How to improve REACH substance evaluation: AmCham EU's recommendations ahead of the REACH REFIT evaluation

POSITION PAPER

Executive summary

The American Chamber of Commerce to the European Union (AmCham EU) has been fully involved in recent discussions with the European Commission, the European Chemicals Agency (ECHA) and Member State Competent Authorities (MSCAs) on how to improve the process of applying for Authorisation REACH. We have shared our experience and sought to be a constructive actor in these debates in order to improve the process in the future. With this paper, we encourage authorities to consider a similar reflection on how to improve the process of REACH Substance Evaluation (SEV). Ultimately, it is through Evaluation that the largest number of chemicals are being assessed via REACH at the moment.

We acknowledge that genuine efforts to improve the SEV process have been made both by ECHA as well as some Member States and stakeholders. However, more can and must be done to enable further improvements. In particular, AmCham EU considers that a meaningful analysis and clarification of roles and responsibilities of all the actors is needed to improve the SEV process.

AmCham EU intends this paper to be a contribution to the 2017 REACH REFIT evaluation, which we would like to see address the current shortcomings we experience with SEV. This is all the more important since SEV is a decisive step before the selection of other regulatory measures.

* * *

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled €2 trillion in 2014 and directly supports more than 4.3 million jobs in Europe.

* * *

American Chamber of Commerce to the European Union (AmCham EU)
Avenue des Arts 53, B-1000 Brussels, Belgium
Register ID: 5265780509-97
Tel: +32 (0)2 513 68 92 | www.amchameu.eu

Secretariat Point of Contact: [Stéphanie Brochard]; [sbr@amchameu.eu] +32 (0)2 289 10 15

2 December 2016

Introduction

Since 2012, members of the American Chamber of Commerce to the European Union (AmCham EU) have been involved in the REACH Substance Evaluation (SEV) process. We have previously shared our experiences and provided a number of recommendations to the European Commission and the European Chemicals Agency (ECHA) before their workshop on SEV in November 2015.[1]

Several efforts were made after the 2014 and 2015 workshops to introduce a number of improvements, which include:

- Clarifying the role of Compliance Check vs SEV in requesting more data from registrants;
- Developing standardised documents for communicating decisions;
- Agreeing on clear screening criteria for substances to be added to the Community Rolling Action Plan (CoRAP),
- Stressing the importance of good interaction between industry and the evaluating Member State Competent Authority (eMSCA).

However, many of the challenges identified have not been effectively addressed yet. In fact, many SEV shortcomings stem from a misunderstanding of the roles and responsibilities of various actors in the process.

This paper outlines our understanding of what these roles and responsibilities ought to be for ECHA, MSCAs and registrants. We hope that the reflections included here will spark the discussion on how to improve the process as part of the upcoming REACH REFIT evaluation.

ECHA's coordination duty: Ensuring substances and registrants are being treated fairly and equally

AmCham EU sees ECHA as the coordinator of the SEV process and, as such, believes it has a role to play in ensuring that SEV decisions are coherent with one another. Unfortunately, we notice an unwillingness from ECHA to be involved as a stakeholder of the SEV process, and therefore fulfil the coordination role we believe the REACH text sets as its duty. This leads to confusion as, although eMSCAs run the evaluation process, ECHA is the one who assumes responsibility for the final decision.

The European Commission, as the guardian of REACH, should call upon its agency to take on a more proactive role to ensure the equal treatment of substances – no matter who the evaluating member state is – and to guarantee the consistency of final decisions amongst themselves. AmCham EU believes the coordinating and monitoring responsibility inherent in articles 44, 45 and 47 of the REACH regulation means it is the Agency's role to intervene when necessary to ensure a harmonised approach to SEV under REACH.

ECHA must ensure that the listing and prioritisation of substances follows a risk-based approach and is not merely a tool to serve national political agendas. ECHA should therefore get involved as early as the Risk Management Options Analysis (RMOA) stage, so the decision to submit substances to SEV,

[1] See AmCham EU's input for the ECHA workshop on REACH substance evaluation, November 2015.

Restriction, Authorisation, harmonised classification, or any other regulatory scrutiny process, is justified and proportionate.

This means substances should be selected because of identified potential concerns. Their assessment by eMSCAs should follow predetermined risk-based priorities which are not open to interpretation. Moreover, following recent Board of Appeal (BoA) decisions, ECHA will conduct prior Compliance Checks of the registration dossiers of substances due to undergo a SEV process. This will ensure that their evaluation is based on the best available information and that dossier information, or read-across justifications, are not criticised at a later stage in the process.[2]

ECHA should also fulfil its coordinating responsibilities during the evaluation of substances by eMSCAs. For example, ECHA could intervene by facilitating contacts between the registrants and the eMSCA. Additionally, its 'monitoring role' as laid out by article 47.2 of the REACH regulation means that ECHA should engage with an eMSCA after each commenting period to adapt a decision's request for additional testing and to ensure proportionality and coherence in the risk assessment process. ECHA should also ensure there is a proper coordination between MSCAs which are assessing the same group of substances, so that information is properly shared and decisions taken in a coherent manner.

