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# Need for greater predictability in targeting substances under REACH: thoughts on the SVHC Roadmap and the REACH Review

The American Chamber of Commerce to the European Union (AmCham EU) has long called for greater predictability in the way substances were identified and prioritised for review under the REACH risk management procedures.[1] As such, we welcome the Commission's efforts to provide greater transparency, predictability and legal certainty in the process that adds substances to the candidate list, and eventually subjects them to the Authorisation or the Restrictions process.

In particular, AmCham EU welcomes the European Commission's strengthened support for the use of Risk Management Option (RMO) assessments ahead of proposals leading to SVHC identification.

However, after close consideration of the Roadmap, AmCham EU considers that the proposed SVHC roadmap must be clarified and adjusted in order to meet its objectives. AmCham EU is calling on the European Chemicals Agency (ECHA) to consider the comments and suggestions in this paper, while working on more detailed proposal for implementation it has recently announced..

Although we welcome some suggestions proposed in the Roadmap, as well as in the staff working document attached to the REACH review, below is a list of the some of the problems our members have encountered with the various REACH risk management processes, and which we find the SVHC Roadmap fails to address.

## The Candidate List and Authorisation

As noted by the Commission, the 'black list effect' of the candidate list is real. Indeed, downstream users have the perception that a listing on the candidate list means a future ban and the need for substitution. Several retailers and service providers have demonstrated over the last five years that they consider the Candidate List a black list and react to it immediately, long before a decision is taken on what the appropriate outcome of such a listing may be. AmCham EU notes the Commission's intention to consider information activities on the subject. It would be helpful for the Commission and ECHA to add, in relevant communications on the candidate list, a clear and visible explanation that if a substance is on the list it does not mean that it is banned; it can continue to be used and be present in articles until and unless subject to a ban pursuant to an authorisation and/or restriction process. Some national authorities have been proceeding this way for some time. As example of such best practice is that of

[1] AmCham EU Position paper: Consistency necessary in EU environmental policymaking

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POSITION STATEMENT

the French authorities, who publish an 'avis' explaining that the listing of a substance is not a ban on the Official Journal of the French Republic.

AmCham EU welcomes the Commission acknowledgement that options to 'de-select' substances from the candidate list should be investigated as soon as possible. It is indeed essential that new information on the hazards of a substance, or on the risk management measures already in place, can remove a substance from the candidate list. Such a procedure would clarify that certain substances should not be prioritised for Annex XIV, and would free those substances from the stigma associated with the candidate list.

AmCham EU encourages the drafting of clear criteria to identify which sensitisers would be relevant for the candidate list. In the interest of transparency and better law-making, we look forward to the publication of these criteria in the near future.

AmCham EU is concerned that the Commission still intends to list PBTs, vPvBs and Endocrine Disruptors on the candidate list without mandatorily going through an RMO assessment beforehand, as is the case for other SVHCs, such as CMRs. Such uncertainty regarding what substance will come under scrutiny when, greatly reduces the predictability that the Commission is aiming to provide with its Roadmap.

**Restriction**

AmCham EU has always taken the position that the Authorisation and Restrictions processes should not run in parallel, be safe in exceptional circumstances[2] and welcomes ECHA's declaration that even though this may be legally possible, efficient use of resources, legal clarity and predictability requires that a two-track investigation of the same substance be avoided. We urge the Commission to fully support this analysis as well.

AmCham EU is particularly concerned that a prior decision in the Restriction process may prevent companies from having their Authorisation requests duly considered. The first precedent has been recently created by the Danish proposal for restriction of four phthalates, while the same substances are included in the REACH Authorisation Annex XIV.[3] The adoption of a prior restriction would therefore de jure or de facto significantly factor into any Authorisation decision, a situation that would certainly trigger legal challenges, as well as confusion in the supply chain. AmCham EU therefore welcomes that the Commission will engage in a reflection on how to improve the implementation of the Authorisation and Restrictions processes to help ensure legal certainty and predictability. We also believe that industry should participate to this reflection and our members are available to do so.

