ASMoR recommendations on the Risk Management Option Analysis (RMOA)

An effective and modern chemicals management needs to take into consideration protection, competitiveness, and innovation. It needs to be dynamic to react on emerging risks, while at the same time be precise to avoid unnecessary damage by over-regulation.

This can be achieved with an effective RMOA framework, evaluating various options of assessing safe uses, analysing viable alternatives, developing adequate risk management options, and essentiality. Such an approach would optimise the workload for authorities and industry without jeopardising safety and innovation, while being systematic, transparent and predictable.

The protection of the environment and human health, while strengthening the competitiveness and innovative power of the European industry is the central objective of the REACH regulation. This was reiterated also by the President of the European Commission, Ursula von der Leyen, when she emphasized the importance of competitiveness of European industries and even more of SMEs already in her statement to the European Parliament[1]. Regarding chemicals policy, this is also reflected in the mission statements of Executive Vice-President Stéphane Séjourné[2] and Commissioner Jessika Roswall[3] for example, in the context of the Chemicals Industry Package.

The REACH revision is a central element of the Chemicals Industry Package. As part of this process, the current authorisation system should be carefully assessed. It is widely acknowledged that this regulatory framework faces significant challenges in managing the volume of submitted authorisation applications. The authorisation process has proven to be a lengthy and burdensome for both industry and authorities. Additionally, it generates significant legal uncertainty, negatively impacting innovation and investments.

With the objective to improve predictability, transparency and resource efficiency, the European Commission published its Communication *Guiding criteria and principles for the essential uses concept (EUC) in EU legislation dealing with chemicals*[4]. The Communication states: *"The overall aim of the essential use concept is to facilitate decision-making and increase regulatory efficiency to achieve a fast phase-out of the most harmful substances in non-essential uses while allowing uses still essential for society and continued availability of products serving human and animal health needs."*

An essentiality assessment should not apply to all substances but should be exclusively limited to the most harmful substances, as defined on p.4 of Communication C/2024/2894 (see Table 1. Terms for

[1] Statement President von der Leyen
[2] Mission Letter EVP Séjourné
[3] Mission Letter Commissioner Roswall
[4] European Commission, 2024

the essential use concept.)[5]. This approach, as elaborated in the Commission guidelines, prioritizes addressing the most pressing chemical hazards, ensuring that resources and actions are focused on substances with the greatest potential to harm human health and the environment. For other substances, a risk-based approach should remain the guiding principle, allowing for proportional application of regulation and other measures that balance safety, innovation, and practical application.

Recent discussions strongly support our perspective that an implementation of the Commission's proposal of an EUC will not simplify current chemicals regulation but rather make it more complex. For example, a recently published study applied the EUC to 100 REACH authorisation applications. showed that 10% of uses were identified as non-essential, 55% as essential, and 35% fell into a complex category, where no clear determination of essentiality could be made[6]. This clearly demonstrates the significant proportion of unclear (complex) cases that would require a formalised process to assess essentiality and may require a high degree of subjectivity in the determination, that could imply significant deviations from a scientific approach. As the number of concerned substances and their uses increases, administering and organising such a regulatory framework becomes increasingly challenging. Since the EUC scopes all MHCs, it potentially involves several thousand substances and their respective uses, further complicating implementation.

The example below illustrates the power of the multiplying effect based on substance-use combinations. In the current Union's chemicals regulation, this effect not only causes backlogs in the REACH authorisation but also impacts other sectoral legislation. For instance, in the Biocidal Product Legislation, the approval of biocidal active substances should have been finalised more than a decade ago. Despite the number of individual biocidal cases being relatively low compared to the workload we expect in the context of the EUC, only around 50% of the workload has been completed to date due to resource constraints.

[5] Communication from the Commission – Guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals (OJ C, C/2024/2894, 26.04.2024

[6] Identifying non-essential uses to phase out substances of very high concern under REACH

Example

Filtering the Classification and Labelling Inventory (CLI) at www.echa.europa.eu for MHC properties (excluding the new CLP properties related to endocrine disruption and persistency) gives 11.027 hits. Based on this, we make the following assumptions for the further calculation:

- The CLI contains erroneous entries, and some substances may exhibit more than one MHC property. Therefore, we estimate that only 50% (5.500) of the entries represent unique substances.
- On average, each substance is associated with only one use.

Based on these assumptions and the 35% share of "complex cases" identified in the referenced study, we estimate the current number of EUC assessments required as follows:

5.500 (substances) x 1 (use per substance) x 35% (complex cases) = **1.925 EUC assessments**

If we adjust the assumption to consider that each substance has three uses, the estimated number of assessments increases significantly:

5.500 (substances) x 3 (uses per substance) x 35% (share of complex cases) = **5.775 EUC assessments**

In practice, the EUC may become a fundamental bottleneck due to its disproportionate focus on hazard properties. Furthermore, banning materials solely based on their hazard and the EUC represents a critical oversimplification of complex matters. Such an approach would lead to prohibition of countless safe applications that, while not classified as essential, are highly useful and beneficial to society. It would also contribute to further de-industrialise Europe, as well as increase EU dependency on non-EU countries. To overcome this limitation, an effective and dynamic system must address the inherent weaknesses of the EUC. By transforming it into a more targeted, well-coordinated, and top-down approach, we can avoid unnecessary restrictions on innovation while maintaining a robust chemical safety standard.

