and may orient the data collection.

   It may also affect the Industry view of the concern.

4. **It may be recommended to hold a ROLE PLAY with those participating in the first meeting**.
   a. **Purpose:** familiarise participants with an exercise where they will be invited to not only defend their company's interests (and imagine a path forward) but to adopt a holistic view, taking into account concerns of the value chain(s) and of regulators and society)
   b. Role play organisation:
      i. Organise small groups (6 to 7 people maximum) that will discuss one or several parts of the value chain.
      ii. Ask participants to play the role of a company representative defending the interests of a particular segment of the value chain.
      iii. Have a moderator – familiar with the RMOa tool - who starts the discussion and challenges the views expressed by the participants, such as "Regulator X has stated to be concerned that there is an unacceptable risk or concern"
      iv. Provide participants with a small briefing note with 'imaginary' company objectives such as "Company is very close to having an alternative available but doesn't want the competitors to know" for example.
      v. Let them consider, during half an hour, how they would address the concerns voiced by regulators, i.e. the substance has a profile that would qualify it for consideration as SVHC or for other RMOs.
   c. **Conclusion:** In plenary, moderators provide feed-back on interesting elements of the discussion such as issues ignored (on purpose?), on the level of understanding between value chain actors etc. This proves to be an interesting introduction to the complex assessment of the issues across value chains.

5. Following up on point 2, i.e. the regulators' point of view, it may be useful to **assess this identification of concerns**
    a. **Relevance?** Is the assessment of the risk i.e. respiratory sensitizer as the main/only focus point to consider, in the life cycle stages/uses described, a good reflection of the reality of risks for a policy-maker to suggest a conclusion?
    b. **Credibility?** How likely will this assessment be accepted by regulators / other stakeholders as being honest and unambiguous?
    c. **Acceptability**? To what extent will this risk identification be accepted and supported in the companies and the value chain?
    d. **Easy to validate?** Is this assessment of risks easy to check and validate by external experts/regulators?
    e. **Robust?** Are these conclusions able to stand the test of time? Could they be put into question by the resolution of existing uncertainties or ongoing research?

2. CONSIDERING SUBSTITUTION

As the main policy aim of dealing with SVHCs is to substitute, it is recommended to take up "substitution" as the first RMO on the list.
Some consortia have been able to perform **generic analyses of alternatives** which, although not reflecting all the cases that may exist, provided a good overview of the issues and possibilities regarding substitution across a supply chain or parts thereof. Such exercises involved the participation of R&D experts including academics.
The findings of these discussions could be shared with regulators and provided a good picture of what the possibilities where and of those uses where substitution did not appear feasible in the foreseeable future.

3. PRACTICAL I-RMOA CHALLENGES (PARTICIPANTS)

Challenges to address:

- ***Too few participants or too different or too sensitive:***

The exploratory exercise may show that there is a limited number of sites and/or different technologies, or that there are business considerations that are difficult to 'reconcile'.
It is then advised to divide the exercise into a generic part (understanding the potential concerns related to e.g. risk characterisation in the RCRs) and more specific parts that will be discussed separately.
Depending on the findings, a common conclusion or recommendation may be suggested.
This is time- and resources consuming, but it offers the potential to yield much more information than with a common exercise, especially when exploring substitution, socio-economic feasibility etc. These separate discussions may be useful to companies when they consider their own options later on.

- ***Too many participants (huge value chains):***

The suggestion is to consider working in a modular way with, with preferably a champion per module (a company a step ahead of the other companies and thus a useful support to the process moderator)

- ***Criteria for estimating overall proportionality may vary, depending on the substance, its use, policy context:***

Flexibility is allowed.

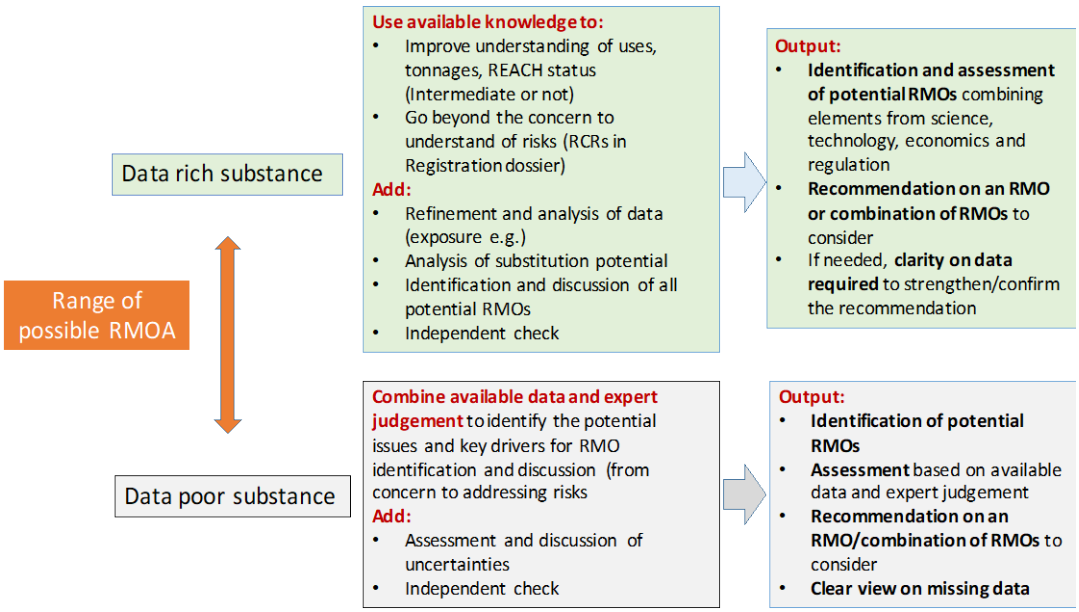
4. DIFFERENT APPROACHES IN FUNCTION OF DATA

1. It may be advisable to **differentiate between gaps in data** that are relevant to come to a credible conclusion. Initially, in the identification of the RMOas, one will tend to rely more on expert judgment than when considering input into Public Consultations and beyond (ultimately Authorisation e.g.).
   So, in order not to discourage participation and clogging the system with irrelevant information, it is important to be selective (what is relevant at what time?).
   So ideally, map the gaps according to their relevance vs. the stage of the process.

2. **Data rich substances** will allow a much easier **analysis of the concern so as to see whether there is a risk that needs to be addressed.** For example, an EU-wide risk may lead to explore the possibility of a Restriction.

The range of I-RMOa possible and their output ijn function of data availability is illustrated in Figure 24.

FIGURE 24: RANGE OF POSSIBLE I-RMOA IN FUNCTION OF 'DATA RICHNESS'



3. It has proven of high value and therefore highly advisable to submit the report and its conclusions to an **external review**. An independent view on the proceedings may bring to light logical flaws, weaknesses in the argumentation etc.

5. VALUE CHAIN IMPACTS FROM AN ECONOMIC POINT OF VIEW

Economic dimensions of proportionality

The discussion on the **economic dimension of the proportionality** of each RMO may include the following aspects:

4. Potential economic costs or impacts such as
    - Investments and operating costs of new investments that woud be required
    - Disruption of value chains due to shortages of supply or the disappearance of a segment of the value chain (closure of activities etc.).
    - Loss of turnover/profit in one or more of the segments of the value chain.
    - Loss of production in the EU and increased imports.
    - Rearrangement of the value chain (new supply loops or new outsourcing circuits in the EU or outside the EU).
    - Relocation of one or more parts of the value chain.
    - Loss of confidence in the future of the value chain (loss in stock value, higher interest rates, higher insurance premiums etc.)
    - Effects between supply chains (also involving other metals)
    - Unexpected effects on economic infrastructure and on operations from a Circular Economy point of view
- Potential benefits such as
    - At company/sector level:
        - Introduction of innovative technologies
        - Productivity and competitiveness gains
        - If planning security is offered: regained confidence in the value chain with positive impact on investment planning and cost
    - From a human health and environmental point of view:
        - Improvement of human health (workers, general population etc.) and of health-related costs
        - Reduction of environmental damage
        - Reduction of ‘man via environment’ impacts

Such arguments should be used with care and only when they can be substantiated (qualitatively or quantitatively) so as not to create a bias in the assessment by, for example, inflating negative impacts and ignoring the positive ones. In this context, one has to be aware of the existing concern that future effects on health and environment tend to be assessed poorly because of the uncertainties surrounding these effects. When a monetary valuation is than performed, weak starting assumptions may lead to wrong conclusions.

It is also not realistic to expect a value chain to be able to accurately estimate impacts across other value chains (substitute substances). In a first stage, experts in the value chain can provide a qualitative assessment of the expected impacts, which may be confirmed and quantified later when required.

