How to make REACH Authorisation work

AmCham EU recommendations on how to streamline the REACH Authorisation process

Executive summary
AmCham EU welcomes the initiative of the Commission, ECHA and Member State Competent Authorities (MSCAs) to discuss and seek to improve the process of applying for authorisation under REACH. Our Members also believe that this process can be streamlined, simplified and be made more predictable for all actors in the future without reopening the REACH legal text.

This paper looks at all the steps of the authorisation process from RMOA to application, and is AmCham EU's initial contribution to this debate. We intend to be a fully engaged and constructive partner in these discussions with the EU's chemical authorities.

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Introduction

AmCham EU welcomes the initiative of the Commission, ECHA and Member State Competent Authorities (MSCAs) to discuss and seek to improve the process of applying for authorisation under REACH. Our Members also believe that this process can be streamlined, simplified and be made more predictable for all actors in the future without reopening the REACH legal text.

The following paper is AmCham EU's contribution to this debate. It is based on the experience of our member companies with the REACH authorisation processes. It is also a response to the SHVC Roadmap, its subsequent implementation plan and the recent DG Enterprise document on '*Streamlining and simplifications of the authorisation process for some specific cases*', which is being discussed by CARACAL members.

I. Initiating a robust and proportionate Risk Management Option Analysis (RMOA)

First and foremost, AmCham EU would like to insist that a thorough RMOA conducted at the start of the process is the most efficient way of discovering and addressing concerns related to the use of a substance. We believe a good RMOA will avoid the current situation where substances on the Candidate List, or in the prioritisation process, cannot be selected for the authorisation annex because they were never good candidates for this risk management tool in the first place.

AmCham EU supports the risk management option (RMO) approach as presented in the SVHC Roadmap and in the ECHA implementation plan. In our opinion, the greatest added value of this process is in helping to identify which is the best regulatory tool to address the risk associated with a given chemical substance; whether it be within REACH (authorisation, restriction or substance evaluation) or beyond REACH using other pieces of sectorial legislation. All relevant regulatory options such as OELs, ELVs, RoHS or EQS, should be considered for the sake of regulatory efficiency and to avoid overlaps with existing legislation. For example, AmCham EU[1] recommends setting OELs for the manufacture, or use, of hazardous substances which have raised concerns exclusively in the workplace instead of using authorisation. An OEL must be recognised as a '*specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance*' (REACH, art; 58.2) allowing this substance, and its identified uses, to be exempted from the authorisation process.

We would also like to stress that based on our experience an effective RMOA should include the following elements:

[1]For more information, *Occupational exposure limit (OEL) values should be considered during REACH's risk management option analysis (RMOA)*, AmCham EU, June 3 2014

- At least a preliminary **weight of evidence analysis**[2] of the registration dossier, which is necessary to determine if a substance should either be sent to the Candidate List or assessed via Substance Evaluation;

- **An assessment of the exposure context** (consumer, professional or industrial use) to see if sector specific legislation might not be the best risk management tool;

- **An understanding of whether the substitution of the targeted substance is possible**. If not, authorisation should not be considered the best regulatory tool.

This means that the European Commission proposal to conduct a socio-economic impact assessment during the prioritisation of SVHCs will happen too late in the process. It would be more effective if conducted upfront during the RMOA process.

RiME (Risk Management Expert) meetings will be an essential forum to discuss technical and scientific issues and share experience between Member States and the European Commission. AmCham EU fully understands the need for authorities to exchange on ongoing RMOAs in an informal manner. However, we believe that industry input could be helpful and should be taken into account by this group, when appropriate, on an *ad-hoc basis*. AmCham EU believes there is a balance to be struck between efficiency and transparency in these meetings.

Our members understand that it is their responsibility to keep their registration dossiers up-to-date, since some of the information needed to perform a thorough RMOA is available there. However, critical data needed to identify the right risk management tools, such as substitution potential or socio economic information is not present in registration dossiers. We therefore recommend interactions (e.g. through at least limited and targeted public consultation) between the MSCAs in charge of the RMOA and relevant stakeholders (e.g. industry, third parties…) at different stages of the process to ensure that all the relevant data will be available for use in the RMOA.