Proposed solution

Effective regulatory tools are essential to ensure a comprehensive and balanced approach to chemicals management. These tools should be capable of identifying, prioritising, and addressing cases of genuine concern based on their specific risks, societal impact and essentiality and Europe's strategic autonomy. In our view, the Risk Management Option Analysis (RMOA) process is the most suitable framework to achieve this, offering several distinct advantages.[7]

In our design, the RMOA is a stepwise approach (see also the below Figure 1).

[7] ASMoR's assessment of possible impact of the EUC and proposed solution

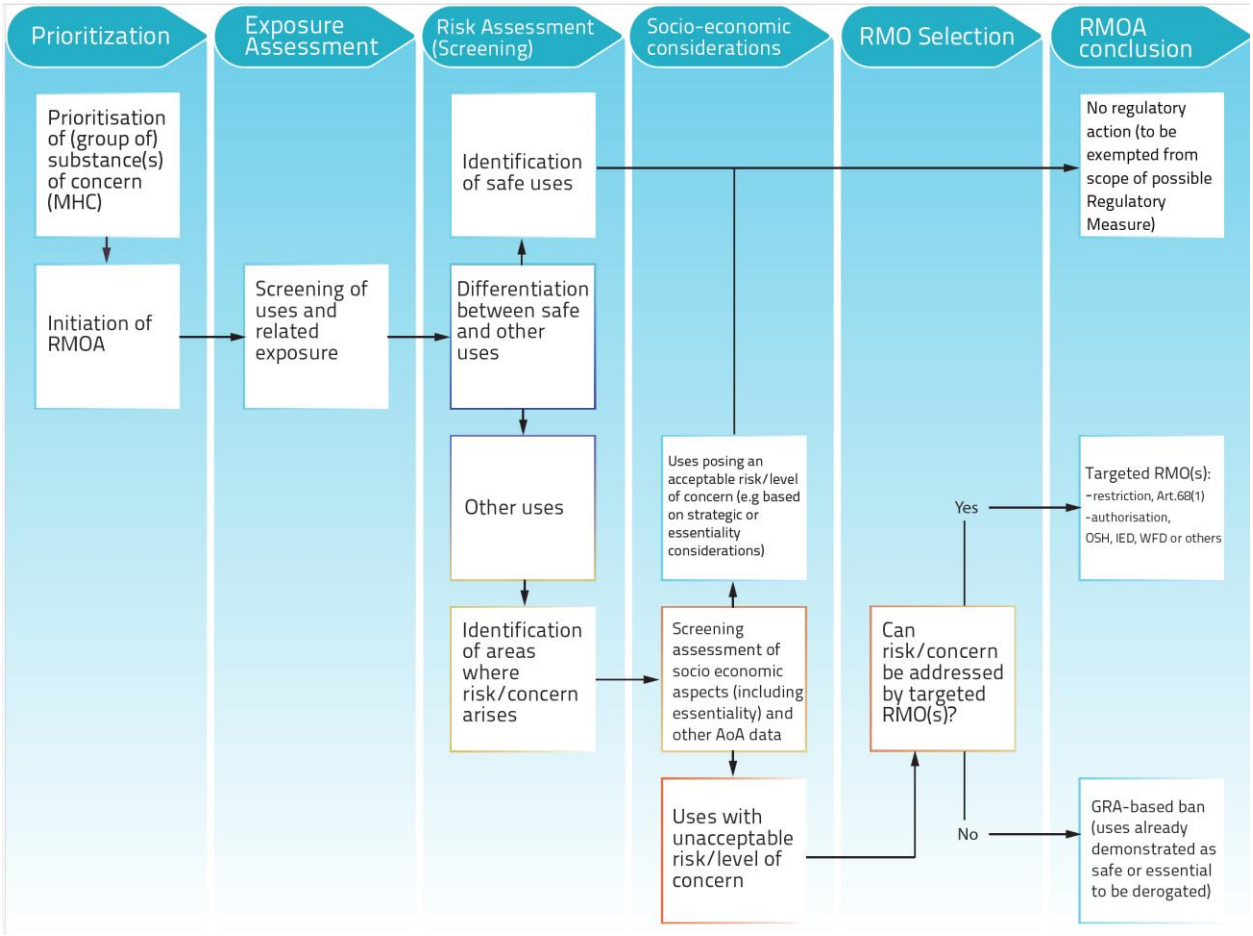

Figure 1: proposed solution for stepwise RMOA incl. safe use & essentiality assessment

This approach aims to target cases that can cause concern and that require further regulatory scrutiny, focusing on individual substances or groups of substances in combination with their specific uses. Under this approach, industry stakeholders would be required and empowered to provide relevant data at an early stage, prior to determining the appropriate regulatory pathway. This early-stage data submission allows for the efficient screening of uses, filtering out those that are either proven to be safe, or are clearly essential and lack acceptable alternatives.

