EUROMETAUX
EUROPEAN ASSOCIATION OF METALS

Guidelines for an Industry Risk Management Options Analysis

VERSION 3 – 18 May 2017

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

Content

INTRODUCTION

The Introduction will, in 4 subsections:

1. **Outline the purpose of this Guidance document**
2. **Discuss the need for an Industry-specific Risk Management approach which can go beyond the REACH context**
3. **Describe what an Industry-Risk Management Options Analysis is, from the definition of its purpose and scope to the screening of substances. It will also consider how the approach may vary depending on whether the I-RMOA is perfomed by a company, a consortium or a commodity organisation.**
4. **Consider the orienting principles for an I-RMOA that creates value**

1. PURPOSE AND STRUCTURE OF THIS GUIDANCE

This document aims at providing Industry with a road-book for internal analysis of Risk Management Options, hence its designation as a Guidance for Industry RMO Analysis.

The RMO exercise presented here will contribute to focus the minds of Industry stakeholders on potential risks and risk management needs and to prioritise and structure data collection and analysis, whatever the regulatory context considered (REACH or not), hence also the introduction of the concept of Broad I-RMOA.

In the REACH context, it is a valuable instrument to help explore and develop risk management options (**RMO**), including alternatives to the Authorisation or Restriction processes under REACH by integrating the views of industry as well as of authorities and society.

It should help Industry to contribute credibly in the RMO Analysis (**RMOA**) and decision processes at EU level. More than a "shadow RMOA" used to counter an official RMOA, the exercise should be an "enriching RMOA" where Industry makes use of its expertise to contribute to the discussion and help find the most effective and acceptable risk management measure. The presentation of additional tools (cf. Broader I-RMOA) such as Materials Mass Flow Analaysis, possibly linked with specific material 'loss' analysis and Diffuse Sources Analysis aims at such an 'enrichement'.

This Guidance is built in such a way that its three parts can be read separately This has as consequence that repetitions may occur between "Introduction", "Part 1: Broad I-RMOA" and "Part 2: I-RMOA in a REACH context".

2. NEED FOR AN INDUSTRY-SPECIFIC RISK MANAGEMENT OPTIONS ANALYSIS APPROACH

Initially aimed at helping the industry to identify and address the risk management challenges it may have to consider under REACH *and other EU regulatory regimes*, this document has proven useful in a broader context, beyond REACH and thus with other points of attention.

This experience has led to an update of the Guidance to integrate the broader analysis next to the REACH-specific step-by-step methodology.

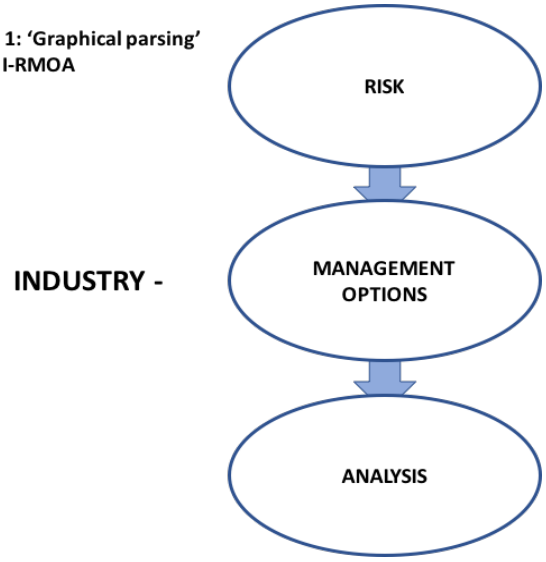
As the I-RMOA approach may cover ground way beyond the scope of an RMO Analysis in the SVHC Roadmap 2020 context, *sensu stricto*.

The Guidance will therefore be divided in 2 main blocks not mutually exclusive, **Part I will cover the broader picture** Industry (at sector- or at company-level) may want to analyse, whilst **Part II** will focus on how to perform and what to expect from an Industry RMO Analysis within the framework of REACH, where the focus will much more be on regulatory approaches.

3. WHAT IS AN INDUSTRY RISK MANAGEMENT OPTIONS ANALYSIS?

Risks affecting companies because of the use of a substance can have consequences in terms of occupational health, environmental impacts, economic performance, professional reputation, as well as societal outcomes. Managing risk effectively whilst addressing policy and societal concerns helps companies to operate in an environment full of uncertainty.

Figure 1: 'Graphical parsing' of the I-RMOA



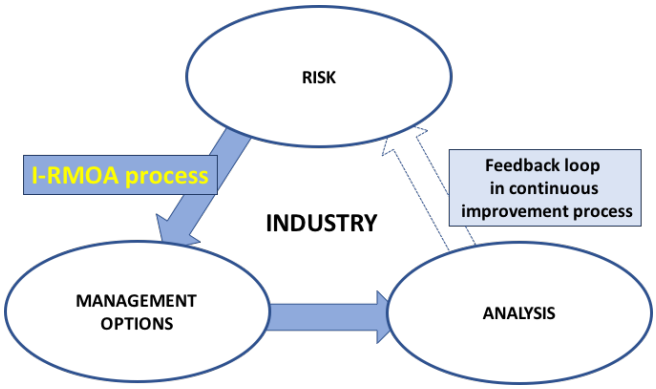
An **Industry Risk Management Options Analysis** (I-RMOa) consists in the identification, discussion, and prioritization of **risks** related to a substance, followed by the identification of all potential risk **management options** to eliminate, minimize, monitor, and control the probability and/or impact of these risks. Finaly, the potential risk management options are subjected to an **analysis** so as to identify the most suited risk management option in function of a set of proportionality criteria.

Options to manage risks typically include avoidance through substitution of substances 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 exercise described in this paper has been designed in such a way that it can be performed efficiently when relevant data and expertise are at hand to go through the different steps of selection and justification of an appropriate risk management measure (RMM). Its outcome will allow Industry experts and consultants to proceed to a targeted collection of additional data and to develop the arguments, thus "putting flesh on the bones" of a solid I-RMOA that will reflect the views and interests of the value chain.

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.

Figure 2: Industry Risk Management Options Anaysis as a continuous process



I-RMOA can be

- *A punctual exercise driven by a regulatory obligation or challenge*
- *A continuous process driven by a variety of motivators (EHS strategy, definition of future product portfolio, progress of knowledge and science)*

By establishing a systematic, coherent and transparant approach, the I-RMOA allows for an analysis and its outcomes that can be periodically reassessed, hence the feedback loop inserted in Figure 1.

1. PURPOSE OF AN INDUSTRY RISK MANAGEMENT OPTIONS ANALYSIS

The purposes of the Industry Risk Managegement Options Analysis can be manifold and will depend on the stage of regulatory review afor a substance:

- **Respond to a 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 of risks** so as to help prioritize measures, identify and enter into dialogue with other stakeholders etc.

- **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 anticipation and assistance work can be
  - **Update** of the REACH Registration dossier
  - **Collection of data** to better understand the risks or assess progress
  - **Collection and/or structuring of 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 unbderstand their properties, risks etc.
    - Public Activities Coordination tool (PACT) : Risk Management Options Analysis by a Member State or ECHA in view of a decision on a risk management measure such as Candidate Listing wand 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 will allow to identify the data to gather (such as exposure) or the stakehlders t involve (Downstream Users) and will help shape and structure the further in-depth work on Analysis of Alternatives and socio-economic analysis.

Initially aimed at helping the industry to identify and address the risk management challenges it may have to consider under REACH *and other EU regulatory regimes*, these Guidelines have proven useful in a broader context.

It is a valuable instrument to help explore and develop risk management options, including alternatives to the Authorisation or Restriction processes under REACH for industry as well as authorities.

The I-RMOA exercise presented here will contribute to focus the minds of Industry stakeholders on potential risks and risk management needs and to prioritise and structure the data collection and analysis. It should also help Industry to contribute credibly in the RMO Analysis (**RMOA**) and subsequent decision processes at EU level.

2. WHICH SUBSTANCES ARE CONCERNED?

ECHA'S VISION OF SUBSTANCES "THAT MATTER MOST"

At the 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 1 below, to a situation where Risk Management is "in place" or "planned" and to reduce the number of substances of potential concern.

Table 1: 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.

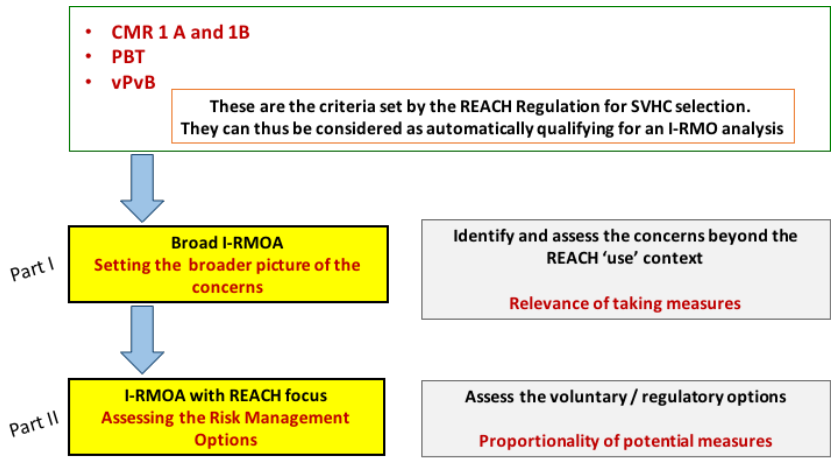
SCREENING FOR SUBSTANCES TO ASSESS

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

1.1. Is the substance likely to be concerned by a screening according to the SVHC Roadmap to 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).

Figure 3: SVHC selection vs. I-RMOA types



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 (the broader picture as discussed in Part I) as well as on assessing the Risk Management Options in a regulatory context (See Part II built around REACH).

However the screening activities will cover the 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

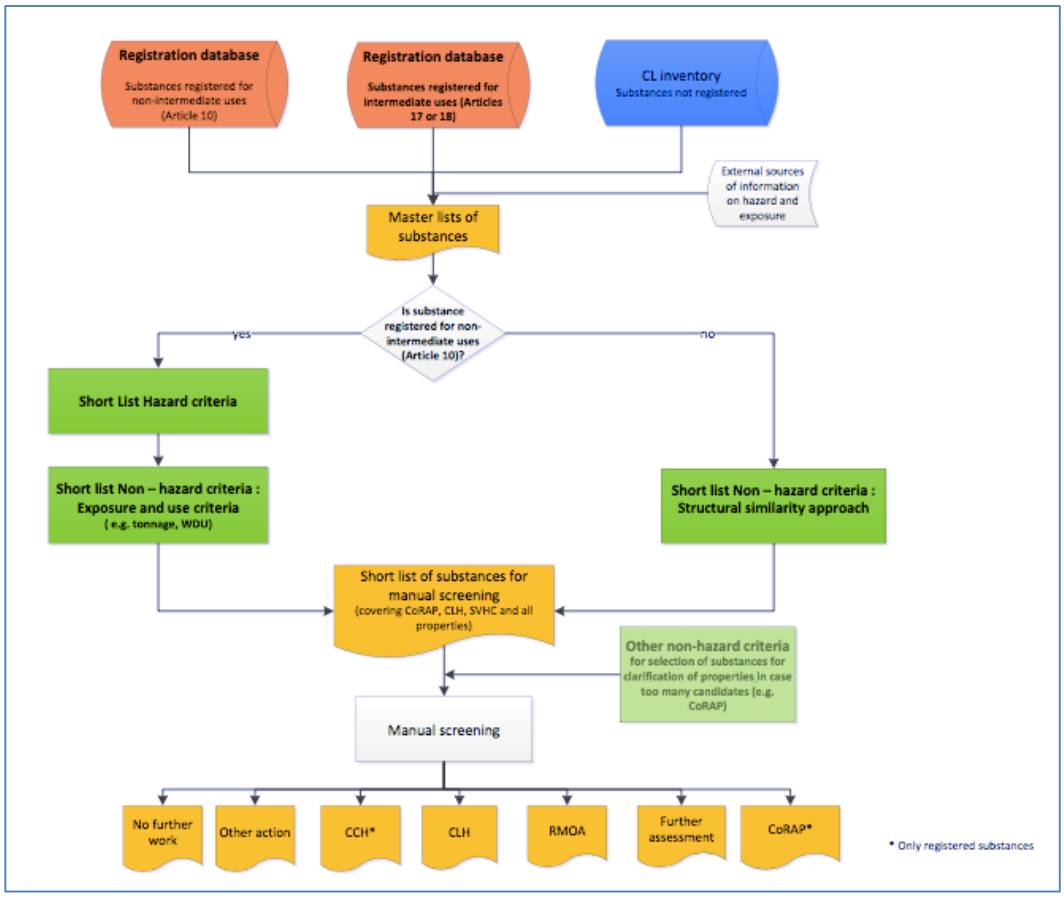
- Endocrine disruptors (EDs).