6. DEVELOPING THE SOCIETAL VIEW

Underlying concepts for bringing in the broader societal perspective

- **Precautionary principle**

  The EU Commission indicated in a Communication in 2000 that five elements underpin the precautionary principle:

  1. **Proportionality** of the measures considered
  2. **Non-discrimination** (no difference in treatment when situations are comparable and different situations should be treated differently unless there are objective grounds to not do so)
  3. **Consistency** (Measures adopted should be consistent with the measures already adopted in similar circumstances or using similar approaches, especially when addressing uncertainties).
  4. Examination of the **benefits and costs** of action or lack of it
  5. Examination of **scientific developments**

  Article 3 of the REACH regulation stipulates that the provisions of REACH are underpinned by the precautionary principle which is an approach to risk management where there the public and the environment must be preserved from exposure to harm when scientific assessment has found a plausible risk, even where this risk is uncertain.

  The societal dimension is not absent from the I-RMOa and the underpinning elements of the Precautionary Principle can be found in the I-RMOa, although the analysis will differ in the way of approaching them (see Table 34).

TABLE 34: COMPARING APPROACHES: EU PRECAUTIONARY PRINCIPLES VS. I-RMOA

5 elements of the EU Precautionary Principle	I-RMOA approach
Proportionality	**Idem**
Non-discrimination	Idem
Consistency	Idem
Examination of C/B of action and non-action	Idem
Examination of scientific developments	Idem
	Alternative approaches

Decision makers should explicitly adopt criteria that have the precautionary principle at their heart – such as a requirement that a certain amount of harm to humans or the environment will not be tolerated, regardless of economic effects.

- **Discount rates**

As Sarah Arnold from the New Economics Foundation writes, "*the choice of discount rate, and how it is used is not just a dry academic exercise, but is laden with implicit moral decisions and value judgement about the importance of future impacts relative to current costs*"(Discounting future damage? NEF, September 2019)

Tools for debating the broader perspective

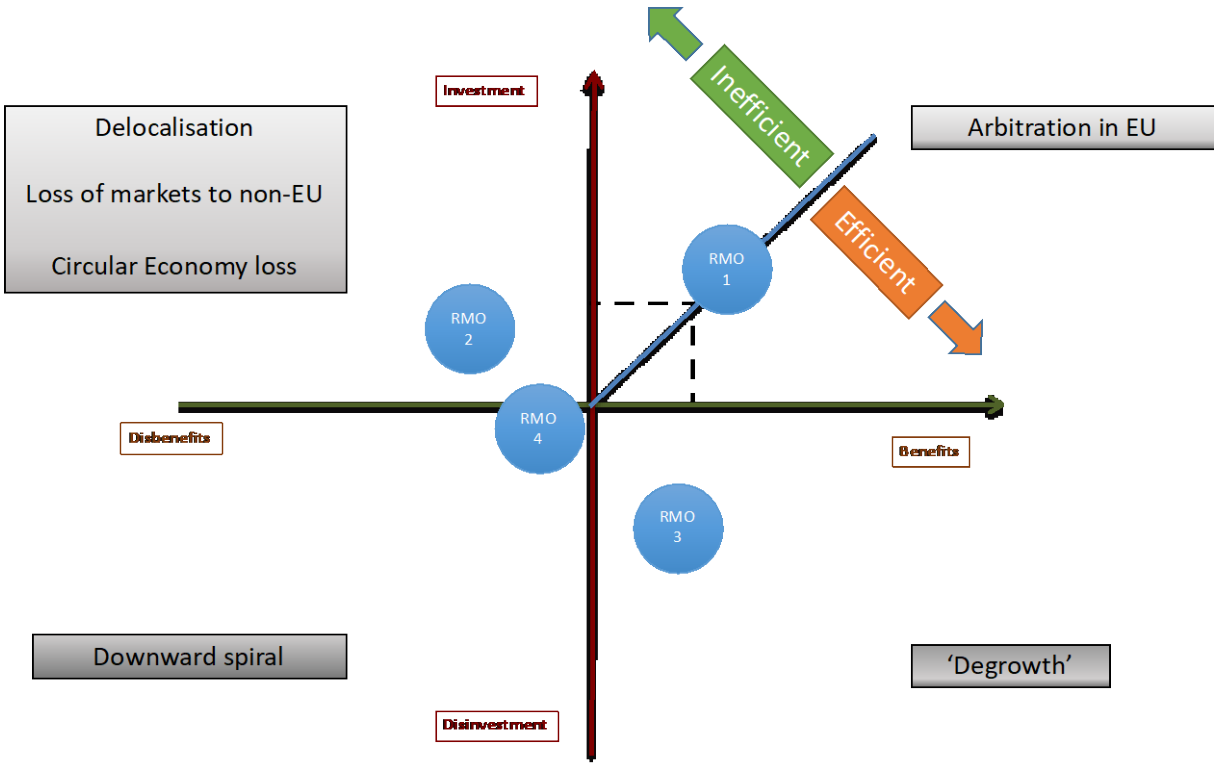
It may be valuable to put the value chain impacts in a broader perspective that includes the direct and indirect benefits of the RMOs considered as well as the possible drawbacks.

An indirect impact of relocation to the rest of the world might, if of sufficient magnitude, be social disarray, health challenges and lower education standards in regions already affected by high unemployment.

Such an exploration allows to develop another view on how, from a societal point of view, costs compare to benefits. However, enough solid data should be available to draw a credible conclusion (see illustration in Figure 25).

Note that the concepts used in this example are subject to controversy, but they may help initiate the discussion, the idea being if it is possible to place the options at hand in a picture of broader societal acceptance.

FIGURE 25: POSITIONING OF RMOS ON A SOCIETAL IMPACTS SCALE



1. **Society benefits from RMO 1**

   RMO 1 requires a certain allocation of wealth (investment) but produces a higher level of wealth (benefits).
   Ideally, and provided all costs can be accurately estimated (including impact on share value e.g.)

and all benefits can be valued, society would be satisfied with an outcome along or under the blue line (Benefits > costs). In that case the investment might be worth doing. If it can be proven that the RMO leads to an outcome above the blue line (Benefits < costs), the RMO can be said to be inefficient from an overall societal point of view.

2. **Society loses with RMO 2**

   The costs to Industry (relocation, loss of business to non-EU competitors etc.) are not matched by a net benefit (because of higher net health costs due to unemployment, fiscal challenges for the government, reduced care of the environment etc.). One may qualify this option as 'contra-economic' growth.

3. **Society 'loses' with RMO 3**

   The net positive effect for society results from an increase in essentially qualitative improvements (less noise from transport, reduced air pollution etc.) due to a reduction of the size of the activity. The economy is said to lose financially even if there might be greater benefits on the long run, for instance, due to enhanced sustainability.

4. **Society loses with RMO 4**

   The reduction of activity leads to a net loss of benefits that may be a loss in well-being (unemployment leading to poverty e.g.). The more the net effects of policies hint towards this quadrant, the more one can say that society risks falling into a downward spiral.

6. HOW TO USE A SCORING SYSTEM

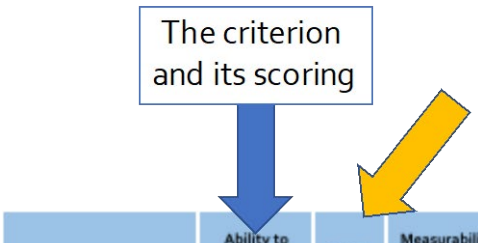
A matter of documented and consistent choice

The Guidance presents different modes of scoring from the use of "+" and "-" to more quantitative scoring systems that may include weighting mechanisms. It is up to those performing the I-RMOa to opt for the approach they feel best suited. They should however make sure that the method is explained clearly and used consistently throughout the assessment.
When adopting a scoring system, as described here, one should keep in mind that it will often rank perceptions and in the best of cases, qualitative expert judgments on (yet) not quantified cause-and effect processes. The I-RMOa is not to be confused with an SEA as impact analyses & feasibility assessments based on numbers are to be seen as a step further in the policy process.
Before discussing some of the scoring systems, it has to be said that a scoring is not absolutely required to select an RMO. Participants will have difficulties in not biasing their score in one direction. However, there is a major advantage in it as it can make participants aware of the 'objective' merits of other options and of the fact that these might 'justifiably' be considered better by other stakeholders.

Quantitative scoring systems

Quantitative scoring systems most often combine a **scoring of the criterion** with a **weighting of that criterion** as illustrated in Figure 26.

FIGURE 26: EXAMPLE OF SCORING AND ITS WEIGHTING



		Ability to reduce risks	Weight	Measurability / Monitorability	Weight	Proven technology available	Weight	Overall EFFECTIVENESS score	Ranking
Substitution (Industry)		5	10	7,5	8	0	10	110	5
Existing legislation (e.g. OEL, BATNEEC, etc.)	OEL	8	10	7,5	8	7,5	10	215	1
	BAT	7	10	7,5	8	7,5	10	205	3
Restriction		6	10	7,5	8	2,5	10	145	4
SVHC selection		1	10	1	8	1	10	18	6
Authorisation		8	10	7,5	8	7,5	10	215	1

- The **scoring/rating of the criterion** such as "ability to reduce risks" in the following example, should best happen in accordance to a scale the participants have discussed and understood.

