AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

Improving REACH in 2018 and beyond

How to improve REACH authorization going forward?

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 more than €2 trillion in 2016, directly supports more than 4.5 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

American Chamber of Commerce to the European Union
Speaking for American business in Europe

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Streamlining the process leading to Authorisation

Based on their experience with Authorisation, from candidate listing to application, American Chamber of Commerce to the EU (AmCham EU) members agree that, to avoid a number of problems, the process leading substances to Annex 14 needs to be streamlined.

Full understanding of substance uses, substitutability and economic impacts should improve choice of most efficient regulatory tool to achieve environmental and health objectives.

REACH should only prioritise substances for Authorisation with a real impact on the environment and human health. Consequently, companies should report and share with authorities specific and socio-economic data at an earlier stage of the process. This information should be presented as early as at the informal Risk Management Option Analysis (RMOA) process, but no later than the consultations before the insertion into the Candidate List. This would allow a proper assessment of the best regulatory tool to manage environmental and health risks. This would make a focus on Authorisation for uses where substitution is cost-efficient and easier possible. Additionally, using other REACH procedures or sectoral legislation would be a better option for some non-RMOA assessed substances that have been added to the candidate list.

As some of these substances go through the Authorisation process, it may become apparent that their main use is as an intermediate, or that the number of uses concerned complicates the application process significantly. In other cases, Restriction and specific worker protection exposure limits could achieve the desired risk management, while allowing high-tech sectors to continue to use key substances in niche processes. As a result, it should be possible for substances to be delisted or deprioritised from the Candidate List, to allow for another appropriate risk management measure to be selected.

An interactive and inclusive process will ensure balanced and realistic Authorisation decisions and improve their practical implementation by industry

A Simplified Authorisation process is critical where the path toward substitution is very long or not environmentally efficient. The European Commission proposed to develop such a process for legacy spare parts and very low volume uses. We agree with this simplification focus, and argue that products using substances in relatively low volumes should benefit from such a procedure. This would apply to situations where substances are used as process chemicals, have no intended release during use or, as is the case of cobalt dichloride and boric acid, are used as essential trace elements (i.e. in biological fermentation processes).

Definitions for simplification proposals have been restrictive and other groups of substance uses could also need a simplified process. For example, a Simplified Authorisation process should also cover other critical uses of SVHCs, such as safety certified aerospace parts. A simplified approach could also be justified for repeat applications.

The current review periods recommended by RAC/SEAC are not proportional to the ease and cost-effectiveness of substitution. Short review periods are penalising upstream applications by default. Member States should review guidelines on how to justify longer review periods to better reflect upstream application needs. Review

periods should take into account, among others, patent timelines or return on investment for new manufacturing facilities.

Developing upstream applications acceptable to ECHA's Risk Assessment (RAC) and Socio Economic (SEAC) Committees requires more support and guidelines. Currently, ECHA expert committees require more detailed use-information from the whole supply chain than is currently proscribed by the guidelines. This sanctions upstream applications with short review periods which can be very damaging, especially in industries that require long review periods. For example, industries whose articles have very long lifetimes, and whose substitution processes are burdensome due to special certification procedures. In the case of aerospace, articles may need both safety certification and design approval from customers if any change to substances occurs. It is also important to note that industries with global and long supply chains are likely to use upstream applications for authorisation. ECHA would therefore find it difficult to manage the flow of individual downstream-user applications for every separate use in the chain. In some cases, an Authorisation needs to cover the whole supply chain, ideally with several possible suppliers to avoid single-supplier issues.

For proper understanding of supply chains and process specifics, industry calls for sectoral experts to assist RAC and SEAC when they are working on their recommendations for an application.

Consider Enforceability early on

Given the complexity of REACH, detailed guidance on how to enforce the different requirements of the regulation (e.g. Registration, Authorisation, Article 33, CLP) should be collaboratively developed. This will ensure uniform understanding and enforcement practices by the member states.

Enforcement practicability should already be considered at the RMOA stage, as a part of the decision making process to choose a process for impact on human health and the environment. Enforceability considerations may impact the regulatory path due to their mechanism and requirements.

An example of substances, where difficulties in implementation and enforcement are expected, are nonylphenol ethoxylates (NPE) and octylphenol ethoxylates (OPE). These have been placed on the Candidate List and then prioritised for Authorisation as the first entries onto Annex XIV, without specific identifiers, but rather as chemical groupings. Without the defined specific Chemical Abstracts Service (CAS) numbers, end users will struggle to determine those substances that meet the criteria of the listing, and would therefore require Article 33 compliance and subsequently Authorisation. Equally, enforcement authorities will have similar struggles when determining and putting into practice enforcement decisions.