The SVHC Roadmap gives priority to substances registered for non-intermediate uses. Screening and later on, RMO analyses of these registered substances are referred to as the "Core Activities" in the SVHC Roadmap implementation plan.

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

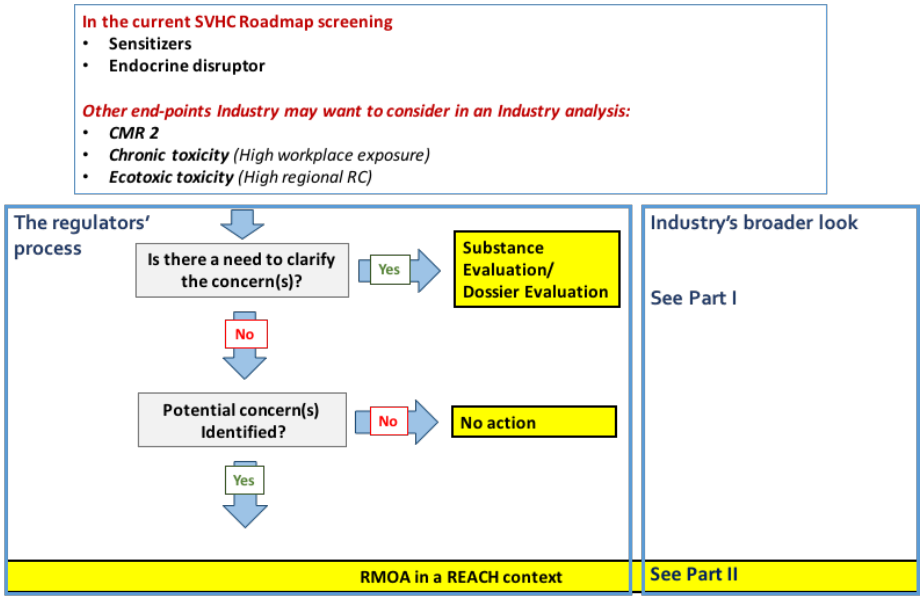
At this point, it may be relevant to refer to ECHA's Screening Definition Document released in January 2016 under the title *Scenarios to be Implemented for Searching Potential Substances of Concern for Substance Evaluation and Regulatory Risk Management.* It provides an illustration that a broad scoping of substances, beyond the REACH Regulation criteria for SVHC selection, can make sense. Screening scenarios are evolving 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



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



How the I-RMOA is performed is described in Part I, Part II and in the Annexes.

3. BY WHOM AND WHEN SHOULD AN INDUSTRY RISK MANAGEMENT OPTIONS ANALYSIS BE PERFORMED

As the I-RMOA, or parts of it, can be perfomed 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.

The following paragraphs provide an indication of what roles can be taken up by the different Industry actors. REACH will be a key driver in such processes but it needs to be stressed that the I-RMOA is a tool that can be resorted to independently of that particular regulatory challenge. PART 2 of these Guidelines will show how critical the **scoping** of an I-RMOA is as it will determine what exactly will be done, when and by whom.

The general advice on when to get started is to conduct the RMOA screening for all substances that meet the SVHC 2020 Road Map criteria or even 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 and a realistic solution for when one's substance is scrutinized.

A. COMPANIES

Companies which should get involved are all those directly concerned by the use of a substance likely to be scrutinized or under 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 will have an essential role in helping to set the broader picture of hazards, risks and exposures, downstream users as the effective users of the substance have a strategic interest in setting 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 2.

Table 2: 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 3 provides an indicative overview of possible activities of commodity organisations in this context.

Table 3: 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 aluded 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 4 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 (see Part 2).

Table 4: 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	Fulfill regulatory obligation of keeping up-to-datre 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.

4. ORIENTING PRINCIPLES OF AN INDUSTRY RISK MANAGEMENT OPTIONS ANALYSIS AND CHOOSING BETWEEN APPROACHES

An 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 the following table.

Table 5: Principles for an 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***	…and once the knowledge and process foundations laid, a feedback loop can be easily introduced
*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*	Poor data often lead to poor decisions…
*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 life-cycle of a substance and to integrate regulatory and societal parameters
*Be **transparent** and **inclusive***	Each part of the analysis should be understandable and open for discussion by those not having participated directly in the exercise
*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

There is no fundamental difference or antinomy between the two approaches described in the guidance.

Their difference resides in the ambitions of the initiators of the risk management options exploration and in the constraints that weigh on them. Such constraints may be the regulatory framework to address or the availability of resources, data or the range of participants e.g.

The following illustrations sketch out the first decisions that will lead to whether the 'broader' or the a more limited REACH RMO-related approach are chosen.

Table 6 summarizes what approach (the broader or the immediate regulatory) may be chosen in function of the assessment aimed for.

Table 6: I-RMOA approaches in function of assessment

DESCRIPTION OF ASSESSMENT	AIM	APPROACH	
		BROAD I-RMOA	**REACH I-RMOA**
Critical self-reflection within sector or by companies	Identify potential need for RMM	**Allows holistic approach**	-
Internal company audit	Identify remaining risks and most efficient RMM	**Allows company to identify RMM pathways and product strategies**	*(No individual company's impact on regulatory choices)*
Audit of available information in CSR and beyond	Identify the appropriate RMOa	**If time and context allows (substance not on the radar screen), work may involve holistic approach**	*When time pressure, work will be focused on the main points of attention of Member States*
Audit of CSR (existing Registration dossier)	Address data relevant to RMO analysis	*Exploratory assessment on the basis of different screening scenarios*	**Work is focused on the main points of attention of Member States**
Assessment of future Registration dossier (2018)	Provide and present data in a manner relevant to RMM identification and assessment	*Maybe at later stage: Exploratory assessment on the basis of different screening scenarios*	**Work is focused on the main points of attention of Member States**
Collection of data for contribution to likely or ongoing RMOa's	Contribute timely data to Member States performing RMOa's	*Time constraint!*	**Work is focused on the main points of attention of Member States**

PART 1 - BROAD I-RMOA, A STRATEGIC REVIEW BY INDUSTRY

Part 1 will, in 3 subsections:

1. **Set the scene of a broad I-RMOA depending on the objectives st by its initiators**
2. **Discuss how a broad I-RMOA can be performed with the use of particular tools such as a materials mass flow assessment, a circular economy assessment or a diffuse source assessment**
3. **Discuss the outcomes one may expect from a broad I-RMOA.**

2. SETTING THE SCENE

The Broad I-RMOA may be ambitious in its scoping and correspond to different necessities. It may be aimed 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 Introduction**, when discussing the screening of substances already went into the questions to consider to help scope the analysis. It should however be stressed that a broad, strategic review may be performed entirely outside the scope of REACH.

Its initiators may decide to perform an analysis that will

- **Screen 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, potentially remaining concerns, that may need to be addressed by means of risk management measures.
  This screening may not focus only on the notion of 'concern' as in the concept of SVHC in the REACH Regulation.
- **Identify 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 them
- **Compare 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.)
- **Focus on improving the REACH Registration dossier**
  The analysis helps to get a better understanding of how the existing screening processes may come to conclusions based on the Registration dossier. It may also help identify data that are weak or in need of refinement when used for identifying and analysing risk management needs.
- **Put the potential concerns in context**
  A series of analyses are at hand 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 natural occurring substances.

The Broad I-RMOA will ideally cover identification/investigative work carried out before the substance gets covered by 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 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 how a Broad I-RMOA can quickly help identify RMM pathways that are relevant to Industry and Society by a combination of support tools, especially, **substance/materials mass flow assessment**, **diffuse sources assessment** and **circular economy assessment**.

3. PERFORMING THE BROAD I-RMOA WITH USE OF SUPPORT TOOLS

3.1. LOGICAL STEPS

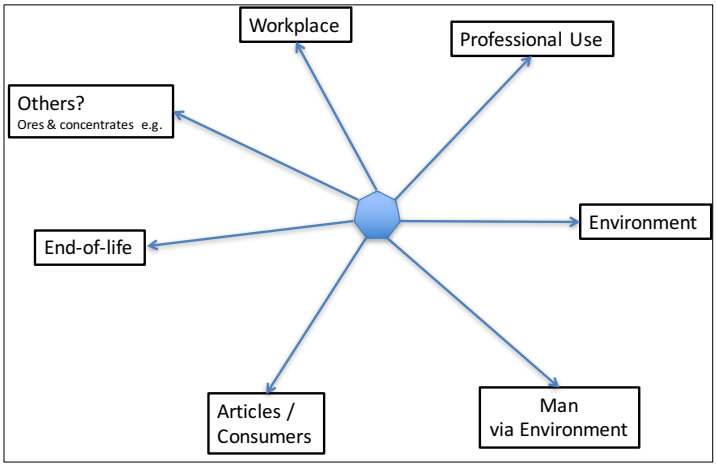
3.1.1. WHERE IS THE SUBSTANCE PRESENT?