  Examples:

  Score 10: The RMO entirely fulfils the criterion (certainty risk is entirely removed). Or there are technically and economically feasible alternatives that are readily available.
  Score 7,5: The RMO fulfils the criterion to a satisfactory degree (risk is adequately controlled, the RMM is adequately targeting the issue, or alternatives are available for the most relevant uses.
  Score 5: The RMM will allow to adequately control the risks in only part of the cases, e.g. the measure will not protect all workers (cf. intermediates in an Authorisation process)
  Score 2,5: Most of the risk identified will not be addressed by the RMM
  Score 0: The RMM is not felt to be able to address the issue
  One could even imagine a negative score!
  Score -2,5: The measure is expected to have an adverse effect on the risk

  Recommendation: Participants should, ideally, participate in the definition of the scoring so as to 'integrate' its logics.

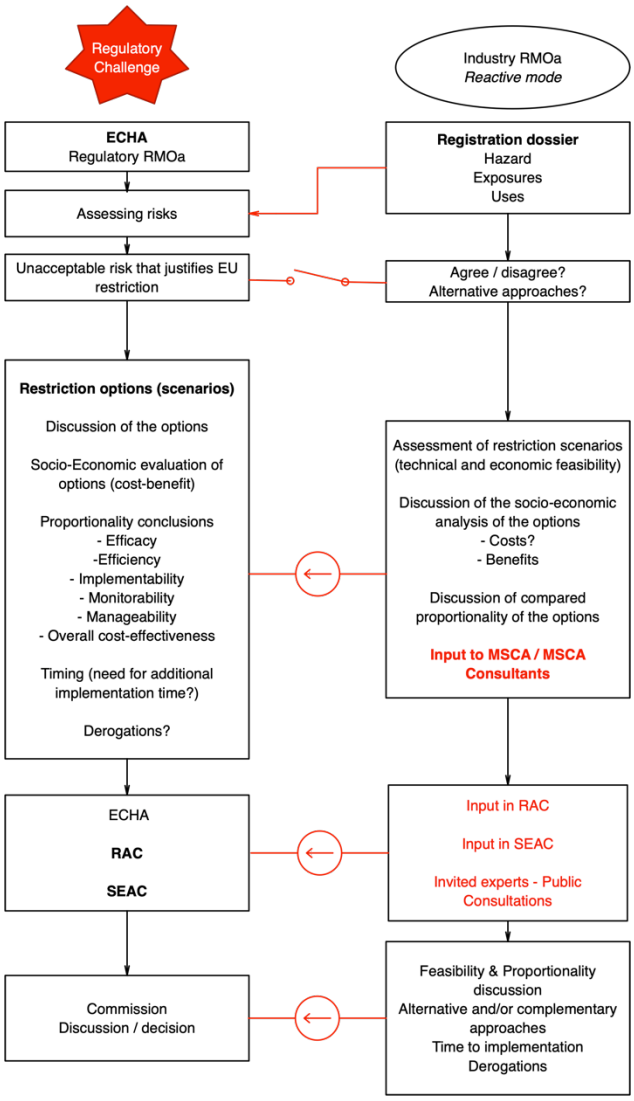
- The **weighting of the criterion** allows the participants to indicate the relative importance of the criteria on a scale that may be from 0,5 (low importance) over 1 (neutral) to 1,5 (high) or 1 to 10. The advantage of this system is to ensure that the less important criteria have less chance to skew the conclusions.

7. LEARNING LESSONS FROM ANTICIPATED RESTRICTION DISCUSSIONS

Advantages of an anticipative I-RMOa

Identify data gaps for the starting assessment! First of all, an anticipative/integrated I-RMOa allows to identify and possibly address data gaps in the Registration dossier which will serve as basis for a Regulatory Management Options analysis. In the absence of such an anticipative action, Industry starts the process at a disadvantage, especially when informed late in the regulators' RMOa process.

FIGURE 27: I-RMOA PERFORMED ALONG A RESTRICTION DOSSIER PREPARATION



The discussion of the risk is a critical one – especially for non-threshold substances - where parties (Restriction Dossier submitter, ECHA rapporteur, Industry, NGOs) may and will disagree. It sets the scene for the further discussion as it will justify regulatory intervention, the severity of the measures imposed and the benefit estimates of risk reduction.

The discussion of a proposal for a restriction at ECHA level can reach conclusion in less than a year and a half where a great number of contentious issues may have to be settled as shown in Figure 27.

Lessons drawn: Good to perform exhaustiveness check of the Registration dossier content and develop a good understanding of the strength and weaknesses (vs. potentially maximalist interpretations in terms of acceptable risks).
New concepts such as risk equity where approach is focussed on inequalities vs. the risk rather than on the overall level of risk.
Consider *What-if* scenarios in case one's assessment of exposure/risk is not accepted… (moving concept of politically acceptable risk).

8. LEARNING LESSONS FROM RESTRICTION DISCUSSION: COBALT SALTS

What an anticipative I-RMOa would not have identified…

This restriction dossier introduced new concepts such as:

- Proposing a *Reference Exposure Value (REV)* for use in downstream users' CSA and communicated through extended Safety data Sheet
- *Minimum technical requirements* for a prescribed Risk Management Measure (BATNEEC)

In practice, the Co salts industry had to address 3 challenging elements (precedent!) that it had to address:

a) REV concept
b) Risk equity concept
c) Acceptable risk 1/100,000

Lesson drawn: Industry reacted promptly, and Industry survey got a good level of response because of the urgency.
An anticipative I-RMOa will not benefit from such a sense of urgency and will most often rely on the participation of a few players, not necessarily representative of the working practices and exposure situation across the industry.

The challenges from such a case should serve as inspiration for the outlining of future integrated I-RMOa exercises.

ANNEX VI - I-RMOA – ILLUSTRATION WITH HYPOTHETICAL SUBSTANCE X

1. Introduction

2. Meeting to start the I-RMOA: Agreeing on potential concerns and potential RMOs

   Setting the scene
   Participants
   Purpose
   Uses
   Exposure
   Substitution
   Identification of potential RMOs

3. Individual company exercise: scoring of potential RMOs

4. Final meeting: agree on conclusions and path forward

1. INTRODUCTION

I-RMOa Process description:

This is an exercise that refers to a theoretical substance X used as a stabiliser in plastics.

The process consisted in:

a) Preparatory data gathering
b) Meeting of companies to identify all possible RMOs and agree on data that should be collected
c) Companies individually discussed and scored the different RMOs
d) Bringing together of the company evaluations and proposal of synthesis
e) Consensus on outcome and agreement on next steps

At each of the different stages, notes are provided with learning lessons from other similar RMOA exercises.

Hypothetical substance:

Substance X: metal compound

Hazard profile: fits with SVHC criteria (reprotoxicity)

Exposure through humans occurs via migration from plastic materials

Caution:

The discussions and outcome of this I-RMOa are purely hypothetical, although they do reflect the logic in the discussions and the types of findings in several groups and consortia.

This overview provides a flavour of a I-RMOa. Depending on the complexity of the substance and of its uses, the RMOA may be much more elaborated and richer in data.

2. MEETING TO START THE I-RMOA: AGREEING ON POTENTIAL CONCERNS AND POTENTIAL RMOS

SETTING THE SCENE

Participants

Several companies using substance X for producing **articles made of plastics**

Facilitator: REACH Consortium / consultant

Purpose

a. Check agreement on scope (broad or limited analysis, expected use of the I-RMOa etc.)
b. Check agreement and data gaps/uncertainties on
   - Substance use (so as to be sure of life cycle and REACH status)
   - Exposure (to look for potential issues along the life cycle)
c. Discuss potential Risk Management Options for further analysis.

Uses

Uses as in the Registration dossier:

Use	REACH status
Formulation	Not an intermediate
Production of plastics	Not an intermediate

Questions:

I. Is the Registration dossier up to date on uses?

a. Potential uses identified (Google search, analysis of patents, commercial websites and catalogues etc.)

Note: In other I-RMOas, preparatory research, meetings and subsequent consultations led to discover an increasing interest for the substance and potential new uses in the future, for example:

- **R&D in catalyst:** a substance appeared to be a favourite compound in the development of new chemistries for new applications. This information came from companies and was confirmed by literature search as well a scan of recent patents.

- **Inclusion in new rechargeable battery chemistries** for electric vehicles. One of those chemistries is not yet produced in the EU but investment by a non-EU car manufacturer in a European battery production site might change the picture.

The group was of the opinion that such possible developments should be taken into account in a RMOa. It could be done by checking the outcome if the evaluation by companies (scoring and discussion of the potential RMOs) is compatible with potential future developments.

