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Industry-Risk Management Options Analysis

Explanatory documents

This is the second in a series of explanatory sheets:

1. RMOA: Definitions and Concepts
2. Preparatory steps for an I-RMOA: strategy and practical preparations
3. Performing the I-RMOA: from Simple to Integrated-RMOa and the three pillars of the analysis
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Preparatory steps for an I-RMOA: strategy and practical preparations

Content:

The I-RMOA Basics

Key take-aways

- The EU authorities have set out a strategy to scrutinize substances that may be of Very High Concern in the SVHC Road Map 2020.
- The SVHC Road Map should guide industry when selecting the substances that it should consider in an I-RMOa, when not having to respond to an immediate challenge such as the initiation of a Regulatory Management Options analysis by a Member State.
- One should consider extending the criteria for selecting a substance for an I-RMOA as the SVHC discussions broaden to other criteria described as being of "equivalent concern".
- Companies, consortia and commodity and trade organisations have complementary interests in an I-RMOa exercise, and their precise roles will have to be defined at the start of the exercise.
- The policy agenda, the types of data to be collected, the extent of assessments to be performed, as well as the time available will inform the choice between a simple I-RMOa and an Integrated I-RMOa.
- Developing an anticipative I-RMOa strategy may be of critical importance as an I-RMOa is a resource- and time-consuming exercise. One should never underestimate the challenge of addressing data gaps.

Introduction

This part presents the basic steps that precede the performance of the I-RMOa proper. Indeed, it is important for the success of the I-RMOa that several aspects be clearly defined, i.e.:

- The purpose of the exercise: from preparing input to an ongoing regulatory initiative to defining a substance management strategy at company or value chain level…
- The scope of the exercise: from having to address a substance that is under scrutiny to considering one or more substances for analysis in function of relevancy criteria.
- Timing: The success of the exercise will depend on matching expectations with the time constraints
- Deciding who should perform the I-RMOa: individual companies, commodity organisations or substance consortia can perform I-RMOa, depending on the parameters identified earlier.

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

The following pages will guide you through this preparatory process and will describe the types of assessments within the two approaches. We will also devote a particular attention to the principles of an Integrated I-RMOa as it is the least bound by any regulatory template or agenda.

Defining the Purpose

The Industry Risk Management Options Analysis (I-RMOa) can be performed to address an imminent or ongoing assessment by regulators (described here as a 'simple I-RMOa').

I-RMOa can also aim at dealing with a variety of challenges or objectives that may be internal to an industry branch or a company, such as an anticipative assessment of substances in companies' portfolios. This type of I-RMOa is designated by the expression 'integrated I-RMOa' as it allows to broaden the analysis, possibly adding to the chemicals dimension (or pillar) the circular economy and climate dimensions (or the two other pillars of the integrated approach).

Initially designed to assist industry in identifying and addressing the risk management challenges under REACH it may consider other EU regulatory regimes. Indeed, 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 in this guide contributes focusing 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 (if possible, i.e. consulted) in the establishment of a regulatory RMOa and subsequent discussion and decision processes at EU level.

Setting the Scope

The effort here will be to define which substance to consider (or to consider as a priority) if one does not have to react to a regulatory move on a specific substance.
To date, the Roadmap on Substances of Very High Concern for 2020 (https://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205867%202013%20INIT) has been the main source of decision criteria for the selection of the substances for a regulatory review. It can serve the same purpose for an I-RMOa that is independent from any regulatory initiative.

As with the Chemicals Strategy for Sustainability, the Commission will propose "measures to phase out the most harmful chemicals - like endocrine disruptors and persistent substances – especially in consumer products and measures to substitute and minimise all substances of concern in the economy and society", the RMOa is expected to increasingly consider substitutability (considered through the lens of the concept of Suitable alternative Generally Available, or SAGA) as a key motivator for regulatory management. **Here too, some *proactive* actions are advised.**

ECHA's vision of substances "that matter most"