Denmark's decision to move ahead with its proposed phthalates restriction, even after it was rejected on risk and socio-economic grounds by the Risk Assessment Committee (RAC) and Committee for Socio-Economic Analysis

[2] AmCham EU Position Paper: REACH authorisation and restriction processes
[3] AmCham EU Position Paper: REACH restriction process and certain phthalates

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POSITION STATEMENT

(SEAC), is also a dangerous precedent in the restriction process.[4] One of REACH's key purposes was to preserve the Single Market by stopping Member States from unilaterally banning substances. We strongly encourage the Commission, as Guardian of the Treaties and of the integrity of the Single Market, to quickly start infringement proceedings to preserve trust in the REACH system and avoid mixed signals on the Single Market.

AmCham EU would also like to draw the regulator's attention to the paramount importance of robust scientific background and economic feasibility analyses before substances are proposed for restriction. We underline the importance of the procedure laid down in Article 68(1) of the REACH Regulation, with proper scientific and socio-economic evaluations done by the ECHA committees. This would guarantee effective and proportionate legislation, while also giving industry legal certainty and clarity on the decision-making process.

Restriction proposals should be tabled after a full scientific and socio-economic impact assessment. AmCham EU is concerned about the precedent set by proposing a fast track procedure (Article 68.2) to address Polycyclic Aromatic Hydrocarbons (PAHs) under REACH for a broad range of consumer goods.[5] Such a wide-ranging proposal should only be considered according to established rules, and after a mandatory scientific review.

**Risk Management Option (RMO) Assessment**

AmCham EU strongly believes that stakeholders, including industry, should always participate in the RMO analysis stage. This is key to ensure the transparency and efficiency of the RMO process. The decision about whether to seek public consultation should not be left to national authorities alone. The Commission should recommend early involvement of industry, including actors of the supply chain, in the RMO analyses run at national level. AmCham EU is concerned that according to the SVHC Roadmap, around 160 RMO analyses have been made since 2009, and yet, the results of these have never been shared.

AmCham EU also believes that RMO preparation should not be limited to analysing information coming from other REACH processes (registration and evaluation). Previous experience has shown how important it is to collect information on the value chain, and on the different uses of substances. Such data collection would obviously be easier if industry were involved in this process at the earliest stage.

More broadly, AmCham EU encourages the EU institutions to ensure that there is consistency between REACH and other relevant EU legislation. A coherent approach — based on scientific evidence and taking into consideration socio-economic impact — should be systematically followed when evaluating substances and choosing the most adequate risk management regulatory tool to avoid duplication of efforts, regulatory overlaps, that lead to legal uncertainty.

[4] Joint Industry Letter: Danish Phthalates Ban
[5] AmCham EU Position Paper: PAH restrictions

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## Evaluation

The Commission efforts toward additional transparency should also apply to substances of concern subject to 'substance evaluation'. Additional transparency is needed on the criteria used for the selection of these substances, and consistency is needed for the implementation of these criteria by Member States. AmCham EU would therefore welcome a broader roadmap covering all processes related to substances of potential concern, not just the candidate list.

There is also a misperception that a listing on the CoRAP also leads to a 'black list effect'. The Commission should communicate better that a listing on CoRAP does not represent a ban of the listed substances, but simply that the registration dossiers for these substances are being reviewed on the basis of some potential concerns, to determine whether additional information or risk management measures are required.

## Conclusion

The Commission's political objective to have all currently known SVHCs on the candidate list by 2020, and that 55 substances should be RMO assessed each year by then, is incredibly ambitious. Industry needs visibility to anticipate when the substances they manufacture and use might be targeted so they can commission data, prepare exposure scenarios, and when appropriate, plan for substitutions.

Not knowing when a substance may be the target of a REACH risk management process is not conducive to investment security. Uncertainty about which substances will be available in the short to medium term inhibits the ability to innovate and compete globally. A balanced and coordinated legal framework will accelerate business developments that meet citizens' needs and foster growth.

Finally, most AmCham EU members are global companies operating on an international scale. AmCham EU understands that it is not always possible for the EU to seek an international solution to all regulatory issues, but we believe that additional efforts should be made to seek a global view on emerging issues that are not specific to the EU, and this is particularly relevant in the field of chemicals policy. The regulatory frameworks for endocrine disruptors, the combined effects of chemicals or nanomaterials should especially be the focus of extensive consultations by regulators on both sides of the Atlantic and beyond.

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*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 U.S. investment in Europe totaled €1.7 trillion in 2010 and directly supports more than 4.2 million jobs in Europe.*

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