II. Is the Registration dossier up to date regarding tonnages? Double counting?

No reliable trade statistic is available to Industry which might be helpful to identify the net use in Europe as substance X is taken up in a broader category of compounds.

A tentative tonnage allocation (based on estimates from companies) provides:

Use	Intermediate	Non-intermediate
Formulation (In EU, includes exports but excludes imports of ready to use mixes)	0	110-200 tons
Downstream use		
Production of plastics	0	210-250 tons
Total used in EU	**200-400 tons**	**320-450 tons**

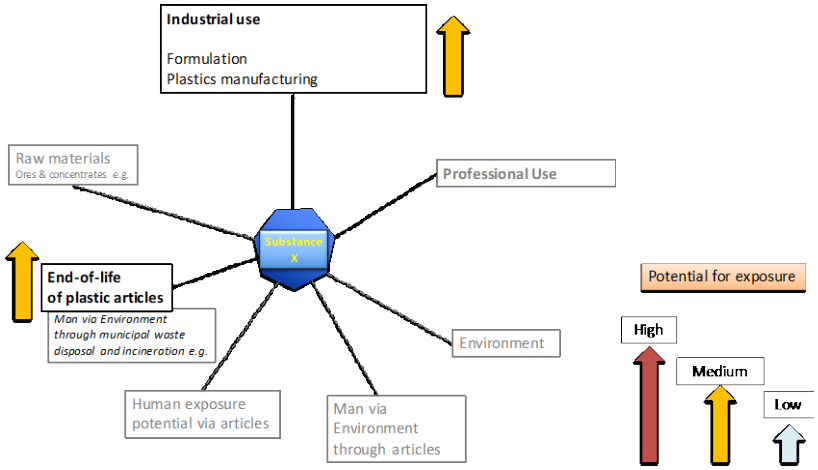
Overall, the tonnage used in the EU was estimated at around 400 to 500 tons.

Decisions:

1. Check **uses** with commercial departments and if needed update Registration dossier
2. Check **tonnages** so as to be able to get a clear picture of the real use (excluding double-counting etc.)

Exposure

The potential for exposure was discussed and considered from a life cycle point of view:



	Number of manufacturing sites / legal entities	Number of potentially exposed workers
Formulators	5	50- 80 (tbc)
Plastics manufacturers	45	880 - 1450 (tbc)

Potentially exposed workers number 1500 maximum. Man via environment exposure is still under investigation to confirm existing studies but companies agreed that the potential for exposure exists at end-of- life.

Substitution

	Substitution potential
Formulators	Alternatives exist and move to them would not lead to business disruption, provided that the market is not taken up by competitors who do not substitute
Plastics manufacturers	Substitution is possible. Concern about the continued presence of substance X in granules produced from recycled articles Concern about import of articles still containing substance X (commercial handicap and end-of-life concerns)

Substitution appeared both technically and economically feasible.Participants indicated that they would be prepared to consider voluntary substitution provided that there are no free-riders.

Identification of potential RMOs

The group discussed the different options that could be identified and were discussed.

Interesting is that the group found that a combination of approaches may be necessary, especially to address the risk of free-ridership and issues of end-of-life management of articles containing substance X (including imported articles).

The following table was agreed upon as a conclusion of the meeting with the request to the participants to assess and score the options individually.

Potential RMO	First discussion	A priori relevance
Substitution (Industry initiative)	Possible approach. Concern for market disruption by free-riders	High
Existing legislation (e.g. OEL, BATNEEC, etc.)	Possible approach. Benefits may not be worth the investment	Medium to High
Harmonised Classification under CLP	Done	No relevance hence no further discussion
Substance Evaluation under REACH	Last uncertainties on exposure levels are being addressed	Low
Restriction under REACH	Possible approach. Maybe useful combination with an industry initiative to address potential end-of-life mismanagement (man via the environment)	High
SVHC selection (Candidate List)	Participants had difficulty identifying SVHC selection as an RMO as such and not as only the antechamber to Authorisation. The market signal function was viewed as being weak	Depends on discussion of Authorisation
Authorisation under REACH	Would be a means to accelerate substitution and avoid free-riders	High

Note: It has to be stressed that each substance may, due to its profile, end up with a different set of potential risk management options.

Participants were invited to consider **all** potential options and to try and imagine how a regulator may consider defining them (e.g. possible scope of a Restriction).Participants had also to try and look beyond their immediate business activity. In this case, they discussed the end-of-life of articles and the fate of the articles (including imported articles) containing substance X (from municipal waste dumps, over incinerators to recycling). The concerns identified and discussed were the potential risk of exposure (man via environment) and the delay in phasing out of the presence of substance X in plastics due to recycling.

3. INDIVIDUAL COMPANY EXERCISE: SCORING OF POTENTIAL RMOs

The following tables summarize the contributions made by the different companies.

The choice was made to rank the option from 0 to 10 (from totally unable to fulfil the criterion to 10 i.e. able to completely fulfil the criterion. Annex V of this Guidance shows such tables where ranking is suggested.

The weights that were suggested for the criterion range from 0,5 (low importance) over 1 (neutral) to 1,5 (high) but this is open for debate and, often companies have suggested a different weighting.

1. Effectiveness of the RMOs

Formulators		Ability to reduce risks	Weight	Measurability / Monitorability	Weight	Proven technology available	Weight	Overall EFFECTIVENESS score	Ranking
Substitution (Industry)		5	1,5	7,5	1	0	1	**15**	**5**
Existing legislation (e.g. OEL, BATNEEC, etc.)	**OEL**	8	1,5	8	1	7,5	1	**27,5**	**2**
	BAT	8	1,5	8	1	7,5	1	**27,5**	**2**
Restriction		6	1,5	10	1	0	1	**19**	**4**
SVHC selection		1	1,5	0	1	0	1	**1,5**	**6**
Authorisation		8	1,5	9	1	7,5	1	**28,5**	**1**

Plastics manufacturers		Ability to reduce risks	Weight	Measurability / Monitorability	Weight	Proven technology available	Weight	Overall EFFECTIVENESS score	Ranking
Substitution (Industry)		10	1,5	7	1	10	1	32	3
Existing legislation (e.g. OEL, BATNEEC, etc.)	OEL	8	1,5	8	1	5	1	25	4
	BAT	8	1,5	8	1	5	1	25	4
Restriction		9	1,5	10	1	10	1	33,5	1
SVHC selection		1	1,5	0	1	0	1	1,5	6
Authorisation		9	1,5	10	1	10	1	33,5	1

Formulators ranked OEL and BATs higher than the plastics producers because the exposure situation is less complex and difficult to manage than the plastics producers. The viewed SVHC selection, when considered as an RMO per se, thus independently from Authorisation, as the least relevant option.

Note: In other RMOas performed with this scheme, one could identify a definite divide between sectors where the use could be easily or foreseeably substituted and those where substitution is a no-go.

Those who are set on a path of substitution indicated that Authorisation or Restriction might provide a safeguard against unfair competition, feeling that these instruments could "rubber-stamp" their efforts.

For those who will continue to depend on the substance under scrutiny, the main challenge is to identify a path that will allow business planning and continuity whilst optimising operational conditions in terms of potential exposure of man and the environment.

2. Efficiency of the RMO

Formulators		Ease of implementation by Industry	Weight	Ease of implementation for regulators	Weight	Time to result	Weight	Overall PRACTICABILITY Score	Ranking
Substitution (Industry)		5	1,5	0	1	5	1,5	15	4
Existing legislation (e.g. OEL, BATNEEC, etc.)	OEL	6	1,5	9	1	7,5	1,5	29,25	1
	BAT	4	1,5	1	1	2,5	1,5	10,75	5
Restriction		5	1,5	9	1	8	1,5	28,5	2
SVHC selection		0	1,5	0	1	0	1,5	0	6
Authorisation		8	1	9	1	6	1,5	26	3

Plastics manufacturers		Ease of implementation by Industry	Weight	Ease of implementation for regulators	Weight	Time to result	Weight	Overall PRACTICABILITY Score	Ranking
Substitution (Industry)		10	1,5	7	1	7	1,5	32,5	1
Existing legislation (e.g. OEL, BATNEEC, etc.)	OEL	6	1,5	9	1	5	1,5	25,5	3
	BAT	4	1,5	2	1	3	1,5	12,5	5
Restriction		8	1,5	7,5	1	8	1,5	31,5	2
SVHC selection		0	1,5	0	1	0	1,5	0	6
Authorisation		7	1	9	1	6	1,5	25	4

The relatively easier implementation of an OEL at formulator level is reflected in the outcome of their scoring, potentially coupled with a Restriction.

Plastics manufacturers, because of the ease to substitute, favoured the voluntary substitution option, possibly backed by a Restriction. They found the Authorisation not so 'practicable'.

Note: The ability to push through an industry initiative depends on where an industry actor is situated in the value chain.

One of the merits of such an RMOa approach is that it allows early in the process to bring around the table different actors and to identify the conditions for success of an industry initiative (substitution, BATNEEC in particular).