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

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

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

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

The Chemicals Strategy for Sustainability introduces the concept of Substances of Concern (SoC) which covers those substances that cause any chronic effect for the human health or the environment as well as substances that hamper recycling for safe and high quality secondary raw materials.
Another new category of substances (Most Harmful Chemicals – MHC) focused initially on those displaying endocrine disrupting properties but later extended to essentially Specific Target Organ Toxicity (STOT) and for which general bans by means of restrictions could be introduced, applicable to all their consumer uses (and later on to professional uses) except for those uses that have been demonstrated to be essential to society.[1]

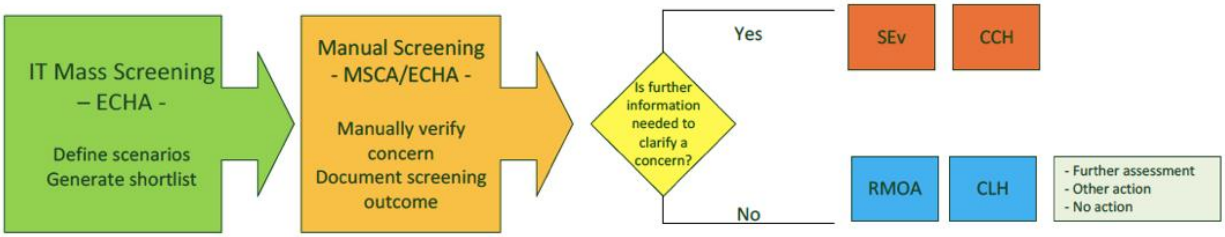
[1] The Essential Use concept will be further defined by the European Commission in 2021. Depending on its definition, criteria and scope of use, it may make an update of this guidance document necessary.