As illustrated in Figure 6, the 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 any more, 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 6: Life-cycle scan of the substance



Tool: **Materials Mass Flow Assessment**

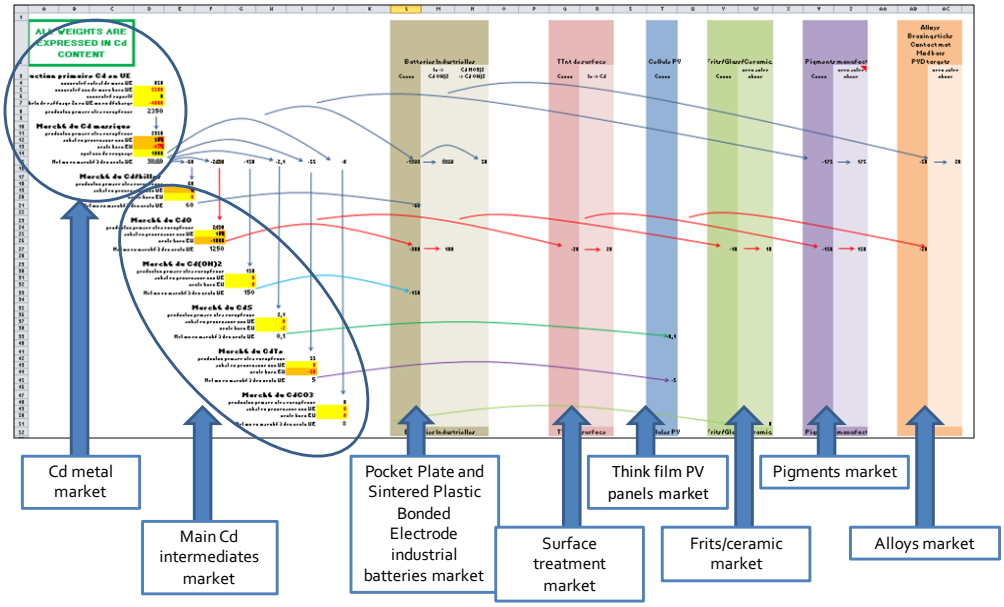
It will be a valuable support tool for the assessment. It provides an overview of the pathways for substance use and industrial processes (cf. Environmental risk or impacts assessments, links with LCA). It will identify under which form/speciation the substance – a metal element e.g. - is present and if/ when it is transformed into another form/speciation.

This assessment may also help ascertain and refine the intermediate status of the substance use 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 (see example on mist suppression in plating).

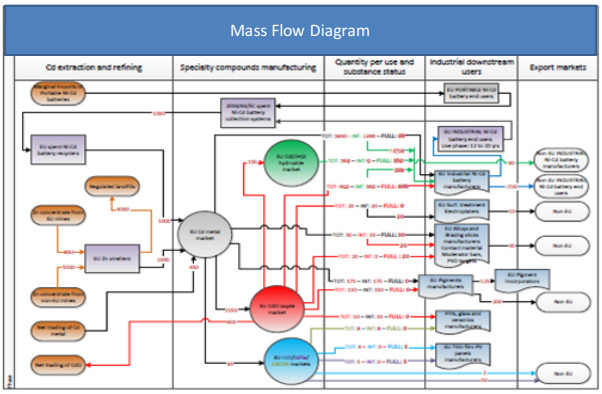
An illustration of such a mass flow assessment is provided in Figure 7 where a materials flow diagram for Cadmium and its compounds is sketched out. This is an effort to reconcile the 'business segments / markets' point of view common to Industry with the REACH approach focussing on 'uses'.

Figure 7: Materials Mass Flow Assessment diagrams 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).

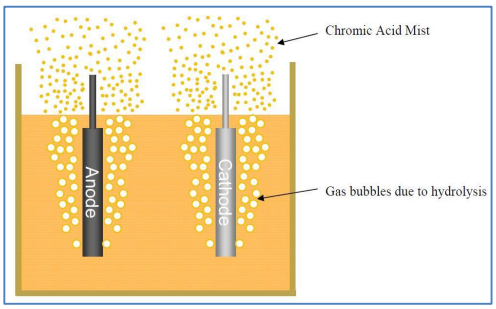
Figure 8 illustrates how the mass flow assessment can lead to make an inventory of the ways through which parts of the material are 'lost' through e.g. emissions.

Figure 8: Materials Mass Flow Assessment and understanding exposures to hexavalent chromium

Hexavalent chromium

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.

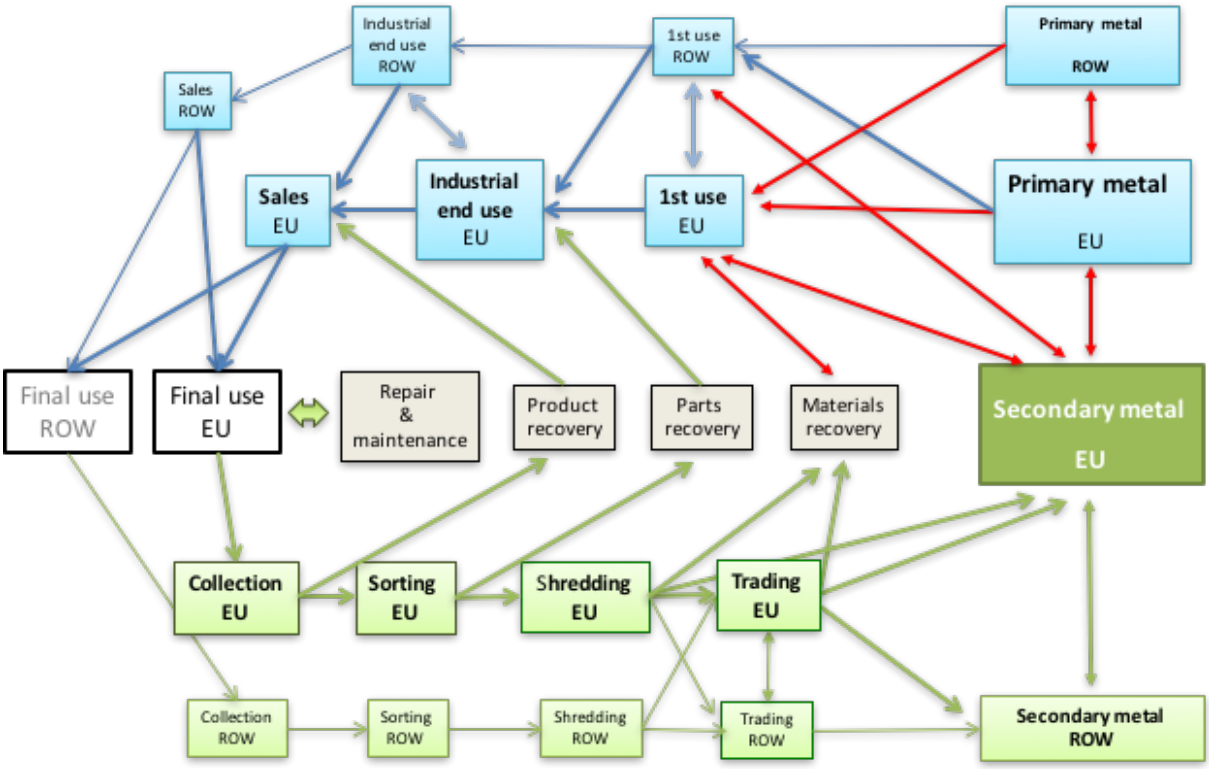
Tool: Circular Economy Assessment

The Circular Economy Assessment, as illustrated in Figure 9, enriches the Materials Mass Flow Assessment by focussing on whether the life-cycle includes a closure of loop and what its significance is.

The recycling dimension is complex to analyse as it includes the level of materials recovery and issues such as impurities (dilution or not of impurity and its future fate, as use or not etc.). This assessment is of relevance as it may help identify/highlight measures (regulatory or not) that may benefit both Industry and Society.

The **circular economy approach will consider the life-cycle as a web of potentially feed-back rich systems with the ambition to optimizing the overall system rather than individual components**. It breaks out of the notion of cradle-to-grave to consider the cradle-to-cradle approach where the performance of the overall system will depend, for a significant part, on closing the materials loop. The analysis de facto integrates the concept that the availability of materials for the economy cannot be considered as granted any more due to increased global competition to finite resources and that losses of materials are losses for the economy.

Figure 9: The Circular Economy dimension in a metals context

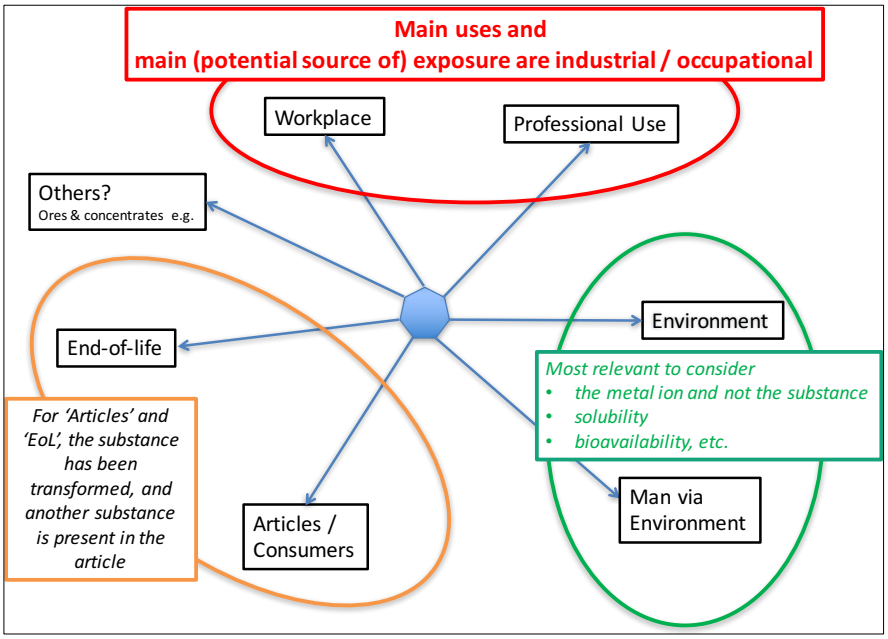


3.1.2. WHERE IS THERE EXPOSURE / RELEASE?

In this case, the 'uses' that are relevant, including in terms of REACH Authorisation, are industrial and occupational. The information available in the substance CSR can be used to make sure the latest data is taken up in 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..

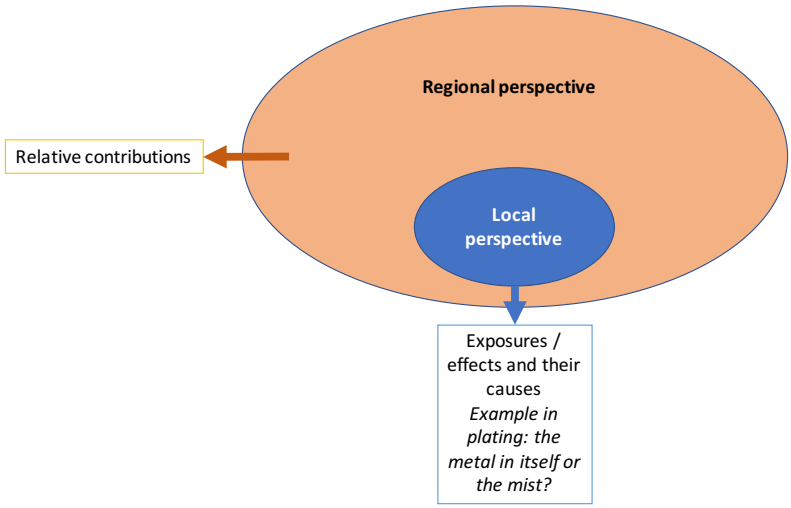
In the illustration provided in Figure 10, the life-cycle scan allowed to confirm that the main sources of exposure or potential exposure were occupational, in industrial and professional settings. The analysis of the environmental dimension (environment and Man via the environment) led to consider the 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.

Figure 10: Example of identification of exposure



One may want to develop a more holistic view of the contributors to emissions/exposures to the substance. For that purpose the a Diffuse Sources Assessment (see Figure 11) discussed in point 2.1.4. may prove to be a very valuable tool, as illustrated in the next steps.