3. Regulatory consistency

Formulators		Regulatory consistency across the EU	Weight	Consistency with existing EU regulations and policies	Weight	Overall REGULATORY CONSISTENCY score	Ranking
Substitution (Industry)		0	0,5	2	1,5	3	6
Existing legislation (e.g. OEL, BATNEEC, etc.)	OEL	7,5	1,5	9	1,5	24,75	2
	BAT	1	1	7,5	1,5	12,25	5
Restriction		10	1,5	6	1,5	24	4
SVHC selection		10	1,5	10	1,5	30	1
Authorisation		9	1,5	7,5	1,5	24,75	2

Plastics manufacturers		Regulatory consistency across the EU	Weight	Consistency with existing EU regulations and policies	Weight	Overall REGULATORY CONSISTENCY score	Ranking
Substitution (Industry)		3	0,5	9	1,5	15	5
Existing legislation (e.g. OEL, BATNEEC, etc.)	OEL	8	1,5	9	1,5	25,5	4
	BAT	1	1	7,5	1,5	12,25	6
Restriction		10	1,5	10	1,5	30	1
SVHC selection		10	1,5	10	1,5	30	1
Authorisation		10	1,5	10	1,5	30	1

Companies from both use groups understood that an initiative carried only by industry has less 'regulatory weight' and carries a risk of unsanctioned free-ridership.

From a purely regulatory point of view (consistency with the texts of the law), SVHC selection came out as the option with the highest score followed, in function of industry characteristics, by either OELs or Authorisation.

Note: In other cases, companies identified risks of policy inconsistencies. If they agreed that in purely regulatory terms an identification as SVHC appears logical, they questioned the relevance of such a move. The 'eventual' prioritization for Authorisation may lead to subjecting to a costly and potentially disruptive process uses of a substance for which there is no alternative or which are necessary to contribute to the realisation of EU objectives in the field of energy, human health or environment.

In such cases, the scoring for SVHC selection is either very high (when seen independently) and Authorisation is scored low. Other sectors have opted, from the beginning to not separate the discussion of SVHC selection and Authorisation and scored both options low.

4. Economic impacts

CAUTION! Scores are from 10 to 0 (10 = most positive impact to 0 = most negative impact)

Formulators		Value chain impacts								Company-specific impacts				Overall economic impact	Ranking
		Supply disruption	Weight	SME-specific impacts	Weight	Costs	Weight	Invest-ment	Weight	Costs	Weight	Business model and continuity	Weight		
Substitution (Industry)		8	0,5	7,5	0,5	5	0,5	10	0,5	5	0,5	10	1	27,75	1
Existing legislation (e.g. OEL, BATNEEC, etc.)	OEL	10	0,5	2,5	0,5	2,5	0,5	5	0,5	2,5	0,5	7,5	1	18,75	5
	BAT	10	0,5	5	0,5	2,5	0,5	5	0,5	2,5	0,5	10	1	22,5	4
Restriction		7,5	0,5	5	0,5	6,5	0,5	7,5	0,5	5	0,5	7	1	22,75	3
SVHC selection		7,5	0,5	7,5	0,5	10	0,5	2,5	0,5	10	0,5	5	1	23,75	2
Authorisation		7	0,5	5	0,5	5	0,5	5	0,5	2,5	0,5	5	1	17,25	6

Plastics manufacturers		Value chain impacts								Company-specific impacts				Overall economic impact	Ranking
		Supply disruption	Weight	SME-specific impacts	Weight	Costs	Weight	Invest ment	Weight	Costs	Weight	Business model and continuity	Weight		
Substitution (Industry)		10	0,5	7,5	0,5	7	0,5	8	0,5	6	0,5	6	0,5	22,25	2
Existing legislation (e.g. OEL, BATNEEC, etc.)	OEL	10	0,5	2,5	0,5	2,5	0,5	5	0,5	2	0,5	7,5	0,5	14,75	6
	BAT	10	0,5	5	0,5	2	0,5	5	0,5	1	0,5	10	0,5	16,5	5
Restriction		7,5	0,5	8	0,5	7	0,5	8	0,5	7	0,5	6	0,5	21,75	3
SVHC selection		9	0,5	7,5	0,5	10	0,5	8	0,5	10	0,5	5	0,5	24,75	1
Authorisation		8	0,5	5	0,5	6	0,5	6	0,5	6	0,5	5	0,5	18	4

Logically, considering the consensus in favour of substitution, companies considered that SVHC selection will have the least economic impact as no harmful stigmatisation should be feared. Investing in OELs or new technologies didn't seem to make sense.

Note: In all cases discussed in industry, companies gradually developed a more holistic view of the economic impacts, looking at how to optimize risk management along the value-chain.

5. Human health and environmental benefits

CAUTION! Scores are from 10 to 0 (10 for most positive impact to 0 most negative impact)

Formulators		Human health impacts				Environmental impacts				Overall Human Health and Environmental impact	Ranking
		Improvement of affected population (workers, etc.)	Weight	Other health impacts (benefits)	Weight	Specific benefits	Weight	Other environmental benefits	Weight		
Substitution (Industry)		7	1,5	5	1	2	1	1	0,5	**18**	**2**
Existing legislation (e.g. OEL, BATNEEC, etc.)	OEL	7,5	1,5	2,5	1	2	1	1	0,5	**16,25**	**4**
	BAT	7,5	1,5	2,5	1	2	1	1	0,5	**16,25**	**4**
Restriction		7,5	1,5	5	1	2	1	1	0,5	**18,75**	**1**
SVHC selection		1	1,5	0	1	0	1	0	0,5	**1,5**	**6**
Authorisation		7,5	1,5	5	1	2	1	1	0,5	**18**	**2**

Plastics manufacturers		Human health impacts				Environmental impacts				Overall Human Health and Environmental impact	Ranking
		Improvement of affected population (workers, etc.)	Weight	Other health impacts (benefits)	Weight	Specific benefits	Weight	Other environmental benefits	Weight		
Substitution (Industry)		8	1,5	5	1	2	1	1	0,5	**19,5**	**1**
Existing legislation (e.g. OEL, BATNEEC, etc.)	OEL	7,5	1,5	2,5	1	2	1	1	0,5	**16,25**	**4**
	BAT	7,5	1,5	2,5	1	2	1	1	0,5	**16,25**	**4**
Restriction		7,5	1,5	5	1	2	1	1	0,5	**18,75**	**2**
SVHC selection		0	1,5	0	1	0	1	0	0,5	**1,5**	**6**
Authorisation		7,5	1,5	5	1	2	1	1	0,5	**18,75**	**2**

From a human health or environmental impact point of view, the different options are very close (except for SVHC selection for the reasons of non-effectivity already indicated).

Companies estimated that positive environmental impacts could not be excluded but would be minimal.

6. Synthesis

The point of view of the ***formulators***:

Formulators		Overall effectiveness	Overall practicability /efficiency	Overall regulatory consistency	Overall economic impact	Overall Human Health and Environmental Benefit	Overall proportionality ranking	Final ranking
Substitution (Industry)		**5**	**4**	**6**	1	2	**18**	**4**
Existing legislation (e.g. OEL, BATNEEC, etc.)	**OEL**	**2**	**1**	**2**	5	4	**14**	**2**
	BAT	**2**	**5**	**5**	4	4	**20**	**5**
Restriction		4	**2**	**5**	3	1	**15**	**3**
SVHC selection		**6**	**6**	**4**	2	6	**24**	**6**
Authorisation		**1**	**3**	**1**	6	2	**13**	**1**

The ranking by the formulators of the OEL, Restriction and Authorisation options are very close which is confirmed when looking at the sum of scores in the following table.

Having taken full consideration of regulator's concerns, formulators ended up ranking Authorisation first as they felt that regulators had a case for wanting Industry to abandon the use of substance X and that Authorisation might allow bringing to light very specific uses, not generally known, that could still get an Authorisation. Looking at their business, they didn't see the benefit of going through the process of Authorisation as substitution looks the most straightforward option.

The participants in that use group indicated that the apparent lack of clarity or indecisiveness of this synthesis reflects their more neutral position vis-à-vis the continued use or not of substance X.