Screening for substances to assess

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

To focus the work under different REACH (and CLP) processes on the substances that matter most, ECHA, the Commission and Member States Competent Authorities (MSCAs) have agreed on a process to identify substances of potential concern (cf. screening workflow in Figure 1). [2] These substances include those for which more information is needed to conclude on the hazards or risks they might pose as well as those for which it is deemed necessary to consider further regulatory action:

FIGURE 1: ECHA SCREENING WORKFLOW



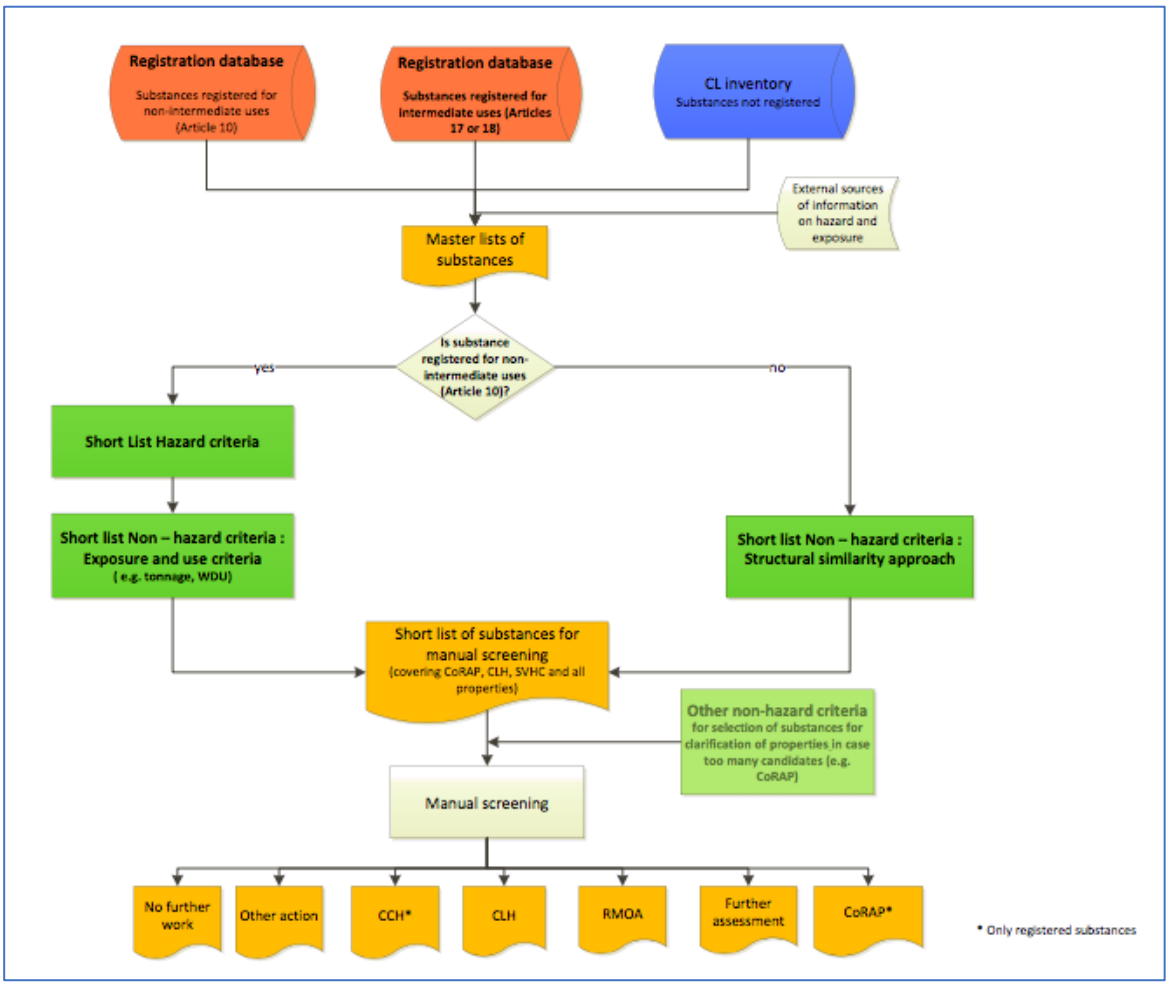
In the SVHC Roadmap, priority is given to substances with SVHC properties with uses within the scope of Authorisation (non-intermediate uses, in particular).
The common screening approach systematically screens available information for substances in the REACH registration dossiers and other databases to identify substances for the following REACH and CLP processes. The different steps are detailed further in Figure 2 :