II. Placing only the right substances on the Candidate List

Once a proportionate and thorough RMOA has been completed and approved by ECHA, and provided the substance does not raise questions which would be better addressed by the Substance Evaluation process, we believe it will be clear which substances are appropriate for the Candidate List. Meaning, only the substances which should eventually be on Annex XIV, and be substituted by a predetermined sunset date, should be on the Candidate List.

AmCham EU is aware that this interpretation is not unanimously accepted by MSCAs. Some of these believe that the Candidate List is a tool to increase information on the EU market (through Art 33 notifications), and as such should include as many substances as possible. Others believe that the Candidate List is a tool to raise awareness of SVHCs, such as EDCs and PBTs, which do not have a classification. AmCham EU disagrees with both these approaches to the Candidate List, and believes that many of the problems encountered with the 5th and 6th prioritisation lists are the result of substances which were poor candidates for authorisation being listed on the Candidates Lists on the grounds listed above (see section on prioritisation below).

[2]For more on AmCham EU's position on the current *Weight of Evidence* in EU chemicals policy debate, please see our 12 November 2014 position paper.

To ensure that only substances which clearly pose a risk which is not managed, we believe that the public consultation at this step is of extreme importance. Given we can only expect a limited consultation with industry during the RMOA stage (registrants and a sample of national actors for example), this consultation is when a wider group of actors in the supply chain can raise socio-economic arguments - information which is critical to anticipate problems during the prioritisation and authorisation phases. This consultation could help identify if another regulatory tool is a better choice than authorisation.

III. Effective prioritisation of substances to Annex XIV

Overall, AmCham EU agrees with the improvements made to the new Member State Committee prioritisation methodology, which places more emphasis on less known substances and on an improved Wide Dispersive Use Assessment (based on potential for exposure of industrial, professional or consumer use[3](s)). These changes should help to improve the transparency and the predictability of the process, provided it is adequately coupled from now on with a thorough RMOA early in the process. However, we are concerned that the double scoring for multiple hazards may harm this transparency. While we do not question that substances with multiple hazards should be considered for prioritisation, we worry that political motivations may lead MSCAs to 'misuse' this tool. Indeed, the multiple hazard scoring for substances could encourage certain authorities to craft Annex XV dossiers with multiple hazards just to increase the speed at which a substance will be prioritised. Such an approach would make the process less predictable and transparent than it should be.

AmCham EU also believes it is important to stress that several substances which are currently on the Candidate List have not been RMO assessed. Therefore authorisation may not be the best risk management tool for some of these which will continue to pose problems during the prioritisation process, as seen in the case of the 5th and 6th prioritisation lists. We therefore recommend that an 'after the fact' RMOA be run on the substances which were added to the Candidate List without an RMOA to identify if another regulatory option might not be more appropriate and efficient. This will ensure a more efficient prioritisation process in the future. AmCham EU would also like to insist on the need for authorities to use the most recent version of the registration dossiers during this process, as the critical information for prioritisation (e.g.: uses, volumes and volumes per use) can vary widely between dossiers and therefore impact the overall prioritisation process.

In addition to this, AmCham EU encourages the drafting of **clear guidelines on when an exemption from the authorisation process may be justified**. AmCham EU believes that Article 58 (2) is too vague, especially since '*legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance*' already exists and can be referred to explicitly. We understand that human health, environmental protection and risk management are the key conditions to claim an exemption from authorisation, but the EU institutions should ensure there is consistency between REACH and other EU legislation protecting human health and the environment. This would avoid excessive regulation and unnecessary double legislation. AmCham EU would like to highlight a short list of sector specific laws which could be an alternative to REACH authorisation: European OELs, European biological exposure limit, Air Quality Directive, Water Framework

[3] Although we encourage authorities to keep in mind that just because a substance is used in the manufacturing of an article destined for consumer use, does not mean that it is present in the finished article, and therefore providing a possible exposure for consumers.