Moreover, ECHA should use its power to monitor draft decisions (article 47.2) and address shortcomings in the SEV process as early as possible, before any inappropriate final decisions are taken. Such monitoring activities could include:

1. Checking the coherence of the draft decision with other evaluation activities (SEV and DEV) to avoid duplication of information requests;
2. Ensuring that all affected actors are involved in the process, including identified or identifiable downstream users – for exposure related concerns;
3. Guaranteeing the scientific and legal soundness of the draft decision, especially in light of the three tier necessity test recently developed by the BoA of ECHA in cases such as *Akzo Nobel;*
4. Assessing the proportionality of the information requirements – both in terms of cost and animal welfare – requested in the decision with the level of concern or risk identified at the start of the process,

Intervening at these stages would prevent registrants from unnecessarily planning laboratory time and setting aside resources for what may be unjustified requests for additional testing. It would also prevent a plethora of inconsistent Final Decision Letters (FDLs) being adopted and a continued stream of potentially unnecessary BoA cases being filed[3].

Large differences in how MSCAs conduct SEV: Unacceptable differences in how registrants are treated

The main dissatisfaction recorded among AmCham EU members is that their evaluation process can often feel subjective, and sometimes even biased. Registrants should not have to fear that they will be treated more severely by one member state than another, and yet, this seems to be a staple of the current SEV process.

We have particularly noted wide differences on two fronts:

[2] Akzo Nobel case, 005-2014, 23 September 2015, available on ECHA's website.
[3] Since 2013 and the first final decision letters, 13 appeals have been published, and 8 are pending. In addition to this there has been one annulment, 2 rectifications and 2 dismissals.

- Access to the eMSCA during the one year evaluation, which can vary between one meeting during the whole evaluation period to monthly meetings and calls depending on which member state runs the process.
- The amount of testing requested in a single decision. Some MSCAs make requests which are justified and understandable, others are inclined to request many tests on multiple hazards and may even go as far as requesting experimental non-guidance testing for which no pass/fail criteria exist.

AmCham EU believes in predictable regulatory procedures. Politically motivated decisions should not have their place in the REACH SEV process. FDLs driven by a national agenda or by scientific curiosity alone are setting a precedent. The entire legitimacy of the SEV process, and REACH as a whole, willl suffer if this situation is not addressed soon.

The unequal treatment of registrants, depending on which eMSCA is running the evaluation, is not new to either the European Commission, ECHA or the MSCAs, since they produced '*Recommendations on Interaction*' in January 2014 to try to address the problem[4]. However, this document falls short of what is needed as the behaviour of eMSCAs is not improving with time. We encourage the Commission and ECHA to find other means of addressing this situation as soon as possible.

We also believe that eMSCAs should be more collaborative during this process, and that registrants should be allowed to reach out to other MSCAs who may have relevant expertise. The fact that registrants are forbidden from reaching out to MSCAs, even when they may have worked on substances of the same family as theirs in previous evaluations, is counterproductive. Limited communication between registrants and all MSCAs will become an increasing source of inefficiency as more substances undergo the evaluation process.

The registrant's role, responsibility and right to be heard

AmCham EU members take human and environmental safety, as well as compliance with regulation, including REACH, very seriously. We are aware that registration dossiers are our responsibility, and that being compliant entails not just a 'one off' registration, but a regular update of the dossier information.

As more and more substances get listed on CoRAP, the importance of having an up to date registration dossier is clear. We understand that these updates can determine the next steps of the regulatory assessment, particularly the selection of the appropriate risk management measures.

We also acknowledge that by the time a substance is placed on CoRAP an overhaul of the registration data should take place to make sure there is not just a focus on hazard classification, but also an understanding of exposure scenarios. Acquiring this data may require a discussion within the supply chain to gather additional information.

However, registration dossiers entail responsibilities for authorities as well. If a registration dossier stresses a particular use or user it would be appropriate to involve downstream users in the evaluation process, so real conditions of exposure and an adequate risk assessment are taken into account. Downstream users may possess information or data, such as exposure monitoring data, which is not available to the registrant. Downstream users should notify their desire to provide data on a particular

[4] Recommendations on the best practice for interaction during substance evaluation, ECHA, 21 January 2014.

substance in the course of the SEV process. Similarly, authorities may wish to contact downstream user associations to gather more information. ECHA could have a role in coordinating such contacts.

However, it must be stressed that even the most complete registration dossier cannot replace an open and constructive discussion between registrants and their eMSCA to identify any existing data gaps and clarify the grounds of concern. This is especially the case for difficult to test substances, or for new testing protocols whose results may not be as repeatable as one would like.

AmCham EU thinks ECHA could help the industry actors in need of additional guidance to understand what is expected of them. The scope of what can or cannot be commented upon changes at each commenting phase. For example, the Member State Committee (MSC) hearing is limited to only what was mentioned in other MSCA Proposals for Amendment (PfA)s, and whether these touch upon what the registrants find to be key argumentation or not.

Registrants also find it difficult to participate in each commenting period in the tight 30 day deadline set by the REACH regulation. After such efforts, it can be especially frustrating to find that those comments were not, or barely, taken into account by either the eMSCA or other MSCAs. Registrants have a legitimate expectation that their comments should be considered, but given the shifting boundaries on what they are allowed to comment upon at any given point of the SEV process this does not seem to be the case. ECHA's coordination role could be helpful here as well.

Conclusion: What the REACH REFIT valuation can do to improve SEV

We hope the present contribution will help raise awareness of the current shortcomings of the REACH SEV process. We believe a thorough discussion of the process, with all the relevant stakeholders including industry, would do a great deal to streamline the process going forward. Once again, AmCham EU is eager to share its experience to arrive at the best outcome possible.