- Compliance check for dossier evaluation
- Community rolling action plan (CoRAP) under substance evaluation
- Potential further regulatory risk management measures under the REACH and CLP regulations i.e.:
    - Harmonised classification and labelling
    - Authorisation
    - Restriction

For substances with an SVHC profile, the Industry approach will ideally (if time permits) focus on setting the context (level of existing or potential risks, uses, existing risk management measures etc.) as well as on discussing the Risk Management Options it considers the most proportionate in a regulatory context.

[2] A Common Screening Approach for REACH and CLP Processes – March 2015
https://echa.europa.eu/documents/10162/19126370/common_screening_approach_en.pdf/b195b928-25ce-4a1c-9eec-8f58ca724f58

FIGURE 2: DETAILED OUTLINE OF THE SCREENING PROCESS



One has to keep in mind that ECHA's screening activities already covers substance groups other than CMRs (Cat 1A/1B), PBTs or vPvBs, considered as of equivalent concern. Some are now included into the category to be known as of now as Most Hazardous Chemicals:

Already screened for Human Health:

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

For the Environment

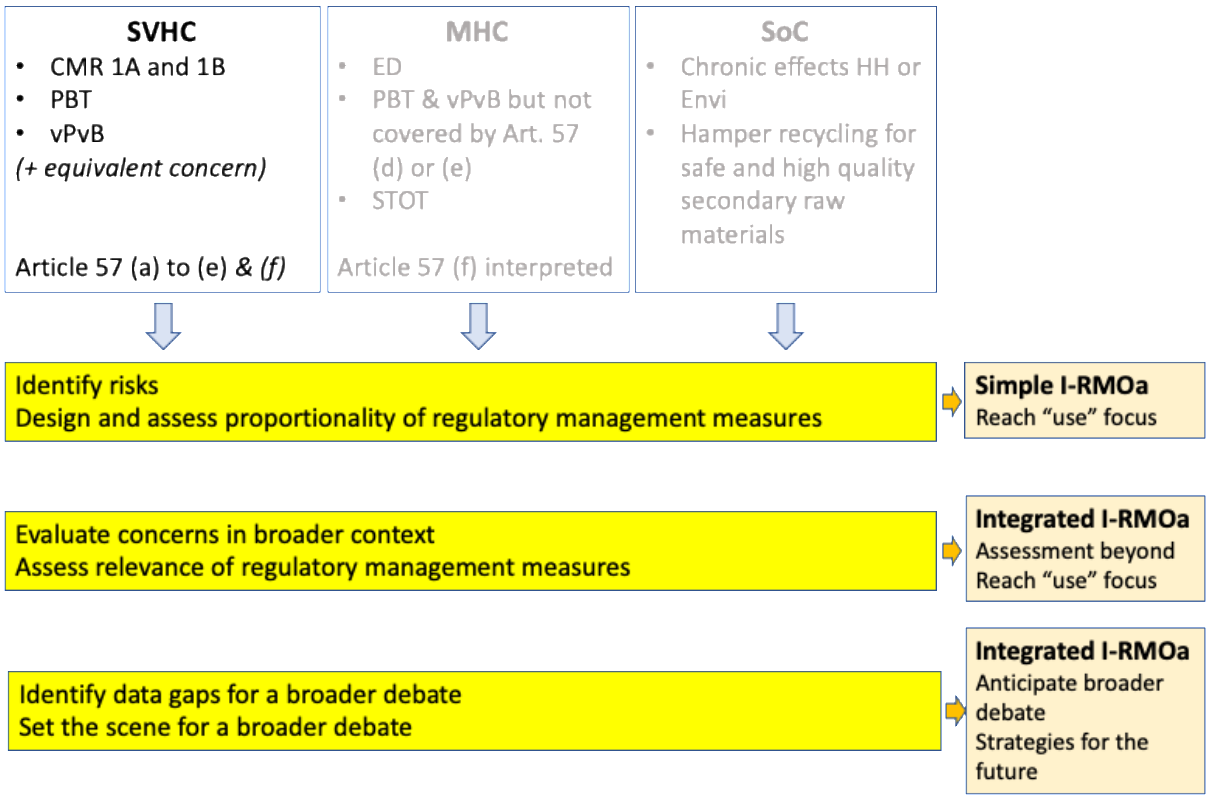
- Endocrine disruptors (EDs).

The SVHC Roadmap gives priority to substances registered for non-intermediate uses, given intermediate uses are out of scope for authorisation.

Screening and subsequent RMO analyses of these registered substances are referred to as the "Core Activities" in the SVHC Roadmap implementation plan.

The I-RMOa tools at hand allow contributing to this process as well as to prepare for future challenges at company or at sector level as illustrated in Figure 3 .

