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Industry-Risk Management Options Analysis

Explanatory Documents

This is the first in a series of explanatory sheets:

1. RMOA: Definitions and Concepts
2. Preparatory steps for an I-RMOA: strategy and practical preparations
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RMOA: Definitions and concepts

General Concept of Risk Management Options Analysis

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

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

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

RMOa is a relatively new concept in chemicals management and evolving fast as it builds on the experience that is being gathered. This remains work in progress and the Eurometaux guidance will be updated regularly to keep pace with developments.

The Regulators' Approach

For authorities, the purpose of an RMOa is to help them decide whether regulatory intervention is (further) required to manage a substance and to identify the most appropriate instrument to address the concern that has been established. The instruments at their disposal to enforce management of risks are regulatory provisions hence the slightly more restricted notion of Regulatory Management Options analysis.

In the EU

RMOa was developed to assist in the implementation of the REACH Regulation

In the EU context, the concept of RMOa acquired its notoriety with the REACH Regulation although it is not foreseen or mentioned in the regulation itself. Authorities have developed an RMOA scheme as a voluntary case-by-case step, by which they would document their findings and facilitate a common understanding on the actions to be pursued. In practice, a Member State or ECHA (at the request of the Commission) performs an analysis to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance and suggest an approach such as harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation. Subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision-making involving Member State Competent Authorities and the European Commission as defined in the REACH Regulation.

Conclusion Document

The best-known document in this approach is the "Conclusion document" which provides the outcome of the RMOA carried out by an authority. In it, that authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required, and which is the most appropriate instrument to address a concern. With this Conclusion document, the EU Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the drafting authority. The fact that the conclusion document proposes further regulatory risk management measures, does not mean that these measures or processes are initiated. They are only considered at this stage in a working document compiled on the basis of the information available to the authority who prepared the RMOA. The conclusions may change in light of new information being made available in following discussions and official processes (such as Public Consultations e.g.). It has to be noted that it is a regulatory approach which has to stick to the regulatory framework such as the articles of the REACH Regulation on the identification of a Substance of Very High Concern (SVHC) and their 'eventual' prioritisation for authorisation.

Typically, a Conclusion document will present its recommendation in a standardized way as presented in Table **1**:

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

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

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

A **Regulatory Management Options Analysis** may be significantly different from an I-RMOa that will also explore non-regulatory chemicals management approaches. In some instances, an authority may take the initiative to launch a ***pre-RMOa*** which is aimed primarily at identifying the scope of a concern and the data gaps that would need to be addressed before a more formal RMOa can be launched. A pre-RMOa does not commit the drafting authority to any further analysis or regulatory action.

The Industry Approaches

Risks resulting from the use of a substance or from its presence as an impurity / minor constituent[2] can have consequences. Impacts can be on occupational health, the environment and, beyond, on the companies' economic performance, their professional reputation, or even broader in society.
An Industry Risk Management Analysis (I-RMOa) is designed to assist industry in identifying and managing risks whilst addressing policy and societal concerns.
The I-RMOa is a stepwise, mainly qualitative approach. Depending on the scope and extent of the analysis, there are two types of I-RMOa

The 3 steps of an I-RMOa

An I-RMOa is a stepwise approach consisting in

a) the identification, discussion, and prioritization of risks related to a substance,
b) the identification of all potential risk management options to prevent, eliminate, minimize, monitor, and control the probability and/or impact of these risks.
c) the analysis of the potential risk management options so as to identify the most suited risk management option in function of a set of proportionality criteria

The 2 types of I-RMOa

There are two approaches to an I-RMOa

- The simple-I-RMOa addresses a regulatory initiative, such as a regulatory management analysis as described earlier. Its scope of work will be defined by that of the regulatory management analysis.

- The Integrated I-RMOa prepares industry/companies to address likely regulatory and societal challenges that may impact the way they operate and the substances they use in their processes. Typically, such an analysis tries to develop the broadest view of the issues at stake. Its assessment horizon includes, next to chemicals management, the Circular Economy and Climate Change. These three dimensions, one could call the 3 C's, constitute the pillars of an integrated-RMOa.

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

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

The Simple I-RMOa

The simple I-RMOa is the approach used to address regulatory reviews and challenges. Industry will want to understand data gaps or weaknesses in key data repositories such as the REACH Registration dossier and will explore and assess possible Risk Management Options.

The approach will be constrained by the regulatory context as well as by the regulators' timing. Especially when a regulatory review has been launched or a public consultation is pending, the I-RMOa will focus on the key elements of the regulator's analysis.

The simple I-RMOa can:

- Identify the need for updating the REACH Registration dossier,
- identify data gaps, or the need to collect data to better understand the risks, assess progress, or identify the best RMO,
- help structure the data to contribute to work and discussions at different stages of the REACH process, such as
    - Community Rolling Action Programme (CoRAP): Substances are then evaluated to better understand their properties, risks etc.
    - Public Activities Coordination tool (PACT): Regulatory Management Options Analysis by a Member State or ECHA in view of a decision on a risk management measure such as Candidate Listing and eventual Authorisation, Restriction or other measure (OEL e.g.)
    - Identification of a Substance of Very High Concern (SVHC): the I-RMOa allows a structured and relevant input to public consultations
    - Prioritisation of SVHC in view of Authorisation: relevant input to public consultations
    - Restriction: relevant input to public consultations and other channels
    - Authorisation: the I-RMOa allows to identify the data to gather (such as exposure) or the stakeholders to involve (Downstream Users). It helps shape and structure the further in-depth work on Analysis of Alternatives and socio-economic analysis.
    - Any other regulatory measure at EU level: Regulatory measures options analyses may foresee processes under other EU legislation (such as the Directive on Carcinogens and Mutagens on the workplace (CMD), RoHS, … e.g.)

The Integrated I-RMOa

The Integrated I-RMOa has been designed to

- Help set strategic company objectives or provide a follow-up on them, such as review product portfolio in view of future investments, consider new data on substance properties or exposures, etc.

- Assist in value chain efforts to achieve measurable reductions of risks, for example by helping in the identification and prioritisation of measures, by entering into dialogue with other stakeholders etc.

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

FIGURE 1: INDUSTRY RISK MANAGEMENT OPTIONS ANALYSIS AS A CONTINUOUS PROCESS