Figure 11: The change of perspective with a Diffuse Sources Assessment

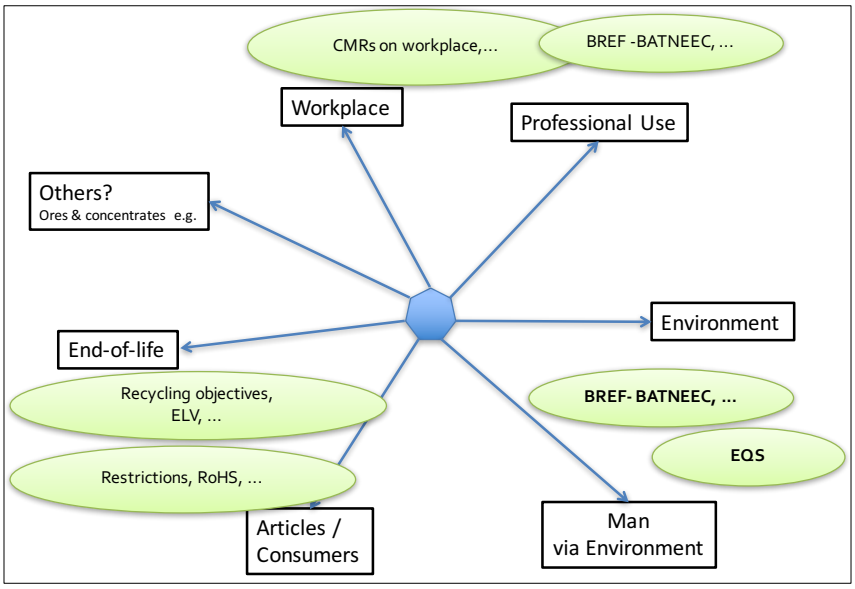


3.1.3. WHAT ARE THE EXISTING REGULATORY RISK MANAGEMENT MEASURES OR WHAT COULD THEY BE?

An inventory is established of the existing regulations (cf. illustration in Figure 11) whilst possible alternative approaches are identified, in function of the knowledge one has of the existing framework). 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 use of the articles where the releases may be assessed (intentional or normal use and wear?).

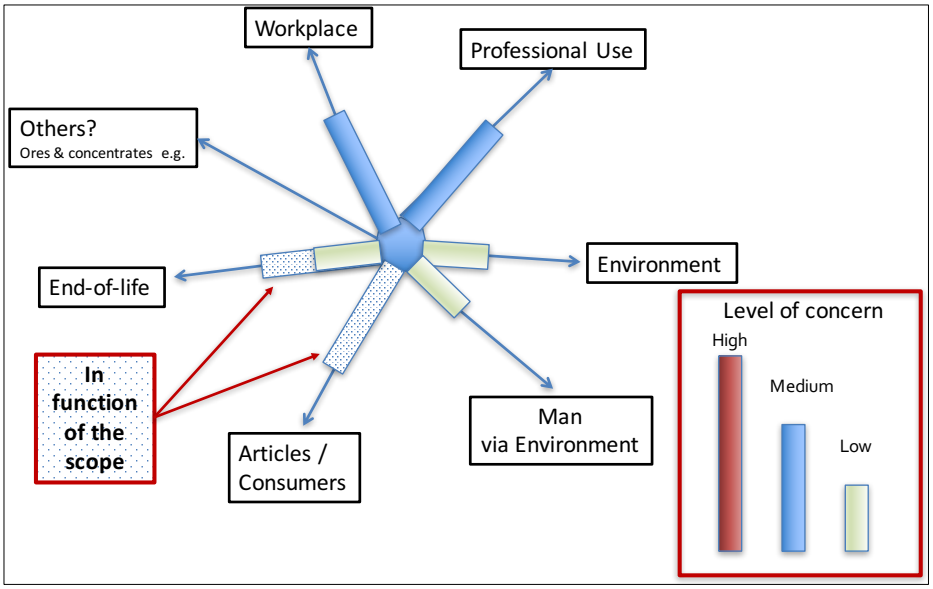
Figure 11: Existing regulatory risk management measures in place



3.1.4. HOW WOULD YOU RATE THE REMAINING LEVEL OF CONCERN?

In function of the scope of the analysis, this step may allow to get a grasp of the broader scene and put the different issues in perspective as illustrated in Figure 12.

Figure 12: Rating the level of concern



In this step and for the example chosen, the analysis will consider 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.

In step 2 (Where is there exposure / release?), one looked at the sources of exposure / release from a life-cycle perspective where one can get a view of point sources and some diffuse sources (often under a different speciation). However, that may be a distorted view of reality as other sources may be significant or even the most relevant ones (agriculture, unintended sources)

The Diffuse Sources assessment described in the following text box may allow to come to a strategic view on the issues related to the substance, which may help identify pathways for an efficient and significant as well as cost-effective reduction of emissions/exposure.

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

Tool: **Diffuse Sources Assessment**

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."*[1]

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.

Two examples of Diffuse Sources Analysis are provided:

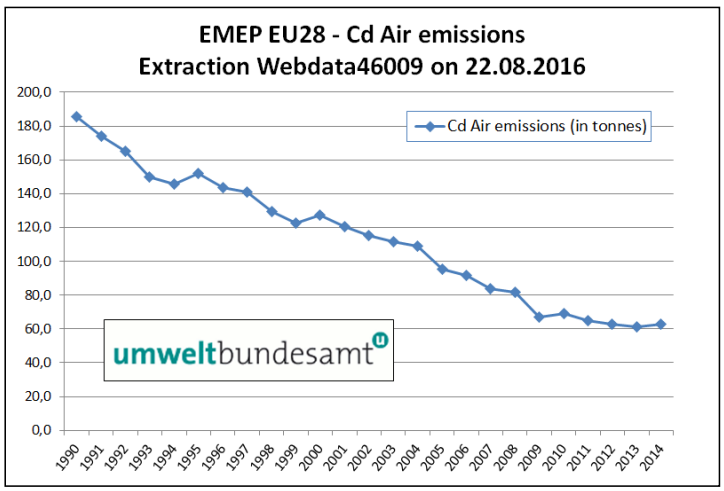
CADMIUM

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 aie emissions (cf. Figure 13)

Figure 13: 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 14: Integration of mass flow and diffuse sources analysis into an initial assessment of concerns (hypothetical example)

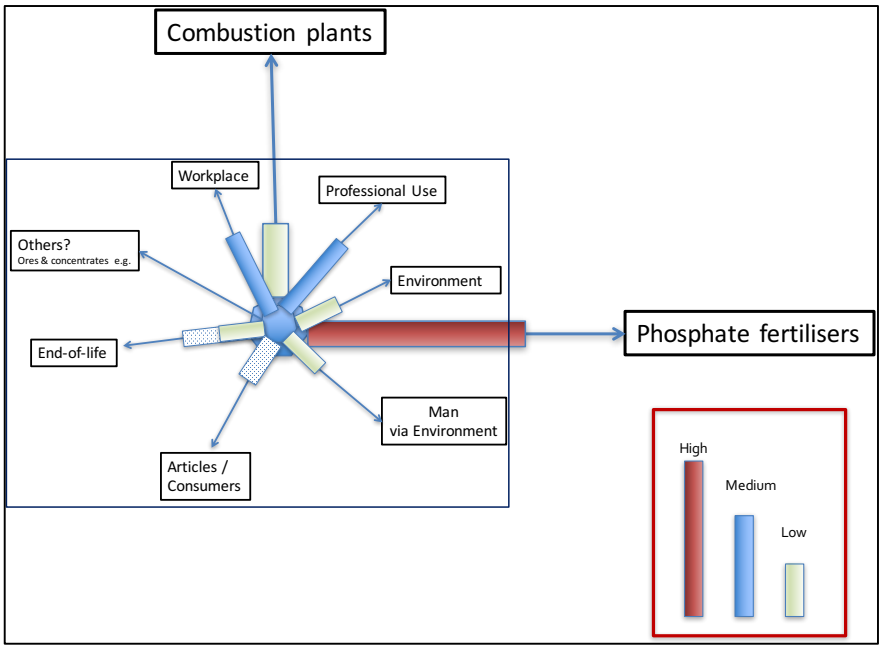


Figure 14 shows that an Industry assessment that would have considered both mass flows and diffuse sources analysis may lead to a interesting conclusions. Starting from an assessment that would have focussed on 'direct' anthropogenic sources (diffuse and point sources), one identifies another significant sources whose persistence would 'dilute' the effect of any measure that may be initially considered.

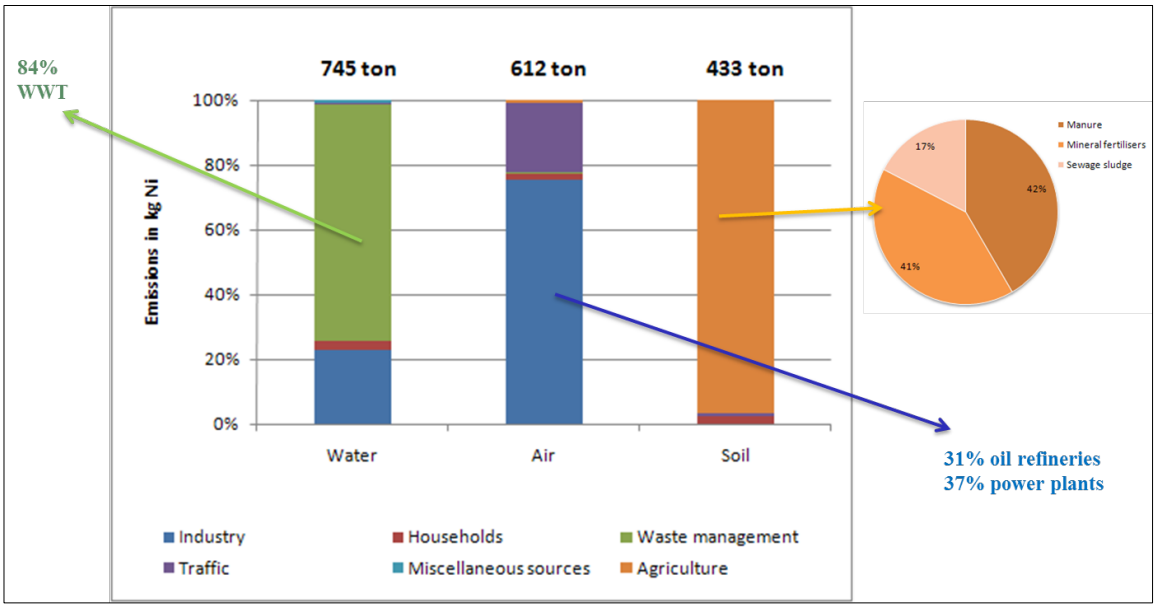
The societal debate on tobacco usage and availability is left aside because out of the remit of the cadmium value chain.