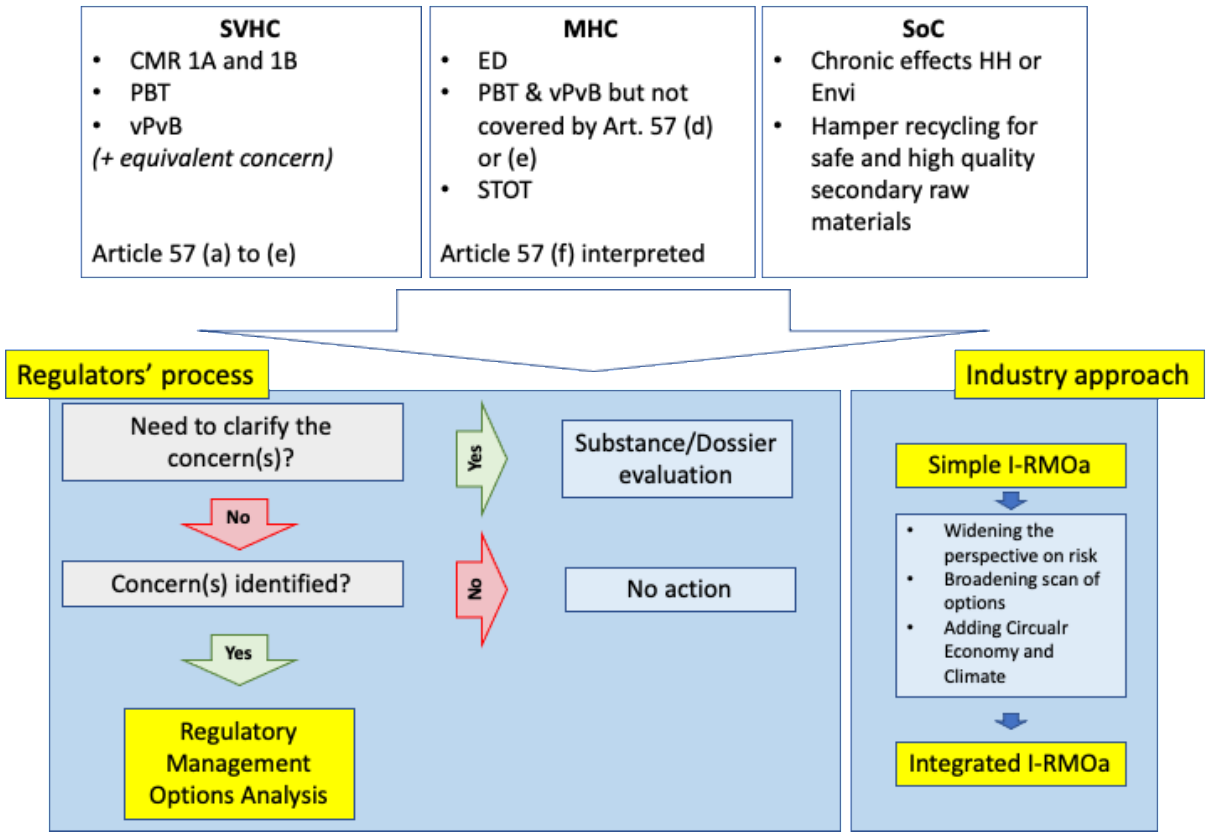
FIGURE 3: ROADMAP SCREENING CATEGORIES AND I-RMOA TYPES



2. What about the future screening priorities beyond the SVHC Roadmap 2020?

It may be relevant to refer to ECHA's webpage on Screening (https://echa.europa.eu/screening) .
To date, the main additional hazard criterion that has been included in the Screening strategy of ECHA is the Long-Term Environmental Hazard and Fate, criteria of importance for both metals and inorganics.
Considering the evolving priorities at EU-level with the Chemicals Strategy for Sustainability, a broad scoping by Industry of substances for Risk Management assessment, beyond the REACH Regulation criteria for SVHC selection, can make sense as illustrated in Figure 4.

FIGURE 4: RMOA VS. BROADER SUBSTANCE SCREENING



As screening scenarios are evolving, even in the REACH context, there is a definite case for anticipating and initiating an assessment.

