AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Brussels, 17 November 2015

Leena YLÄ-MONONEN
Director for Evaluation
European Chemical Agency (ECHA)
P.O. Box 400
00121 Helsinki
Finland

Re: AmCham EU's input for the ECHA workshop on REACH substance evaluation on 19-20 November

Dear Ms Ylä-Mononen,

In view of the 19 November 2015 workshop on the future of the REACH Substance Evaluation (SEV), members of the American Chamber of Commerce to the EU (AmCham EU) would like to share several thoughts for your consideration.

A number of our members have been involved in this process as REACH registrants and have developed opinions on issues ranging from transparency and access to officials, to those linked to new substances being registered and what this may mean for existing decisions.

You will find enclosed suggestions and recommendations which our members have extracted from their experience with the SEV process, and which we believe could help streamline both the SEV procedure and its outcomes in future, without revising the REACH text.

This input is the starting point of our reflection; we look forward to further discussions on how to improve the SEV process with EU authorities, ECHA and evaluating Member State Competent Authorities (eMSCA).

Yours sincerely,

Meglena Mihova
Chair of the Environment Committee of the American Chamber of Commerce to the European Union

Copy to:
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I. ECHA's coordination duty: making sure substances and registrants are being treated equally and the final ECHA decisions are consistent with one another

Since the REACH provisions governing the SEV process refer to ECHA as a formal decision-maker, we believe this means ECHA has a coordination duty within the process. However, we have noticed a certain amount of reservation from ECHA to act as a steering force of the SEV process. The split involvement between eMSCAs and ECHA during the adoption of the Final Decision Letter (FDL) leads to confusion, and may be partly responsible for the large number of appeals being filed before ECHA's Board of Appeal (BoA) over the past years.

The European Commission, as the guardian of REACH, may want to 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 ensure the consistency of final decisions with one another. AmCham EU members believe this coordinating responsibility means it is the agency's role to intervene when necessary.

ECHA could intervene during the initial evaluation to facilitate contacts between the registrants and the eMSCA, even before the draft decision is sent by the eMSCA to ECHA. Each time the draft decision is updated after a commenting period, ECHA could enter into a dialogue with the eMSCA to adapt a decision's requests for additional testing and to ensure coherence in the risk assessment process. In order to find an efficient way to steer a draft decision in a direction which is consistent with REACH and ECHA's policies, ECHA should proactively intervene and review the different drafts produced by the eMSCA working under ECHA's mandate. After all, ECHA often has access to more documents related to a specific SEV than the registrant does. For example, AmCham EU fails to understand why registrants must wait so long before they receive a copy of their substance evaluation report when ECHA receives it at the same time as the Draft Decision Letter (DDL.)

Recommendations/ suggestions:

- ECHA must assess whether it can or cannot stand by the FDL (for which it is responsible) throughout the SEV process.
- ECHA should liaise with eMSCAs throughout the process. In case an eMSCA continues to drive a line of argument which ECHA fears will unnecessarily lead to an appeal, ECHA should exercise its steering and coordination power to review the different versions of the drafts and the comments sent by the registrants.
- ECHA should be more proactive. For example it could ask an eMSCA to take into consideration certain registrant comments or the final outcome of relevant previous SEV findings.
- ECHA should share the draft and final SEV reports with registrants as soon as they are received at the draft decision stage.

II. Formal or open communication: different approaches between eMSCAs

Although the Member States, the Commission and ECHA have agreed to recommendations on best practice for interaction between registrants and eMSCAs during the SEV process, there are still different schools of thought on this issue and diverging practices among eMSCAs.

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AmCham EU members, based on their experiences of the REACH processes in general and SEV in particular, feel the one year evaluation period should be a privileged time to clarify the eMSCAs' concerns and discuss test results which are present in the registration dossier.

However, uncertainty about how to interact with authorities impacts the process' efficiency. Open communication during these critical months would not only help streamline the process, but avoid misunderstandings once the draft decisions, which close the 12-month assessment period, are released.

Recommendations/ suggestions:

- Streamline interaction between eMSCAs and registrants to avoid unequal treatment.
- Encourage open and frequent communication between registrant and eMSCAs as early as Community Rolling Action Plan (CoRAP) listing.
- Edit the format of the SEV mandate. This way, ECHA can be more prescriptive about what the SEV assessment should entail in order to be of sufficient quality. This would avoid having unnecessary recourse to the limited resources of the BoA, and would help both eMSCA and registrants understand what is expected of them.