OTHER METALS

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

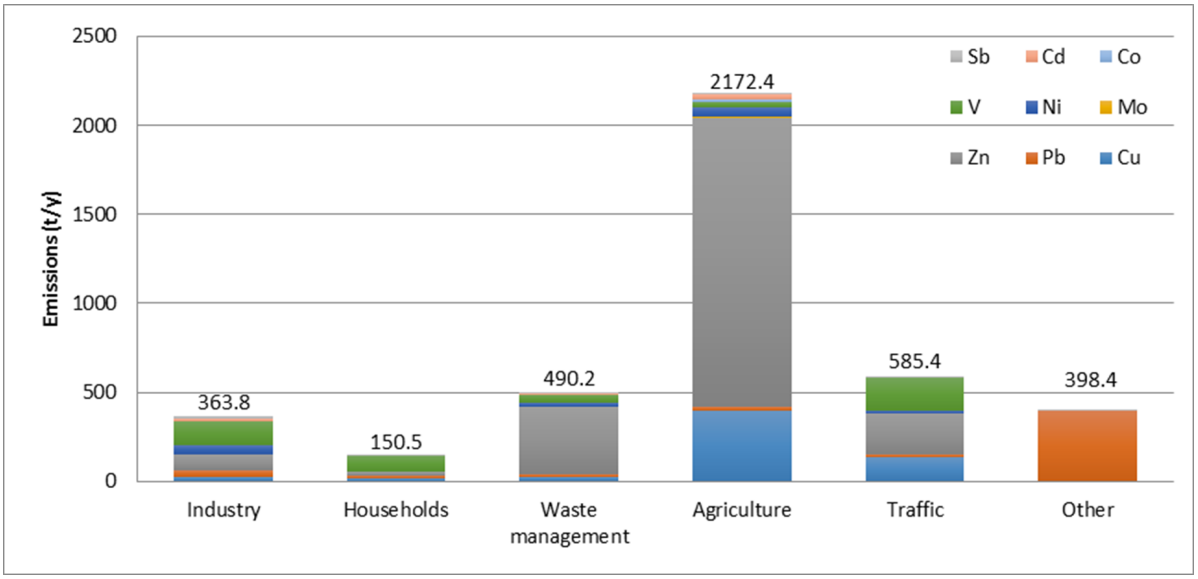
As shown in Figure 15, a diffuse sources analysis of nickel shows that, for the sake of efficiency, traditional risk management measures may have to be considered as only a part of an integrated strategy that would include innovation, energy mix policies etc.

Figure 15: Diffuse sources in water, air and soil of nickel



As a matter of illustration, the following figure 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 16: Total regional emissions by source of 9 metals (EU)



OUTCOMES

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 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 not-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 counter-intuitive.

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.*

- **Identify, thanks to a critical look at the issues, what are the relevant socio-economic information that may usefully contribute to a regulator-initiated RMOA 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 Figure 17, which is an illustration of a very synthetic summary of key elements.

Figure 17: 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: 43% 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

PART 2 - I-RMOA UNDER REACH

Part 2 will, in 3 subsections:

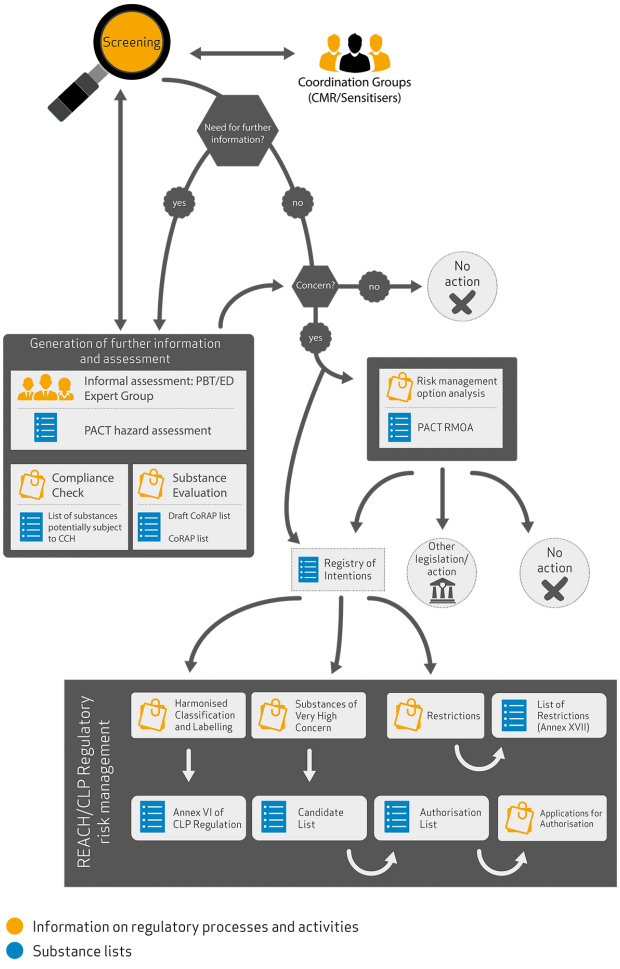
1. **Describe the RMOA in the REACH context of a broad I-RMOA depending on the objectives st by its initiators**
2. **Go through the different stages of a Generic I-RMOA**
3. **Describe more in practice how to proceed with an I-RMOA**

1. RMOA IN THE REACH CONTEXT

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 one stage prioritisation and Authorisation) appears not to always be the most adequate Risk Management Option and that all relevant regulatory option should be considered earlier in the process.

The process initiated by the SVHC Roadmap 2020 involves different steps starting from the screening of relevant substances, as shown in Figure 18 below:

Figure 18: SVHC screening following the introduction of the SVHC Roadmap to 2020 Implementation Plan[1]



[1] http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern

Section 3 of the Introduction discussed the screening at ECHA and Member State level and their ambition in terms of risk management of substances of potential concern. The following decision elements should be kept in mind:

- **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

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The RMOA is based on the following steps:

1. FIRST STEP: SCREENING OF RELEVANT SUBSTANCES

The screening process is mainly based on the REACH registration dossiers although there might be cases when non-registered substances can be selected (entry in CLP without being registered). It allows identifying substances that have a 'profile' that is relevant or about which there is insufficient information in the Registration dossier.

The screening focuses mainly on the following information:

- 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)
- Recommended risk reduction measures.

This process is 'automatic', thus unavoidable and **Industry is highly encouraged to take some *proactive a*ctions. Industry should consider to provide or complete some key data present in the Registration dossiers, as indicated in the recommendations of PART 3. The quality of the assessment discussed in this guidance document will to a large extent depend on the thoroughness of these proactive actions** and it cannot be emphasised enough how useful they will prove to be.

No substance that fits within the criteria for SVHC selection as set in the REACH Regulation, should be overlooked (PBT, CMR as well as Equivalent Concern such as endocrine disruptors, STOT-RE, sensitizers).

Such proactive actions from Industry will already involve significant sectors of the value chain, although not the final industrial users of articles. They will yield both data and useful value chain contacts for the Industry RMOA. Furthermore, weaknesses identified should be addressed as soon as possible, if not in time for the screening, then for the benefit of those conducting the RMOA.

Substances that should be considered in priority by Industry? While all substances fitting with the Road Map criteria should be considered for one form or other of RMOA review, there are indications where priorities may

be. Substances that are listed for CoRAP or focussed by in the ECHA Soft Letter campaigns or PACT (see further) could be priority candidates for RMO assessment.

2. SECOND STEP: RISK MANAGEMENT OPTIONS ANALYSIS FOR SUBSTANCES OF POTENTIAL CONCERN

ECHA or any MS may decide to conduct a RMOA based on an initial concern regarding hazard properties and/or potential exposure. The purpose of an RMOA is to clarify whether risk management activities are required for a substance based on existing hazard and / or risk information and to identify the most appropriate instrument to address a concern. If needed, available risk management measures include:

- **Evaluation** (although not apparent in the figure above, the SVHC Roadmap indicates that the RMOA may still come to a conclusion that additional information needs to be generated)
- **Harmonised classification and labelling (CLH)**
- **Restriction under REACH**
- Inclusion on the **Candidate list** (i.e. selection as SVHC), the first step toward prioritisation for **Authorisation under REACH**
- Other regulatory options, such as **Occupational Exposure Limits (OEL)[2], Environmental Quality Standards (EQS), etc.**

A useful tool for Industry is the Public Activities Coordination Tool (PACT) on ECHA's website that lists the substances for which an RMOA is either under development or has been completed since the implementation of the SVHC Roadmap commenced in February 2013 [3] (http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact)

As soon as an Authority has initiated an RMOA, Industry should engage with this Authority and share the additional data it may have collected on uses, tonnages, etc. Simultaneously Industry will have to make sure that effective communication channels are open with its supply chain, down to the final industrial users.

Rumours are difficult to control and, in a competitive market, the launch of an RMOA may be presented as foreboding 'bad times ahead' for the substance, triggering first precautionary measures of substitution or reshaping of the supply line. However, the RMOA is supposed to dig deeper into the specifities of each risk management option, as well as into the data about the substance, tonnages and levels of exposure.

To be able to weigh on the discussions early enough, Industry should consider other types of preparatory work, hence the concept of "**metals RMOAs**" discussed at Eurometaux[4], which is explained further in this document.

[2] For example: BAUA, the German Member State Competent Authority (MSCA), has submitted an RMO Analysis conclusion document on Acrylonitrile, recommending the introduction of a Europe-wide OEL (28 August 2014)

[3] Note that some Member states will have initiated work on some substances before communicating on it

[4] For the policy dimension of this issue, please read "**To a vision on REACH RMM by the metals sector- Thought starter on a Eurometaux strategy**", a strategy paper developed by Eurometaux (December 2014)

2. GENERIC I-RMOA SCHEME

The key elements of a 'standard' I-RMOA, are to be structured along the following generic scheme. This scheme reflects a broad consensus, including in the regulatory sphere, on what is needed to make an informed decision. It is built on data which as indicated in Part 1 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.

2.1. THE SUBSTANCE

This first stage consists in identifying in a 'neutral' way substances for which an RMOA may be usefull 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 is likely to be considered for a regulatory assessment/RMOA.

FIRST ON THE CHECK-LIST

1. **What does the Registration dossier tell 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 end-points covered? Is the quality of the assessments satisfactory or are there still some end-points 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 wil 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

2.2. USES, VOLUMES AND POTENTIAL EXPOSURES THROUGHOUT THE LIFE CYCLE

Once the substances that may fall under a regulatory scrutiny identified, its life along the supply chain, actually its entire life-cycle should be mapped.

SECOND STAGE OF THE CHECK-LIST

5. **Uses**

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

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

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

    1) **Material flows (ideally)**

    For each step of the substance and product life time; 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.

    2) **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?

    3) **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.

    4) 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-craddle approach) as the fate of the substance would stop there.

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

    6) **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.?

7. Exposure

1) Identification of **(potential) exposures**.

2) **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 suggests an approach on this, taking into consideration the fact that authorities may want to proceed further with their analysis on the basis of the intrinsic properties of the substance.

2.3. MAPPING THE REGULATORY ENVIRONMENT

At this stage it is usefull to understand whether regulators or Industry have set in place instruments to manage the (potential) risk. That overview of regulatory or voluntary instruments will allow to assess whether the tools needed to efficiently manage risks are in place in such a way that it can be considered that there is no need for additional instruments.

The review may highlight the weakness of such instruments, the causes of which can be diverse: incomplete geographical coverage, divergence of scope and severity, need for update, weak enforcement and reporting etc.

THIRD ON THE CHECK-LIST

8. **Regulatory status** in the EU (REACH, Water Framework Directive etc.) of the substance, the processes in which it is used (use sectors), or articles containing the substance. This collection may have to be refined later on, with the further analysis of the fate of the substance as there may be uses to be discovered or better understood.

9. **Non-regulatory product stewardship schemes** 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[5]. Some of those systems are the result of an agreement between government and Industry, such as BEBAT (collection and recycling of batteries in Belgium).[6]

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

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

2.4. 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.