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

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

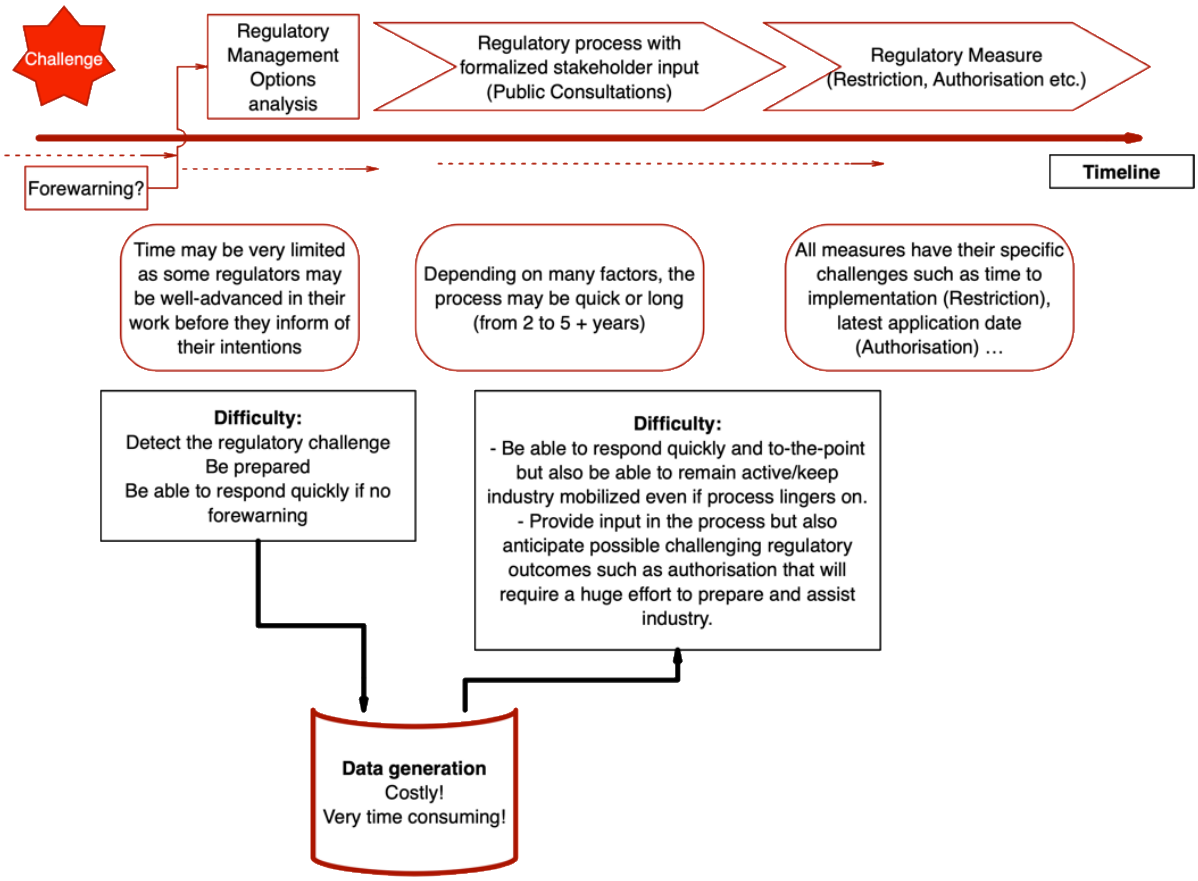
This process is 'automatic', thus unavoidable and some proactive actions may be advisable. Industry should consider providing or complete some key data present in the Registration dossiers. The quality of the assessment following the method presented in this guidance document will to a large extent depend on the thoroughness of these proactive actions.
The general advice is to conduct an RMOa screening for all substances meeting the above-mentioned criteria and to get started as early as possible.

The increasing pressure to substitute or minimize the use of substances with a certain hazard profile is expected to be reflected in the way a Regulatory Risk Management Options Analysis is performed with some exploration of available information on possible alternatives (cf. the concept of "Suitable Alternative Generally Available" or SAGA).

Timing considerations

An I-RMOA can be a challenging exercise in terms of time constraints and resources to mobilise as sketched out in Figure 5 for the case of response to a regulatory management initiative.

FIGURE 5: TIME CONSIDERATIONS OF A SIMPLE I-RMOA



Advice regarding timing: Consider an anticipation strategy (inventory of substances of potential concern, preparatory data collection or data collection strategy, use update of registration dossier to collect and provide data that may be of use to a regulator…).
The time challenge for an Integrated I-RMOA will be different but the broader the assessment, the more time and resources will be required.

Deciding on who should perform the I-RMOA

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

We discuss here the roles which can be taken up by different Industry actors. The REACH processes will be a key driver, but it needs to be stressed that the I-RMOa is a tool that can be resorted to independently of a particular regulatory challenge under REACH. The preparatory work of an I-RMOa will determine what exactly will be done, when and by whom.

A. Companies

Companies which should get involved are all those directly concerned by the use of a substance likely to be scrutinized or under I-RMOa review.
Companies as part of a broader effort:

- Consortia will often be pivotal in raising awareness of Downstream Users and getting them involved. Consortia have an essential role in helping to set the broader picture of hazards, risks and exposures. Downstream users, most often the companies that are the effective users of the substance, have a huge interest in considering their own options and strategy vs. the use of the substance under scrutiny.
- 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:

- Companies may want to perform their own I-RMO as a response to a regulatory initiate in the absence or impossibility of a sector initiative or as a complementary exercise
- The I-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.

