REACH Authorisation: Substance RMOA process and the REACH Substance Evaluation Process

The need for coordination

Executive summary

Registered chemical substances put forward or undergoing substance evaluation under the Community Rolling Action Plan for Evaluation (CoRAP) should not be selected simultaneously for consideration as potential Substances of Very High Concern (SVHC) and subjected to a Risk Management Options Analysis (RMOA).

Substances "screened" under the SVHC RMOA process may, nevertheless, be further screened under CoRAP if there is a need to clarify their properties and that the CoRAP process is deemed the most appropriate way forward

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POSITION PAPER

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Introduction

The REACH Authorisation process (Articles 57 – 61 of the REACH Regulation) is intended to identify Substances of Very High Concern (SVHC) and to set a time limit (sun-set date) for the discontinuation of their use save where use or uses have been formally authorised in accordance with the REACH Regulation. Any authorisation is granted for a defined period with the ultimate goal of substituting the relevant substance or use where technically and economically feasible.

The process is still in its formative stages – the first actual authorisations granted only being awarded in 2014. However, its application has given rise to a range of concerns and issues which pose challenges for industry value chains and regulators alike. This has led to a number of calls for the process to be streamlined and made more efficient. Of particular concern to industry is the manner in which SVHCs are identified, placed on the candidate list and subsequently prioritised for inclusion on Annex XIV[1].

In 2013, the Commission, following a review of the process and consultation with Member States, published its SVHC (identification) Road Map. Within this communication, the Commission set out its revised process for the identification of "relevant SVHCs" for inclusion in the REACH Authorisation Candidate List. This "voluntary" process would require Member States and ECHA to undertake a "Risk Management Options Analysis" (RMOA) of potential SVHCs to evaluate whether Authorisation or other risk management options might be considered (i.e. OEL, Restriction of uses, tighter EQS, referral for evaluation). The purpose is to ensure that only "relevant" SVHCs are included on the candidate list. The overall goal of the Road Map is to have all relevant currently known substances of very high concern (SVHCs) included in the Candidate List for authorisation by 2020.

The RMOA Process

The addition of the RMOA step, even if voluntary, is an important and practical innovation and is in accordance with seeking the best regulatory outcome for managing risks associated with the use of hazardous substances. It also reinforces a risk-based approach in achieving that outcome. However, AmCham EU considers that the new RMOA process has elements which overlap or are akin to actions within substance evaluation which has its own separate process under REACH. AmCham EU believes that the Commission, ECHA and the Member States, in the interest of regulatory efficiency, should seek to ensure that the processes are well coordinated.

REACH Substance Evaluation Process

The REACH Evaluation involves Member States evaluating certain substances to clarify whether their use poses a risk to human health or the environment. The objective is to take a deeper dive in the registration dossier of certain substances to assess if additional risk management measures are needed. In practice, so far there has been very little focus on use/exposure in evaluation. It has been largely hazard-based and examining hazard-characterisation.

[1]Further information on AmCham EU concerns regarding the listing and prioritization of substances for Authorization is contained in our position paper on How to Make REACH Authorisation Work

The Substance Evaluation process (SEv) may conclude either directly or after further testing, that the risks are sufficiently controlled with the measures already in place. However, it may also lead to the proposal of EU-wide risk management measures such as restrictions, identification of substances of very high concern, harmonised classification or other actions outside the scope of REACH.

Is there a potential overlap between the developing RMOA process and REACH Evaluation?

To the extent that Member States are involved in both processes and that the outcome is to identify whether or not risk management measures are needed, there is some overlap between them. For instance, both processes involve risk assessment and assessment of existing risk management measures (RMM).

Both processes attempt to reach a judgement as to whether existing RMMs are sound or whether or not the risk is adequately controlled. Therefore both exercises require Member States and ECHA to rely primarily on up to date registration dossiers for substances under consideration.

