AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

Response to the stakeholder consultation on the draft RoHS substance methodology manual

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 2017, directly supports more than 4.7 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
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The American Chamber of Commerce to the European Union (AmCham EU) speaks for European companies of American parentage that invest in Europe and significantly contribute to European economic growth. AmCham EU is committed to a coherent and balanced approach to environmental legislation, based on sound science and the better regulation approach.

The RoHS Directive impacts a large number of US companies, especially in terms of product design, sourcing, supply chain management and market access. RoHS has become a global reference, with similar laws being introduced in more than 40 jurisdictions outside the European Economic Area (EEA). The development of a RoHS methodology for the identification and assessment of substances in view of potential restriction is absolutely critical. Such a methodology should create a predictable regulatory environment favouring investment and innovation.

AmCham EU has been an active participant in all stakeholder consultations and meetings of the expert group related to the preparation of the RoHS substance methodology. Having previously provided detailed and constructive comments and recommendations, AmCham EU is delighted to provide its comments to the draft methodology that has been proposed by the Oeko Institute.

Preliminary remarks

The RoHS substance methodology should build on the work that had already been carried out by the Commission expert group. The guidance documents and recommendations prepared in 2014 referred to key aspects of the methodology such as: data quality and data gaps in substance dossiers; assessment of substitutes; grouping of substances; interlinkage between restrictions and exemptions (Article 6 and Article 5); content of Member States restriction dossiers and process for the submission and assessment of restriction proposals. The work conducted then led to recommendations, and outstanding questions on the frequency of new restriction proposals and the transition period before new restrictions apply. AmCham EU has serious concerns that these recommendations have not been sufficiently taken into account by the proposed draft methodology.

The draft methodology includes details on substance identification, prioritisation, and the assessment process. However, it fails to address the frequency of substance restriction initiatives, define which institution/organisation will be in charge, and to provide greater clarity on the assessment processes that apply.

The questionnaire focuses primarily on data gathering and substance analysis and does not consult stakeholders on the actual methodology. Discussing substances and gathering data prior to defining the RoHS substance methodology is a premature exercise. AmCham EU will therefore provide comments and recommendations on the Oeko Institute draft methodology, and will not engage on the substance specific questions of the consultation.

Concerns relating to the general approach of this RoHS substance methodology

The scope of the Oeko Institute's RoHS methodology goes beyond the provisions of the 2011 RoHS Directive. The proposed approach of looking at substances used during the manufacturing process of EEE is based on a disproportionate notion of potential risk.

Risks during the manufacturing process should not be a focus for RoHS

The RoHS Directive's primary focus is on environmental and health impacts during use and/or waste management. The proposed methodology now seeks to also address risks that could arise during manufacturing of electronical and electronic equipment (EEE).

This goes beyond the objective and provisions of RoHS. Substances representing potential risks during the manufacturing process should be assessed under REACH, in view of potential inclusion in the Authorisation Annex XIV or Restriction Annex XVII, or under the Workers protection legislation (OSH).

Potential risk should not be used to justify restrictions under RoHS

According to Oeko Institute's methodology, the potential risk during the use or waste phase is enough to justify a RoHS restriction. Currently, RoHS restrictions are justified if the substance is classified with a hazard that could potentially result in risk, regardless of actual occurrence and risk management options. An approach focussed on potential risk is disproportionate and could result in RoHS introducing stricter restriction conditions than those required in the context of REACH. In fact, in the context of a REACH restriction, any proposal must first be based on a proven level of unacceptable risk.

Substance identification

The criteria proposed for the identification of substances to potentially be restricted are heavily based on hazard, and refer to other regulatory measures that will inevitably lead to overlaps and regulatory inconsistencies.

Substance listed in Annex VI CLP or fulfilling the criteria

Only substances with confirmed classification as result of the CLP process should be considered for RoHS. This means that substances undergoing REACH Evaluation or subject to the REACH CLP process should not be assessed before the REACH process has been finalised and a classification is confirmed.

AmCham EU does not support that substances fulfilling the criteria of CLP classification, but not yet classified, should be identified as potential substances for restriction under RoHS. The proposed methodology does not specify who will determine if a substance has fulfilled the criteria for hazardous classification, and what criteria will be used to determine whether the criteria have been met. This approach will lead to significant legal uncertainty, and risks creating a parallel to the CLP process.

Substances of very high concern (SVHC)

Substances are identified as SVHC candidates solely on the basis of their classification. Such an approach is not appropriate for the purpose of a RoHS restriction without first assessing the risk in EEE. There is a strong case for recommending that RoHS substances to be assessed should not be taken from the REACH SVHC list, Annex XIV, or Annex XVII, since the concerns related to these have already been addressed by the respective regulatory tools under REACH. The RoHS methodology should integrate the common understanding paper on the overlaps between REACH and RoHS to ensure consistency and avoid overlaps.

Persistent and Bioaccumalative (PB) classification

AmCham EU is concerned by the emphasis the draft methodology places on a 'so called' persistent and bioaccumulative (PB) classification. RoHS assessment should be aligned with official EU classification of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), and should not consider PB as a separate category.

Radioactive substances

Identifying radioactive substances as a priority for restriction under RoHS lacks coherence with existing legislation. EURATOM, for example, is not referenced in the methodology, even though it precedes the WEEE and RoHS Directives by more than a decade.