Formulators (sum of scores)		Overall effectiveness	Overall practicability / efficiency	Overall regulatory consistency	Overall economic impact	Overall Human Health and Environmental Benefit	Overall proportionality scoring	Final ranking
Substitution (Industry)		15	15	3	27,75	18	**78,75**	**5**
Existing legislation (e.g. OEL, BATNEEC, etc.)	**OEL**	27,5	29,25	24,75	18,75	16,25	**116,5**	**1**
	BAT	27,5	10,75	12,25	22,5	16,25	**89,25**	**4**
Restriction		19	28,5	24	22,75	18,75	**113**	**3**
SVHC selection		1,5	0	30	23,75	1,5	**56,75**	**6**
Authorisation		28,5	26	24,75	17,25	18	**114,5**	**2**

The point of view of the ***plastics manufacturers***:

Plastics manufacturers		Overall effectiveness	Overall practicability / efficiency	Overall regulatory consistency	Overall economic impact	Overall Human Health and Environmental Benefit	Overall proportionality ranking	Final ranking
Substitution (Industry)		3	**1**	**5**	2	3	14	2
Existing legislation (e.g. OEL, BATNEEC, etc.)	**OEL**	4	**3**	**4**	6	1	18	4
	BAT	4	**5**	**6**	5	1	21	6
Restriction		1	**2**	**1**	3	3	10	1
SVHC selection		6	**6**	**1**	1	6	20	5
Authorisation		1	**4**	**1**	4	5	15	3

Plastics manufacturers (sum of scores)		Overall effectiveness	Overall practicability / efficiency	Overall regulatory consistency	Overall economic impact	Overall Human Health and Environmental Benefit	Overall proportionality scoring	Final ranking
Substitution (Industry)		32	32,5	15	22,25	19,5	**121,25**	**3**
Existing legislation (e.g. OEL, BATNEEC, etc.)	**OEL**	25	25,5	25,5	14,75	16,25	**107**	**4**
	BAT	25	12,5	12,25	16,5	16,25	**82,5**	**5**
Restriction		33,5	31,5	30	21,75	18,75	**135,5**	**1**
SVHC selection		1,5	0	30	24,75	1,5	**57,75**	**6**
Authorisation		33,5	25	30	18	18,75	**125,25**	**2**

The ranking by the plastics manufacturers reflects the consensus in favour of substitution, supported by a regulatory 'fire-wall' against free-riders (i.e. restriction).

Closer to the markets and their expectations – including societal concerns – they favoured a set of initiatives, with a voluntary phase-out by industry backed-up by regulatory initiatives that would prevent free-riders at use-level and mismanagement at end-of-life stage (incineration) where a concern was identified of man-via-environment exposure.

4. FINAL MEETING: AGREE ON CONCLUSIONS AND PATH FORWARD

A consensus-finding meeting was held with the participants of the RMOa exercise. Such a meeting is especially interesting when participants may have a different stake (formulators and plastics manufacturers, in this case). It may be that the participants agree to reconsider their first conclusions or identify further gaps in knowledge or data.

At the meeting, participants opened a discussion on issues they had felt difficult to address during their internal exercise or were not directly of their field of expertise. One example was the trade dimension (import of articles still containing substance X which would lead to continued contamination of the end-of-life flows.

1) The participants discussed the synthesis of the scoring exercise and explained the reason of some of the scores.

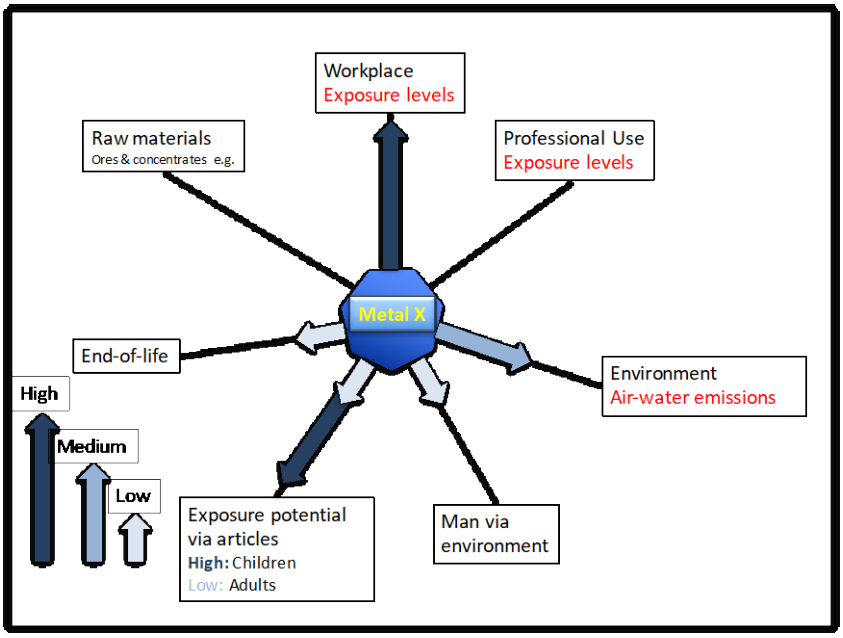
2) They examined whether a common conclusion could be identified and what to do with this conclusion.
    a. There was agreement that there was:
        i. no technical or economical obstacle to substitution of substance X and that substitution was an economically better option than technical risk reduction measures such as the implementation of OELs
        ii. a concern regarding the possibility for some to delay or relinquish phasing out substance X which may create an economic disadvantage for the adopters of the substitutes. Participants indicated that they would not resist a call for Authorisation as that would affect those not wanting to phase-out the use of substance X
        iii. a concern that needed to be addressed related to the possibility of continued import of articles containing substance X. Some further work would be needed to scope and define the content of a possible Restriction and consider its costs and benefits. It was felt that it that might complement Authorisation
        iv. a concern at the end-of-life management stage of the substance that may be addressed with a Restriction related to issues such as incineration
    b. A plan for communication and broader debate within industry was established. A second plan concerned future communications with other stakeholders, i.e. article users, national competent authorities for REACH, waste management authorities etc.

3) They finally agreed on a path forward regarding the collection and updating of data needed to substantiate the conclusions and to better understand the impacts. Attention was devoted to the update of the Registration dossier.

ANNEX VII - TEMPLATES FOR THE PILLAR 1 - CHEMICALS MANAGEMENT I-RMOA

This is an example of templates one can use. Tables can be used as such or copied and pasted in Excel but the Excel workbook can be obtained from Eurometaux.

Identification of the potential issues to be addressed



- What end-points should be considered?
- Have all uses been identified and described?
- Where is the exposure occurring?

Discussion:

- **UNCERTAINTIES:**

What are the uncertainties in this assessment?

- Share between intermediate and non-intermediate uses?

- Number of workers that are exposed?

- Uses that have not been accounted for?

- Trends in some uses?

- **How would you assess this identification of risks?**

Relevance? Is the assessment of the risk i.e. respiratory sensitizer as the main/only focus point to consider, in the life-cycle stages/uses described, a good reflection of the reality of risks for a policymaker to suggest a conclusion?

Credibility? How likely will this assessment be accepted by regulators / other stakeholders as being honest and unambiguous?

Acceptability? To what extent will this risk identification be accepted and supported in the companies and the value chain?

Easy to validate? Is this assessment of risks easy to check and validate by external experts/regulators?

Robustness? Are these conclusions able to stand the test of times? Could they be put into question by the resolution of existing uncertainties or ongoing research?

Basically, consider the elements in the Check-list discussed in Annex II:

- **The substance**
- **Uses, volumes and potential exposures throughout the life cycle (substance, constituent of another substance, impurity)**
- **Alternatives per (identified) use** (at a level relevant at this stage of the analysis)
- **Parameters for later Socio-Economic Assessment, per Use**

Identification of all the potential Risk Management Options that may be considered

Step 1: Identification / listing of potential RMOs		
RMO	**What are the conditions that are required to make an RMO feasible and ensure it can be implemented**	
Substitution (Industry initiative)		

Discussion:

Step 2: Feasibility requirements of potential RMOs		
RMO	**Relevancy**	**Description/ scope / justification / comment**
Substitution (Industry initiative)		

NOTE: Among the prerequisites for an RMO to be feasible, it may be important to consider elements such as **data**, **resources**, **time to implementation**, **type of stakeholder involvement** (public-private 'partnership' for a BAT e.g.) on top of regulatory requirements (cf. EU-wide risk for a restriction or scoring for Authorisation after selection as SVHC).

Another political prerequisite is likely to be that the RMOs are proposed with clear and monitorable objectives, hence the importance of providing a scope of the RMO, i.e. an idea of how it key objectives might be worded.

Synthesis:

The common approach of RMO-definition has initially be limited to the identification of suitable regulatory management measures.

Simple I-RMOa
Approach at the basis of the development of RMOa methodology Focus is on identifying the most suited regulatory risk management measure No technology-driven integration of management options or use-specific options will be considered

The risk management approach that consists of a combination of risk management measures which may include non-regulatory measures can be said to be the 1st type of an Integrated I-RMOa. It may still fit within the current approach toward regulatory management options analysis. Some

Less likely to fit within a regulatory risk management options assessment are the more complex Integrated-RMOa types (2nd and 3rd type below) where the analysis by being holistic excludes no avenues to address the identified risks. It may be better suited for anticipative RM exercises as well as for strategy-setting.