Directive, Directive on the protection of the health and safety of workers from the risks related to chemical agents at work, Directive on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding etc.

We specifically welcome the European Commission's recognition that there is a "risk of potential" overlap between the REACH Regulation and the End-of-Life Vehicles Directive (ELV)[4]. The ELV Directive encourages the substitution of different products (e.g. automotive Lead-based batteries) and any authorisation process under the REACH Regulation would overlap with the revision of exemptions granted under ELV. In practice, even if an operator has already applied for a time-limited exemption for a use under the relevant sectoral legislation, there is no guarantee that the authorisation under REACH will be granted by the Commission for the same use.[5] It would not be an efficient use of either authorities or industry's resources to go through two separate and independent procedures in order to continue to use the substance.

The same situation applies in the case of the second RoHS directive, where substances currently undergoing REACH authorisation are being considered for restriction under RoHS.[6] Beyond the lack of legal certainty this situation entails, it also raises the questions of what will happen for uses which have already been granted exemptions under RoHS, but may need to also apply for authorisation in the future.

These same guidelines would also be useful in the case of intermediates. Based on article 2.8.b, isolated intermediates are exempted from authorisation. The definition of intermediates (article 3.15) has been interpreted until now by the European Commission, Member States and industry in different ways. The European Commission issued, in January 2010, a clarification of the concept of intermediates under REACH[7]. However, discrepancies in the interpretation still exist between some Member States. This could have serious effects in some cases, and questions whether all intermediates cases will be treated equally.

So far, ECHA and the European Commission refuse to identify clearly the intermediate uses which are exempted from authorisation and taken into account during the prioritisation process. This means industry does not know whether its interpretation of intermediate use has been accepted. This interpretation is critical during the prioritisation process, since the volumes of exempted intermediates are not taken into account for the prioritisation ranking. AmCham EU believes this situation could be addressed were ECHA to publish the list of uses which have been considered by the Member States Committee (MSC) as intermediates in the context of authorisation during the public consultation. This will also allow industry to comment on the interpretation of 'intermediate' and provide additional relevant information during the public consultation if their intermediate use has not been recognized during the process.

Finally, longer sunset dates should be allowed for certain uses (ex: long life-time durable articles) and industry sectors. For example, this would be justified in the case of legacy products, spare parts and

[4] *Staff Working Document accompanying the General Report on REACH*, reference: Document SWD(2013)25 of 5 February 2013: http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/general-report-swd_en.pdf
[5] Please see *REACH and RoHS: A Common Understanding*: http://ec.europa.eu/DocsRoom/documents/5804/attachments/1/translations/en/renditions/native
[6] For more on AmCham EU's position on REACH overlap with RoHS please see *AmCham EU's comments on the Commission discussion paper on the interface between REACH and RoHS*, 3 March 2014
[7] http://inforeach.gencat.cat/pdf/ECHA_Clarification_concept_intermediates.pdf

their maintenance in the automotive and aerospace industries. Due to the complexity of the supply chain[8] and the strict safety certification requirements[9], substitution as well as authorisation could be very complex. At the same time, the industry has very high worker health and safety standards and adequately controlled risk of uses. We believe that longer, or even renewable, sunset-dates would allow those industries to progressively find the best substitution solutions for these complex products and their supply chain.

IV. How to streamline the application for authorisation

Response to the Commission's '*Streamlining*' proposal

AmCham EU has read with attention the DG Enterprise document entitled '*Streamlining and simplifications of the authorisation process for some specific cases.'* We welcome this initiative since we also believe the authorisation process can be streamlined without reopening the REACH text, and have already made suggestions to this effect in this paper's previous sections.

We agree that greater communication during and before the application process could help prevent unnecessary administrative burden, and welcome the proposals to update the Socio Economic Analysis template and to streamline the Analysis of Alternatives (AoA.) However, we find that overall, the input provided by the Commission in the 'general solutions' and 'specific cases' sections of its paper seem contradictory, as outlined below.

