AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

Making greater use of ECHA data and expert committees (SEAC, RAC) in the RoHS substance and exemption methodology

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 2018, directly supports more than 4.8 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

Avenue des Arts/Kunstlaan 53, 1000 Brussels, Belgium • **T** +32 2 513 68 92
info@amchameu.eu • amchameu.eu • European Transparency Register: 5265780509-97

Executive summary

Building on the European Commission's "One substance – One assessment" principle, there needs to be greater coherence between analysis, classification and risk management in different pieces of EU chemicals legislation. Discussions on hazard identification, assessment, classification, and general risk management of substances should be managed by horizontal legislation such as REACH and CLP and not under separate sectoral pieces of legislation. A single, authoritative determination of the hazardous properties of chemicals and substances could then be used across all EU legislation, and would be a source of effectiveness and efficiency.

Sectoral legislation, such as RoHS, should fully take into account existing assessments under REACH and CLP and be used to adequately manage any outstanding potential risks identified in specific sectors. These laws, are the regulatory tools most adapted to take into account sectoral specificities, proportionality and cost-efficiency analyses.

Introduction

Evaluation of substances for potential restriction or exemption under RoHS should be based on existing data, processes and guidelines generated under REACH and CLP, including risk and socio-economic evaluation methodologies, as well as existing assessments by ECHA's scientific committees, . We believe managing these processes affectively requires greater technical cooperation. This is not only the case among EU and national institutional actors, but also for the EU Commission and third countries who have introduced, or plan to introduce, RoHS-like legislation. A forum where all these actors could exchange, and coordinate is sorely needed.

The current RoHS Directive (2011/65/EU) does not openly require the Commission to take into account previous assessments conducted by ECHA's Risk Assessment Committee (RAC) and Socio-Economic Analysis Committee (SEAC) in the assessment of substances for RoHS restriction or exemptions, nor does it mandate the involvement of the two committees in these processes under RoHS. However, it does not exclude it either. AmCham EU members believe making use of ECHA's expertise should be considered, and thoroughly assessed in the upcoming RoHS revision (July 2021.)

We particularly recommend investigating how ECHA could help address the current shortcomings of the RoHS processes:

- **Sufficient resources must be allocated to assessing RoHS exemptions**. The current process takes far too long for any one exemption. If more substances are to be banned under RoHS, the volume of exemption applications will explode, and the process will become even more strained than it is now. The Commission should consider dedicating sufficient resources to the evaluation of RoHS exemption applications: it should assess whether more, internal or external, resources are needed to ensure exemption applications are evaluated in a timely manner.

- **Need for a thorough socio-economic assessment**: Since RoHS 2's entry into force, the Social Economic Assessment (SEA) has become a greater part of the exemption process. SEAs are particularly essential in choosing the right review period for each exemption granted. Yet, the resources needed to do this work effectively are lacking in the current RoHS structure. We believe the Commission should consider involving ECHA Committees – RAC for risk assessment and SEAC for socio-economic impacts, in this work, to make efficient use, and mutualise ECHA's expertise

- **Evaluation and prioritisation of substances under RoHS must take into account existing assessments and regulatory conclusions under REACH and CLP. This would be in line with the "One substance – One assessment principle" and would help avoid duplication and prevent inconsistent regulatory outcomes.** Current prioritisation criteria for substances under RoHS are based on a "tick the box" approach (e.g. whether or not substances are restricted under REACH Annex XVII). More resources should be spent to fully review the detailed outcomes of previous REACH and CLP assessments when deciding on prioritisation under RoHS, in particular where conclusions were made that no further risk management is necessary at the EU level.

Lessons learned from REACH authorizations: what could work for RoHS and what must be avoided

The REACH authorisation process, although burdensome, functions in a much more transparent and structured manner than the RoHS exemption process, whereas both processes, in essence, deal with the same things. The RoHS process could therefore be improved upon by learning from the most effective aspects of the REACH authorisation process, notably:

- Administrative & process reliability;
- Clarity about data required for an authorization/ exemption;
- Transparency around the role of third parties and public consultation;
- Clarity on how to frame the discussion on the availability of alternatives.

Administrative process reliability

- The REACH process publishes **clearly defined windows for applicants to make submissions.** The latter are sure that any submission within those windows will be treated in the 10 months set by the administration. This is a notable improvement on the **uncertainty inherent in the RoHS process.** There, windows are published, but not respected, and a response to an exemption request can take several years. Such arbitrary timelines are deadly for certain products and businesses. We therefore ask that the RoHS review streamlines the exemption application process by: Publishing clear submission windows 4 times per year;
- Guaranteeing that every application will be assessed on scientific and socio-economic grounds within 10 months;
- That exemption requests will receive a clear answer for adoption or rejection, and that review timelines will be aligned to those of REACH authorization of either four, seven or twelve years.

Clarity on what information needs to be submitted for an exemption

The REACH authorisation process requires that four clearly separate analyses/ sources of data be submitted to grant an authorisation. Under RoHS, documents are submitted haphazardly making good or weak arguments in

no particular order or logic. This lack of structure means the **process is highly unpredictable. According to the political considerations of the moment,** some exemptions will be subject to far greater scrutiny, whereas others will be adopted with ease. This means the RoHS exemption system currently leads to differences in the **legal treatment of different applications**.

The RoHS process could benefit from the REACH approach of requiring data on the following:

- **Chemical safety report** to outline the excessive risk, or not, following from the continued use of the substance.
- A **socio-economic analysis based on a cost-benefit analysis and life-cycle assessment** that:
    - Assigns a quantitative value to the 'excess risk;
    - Assigns a quantitative value to the benefits of the continued use;
    - Draws a conclusion on the two points above.
- An **analysis of alternatives** that shows:
    - Either that:
        - Alternatives are not available at all;
        - Alternatives are available for some, but not all the use which the applicant wishes to see covered by the exemption (need for further evaluation of technical and economical suitability for all uses);
        - Alternatives are generally available, but their use requires more time due to socio-economic and practical considerations (ex: manpower, product life, manufacturing specificities, timing associated with product testing…);
    - Insofar as substitution is possible – a **proposal for the substance's phase-out and substitution**.

Role of 3rd parties public consultation

Learning from the REACH experience, third parties should be allowed to contribute to the RoHS exemption process, but only with input on the availability of alternatives. At the moment, far too many submissions relate, not to alternatives in the case at hand, but to broad socioeconomic considerations. As third parties cannot be expected to know the applicant's use better than the applicant does, we feel they should not be allowed to comment where they do not have technical experience. At the moment, this 'out of scope input' does not help the exemption process, on the contrary, it polarises discussions and slows down the decision-making process.

Clarity on availability of alternatives (AoA) during the RoHS exemption process

As described above, the debate on alternatives should be clarified, and re-centered around concrete data needs. An AoA will not require the same evidence, or focus, in cases where substitution is truly, and technically impossible, as when it is only impractical. The exemption process should be able to differentiate, upfront, what is required of the AoA in cases where substitution is impractical, possible, but only on specific timelines, or downright impossible.

If substitution is feasible, applicants should provide a phase-out plan for the substance in a specific use and explain the advantages of granting the extra time for substitution. Such a commitment would also ensure that the exemption is granted with a view to substitution, rather than fall in a debate on whether it is opportune, or possible (now or later), to substitute a substance.