III. Access to other Member State Competent Authorities (MSCAs) to increase the efficiency of the SEV process

The issue of whether registrants undergoing SEV should be allowed to reach out to other authorities is another grey area which complicates the SEV process. The recommendations on interaction fall short of what would be useful, since they only address the interaction of registrants with their own eMSCAs. We believe registrants have the right to interact with other MSCAs. Such interactions will be necessary as more and more substances undergo SEV on similar grounds of concern.

Contacting other MSCAs is even strictly forbidden once ECHA has submitted the draft decision to the Member States Committee (MSC). The current state of things is based on the erroneous assumption that neither the registrants, nor authorities, would benefit from discussing some of these developments before the MSC hearing takes place. AmCham EU believes such exchanges should be encouraged, not prohibited.

Recommendations/ suggestions:

- ECHA should clearly lay out circumstances in which access to other MSCAs is not only allowed, but encouraged, and if not, provide an explanation.
- Create a forum where regulators and industry can raise horizontal questions which are regularly raised during the SEV process.

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IV. The role of ECHA expert groups[1]

We would like a clarification on the role played by ECHA's expert groups in the SEV process. Although according to the letter of the REACH regulation they play no role at all, in practice, they may be the forum where substances, either undergoing evaluation, or being considered for CoRAP are being discussed first. The registrants of these substances however are not systematically informed nor invited to participate in these discussions.

The SEV process will only be successful if registrants can trust it. At the moment, the lack of transparency as to when and how given substances are being debated within the expert groups is not helping registrants to play their full and constructive role in the process.

Recommendations:

- The expert group could release a progress report yearly/ each semester outlining key issues they have addressed and which may be relevant to REACH processes such as SEV.
- Internal rules on reporting and minutes publishing are needed and the turnaround of meeting minutes should be prompt.
- Registrants should be allowed to question conclusions reached by these bodies, and ECHA should ask these bodies for further assessment when necessary.

V. Need to reconcile the substance evaluation timelines with those of the registration phase-in system and with other processes such as harmonised classification

Experience acquired during the first three years of the SEV process has also highlighted the potential difficulty in aligning the classification, registration and substance evaluation respective timelines and cycles.

This difference in rhythm, means it is possible for other registrants to join the submission in the course of, or after, the evaluation process. This does not mean, however, that all registrants will be equally involved in the evaluation of the substance they all have registered. Only those who are considered as 'concerned registrants' will be addressees of the final decision.

New registrants are simply not formally included in the evaluation procedure and therefore not legally bound by its outcome. This question is far from trivial as it can impact the relevance of the SEV process itself. For example, some crucial information may be missing from scope of the SEV as it is only part of new registrants' dossiers. The relevance of testing results may also vary as there are differing standard information requirements depending on the tonnage category.

The BoA (Case A-005-2014) recently recommended that a dossier compliance check should be undertaken by ECHA before any SEV is initiated. This is a welcomed development, and AmCham EU would like to

[1] on Endocrine Disrupters, Persistent, Bioaccumulative and Toxic substances (PBTs), substances of equivalent concern/ sensitizers and Carcinogenic, Mutagenic and Reprotoxic substances (CMRs).

understand whether this policy will be put in practice to ensure that the eMSCA is ensured that the dossier it is due to evaluate is compliant with the REACH annexes before it embarks on an evaluation of the substance. This would prevent the SEV process from generating standard information. It would also ensure that the concerns, if any, are based on data, or alternatives to data which have been deemed compliant further to comments by the registrant.

Finally, the CoRAP and harmonised classification should be better coordinated. This would prevent premature harmonised classification and labelling (CLH) proposals, which an SEV could clarify. Conversely, data generated for the purpose of CLH could be relevant at the time of SEV. ECHA is invited to take a more proactive role in coordinating these procedures.

Recommendations:

- A compliance check (CCH) should be undertaken by ECHA on at least the same endpoints as the CoRAP concerns, prior to the evaluation year.
- When CoRAP proposals are examined, ECHA could organise, through the designated committees, a dialogue among the MSCAs concerned with SEV and CLH proposals to ensure SEV is completed, and where relevant, the dossier is updated with new data before CLH is initiated.
- If data present in only certain registration dossiers raise concerns, these specific dossiers should undergo CCH to avoid that all registrants are requested to generate data that would address perceived concerns relevant for some registrants only.
- ECHA must enforce the 'one substance, one registration' principle through a mechanism whereby both addressees of a final decision and later registrants are subject to a dossier compliance check to ensure that they all contribute fairly to the costs of the dossier update as a result of the SEV process, while preserving their legal rights.