Integrated I-RMOa
1st type: combination of regulatory management approaches The optimum may consist in a mix of RMOs. This may be a set of complementary regulatory approaches based on use-specific characteristics (cf. restrictions, or OEL (generic for occupational health) combined with specific restrictions (consumer protection e.g.)
2nd type: holistic, broader vision beyond single substance It may consist in different approaches such as: • Considering a technology response or a mix of technology and regulatory measures • Addressing issue through value chain initiatives (R&D, market initiatives etc.) • Involving other substances with the same or similar hazard profile used in the same process (plating e.g.). The solution may then consist in a measure (such as abating plating mist e.g.) that will reduce the risks for the whole set of substances used in the process. This would typically be a type of solution companies can implement rather than a regulator could impose, unless the framework is created for such a joint evolution (structured dialogue, pilot programmes etc.). In some cases, it may only become possible with the active support or encouragement of regulators if the integrated approach is across the supply chain or crosses supply chain borders.
3rd type: beyond chemicals management with consideration of Circular Economy and Climate dimensions This type of assessment is described in Annex VIII.

Analysis of the potential Risk Management Options

The following templates assume, for the sake of completeness, that different approaches may be considered.

1. EFFECTIVENESS:

Is the RMO able to reduce possible risks and will its effects be measurable?

What is the availability of proven and affordable technology? What is known about alternatives?

The elements developed in previous steps should be synthesised into a couple of sentences per RMO considered for the final comparison.

In function of the options chosen and of the approaches tested, a table will be built to discuss the possible effectiveness of the different RMOs.

RMO	Ability to reduce risk	weight	Measurability / Monitorability	weight	Proven technology available	weight	Overall effectiveness	**Ranking**
Simple I-RMOa: simple approach (1 measure)								
Integrated I-RMOa: combined measures (focus on single substance)								
Integrated I-RMOa (holistic vision on processes, value chains etc. possibly beyond the single substance)								

Scoring choice: One may rank the option from 0 to 10 (from totally unable to fulfil the criterion to 10 i.e. able to completely fulfil the criterion)

The **weights** suggested are debatable: 0,5 (low importance); 1 (neutral); 1,5 (high importance of the criterion)

Discussion:

2. PRACTICABILITY:

Can the RMO be implemented easily?

RMO	Ease of implementation by Industry	weight	Ease of implementation by Regulators	weight	Time to result	weight	Overall effectiveness	**Ranking**
Simple I-RMOa: simple approach (1 measure)								
Integrated I-RMOa: combined measures (focus on single substance)								
Integrated I-RMOa (holistic vision on processes, value chains etc. possibly beyond the single substance)								

Scoring choice: One may rank the option from 0 to 10 (from totally unable to fulfil the criterion to 10 i.e. able to completely fulfil the criterion)

The **weights** suggested are debatable: 0,5 (low importance); 1 (neutral); 1,5 (high importance of the criterion)

Discussion:

3. CONSISTENCY:

Is the RMO consistent with a fairly level playing field across the EU? Is there a risk of significant differences between national implementation? Are there any potential overlaps with existing regulations?

RMO	Regulatory consistency across the EU	weight	Consistency with existing EU regulations and policies	weight	Consistency with previous EU initiatives	weight	Consistency with other EU policy objectives	weight	Overall REGULATORY CONSISTENCY	**Ranking**
Simple I-RMOa: simple approach (1 measure)										
Integrated I-RMOa: combined measures (focus on single substance)										
Integrated I-RMOa (holistic vision on processes, value chains etc. possibly beyond the single substance)										

Scoring choice: One may rank the option from 0 to 10 (from totally unable to fulfil the criterion to 10 i.e. able to completely fulfil the criterion)

The **weights** suggested are debatable: 0,5 (low importance); 1 (neutral); 1,5 (high importance of the criterion)

Discussion:

4. OTHER IMPACTS: ECONOMIC AND HUMAN HEALTH /ENVIRONMENTAL

The impact categories taken up here will depend on the nature of the substance and its use in value chains.

a. ECONOMIC IMPACTS:

The criteria should be chosen in agreement with the participants. Depending on the substance and the value chain characteristics, it may be that downstream user-specific impacts are considered.

RMO	Value chain impacts								Company-specific impacts				Overall REGULATORY CONSISTENCY	**Ranking**
	Supply disruptions	weight	SME-specific impacts	weight	Costs	weight	Impact on Investments (production and R&D)	weight	Costs	weight	Business model and continuity	weight		
Simple I-RMOa: simple approach (1 measure)														
Integrated I-RMOa: combined measures (focus on single substance)														
Integrated I-RMOa (holistic vision on processes, value chains etc. possibly beyond the single substance)														

Scoring choice: One may rank the option from 10 to 0 (from 10 no impact to 0 maximum impact)

The **weights** suggested here are debatable: 0,5 (low importance); 1 (neutral); 1,5 (high importance of the criterion)

Discussion:

b. HUMAN HEALTH AND ENVIRONMENT:

The criteria will have to be chosen in agreement with the participants, depending on the substance properties and production situation.

RMO	Human health impacts				Environmental impacts				Overall Human Health and Environmental Impact	**Ranking**
	Improvement of affected population (workers etc.)	weight	Other health impacts	weight	Specific benefits	weight	Other environmental benefits	weight		
Simple I-RMOa: simple approach (1 measure)										
Integrated I-RMOa: combined measures (focus on single substance)										
Integrated I-RMOa (holistic vision on processes, value chains etc. possibly beyond the single substance)										

Scoring choice: Here one again ranks the option from 0 to 10 (from 0 no positive effect to 10 maximum positive impact)

The **weights** suggested here are also debatable: 0,5 (low importance); 1 (neutral); 1,5 (high importance of the criterion)

Discussion:

Synthesis

It may be useful to perform the **sum of scores** as well as the **sum of rankings**.

RMO	Overall effectiveness	Overall practicability	Overall consistency	Overall economic impact	Overall human health and environmental impact	Overall proportionality	**Final ranking (based on scoring)**
Simple I-RMOa: simple approach (1 measure)							
Integrated I-RMOa: combined measures (focus on single substance)							
Integrated I-RMOa (holistic vision on processes, value chains etc. possibly beyond the single substance)							

RMO	Overall effectiveness	Overall practicability	Overall consistency	Overall economic impact	Overall human health and environmental impact	Overall proportionality	**Final ranking (based on rankings)**
Simple I-RMOa: simple approach (1 measure)							
Integrated I-RMOa: combined measures (focus on single substance)							
Integrated I-RMOa (holistic vision on processes, value chains etc. possibly beyond the single substance)							

Discussion:

The above-presented tables focus on a single dimensional approach (Pillar I) although the approach may be more holistic with the consideration of broader impacts, including the overall human health and environmental impact.

If the analysis wants to discuss more in depth the Circular economy and Climate dimensions at stake – what we call pillars 2 and 3 – the table may be presented in a more simplified manner, as follows:

Pillar 1: Chemicals Management					
	Effectiveness	Efficiency	Consistency	Broader Impacts	**Conclusion Pillar I**
RMO 1					
RMO 2					
RMO 3					
RMO 4					
RMO 5					

ANNEX VIII - TEMPLATES FOR THE PILLARS 2 & 3 AND OVERALL CONCLUSION

1. PILLAR 2 – CIRCULAR ECONOMY DIMENSION

Preparatory analysis

Circular Economy basics:

For an EU primary and/or secondary metal manufacturer or user, the Circular Economy dimension is of the utmost importance as its company objectives match to a large extent those of the Circular Economy package.

Companies indeed aim at optimising their operations in a way that coincides with the Circular economy objectives as shown by the following elements **at production level:**

- ***Optimisation of yields and of energy consumption***
  This has several dimensions such as:
  - Optimisation of **extraction**/manufacturing of metals (base metals, precious metals, minor metals e.g.) and optimisation of **recovery** of metals from new scrap (DU manufacturing waste) and old scrap (EOL, materials becoming available from the 'stock of metals' accumulated as articles in society);
  - Minimisation of **waste** and ensuring, e.g., that final slags can be of such a quality they can have a useful further life (building industry, infrastructure) rather than ending in landfill sites;
  - Minimisation of **unwanted elements** in input materials (impurities) and optimal processing (concentration in by-products or in waste material or managed re-circulation)
- ***Operational optimisation*** may mean
  - Optimisation of **material mixes** (primary & secondary materials) in the metallurgical process loops;
  - Specialisation in the processing of materials (by-products, often UVCBs) that others cannot treat in a resource -efficient manner (too small quantities, too complex process etc.). This is also a way to ensure a better performance in circular economy terms.

The circular economy dimensions along the supply chain may include the following functionalities (see Table 18 below)

1) **Industrial Ecology:** Eco-efficiency, industrial symbiosis, technically, economically and environmentally sustainable loops… The materialisation of all these concepts requires a regulatory framework that allows durable supply chain commitments, that favour economies of scale, long-term planning comfort. These are based on and grow out of what is technically and economically favourable to all parties, in a context where the interests of society at large are fully considered.

2) **Economy of functionality:** The migration towards service-based relationships may potentially contribute to a sustainable economy. Recycling of products that are not sold and remain property of their manufacturer can greatly facilitate the establishment of efficient recycling loops.