What can be done with or expected from the I-RMOa will depend on whether there is a regulatory process ongoing or not as shown in the following Table 1:

TABLE 1: INDICATION OF I-RMOA ACTIVITY BY A COMPANY AT DIFFERENT STAGES OF A REGULATORY PROCESS

Company	Company I-RMOa 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 including substitution (with first argumentation on the Suitable Alternatives Generally Available that are likely to be presented by regulators/their consultants or other stakeholders)	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, investment in process adaptation, defence of uses, set up of discussion 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 got into full speed once the 2018 Registration deadline passed. Depending on the likely outcome of an ongoing regulatory management analysis, Industry may have to get organised in another way than was the case in the REACH Registration consortia. In many cases, the value chain will have to be heavily involved especially if a substance may be selected for Authorisation. Such types of activities go beyond the usual remit of REACH Consortia, hence an important role for commodity and trade organisations.
An indicative overview of possible activities of commodity organisations in this context is provided in the following Table 2:

TABLE 2: INDICATION OF I-RMOA ACTIVITY OF COMMODITY ORGANISATIONS AT DIFFERENT STAGES OF A REGULATORY PROCESS

Commodity organisations	I-RMOa before regulatory review or initiative	I-RMOa 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 and discuss RMOs (including substitution)	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.

Consortia

As alluded to in the earlier paragraph on commodity and trade 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 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 and trade organisations.
The following Table 3 provides an indicative overview of possible activities of consortia in an I-RMOA:

TABLE 3: 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 (including substitution)	Communicate about this if and when useful and desirable
Analysis of most proportionate RMO	Assist Industry in understanding the strengths and weaknesses of the different RMOs and choose the most adequate one. The consortia's grasp of the uses along the value can provide valuable insights on where data collection and discussion efforts should be focussed	Communicate findings, if possible/relevant. Open channels for dialogue
Next steps	Fulfil regulatory obligation of keeping up to date the REACH Registration dossier (together with the Lead Registrant) and interact with the commodity organisations to open communication and data channels with the broader value chain	Act in function of strategy decided by companies, which may be: - Advocacy - Organisation of Industry (communication, facilitation of exchanges in value chain, assistance in setting up of co-operation frameworks for Authorisation/Restriction etc.

Choice between approaches and principles of an Integrated I-RMOa

The difference between the two I-RMOa approaches described in the guidance resides in the ambitions of the initiators of the I-RMOa (type of assessment aimed for) and in the constraints that weigh on them.
Such constraints may be the regulatory framework, an ongoing regulatory process, the availability of data, the motivation of participants and supply chains etc. Most often, the timing constraints will weigh heavily on what can be done.
The following Table 4 sketches out the first decisions leading to either a more limited REACH RMO-related approach (simple I-RMOa) or a broader effort (Integrated I-RMOa):

TABLE 4: I-RMOA APPROACHES IN FUNCTION OF ASSESSMENT

DESCRIPTION OF ASSESSMENT	AIM		
		Simple I-RMOa	Integrated I-RMOa
Collection of data for contribution to likely or ongoing RMOa's	Contribute timely data to Member States performing RMOa's	Work is focused on the main points of attention of Member States	Time may be too limited to have an integrated approach
Audit of available information in CSR and beyond (including alternatives!)	Address data relevant to RMO analysis And/or Identify the appropriate RMOa	Under time pressure, work will be focused on the main points of attention of Member States	If time allows, the simple I-RMO analysis can be broadened, integrating broader views Possible consideration of data that can be useful for assessing the Circular Economy and Climate dimensions
Critical self-reflection within sector or by companies	Identify potential need for RMM		Allows holistic approach (refined analysis including of diffuse sources, integrating Circular Economy and Climate in the analysis)
Internal company audit	Identify remaining risks and most efficient RMM	(No individual company's impact on regulatory choices)	Allows company to identify RMM pathways and substance/product strategies vs. a broader set of company values and priorities

An Integrated I-RMOA is not performed in isolation of wider contexts and considerations. It may be expected to create value to other stakeholders such as authorities. through the quality of the data and the pertinence of the analysis, hence the principles for an Integrated I-RMOa in the following Table 5.

TABLE 5: PRINCIPLES FOR AN INTEGRATED I-RMOA

The I-RMOA should	Comment

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

LINKS

Regulatory Management Option Analysis: https://echa.europa.eu/nl/understandng-rmoa