Substances suspected of hazardous properties

The draft RoHS substance methodology suggests that substances suspected of being hazardous could also qualify as candidates for restriction. It however fails to specify who is going to decide on the presence of this suspected hazard and what criteria and the process would be used to judge whether such a 'suspected status' has been met or not. Such an approach is unacceptable as it will lead to legal uncertainty.

While the concept of 'equivalent of concern' exists under the REACH SVHC identification process, it is justified by scientific data and subject to detailed assessment by the Member State Committee of ECHA.

Substances not present in EEE

The proposed methodology suggests that substances which are not present in EEE should be included in the inventory to avoid regrettable substitution. We believe it would be inappropriate, and inefficient, to consider a restriction of substances under RoHS that are not present in EEE. REACH is a much better suited regulatory tool to address concerns resulting from process chemicals than is RoHS. It is difficult to consider how the enforcement of such a RoHS restriction would be feasible under such circumstances.

Derivative of a hazardous nature

We are also concerned about the notion that the inventory could include process chemicals which may react during the manufacturing process, and as a result may form derivatives of a hazardous nature, which may occur in the final product. There is no specification of what level of concentration of such a derivate would trigger hazardous concern, and what the assessment process would be.

Additional comments and recommendations related to the RoHS methodology

Frequency of the restriction proposals

AmCham EU strongly recommends that notions regarding the frequency of substance restriction proposals under RoHS be addressed in the final version of the methodology.

Any additional substances restricted under RoHS will impact all EEE, and will trigger substantial work to identify needed exemptions, redesign products, and raising the necessary budget for compliance programs. There should be an alignment of the substance review, and the potential inclusion of new substances, with the review cycle of the RoHS Directive itself. The introduction of new restricted substances, could lead to premature obsolescence and force the withdrawal of products from the EU market. It is essential that a predictable review cycle is established, time set aside for study periods and default transition periods, in order to provide certainty and visibility for equipment manufacturers.

Criteria for determining the restriction timelines

RoHS does not define any timetable for the application of new restrictions. So far, this has been done on a case-by-case basis. As timescales may vary considerably, their revision should be part of the assessment of substances in view of RoHS restrictions. In the context of the four phthalates restriction in Commission delegated directive (EU) 2015/863 of 31 March 2015 the following timelines applied:

- 6 years after entry into force: medical devices, including in vitro medical devices, and monitoring and control instruments, including industrial monitoring and control instruments,
- 4 years after entry into force: all other EEE.

Following the opening of the scope to cover all EEEs, the differences between product categories increased even further, as the products have very different lifespans, reliability requirements, redesign cycles etc. To increase flexibility and make RoHS more relevant, it is essential to introduce more substantial differentiation in treatment for the different categories. To ensure effective and proportional implementation of any new restrictions, differences in the product categories must be recognised. In this respect, substance restrictions should be introduced with differentiated timelines that are adapted to each category.

Coherence with REACH SEA methodology

Regarding Oeko Institute's request to provide input for "the purpose of specifying an exhaustive list of socio-economic impacts", we recommend that the methodology leverages and references the substantive work documented by ECHA with respect to socioeconomic analysis. SEA under RoHS should follow the same methodology.

Substance assessment needs to be done by a scientific body

The proposed process of substance identification and assessment does not foresee scientific assessment, nor does it specify what body/ organisation would bear the responsibility for this assessment. Given the complexity of the analysis, and the very real economic impact associated with substance restrictions, AmCham EU strongly recommends that a scientific body should assist the Commission in the assessment of candidate substances.

Although RoHS does not prescribe the involvement of the Risk Analysis Committee (RAC) or the Socio-Economic Analysis Committee (SEAC) in the assessment of potential candidates for RoHS restriction, this option should be thoroughly considered. Such an analysis is absolutely essential in the elaboration of the RoHS methodology.

Recycling EEE

Given that the criteria stated in Article 6.1 (a) to (c) are focused on the protection of health and the environment during the preparation for WEEE processing, it is imperative that the methodology starts from an assessment of where restrictions are necessary. These considerations should be based on the technologies available to EU licensed WEEE operatives, available associated controls, and should take into account the nature of substances that are present in electronic waste. .

Substitution

AmCham EU strongly recommends that the guidance document on substitutes prepared by the RoHS expert group in 2014, is taken into account. Not only does this guidance detail the approach that should be taken to determine which are adequate substitutes, how the reliability of a substitute is determined, and the availability of suitable alternatives, it also considered how the evaluation of substitutes should feed into the review of the substance considered for restriction.

In the context of open scope, and the large range of reliability and technical requirements, substitutes for one category of products may not, and most likely will not, be a suitable alternative for another product category. If

suitable alternatives do not exist for certain categories, a provisional exclusion from the restriction scope should be foreseen, subject to review, to avoid unnecessary burdens of going through the exemption process.

Substance inventory

With regard to the inventory of substances of potential candidates for RoHS restriction, AmCham EU would like to stress that due to the impact of restrictions on industry, only a realistic number of proposals for restrictions should be considered at one time. In this context, a large working list of several hundred substances is wholly inappropriate. Such a list should be limited to the substances that are explicitly under consideration for identification and assessment.