For uses that cannot be proven to be safe, such as those involving non-threshold substances or where data is insufficient, these would advance to the next step, where their socio-economic and strategic relevance would be carefully assessed. The final stage would then determine the most appropriate risk management option(s) tailored to the case.

For a substance on which a RMOA has been carried out, a new RMOA of substance should not be carried out until new data would justify it - scientific, market (uses) or epidemiologic data. This is essential to provide certainty and predictability to industry. If there is a reference to safe and unsafe

use, it should be underlined that there are cases where a general RMOA has been made covering all uses (case of Beryllium) and that they should be conclusive.

In certain instances, the potential risks associated with a substance may be confined to specific settings, such as the workplace. In these cases, addressing the issue through an Occupational Exposure Limit (OEL) would be more effective. For other cases, depending on the risk-level, a targeted restriction or authorisation may be the most suitable approach.

For cases where neither safe, nor essential uses have been identified during the screening phase, the possibility of derogations under Article 68.2 of REACH should remain available. This flexibility would ensure that the regulatory framework remains adaptive and proportionate, allowing for a nuanced decision-making process that balances risk management with socio-economic considerations.

European RMOAs should meet two criteria. They should advocate technically realistic options and options that are in line with the rest of the world. Considering the EU's recent increased focus on competitiveness, the result of RMOAs should embrace, rather than scare investors.

Conclusion

Integrating a dynamic prioritisation process offers a pragmatic and effective approach to robust chemicals management, while considering the EU's global competitiveness. This process should be embedded into the RMOA framework, alongside with the evaluation of safe uses, the analysis of alternatives, and the application of the EUC. By doing so, chemical management would become more systematic, transparent, and predictable. Furthermore, this integration would also streamline the workload for both authorities and industry, ensuring efficiency without jeopardising safety or stifling innovation.

Annex I - Detailed description of the proposed approach for the RMOA

Prioritization Phase: This phase consists of the identification of the relevant substance (or group of substances). However, this approach can be extended to other hazardous substances that are a threat to human health or the environment.

Exposure Assessment Phase: Registrants of a substance are required to provide detailed information on its uses and associated exposure assessments at the very early stage of the process. This data will be used in the subsequent phase to distinguish between safe uses and those that require further evaluation.

Risk Assessment Phase: At this stage, an initial differentiation is made between safe uses and those requiring further scrutiny. A use is considered safe if, based on exposure considerations, it can be demonstrated that the release of the MHC is minimal or remains below a defined threshold.

Safe uses can then be excluded or exempted from the process at this point. However, for uses where risks or concerns are identified, these must proceed to the next phase for further assessment.

Socio-economic and strategic considerations: This step involves a more detailed screening of substances based on socio-economic aspects, including essentiality considerations and/or the Analysis of Alternatives (AoA). If no acceptable alternatives are available for a specific use, and/or the use is deemed essential for society, and/or the use poses an acceptable level of risk, no further regulatory actions should be taken and such uses can be excluded from the process, according to the EU Commission Communication. However, uses identified as posing an unacceptable level of risk or for which acceptable alternatives exist must proceed to the RMO selection phase.

RMO-selection: Can the risk or concern be addressed through (a) targeted RMO(s)? If the answer is yes, the risk can be managed by means of a targeted RMOA, such as Authorisation or Restriction of REACH.

RMOA-conclusion phase: in this final phase, an in-depth analysis is conducted to determine the most appropriate measure to address the identified risk, taking all relevant considerations into account. An optimal approach may involve a targeted RMO, such as Authorisation or Restriction under Article 68.1 of REACH, or a GRA-based ban under Article 68.2 of REACH, depending on the level of associated risk. In the latter, greater flexibility should be allowed, with derogations provided for uses that have already been demonstrated as safe or essential.

Additionally, alternative measures may be derived from the RMOA conclusions, such as implementing under OSH legislation for risks confined to the workplace or using the Industrial Emissions Directive (IED) for emissions into the air. Similarly, measures under the Water Framework Directive could be applied to manage pollutants in water bodies. These options would ensure a tailored approach to risk management, while maintaining proportionality and flexibility.

About us:

The Alliance for Sustainable Management of Chemical Risk (ASMoR) is an alliance of more than 30 organisations. It covers a wide variety of critical sectors throughout the European value chain and represents 20 million companies through the membership of its members, with a vast majority of SMEs. The common goal of ASMoR's members is to ensure that safe uses of substances remain permitted.

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