Additional guidance on how to define uses for authorisation would be helpful, but it seems that the large, 'all use encompassing' authorisation dossier referred to in the 'general solutions' section, would in no way be able to benefit from the 'streamlined' authorisation process described in the 'specific cases' section. The latter seems to be valid only for narrow process or downstream user specific uses. This double standard may confuse rather than simplify the application process for certain uses, when it is not clear which application should be used.

AmCham EU is also concerned by the notion that different applications could be based on different OELs. This might create competition between different industries and applicants. The risk here is that some application dossiers would be rejected, not because risk is not adequately controlled, but because another applications based their calculations on a lower DNEL.

Streamlining proposals based on AmCham EU member experience with the authorisation process

The section below touches upon a number of lessons learned by our members who have already applied for authorisation. We ask all REACH authorities to take these into account while running their assessment on how the authorisation application process can, and should, be streamlined.

- ***Access to officials***

The application process can be very opaque for applicants. Industry has no access to either RAC or SEAC experts. The only exception is during trilogue meetings, which are one-sided and may not be

[8] For example an Original Equipment Manufacturer (OEM) in the automotive industry can have between 1500-4500 Tier 1 parts suppliers and a tier 1 supplier can have between 500-1500 Tier 2 suppliers.
[9] AmCham EU welcome the 'Streamlining document's recognition that Type Approval certification will complicate the authorization process.

conducive to interaction. AmCham EU believes, that in some cases, interaction may be effective. We therefore encourage ECHA to issue a guidance document clarifying when this interaction would be welcome and when not. After all, both RAC and SEAC members are independent experts, and could benefit from outside information and input. This is especially the case for the rapporteurs on an industry's dossier.

The experience of the Substance Evaluation process can be a useful precedent here. Based on the experience of AmCham EU members so far, Substance Evaluation is much more successful in cases where the registrant and evaluating authorities (eMSCAs) interact with one another. We believe this could also be the case for companies applying for authorisation and their RAC and SEAC rapporteurs.

- ***Length of authorisations***

Applying for authorisation is a very challenging, expensive and time-consuming process for industry. Although we understand the purpose of Annex XIV is to encourage, where possible, substitution, we believe that once the case for authorisation has been made (either on socio economic grounds or because of adequately controlled risks), longer authorisation periods are not only justified, but can also be the most efficient use of both industry and authorities' resources.

We would also like to obtain clarifications regarding what happens in the case of new evidence on a given substance being put forward before the end of the authorisation timeframe.

- ***The timing of RAC and SEAC input***

Industry has always been very supportive of the role of RAC and SEAC in the REACH process. However, AmCham EU members believe that in the process of applying for authorisation it would be useful to streamline, and have a better timing on certain RAC interventions.

This is especially relevant in the case of the publication of RAC's indicative DNELS (or dose response curves, in the case of non-threshold substances), which even though they are only indicative, are relied upon heavily by all institutional actors, and referred to continuously in discussions on whether to grant authorisation, or not. Until now, companies applying for authorisation have been in the unfortunate position of receiving these DNELS late in the process. In the worst cases, this means it is harder for companies to assess whether it makes business sense or not for them to apply for authorisation. At the very least, they are released only after the main risk assessment calculations have already been made based on the company's assessment of what these DNELs should be. This misalignment in timing means that the process of applying for authorisation becomes even more expensive, and unnecessarily so, as these calculations must be made once again, in a rush, on the basis of the RAC data. It seems to us that such occurrences could be limited, if applicants were allowed more visibility in the DNELs setting process. They could even be eliminated altogether, were indicative DNELs were set immediately after a substance has been prioritised, rather than during the application process.

Conclusion

AmCham EU is grateful for the EU institutions' willingness to reassess the REACH authorisation process, and to see how it can be streamlined and more efficient before the volume of applications increase over the next few years. This paper is AmCham EU's initial contribution to this debate. We intend to be a fully engaged and constructive partner in these discussions, both in the run up to next February's workshop in Helsinki, and afterwards.