As will be discussed more in detail later in this Guidance:

- **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.
- **All potential options should be defined,** i.e. their content (scope, basic definitions) should be clear in the minds of the assessors.
  This requires a carefull 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 approachd 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.

2.5. DISCUSSION OF RISK MANAGEMENT OPTIONS

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** stricto sensu: 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 adde, 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…*

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

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 a RMOA under a common denominator (i.e. Euros).

- 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. Let's imagine a substance used as a pigment providing a specific colour:
  - *Absence of alternatives: 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.
  - *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.
  - *Loss of jobs*: 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 or resilience may be interesting 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 (e.g. climate change, circular economy, etc.).

3. PRACTICAL APPROACH FOR AN INDUSTRY-I-RMOA

In practice, the process to follow is described in the following steps:

3.1. Preparatory steps: Identification of the substances

3.2. The RMO identification and discussion process

1st filter: Mapping the areas of concern and identification of need to address a risk

2nd filter: Identification of possible Risk Management Options

3rd filter: Identification of need for use-tailored Risk Management Options

4th filter: Fitness test of the RMOs

3.3. The synthesis of the RMO exercise: overall proportionality

3.1. PREPARATORY STEPS: IDENTIFICATION OF THE SUBSTANCES

If the substances need to be identified, i.e. not yet on a regulatory radar screen or not with a classification that qualify them for scrutiny (cf. Article 57 indicating which types of substances that may be included in Annex XIV, which lists the substances subject to Authorisation), then a screening may have to be set up.

This screening step has been discussed in the Introduction, section 3 and in Section 1 of this Par). For each of the substances that appear from the screening, one then establishes whether there is a need to clarify the concern(s) linked to the substance profile and whether there is a potential concern related to the use of the substance. At this stage, one may identify needs for further data gathering to clarify a potential risk.

3.2. THE RMO IDENTIFICATION AND DISCUSSION PROCESS

The RMOA should consider all possible RMOs and the most adequate RMO should be selected by applying a series of filters.

1ST FILTER: MAPPING THE AREAS OF CONCERN AND IDENTIFICATION OF NEED TO ADDRESS A RISK

Aim: Demonstrate that all possible areas of concern have been considered and that the selection of the areas of concern for further discussion is justifiable.

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 19, 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.

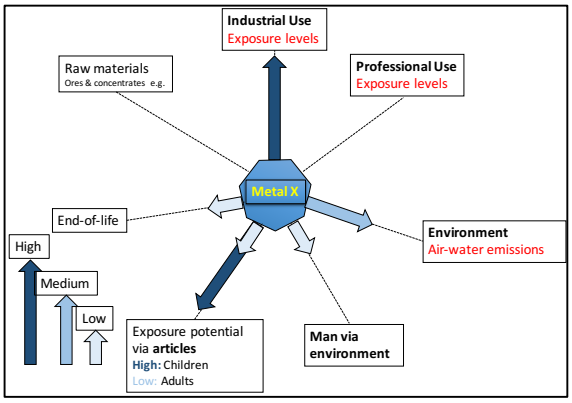


Figure 19: Example of how to present the areas of concern in manufacturing and use of a substance (life cycle approach)

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 Figure 20).

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.

Figure 20: Risk Characterisation Ratios to see whether a risk should be addressed

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 consider a risk management measure**

This leads to apply the following line of reasoning:

1. If the RCRs , even based on the most conservative exposure limit value that an authority may choose remain (considerably) below 1, then in principle the exercise could stop here.

2. If the RCRs, or the most conservatively recalculated RCRs, are equal to 1 or higher, the exercise should continue for the relevant uses.

3. As there is an uncertainty whether the authority carrying out the RMOA would do the step of identifying a risk (some authorities may proceed simply on the basis of the intrinsic properties of the substance) it is recommended that the exercise is also carried forward for uses where the (possibly recalculated) RCRs are below 1.

2ND FILTER: IDENTIFICATION OF POSSIBLE RISK MANAGEMENT OPTIONS

The second filter consists in the identification of **all** the possible risk management options that may be considered, starting from the least demanding "no action required" followed by "substitution" as the gradual phasing-out of some substances (SVHC substances especially) is the declared aim many policies.

Aim: Explore all possible risk management options and describe to what extent and how they might address the risk(s) considered relevant at the end of the previous step

Approach: Company experts should be involved in this step as they may come up with possible solutions, which people in charge of regulatory affairs may not yet be aware of (upcoming technologies e.g.). Depending on the substance and its value chains, it might also be worthwhile to involve downstream users (first use sectors).

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

If action is required:

- Substitution (Industry initiative)
- Existing legislation that may be related to workplace Directives (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.)

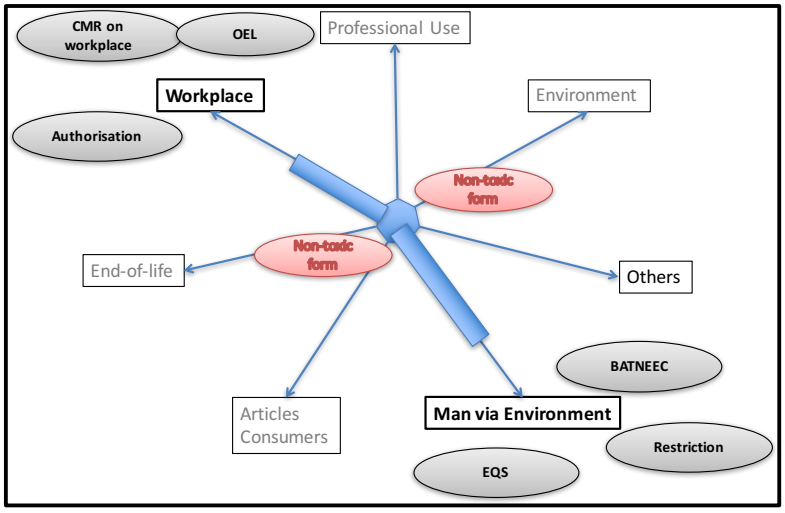
- Harmonised Classification under CLP
- Substance Evaluation under REACH
- Restriction under REACH
- SVHC selection and Candidate Listing
- Authorisation under REACH
- Restriction under RoHS, etc.
- Water Framework Directive
- Other EU legislation
- Other Risk Management Measures?

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.

This may lead to a listing of "potentially relevant or feasible RMOs", as shown in Figure 21 below for an example of a substance where 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, for example, no concerns or these may already be addressed adequately:

Figure 21: 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).



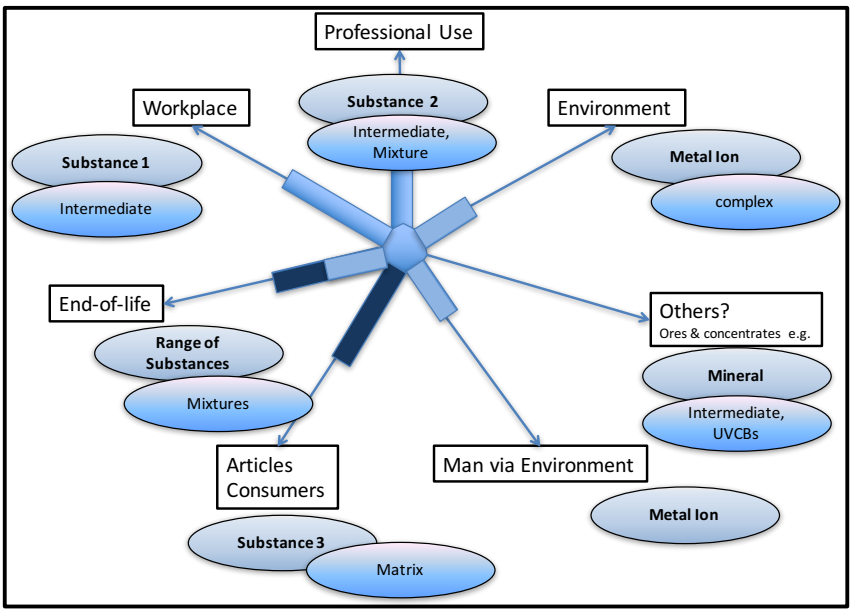


Figure 22: Speciation analysis in concern assessment

Figure 22 illustrates the fact that when considering the fate of the substance, 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'.

3RD FILTER: IDENTIFICATION OF NEED FOR USE-TAILORED RISK MANAGEMENT OPTIONS

The third filter to apply will consider whether the potential RMOs are equally valid for all the sub-sectors that are concerned.

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, and few conclusions can be reached in an "it-depends" situation…

Approach: Three approaches may be taken into consideration to consider whether the substance or its uses justify one of the following approaches:

- **Simple / Non-integrated approach: The risk management measure can be limited to the substance and its use(s).** ***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 as illustrated in Figure 6.

  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 Figure 23. It may reflect a case where the risk can not be efficiently addressed by an alternative risk management measure such as an OEL.

Figure 23: Example of an RMO for a Simple - or Non-integrated Approach

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

- **Combined / or Integrated Approach:**
  - **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 instance, the use of a substance in surface treatment would lend itself to such an integrated approach.
  - **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**.**

Figure 24: Example of an RMO for a Combined – or Integrated Approach

Figure 24 reflects a case where the substance was identified as having critical uses, which may be linked to other substances (e.g. in plating).

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) would help solve the problems.

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* *Would a combination of RMMs be increasing the effectiveness of the approach on the substance?*		*Same/similar hazard profile*	*Same/similar hazard profile*
Combined – Integrated approach	**BATNEEC**			

- **Specialised – or Mixed Approach:** The approach is a mixed one. In some cases, industry characteristics may justify a combination of a substance-based and a process-based approach, for example if there needs to be different solutions sought for large scale versus small scale processes (i.e. proportion of SME vs. non-SME).

One could imagine a combination of Restriction for a Use 1 (consumer use), or a Use 2 (professional use) for which no realistic worker protection can be implemented, compared with a BATNEEC for a Use 3 (use in industrial settings) where potential worker exposure can be controlled by a technological solution (Figure 25).

Sector characteristics, feasibility and other considerations might justify a mixed approach.

Figure 25: Example of RMOs for a Mixed Approach compared to a Simple/ Non-Integrated Approach

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**
Specialised – Mixed approach	• **Restriction**	• **Restriction**	• **BATNEEC**

Here again, it is important that the approach identified is justified to make sure that it is a realistic view. 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 this fit-for-purpose approach requires an investment in time and expertise. The pay-off may however be worth the effort.

4TH FILTER: FITNESS TEST OF THE RMOS

The analysis will now have to come to a conclusion (i.e. identify the best RMO) that fits with the key criteria that have been used in the RMOAs.

Aim: The objective is to test the different 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 criteria to be considered are the following:

- **Effectiveness;**
- **Practicality;**
- **Consistency**
- **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.

- **EFFECTIVENESS**:
  Has the measure considered the capacity to produce the desired effect, especially is it able to reduce possible risks and will its effects be measurable? Effectiveness measures **the efficacy** of the RMO considered.
  What is the availability of proven and affordable technology? What is known about alternatives?
  Here is where the expertise developed in previous steps (filter 2 and 3) has to be synthesised into a couple of sentences per Risk Management Option considered for the final comparison.
  Any **data and expertise on alternatives** will be a valuable input into the discussion.
  Figure 26 provides an example of a scoring of different RMOs in two types of approaches as identified in Figure 25.

