AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

Improving REACH in 2018 and beyond

One substance, one RMOA

Formalise and streamline the role of Risk Management Options Analysis

American Chamber of Commerce to the European Union
Speaking for American business in Europe

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What is an RMOA?

The Risk/Regulatory [1]Management Options Analysis (RMOA) tool was introduced in 2013 under the '2020 SVHC Roadmap' which commits EU authorities to have all known substances of very high concern (SVHCs) included in the Candidate List by 2020 and defines a process for doing so. The SVHC Roadmap implementation plan focuses on two main activity pillars:

- Screening to identify new substances of concern (CMRs, PBT/vPvB, equivalent concern)
- Analysing the risk management options appropriate to the particular substance of concern.

The RMOA is an essential tool for implementing both the roadmap and REACH. The information on on-going assessments and RMOAs is publicly available on ECHA's website under the Public Activities Coordination Tool (PACT).

The purpose of the RMOA is to help decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern (for example, harmonised Classification and Labelling, inclusion on the Candidate List, restriction, or other EU legislation). Subsequently, RMOA-recommended regulatory processes would follow. The RMOA can also conclude that no (additional) regulatory action is required.

Any Member State (MS) or ECHA (at the request of the Commission) can carry out an RMOA on a case-by-case basis. It is important to note that an RMOA is voluntary, as it is not part of the processes defined in the REACH legislation. An authority would typically select a substance, review its hazards and uses, document applicable Risk Management Options (RMOs), make recommendations for further regulatory measures (as needed) and share it with other MS. The Risk Management Experts informal network (RiME, composed of MSs and ECHA) would then discuss the RMOA conclusions and coordinate further risk management action. ECHA clarifies that the responsibility for an RMOA rests with the authority that developed it.

The RMOA is not a guarantee, nor does it bind a substance to any regulatory outcome. It represents only the position of the MS who initiates it based on initial screening. The recommendations resulting from an RMOA may not be followed. For example, RMOA might conclude a Restriction is needed but then discover that the Annex XV requirements cannot be met, or the RAC/SEAC ECHA Committees might reject the restriction. Up to now, 67 RMOAs have been concluded and 92 are on-going.

The REACH Review report and accompanying staff working documents confirmed that, 'the Evaluation processes under REACH, in conjunction with the RMOA, are an essential part of the system, which ensures its consistency and thus contributes to the achievement of the overall benefits of REACH.'

How to improve the RMOA process?

Industry welcomed the RMOA tool for two main reasons: (i) it is generally in line with Better Regulation principles and (ii) it increases transparency and predictability for industry and other stakeholders. It is also an opportunity for registrants to engage with authorities to better understand and clarify concerns at an early stage in the process.

In practice, several issues have emerged, including an uncoordinated approach on how to conduct an RMOA, which regulatory measures should be considered, which data/information needs to be gathered to feed into the

[1] While RMOA was standing for Risk Management Options Analysis in the SVHC Roadmap, the recently published REACH Review report refers to 'Regulatory Management Options Analysis.

RMOA, and the extent to which relevant REACH registrants/downstream users are involved during the RMOA process. One solution already implemented to address these shortcomings has been the development by RiME of a harmonised RMOA template which is now well established (albeit not publicly available).

Another significant issue is that any MS can initiate a new RMOA at any time if it does not agree with the conclusions of an RMOA conducted by another MS. By definition this leads to divergent conclusions by different MS/authorities and overlapping and incoherent new regulatory processes This was the case with aprotic solvents where a restriction for workers was initially proposed by one MS, then a new REACH process was initiated by ECHA (prioritisation for authorisation and recommendation to include in Annex XIV) while only after the prioritisation stage a new RMOA was conducted by the Commission. A similar situation is being faced with the substances D4 and D5 which have been subject to an RMOA run by the UK, then to a REACH restriction as recommended by the UK. Germany has submitted a new RMOA recommending SVHC identification and subsequently submitted an SVHC dossier. In addition, ECHA is working on a new REACH restriction on request of the Commission (without a new RMOA having been conducted). This reality undermines the benefits of the RMOA tool by removing the elements of predictability and avoiding parallel processes.

These shortcomings impact not only registrants but downstream users. RMOA intentions are published on ECHA's website and this is sufficient to trigger concern in supply chains (e.g. the automotive sector uses the RMOA as a trigger for supply chain communication in their Global Declaration System). In recent years and as we approach the 2018 deadline, more and more of the value chain is getting actively engaged in REACH processes. We witness increased proactive substitution based on early stage indicators. This means it is essential and urgent to formalise and streamline the RMOA process.

Several companies and trade associations reported these deficiencies during the public consultation on the REACH review and called for further improvement of regulatory predictability (AmCham EU, Dow, Cefic, CES-Silicones Europe, Eurometaux, etc). The REACH Review report and accompanying staff working documents highlighted that a great majority of industry respondents supported the RMOA, as it improves the coherence between REACH and other legislation, suggesting that the RMOA should become binding. The Commission also considers that the RMOA has benefits and it improves coordination of Member States and enhances transparency. However, other stakeholders (primarily NGOs), consider that the RMOA process has slowed down the process of adding SVHC substances to the Candidate List, hampers the substitution goal and undermines the precautionary principle.

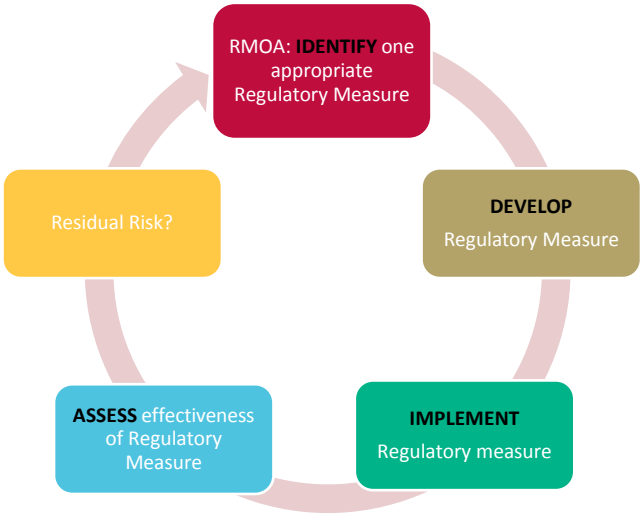
Recommendations for potential improvements

While the RMOA process was a welcome step in the right direction, greater centralisation, harmonisation and formalisation is needed for it to become the tool it aspires to be in helping to select the most efficient and effective risk management measures.

In addition, before a particular regulatory process is proposed, i.e. during the RMOA process, there should be discussion between registrants, ECHA and interested MS.

The RMOA process should also consider whether other (non-REACH) options may be appropriate (e.g. OSH, sectorial approach, etc).

Once a regulatory path is chosen, it should be completed prior to initiating a new regulatory / risk management process, in line with the following stepwise process (see below):



Evaluations and risk management measures ongoing or already in place should be considered, to avoid overlaps and contradictions.