However, the outcomes of both processes are clearly different. Substance evaluation can lead to conclusions ranging from data gap filling on specific risks to reconsideration of endpoints based on assessment of hazard endpoints and risks, leading either to classification or to candidate listing as an SVHC. A reclassification could lead to measures to restrict a substance or indeed classify it as an SVHC. RMOA analysis should lead to conclusions around which regulatory measures are best suited to manage the risk from the use of the substance (generally or in specific circumstances). Table 1 in the annex to this paper provides an overview of RMOA versus Substance Evaluation based on current practices and experiences. Figure 1 below, provides an illustration of the processes in terms of outcomes from a risk characterisation/management point of view.

In May 2014, ECHA and the Member States Competent Authorities held a workshop[2] to discuss Substance Evaluation. A number of issues were discussed including targeting evaluation on particular substances, groups of substances or endpoints.

The workshop also appeared to look at the relationship between the substance evaluation Conclusion Document and the RMOA analysis document (which will also have conclusions relating to specific regulatory risk management options for a substance). The workshop conclusions outlined two possible options for Member States for handling substances that may be involved in both processes:

- *If an RMOA can be made within a four month period or within a reasonable time or if RMOA is not required, a specific conclusion (i.e. indicating which specific regulatory follow up is needed) can be prepared. In this case, the SEv conclusion could also include the outcome of the RMO analysis; therefore a separated RMOA document would not be required.*

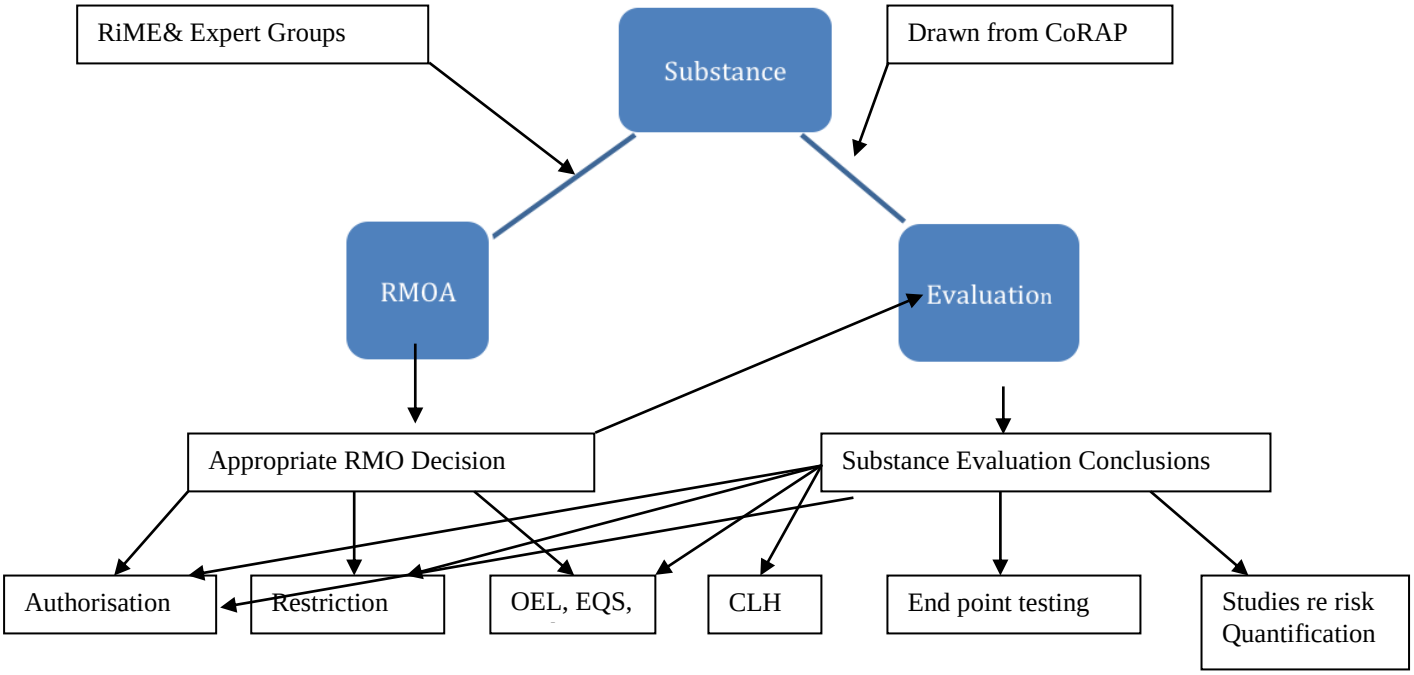
- *If an RMOA is not possible within a four month period or within a reasonable time, but is required to decide on which specific regulatory follow up, a conclusion document can be prepared with a general conclusion only, and an indication that the outcome of an RMO analysis will be published later.*