  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 Figure 9, assessors have decided to **score the criteria from 0 to ++++**[7] 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

[7] ANNEX III discusses scoring approaches

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.

Figure 26: Example of a comparison of the effectiveness of the different RMOs in both a Non-Integrated (or Simple) and a Mixed (or Specialised) approach

RMO	Ability to reduce risk	Measurability / Monitorability	Proven technology available	Overall effectiveness
Simple – Non-integrated approach				
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)	++++
Specialised – Mixed approach				
Restriction For Uses 1 and 2 (based on assumptions made on scope and content of Restriction)	+++	++	+	+++++ +
BATNEEC For Use 3	++	+	+++ (some participants claim ++++)	+++++ +

- **PRACTICABILITY**: Can the RMO be implemented easily? One may consider that practicability, by comparing output to the input such as the means needed, is more process-oriented than the previous criterion of effectiveness. It addresses more the question of the **efficiency** of the risk management option under consideration.

Practicability 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
- **Ease to implement by Regulators**: Under which conditions and at what cost can enforceability be assured?
- **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 (Figure 27), 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.

Figure 27: Example of a comparison of the practicability of the different RMOs in both a Non-Integrated (or Simple) and a Mixed (or Specialised) Approach

RMO	Ease to implement by Industry	Ease to implement by Regulators	Time to implementation	Overall practicability
Simple – Non-integrated approach				
Restriction (based on assumptions made on scope and content of 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)	+++++
Specialised – Mixed approach				
Restriction For Uses 1 and 2 (based on assumptions made on scope and content of Restriction)	+ (between 0 and ++ depending on use, some being intermediates)	+++	+++	+++++ ++
BATNEEC For Use 3	+	+	0 (timing concern for most participants)	++

- **CONSISTENCY**: How do the RMOs being considered perform in terms of a level playing field and coherence? Figure 28 ilustrates 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**: If, for example, the substance can not be substituted in processes that contribute to achieving EU air quality standards, a ban may negatively affect air quality and associated public health objectives. There is an abundance of EU policies that could be considered in this respect and not only related to human health or environmental objectives (energy, resource efficiency etc.)

Figure 28: Example of a comparison of the regulatory consistency of the different RMOs in both a Non-Integrated (or Simple) and a Mixed (or Specialised) Approach

RMO	Regulatory consistency	Consistency with existing EU legislation	Consistency with previous EU initiatives	Consistency with other EU policy objectives	Overall consistency
Simple – Non-integrated approach					
Restriction (based on assumptions made on scope and content of Restriction)	++++	+	++	++	+++++ ++++
Authorisation	++	+	+	+	+++++
Specialised – Mixed approach					
Restriction For Uses 1 and 2 (based on assumptions made on scope and content of Restriction)	+++	+++	+++	++	+++++ +++++ +
BATNEEC For Use 3	0	+++	++	+++	+++++ +++

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.

- **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), but also 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.

  Figure 29 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 (see page 40 and following pages). The templates in Annex V also consider them separately. The choice is left to those performing the exercise and will depend on the substance.

Figure 29: Example of a comparison of the broader impact of the different RMOs in both a Non-Integrated (or Simple) and a Mixed (or Specialised) 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 – Non-integrated approach							
Restriction (based on assumptions made on scope and content of Restriction)	+	+	++	+	0	+	+++++ +
Authorisation	+	0	0	+	+	0	+++
Specialised – Mixed approach							
Restriction For Uses 1 and 2 (based on assumptions made on scope and content of Restriction)	++	++	++	++	0	+	+++++ ++++
BATNEEC For Use 3	+++	++	++	0	0	++	+++++ ++++

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

3.3. THE SYNTHESIS OF THE RMO EXERCISE: OVERALL PROPORTIONALITY

The following illustration (Figure 30) shows how the fitness test could be synthesised, as an indication of overall proportionality, for the case where an EU-wide (potentially) unacceptable risk has been identified that would justify discussing a Restriction or an Authorisation.

In this hypothetical example, the initiative to try and improve the regulatory outcome through a mixed approach has proven useful, altering dramatically the proportionality dimension. This comparison of rankings of the RMOs can also be examined further by applying "weightings" on the proportionality score that consider the respective views of the participants.

Figure 30: Example of a synthesis of comparison of the different RMOs in both a Non-Integrated (or Simple) and a Mixed (or Specialised) Approach

RMO	Overall effectiveness	Overall practicability	Overall consistency	Broader Overall Impacts	Overall proportionality
Simple – Non-integrated approach					
Restriction (based on assumptions made on scope and content of Restriction)	5	6	9	6	26
Authorisation	4	5	5	3	17
Specialised – Mixed approach					
Restriction For Uses 1 and 2 (based on assumptions made on scope and content of Restriction)	6	7	11	9	**33**
BATNEEC For Use 3	6	2	8	9	**25**

Any conclusions drawn from this synthesis can therefore be presented in a transparent manner, using the above table as a summary overview, which is then supported by explanatory comments. See further in Annex IV and its templates more information on scoring systems and their weighting.

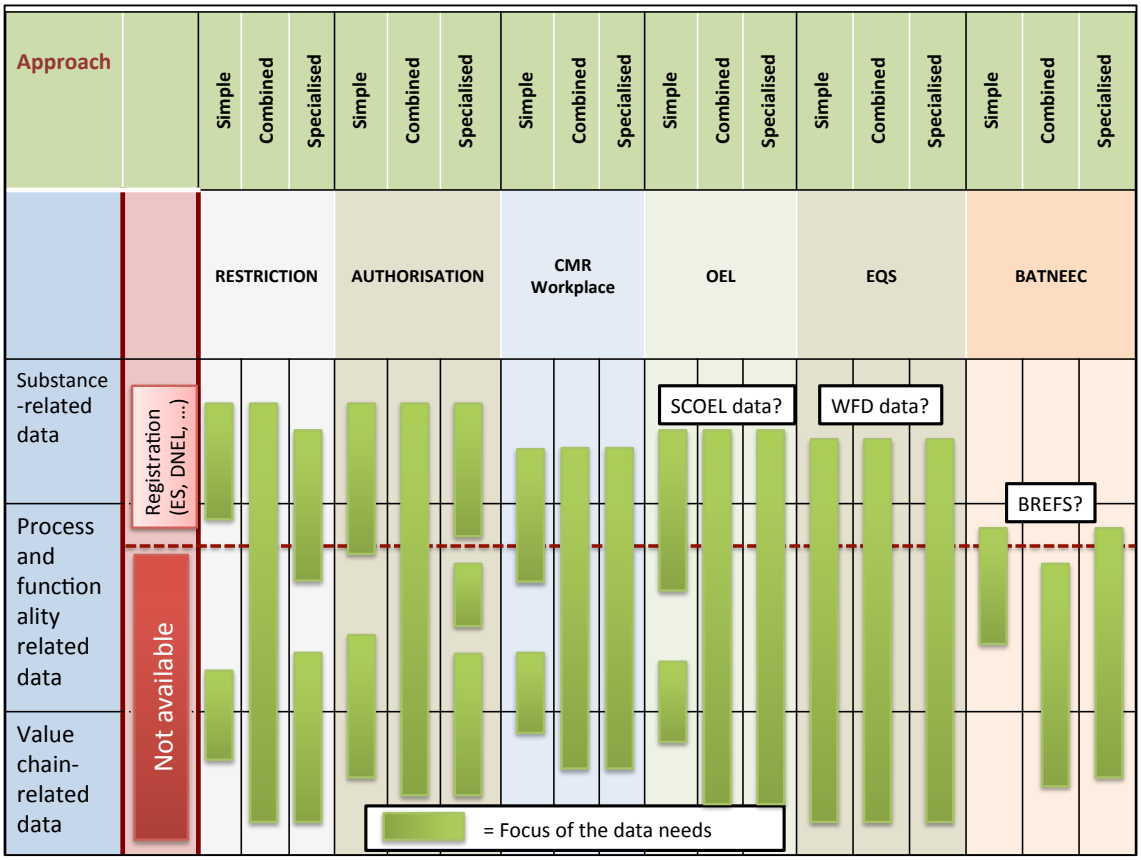
The overall transparency in the approach is important to prevent the introduction of any bias. It is also important to capture and document the reasoning applied in the assignment of the scores, and in the selection and application of any weighting.

ANNEXES

ANNEX I - 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 Figures 31 and 32 whose purpose are only to illustrate that there is no RMO that can be discussed based on REACH Registration dossiers only.

Figure 31: Illustration of possible data gaps in function of the RMO approaches to assess



The above figure 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.

Figure 32: Illustration of key data needs for three Risk Management Options

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 / process			+	+	+
	• Functionality per use/process			+	-	-
	• Alternatives per use/process			+ plus tox profile	-	-
Value chain-related data	• # legal entities / plants			+	Regional	+
	• # Workers exposed and dependent on substance use			+	Population	
	• 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 II - 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)
- 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 7 provides a schematic and incomplete overview of strengths and weaknesses of the different RMOs.

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

Table 7: Indicative overview of possible RMOs

RMO	Strengths	Weaknesses	Possible target conflicts (with other EU policies	Notes
SVHC selection	- Quick process - Allows to send a message to the market that the use of the substance should be reconsidered	- 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	(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 uncerainty	- There are no legal means by an Industry initiative on its own to force companies to join such an initiative - Guarantees of delivery may be burdensome (extensive reporting from Industry vs. administrative enforcement/controls)	- Risk seems a priori limited	(2)
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) - 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	- 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 may reduce appeal of EU products, lead to off-shoring production or impact on recycling chain efficiency and profitability - 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	- 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)	- Difficulty to factor in the sustainable use of natural resources or natural elements	
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 (over-)conservative assessment factors in setting the OEL may have a huge impact on companies		
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		
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		

Comments:

(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 intiative, 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…”

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

This section will be updated regularly as learning lessons come in from different RMOA exercise performed by Industry

ISSUE IDENTIFICATION

1. 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).

2. 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.

3. **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.

4. 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?

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**.

DIFFERENT I-RMOA APPROACHES ARE POSSIBLE

1. Different I-**RMOa approaches are possible, depending on when the assessment is made vs. SVHC Roadmap screening process**:
    a. **Explore and prepare by <u>improving the understanding of the issue</u>** (risk or not?) through development of data (measurements) to be able to better describe what is at stake
        - May remove the concern
        - May bring to light issues that were not visible at first glance (risk may be elsewhere than what was initially thought or estimated)

    The tools described in Part 1 (Broad I-RMOa) may provide a strategic insight allowing to better target the RMOa.

    And then proceed with the RMO analysis proper when considered opportune.

    b. <u>RMOA as such</u>
    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.