3) **Repair and maintenance:** This is classically considered as part of the overall Circular Economy system, but actually more an issue at the consumer-end of the supply chain, facilitated by adapted (eco-) design. However, the quality of the articles will depend on the quality of their components, which relates to upstream in the supply chain, up to the alloy manufacturers.

4) **Reuse:** This concept can be seen broadly from community-scale initiatives to the organised reuse of electric vehicle batteries for home energy storage.

5) **Recycling:** Ultimately, the efficiency of the end-of-life stage will determine whether a virtuous circular economy loop could be established at local, regional, national or EU level.

Circular Economy Dimension along the supply chain

	Industrial Ecology (1)	Economy of Functionality (2)	Repair (3)	Reuse (4)	Recycling (5)
Refiners	X				X
Alloy/ compound manufacturers	X				X
Semi-manufacturers/ chemical processers	X				X
DUs/OEMs	X	X	X		X
Final product manufacturers	X	X	X	X	X
Consumers			X	X	X
Collectors etc.	X				X

As can be seen in Table 18 table above, the most critical elements in terms of circular economy for those metal industries at the high end of the supply chain will be **recycling and industrial ecology** and a number of key questions will have to be considered in an I-RMOA:

- How to ensure a steady/reliable flow of secondary materials?
- Will the future regulatory Risk Management Measure impact the flow of secondary materials?
- Will the regulatory measures allow the current diversity of materials to continue to be collected and processed in the EU?
- If the materials mix is to change, what will be the implications?
- What about elements appearing in streams where they might have a detrimental effect as a consequence of forced material choice (substitute) or phasing out (becoming unwanted element)?
- Will the measure(s) impact the viability of the existing industrial ecology, such as complex non-ferrous metals refining circuits?

Substance check: Unwanted materials as impurities or minor constituents of UVCB's?

With a growing diversity of primary and secondary material sources, a continuous increasing number of substances used in articles, the industry has to face the exposure potential and risk management of unwanted hazardous materials like some unwanted impurities and minor constituents.

Impurities, metals that have no functional role in the 'parent' metal containing them, and minor constituents, raise other types of questions and discussions on possible trade-offs:

- *If hazardous, can they be separated safely and given a safe use on their own?*
- *If not, can they be kept safely in the 'parent' substance/material and recirculate with them without risk (dilution effect)? (recuperation as a material)*
- *If the hazards and risks differ from the mother material, impurities or the minor constituents may need to be handled in a specific I-RMOa*
- *Or requiring specific risk management in case they need to be removed as a waste or as a filler in other materials such as slags*

The discussion on the management of impurities in hazardous elements becomes increasingly relevant for industry and society require data on what the releases and risks may be as discussed in the next points. However, the I-RMOa concepts as developed for main substances apply in an equal way to impurities.

Discussion tables:

POSITIONING OF RMO IN TERMS OF RELEVANCY RE THE CIRCULAR ECONOMY POLICY

Relevancy Category related to the Circular Economy dimension	**Very Relevant (negative)**	**Relevant (negative)**	**Neutral**	**Relevant (positive)**	**Very relevant (positive)**
Definition	• The substance is not or barely recycled or recyclable at end-of-life. • There are very significant known drawbacks to the substance and its use in terms of the Circular Economy.	• The substance is poorly recycled or poorly recyclable. • There are known drawbacks to the substance and its use in terms of Circular Economy.	• One cannot identify a direct or indirect contribution to the Circular Economy of the substance. • The Circular Economy dimension is not relevant	• Is recycled / can be recycled • Used in or researched for applications that allow recycling. • May display properties that make its use relevant from Circularity perspective • Considered a candidate for (improved) recycling efforts • Recycled material does not achieve same performance as the primary product • There may be economic constraints to recycling (energy input and cost e.g.)	• A high percentage of the substance is recycled at end-of-life. • May display properties/potential that make its use very relevant or even critical from a Circular Economy point of view.
Relevancy positioning of Selected RMOs					

PROPORTIONALITY SCORING OF THE CIRCULAR ECONOMY DIMENSION OF A SET OF POTENTIAL RMOS

Scoring of the Circular Economy dimension	Preservation of resource: Reusable/ Recyclable	Preservation of properties / functionalities (Same use possible ?)	Circularity over time: Longevity of use	Relevancy and proportionality from Circular Economy point of view
RMO 1				
RMO 2				
RMO 3				
RMO 4				
RMO 5				

2. PILLAR 3 – CLIMATE DIMENSION

SUBSTANCE RELEVANCY IN RELATION TO CLIMATE POLICIES

Relevancy Category related to the Climate dimension	**Very Relevant (negative)**	**Relevant (negative)**	**Neutral**	**Relevant (positive)**	**Very relevant (positive)**
Definition	There are very significant known drawbacks to the substance and its use in terms of resource conservation, energy use and or climate change. It can be said to directly or indirectly impact in a negative way on the Climate challenges.	There are known drawbacks to the substance and its use in terms of resource conservation and energy use. It can be said to directly or indirectly impact in a negative way on the Climate challenges.	One cannot identify a direct or indirect contribution or potential contribution of any significance in terms of addressing the Climate challenges	The substance is used in or is researched for applications that are directly or indirectly related to addressing the Climate challenges. The substance may display properties that make its use very relevant in terms of energy conservation etc.	The substance is used in or researched for applications that are known to address the Climate challenges.
Relevancy positioning of Selected RMOs					

PROPORTIONALITY SCORING OF THE CLIMATE DIMENSION OF A SET OF POTENTIAL RMOS

	Impact on energy cost during manufacturing	Impact on energy use at use phase (energy consumption per functional use)	Recuperation (or not) of the intrinsic energy during recycling	Relevancy and proportionality from Climate point of view
RMO 1				
RMO 2				
RMO 3				
RMO 4				
RMO 5				

3. OVERAL CONCLUSION OF INTEGRATED I-RMOA (PILLARS 1, 2 & 3)

This section will explore the way to reach conclusions when Pillar II (Circular Economy) and/or Pillar III (Climate Change) are added to the I-RMO analysis.

For the purpose of illustrating the approach, a fictitious case and scoring is considered for a set of possible 4 types of RMOs. So as to avoid any interference of individual opinions on a practical example, the RMOs are not described.

The discussion will start with putting together the conclusions of the analysis of the three pillars, starting with Pillar I (Chemicals management):

PILLAR 1:

The outcome of the RMO discussion in Pillar 1 and the scoring are presented in the following table:

PILLAR 1 PROPORTIONALITY SYNTHESIS

Pillar 1: Chemicals Management					
	Effectiveness	Efficiency	Consistency	Broader Impacts	**Conclusion Pillar 1**
RMO 1					
RMO 2					
RMO 3					
RMO 4					
RMO 5					

Discussion:

PILLAR 2:

The conclusion of the Pillar 2 discussion can be presented in the following table:

PILLAR 2 PROPORTIONALITY SYNTHESIS

Pillar 2: Circular Economy				
	Reusable / recyclable	Preservation of properties / functionalities	Longevity of use	**Conclusion Pillar 2**
RMO 1				
RMO 2				
RMO 3				
RMO 4				
RMO 5				

Discussion:

PILLAR 3:

The conclusion of the Pillar II discussion can be presented as shown in Table 27.

TABLE 35: PILLAR III PROPORTIONALITY SYNTHESIS

Pillar 3: Climate Change				
	Impact on energy cost during manufacturing	Impact on energy use at use phase	Recuperation of intrinsic energy during recycling	**Conclusion Pillar 3**
RMO 1				
RMO 2				
RMO 3				
RMO 4				
RMO 5				

Discussion:

PILLARS I, II & III: The synthesis of the scorings of the 3 pillars is presented in Table 28 below:

TABLE 36: SYNTHESIS OF SCORING OF 3 PILLARS

Overall Conclusion of the 3 Pillars				
	Pillar 1	Pillar 2	Pillar 3	**Overall**
RMO 1				
RMO 2				
RMO 3 (combination)				
RMO 4 (combination)				

Discussion:

Discussion of outcome

The outcome of the three-pillar analysis may be complex to present to the ultimate decision-takers and may require a synthesis table presenting the findings in a SWOT-type of reasoning. This may allow a better understanding of the compromises a decision ultimately may have to make compared to what might be considered an ideal solution.

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SUMMARY OF ANALYSIS OF 3 PILLAR ANALYSIS

	Pillar 1: Chemicals Management		Pillar 2: Circular Economy		Pillar 3: Climate Change	
	Strength Opportunity	Weakness Threat	Strength Opportunity	Weakness Threat	Strength Opportunity	Weakness Threat
	Options considered suitable overall for addressing the risk(s) identified					
RMO						
RMO						
RMO						
RMO						
	Options not considered suitable overall for addressing the risk(s) identified					
RMO						
RMO						
RMO						
RMO						