[2] Workshop on Substance Evaluation, 26-28 May 2014: https://www.echa.europa.eu/documents/10162/13628/sev_workshop_2014_en.pdf

The first option suggests that if the results of an RMOA are known before the completion of a SEv for the same substance, then the results could be incorporated into the SEv conclusions document. Option 2 suggests that if the RMOA is not finalised before the SEv is completed, then Member States can still conclude their SEv but note that an RMOA is being finalised. Both scenarios only indicate what should happen in situations where both procedures overlap.

However, AmCham EU believes overlaps in terms of the same substance being subject to both processes at the same time should be avoided. Once the RMOA process is fully up and running and streamlined this should not occur.

Figure 1: RMOA and REACH Evaluation - Processes



Conclusions

The introduction of the RMOA step into the identification of relevant SVHCs for inclusion in the REACH Authorisation Candidate List is a welcome and practical step in ensuring the consideration of all available risk management options for managing risks from the use of hazardous substances.

However, given the fact that the REACH Substance Evaluation process may also provide similar conclusions in terms of risk characterisation, reduction or management to the evolving REACH RMOA process AmCham EU suggests that registered chemical substances put forward or undergoing substance evaluation under the Community Rolling Action Plan for Evaluation (CoRAP) should not be selected simultaneously for consideration as potential Substances of Very High Concern (SVHC) and subjected to a Risk Management Options Analysis (RMOA).

Annex:

Table 1: Summary of the similarities and differences between Substance Evaluation processes and RMOA Processes

Step	REACH Substance Evaluation	RMOA
Screening & Identification	Substances to be evaluated identified on basis of criteria (?) and included in rolling action plan (CoRAP)	Undertaken on basis of agreed screening approach by RiME
Hazard Assessment	Hazard assessment where no classifications; end points and classifications can be the basis for review and subsequent findings	Based on existing SVHC criteria
Risk Assessment	Assessment of adequacy of risk management measures as described in the substance registration dossier	RMOA clarifies the status of existing risk management measures for a substance and attempts to identify the most appropriate instrument to address the concern
Identification of Risk Management Option	RMO specified in the substance evaluation conclusions	RMO focus on measures to assure minimum adequate control
Socio-economic assessment	Not relevant	Admission of information on use and importance
Co-Operation amongst Member States	Not legally mandated. Recommendation from recent workshop suggests eMSCA may seek views of other MSCA on a substance during 12 month evaluation period	Not legally mandated, however SVHC Road Map agreed by MSCA in 2013 envisages voluntary co-operation at all steps. RiME and Expert Groups for specific end points are involved
Stakeholder involvement	Legally required	Done using the Public Activity Coordination Tool (PACT) that will be available autumn 2014 on ECHA's website

Transparency &Communication	Less known and not as accessible as Authorisation Process	Member States are not required to communicate or consult public during RMOA. Some do, e.g. France
Process Outcome	Legally required evaluation Conclusions document addressed to the substance registrant (Article 48) – eMSCA has ownership Conclusions can include: • Recommendations on classification and/or consideration as SVHC, • Undertaking of studies to quantify further specific risks • Restriction • Classification • Risk management through sector specific legislation (EQS, OEL, RoHS…)	RMOA document – not legally mandated Recommendations or conclusions as to need to include on SVHC list for authorisation or other risk management options e.g. • Restriction • Classification • Risk management through sector specific legislation (EQS, OEL, RoHS…)Substance Evaluation
Business Predictability	Conclusion Document with specific recommendations to registrant – published on ECHA website	Greater certainty as to which substances will eventually be prioritised for authorisation