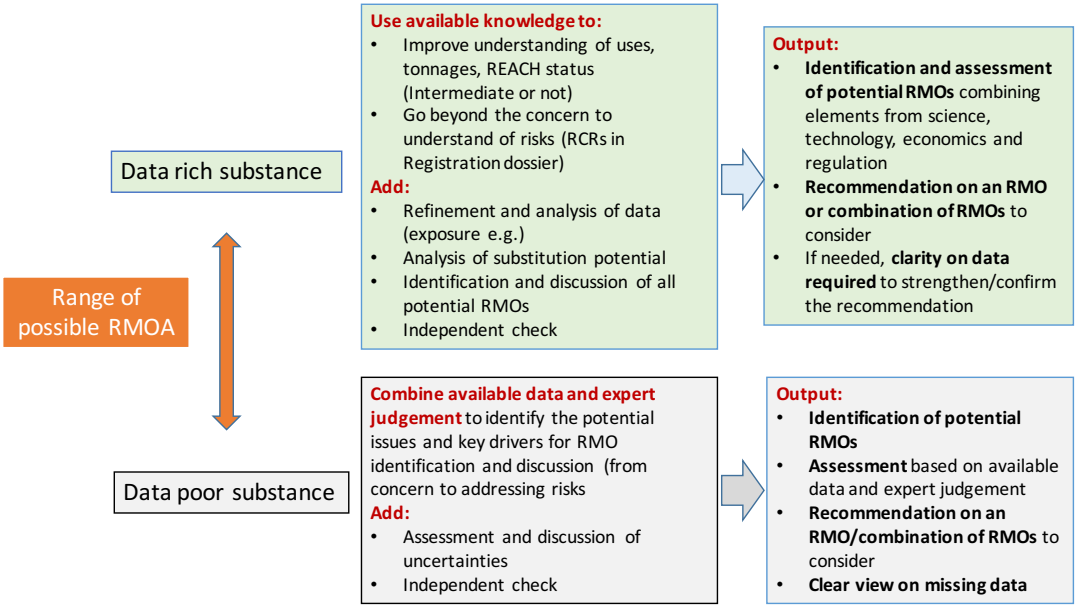
DIFFERENT APPROACHES IN FUNCTION OF DATA

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 33.

Figure 33: 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.

VALUE CHAIN IMPACTS FROM AN ECONOMIC POINT OF VIEW

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

- 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.)

But possibly also:

- 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

Such arguments should be used parsimoniously and only when they can be substantiated (qualitatively or quantitatively) to avoid being suspected of trying to bias the assessment by, for example, inflating negative impacts and ignoring the positive ones. 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 may provide a qualitative assessment of the expected impacts, which may be confirmed and quantified later when required.

CONSIDERING SOCIETAL IMPACTS

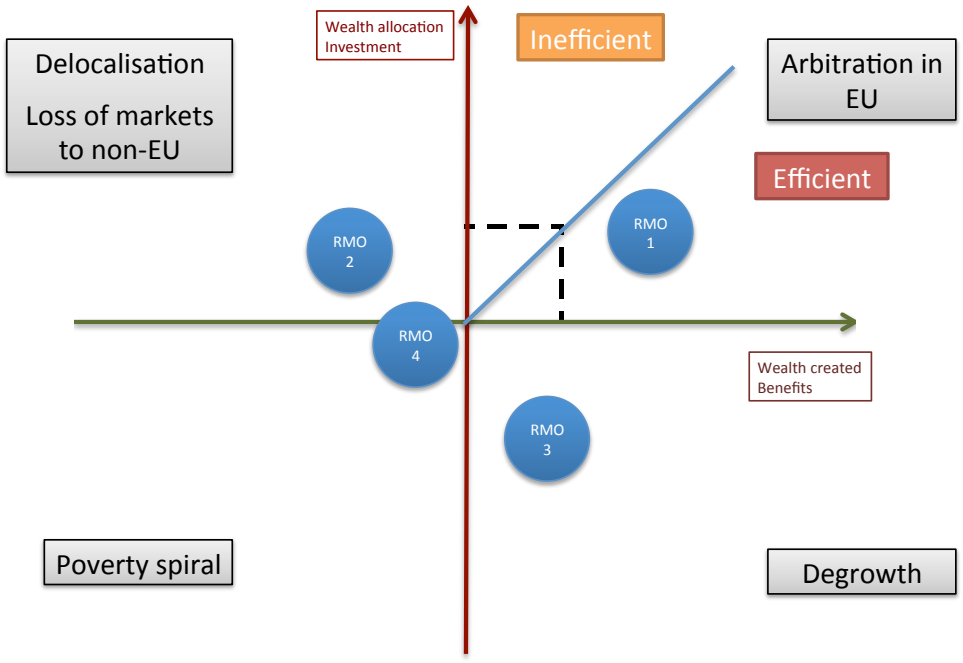
It may be valuable to put the value chain impacts in a broader perspective that includes the direct and indirect benefits of the RMOs considered as well as the possible drawbacks.

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 34).

Note that the concepts used in this example are subject to controversy but they may help structure a broader discussion.

Figure 34: Possible 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 shares value e.g.) and all benefits can be valued, society would be satisfied with an outcome along or under the blue line. 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, 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 'monetised' 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 spiral of poverty.

HOW TO USE A SCORING SYSTEM

A matter of documented and consistent choice

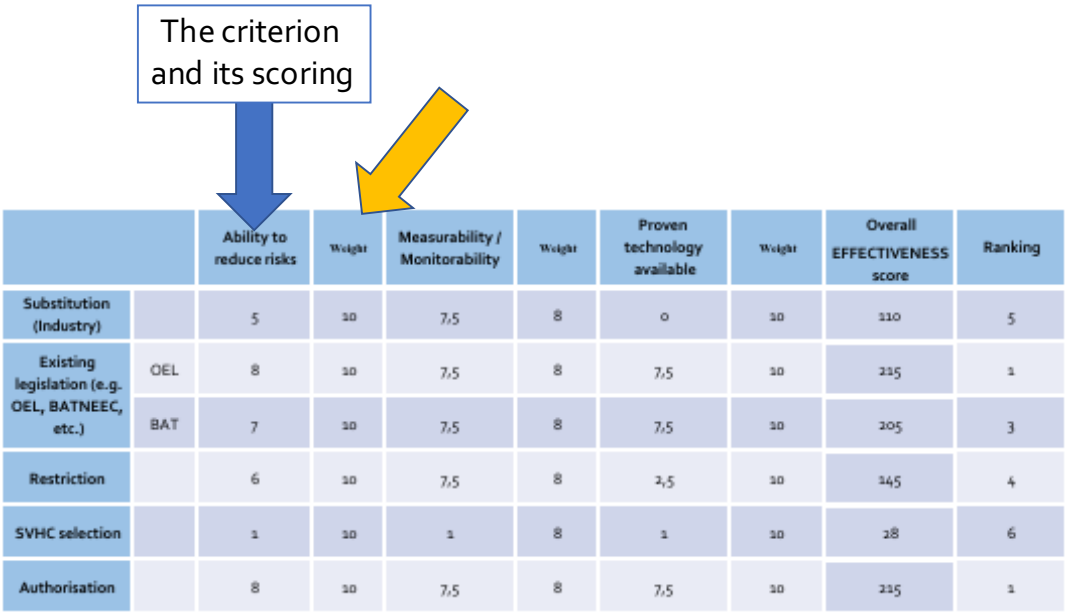
The Guidance displays different modes of scoring from the use of "+" and "-" to more quantitative scoring systems that may include weighting mechanisms. It is up to those performing the I-RMOa to opt for the approach they feel best suited. They should however make sure that the method is explained clearly 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, 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.

Quantitative scoring systems

Quantitative scoring systems most often combine a **scoring of the criterion** with a **weighting of that criterion**. (Figure 35)

Figure 35: 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	28	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 of the criterion on a scale that may be from 1 to 10 but other scales may be used such as the one in the following illustrations where the scores range from 0,5 (low importance) over 1 (neutral) to 1,5 (high).
  The aim of the weighting is to allow a

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

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 rich in data.

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**

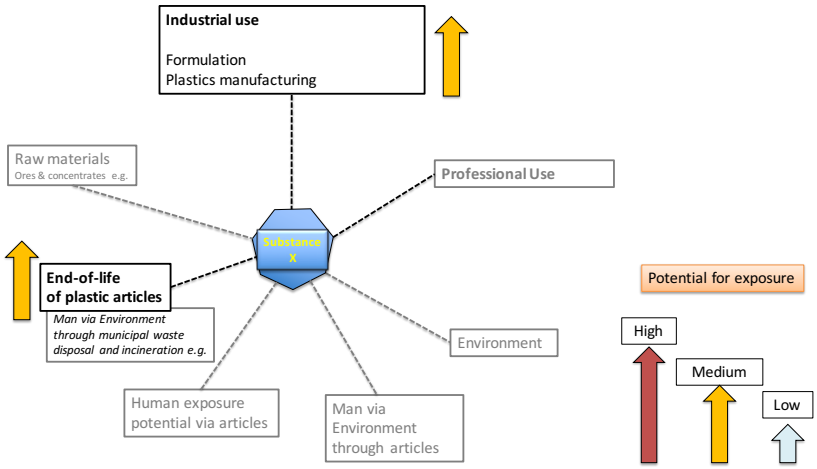
Overall, the tonnage used in the EU was estimated at around 400 to 500 tons.

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.

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

Note that 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. Practicability 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	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	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	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	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.

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 interesing 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.

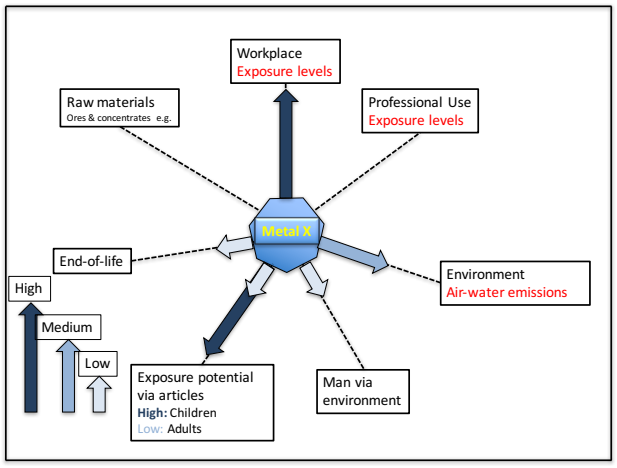
2) They examined whether a common conclusion could be identified and what to do with this conclusion.
    a. There was agreement that there was:
        i. no technical or economical obstacle to substitution of substance X and that substitution was an economically better option than technical risk reduction 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 V - TEMPLATES FOR THE I-RMOA EXERCISE

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 exposed?

- Uses not 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 policy-maker 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**
- **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.

Discussion:

Synthesis:

Possible approaches	Potential RMOs
Simple approach (no technology-driven integration or use-specific options)	
Combined approach (i.e. integrated approach, combining with other substances of same profile used in same process or a combination of RMOs to ensure full efficiency)	
Specialised approach (i.e. a mix of RMOs based on use-specific characteristics)	

Analysis of the potential Risk Management Options

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

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 – Non-integrated approach								
Combined – Integrated approach								
Specialised – Mixed approach								

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:

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 – Non-integrated approach								
Combined – Integrated approach								
Specialised – Mixed approach								

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:

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 – Non-integrated approach										
Combined – Integrated approach										
Specialised – Mixed approach										

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:

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.

ECONOMIC IMPACTS:

The criteria should be chosen in agreement with the participants. Depending on the substance and the value chaincharacteristics, 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 – Non-integrated approach														
Combined – Integrated approach														
Specialised – Mixed approach														

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:

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 – Non-integrated approach										
Combined – Integrated approach										
Specialised – Mixed approach										

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 usefull 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 – Non-integrated approach							
Combined – Integrated approach							
Specialised – Mixed approach							

RMO	Overall effectiveness	Overall practicability	Overall consistency	Overall economic impact	Overall human health and environmental impact	Overall proportionality	Final ranking (based on rankings)
Simple – Non-integrated approach							
Combined – Integrated approach							
Specialised – Mixed approach							

Discussion: