AmCham EU comments on the RoHS methodology guidance

The importance of a predictable regulatory environment

Members of the American Chamber of Commerce to the European Union (AmCham EU) members are committed to a coherent and balanced approach to environmental legislation, based on sound science and the better regulation approach. We have participated actively in all stakeholder consultations and meetings related to the preparation of the RoHS substance methodology and provided our detailed and constructive comments and recommendations. The development of a RoHS methodology for identification and assessment of substances should create predictable regulatory environment favouring investment and innovation.

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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 US investment in Europe totalled €2 trillion in 2013 and directly supports more than 4.3 million jobs in Europe.

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POSITION PAPER

American Chamber of Commerce to the European Union (AmCham EU)
Avenue des Arts 53, B-1000 Brussels, Belgium
Register ID: 5265780509-97
Tel: +32 (0)2 513 68 92 | www.amchameu.eu

Secretariat Point of Contact: [Julie Linde Kjeldsen]; [jlk@amchameu.eu] +32 (0)2 289 10 15

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Introduction

The American Chamber of Commerce to the European Union (AmCham EU) speaks for European companies of American parentage that invest in Europe and contribute substantially to European economic growth. We promote and are 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 our members, especially in terms of product design, sourcing, supply chain management and market access. The development of a RoHS methodology for identification and assessment of substances in view of potential restriction is very important. This methodology should create predictable regulatory environment favouring investment and innovation.

We have participated actively in all stakeholder consultations and meetings related to the preparation of the RoHS substance methodology and provided our detailed and constructive comments and recommendations. Although some improvements were made, we are still very much concerned about some fundamental aspects of the methodology. We urge the Commission not to undertake substance identification and assessment before the methodology is finalised, accepted and supported by a large number of stakeholders, Member States and the Commission.

Criteria for the identification of candidates

We have several concerns about the criteria chosen for identification of substances, as there is no demonstrated correlation between the selected criteria and the potential risk related to the waste phase.

Substances of very high concern (SVHC)

The fact that a substance is identified as a substance of very high concern (SVHC) does not mean that it is used in electronics or electronic equipment (EEE), or that it poses a risk during the waste phase. The substances are included in the candidate list on the basis of their hazard properties, which is not sufficient for a restriction under RoHS, which should be risk, not hazard based, as implied by the criteria under article 6(1)a-d.

PB classification

We are also concerned about the persistent, bioaccumulative (PB) classification. Although the Dutch Institute for Public Health and the Environment (RIVM) has suggested it, this methodology has not been adopted at EU level and should not be considered authoritative. We suggest the RoHS assessment be aligned with the official EU classification of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), and not to consider PB as a separate category.

Nanomaterials

Prioritising nanomaterials is contradictory with the Commission view laid out in the Second Regulatory Review on Nanomaterials, which concluded that nanomaterials should be addressed under REACH, using the regulation's tried and tested substance-by-substance risk management approach.

Moreover, the reference to national nano registers as source of information is not appropriate. The main purpose of national nano-registries is to identify where nano materials are used. None of the existing registries use hazard or risk based criteria for registering these substances. Therefore the fact that a nano is registered does not imply risk associated to its use.

Prioritisation process

Need to apply the same prioritisation criteria

We are very concerned by the fact that despite of the comments made by several stakeholders, the methodology for the identification and assessment of substances for potential restriction under RoHS still suggests two different procedures. If the Commission makes the proposal, it should follow the methodology for identification of substances. If the proposal is made by a Member State, however, it will go straight to the second phase of pre-assessment and even third phase of detailed assessment. We request this approach be changed. Proposals by Member States should comply with the same methodology for substance identification that is required of the Commission to ensure an objective, equal and transparent approach to substance prioritisation. Member States should only propose substances for detailed assessment that have been identified and prioritised according to the RoHS methodology criteria.

Frequency

We would like to stress that any addition of substances under RoHS will impact all EEE, and will trigger substantial work for identifying needed exemptions, redesign of products, and finally investment in compliance programmes. The current experience with only six restricted substances proved how complex the compliance process is, and the number of exemption requests has certainly exceeded the authorities' expectations. Moreover, it will be a real challenge to deal with dynamic REACH and RoHS processes happening in parallel.

We strongly recommend aligning the substance review and the potential inclusion of new substances with the four-year review cycle of the RoHS Directive itself. The introduction of new restricted substances with a shorter delay could lead to premature obsolescence and forced withdrawal of products from the EU market. This is particularly true for product categories with long life times and infrequent redesign. It will be helpful to establish a predictable and periodic time frame for the review cycle, study periods, and default transition periods in order to provide planning certainty for equipment manufacturers.

Substance inventory

With regard to the inventory of substances as potential candidates for RoHS restriction, we would like to stress again that the RoHS substance scope should be reviewed periodically (every four years) and that only a realistic number of proposals for restrictions should be considered at once, due to the impact on industry. In this context, a large working list of several hundred or even 24 substances is inappropriate; the list should be limited to the substances that are explicitly under consideration for identification and assessment. It is extremely important to involve stakeholders, in a transparent and constructive way, from the beginning of the process, giving them the possibility to provide input and

comments on the substances identified for further assessment for potential restriction under RoHS. It is also extremely critical to explain the meaning of this list to avoid a 'black listing effect'.

Need for substance assessment to be done by a scientific body

Another major issue of concern is that the proposed process of identification and assessment of substances does not foresee scientific assessment and does not specify whose responsibility this should be. The substances identified in RoHS I were the result of an impact assessment done by the Commission. Prior to the RoHS recast, the Oeko Institute was commissioned to run a study. We understand that the Commission is responsible for the assessment of substances. However, given the complexity of the analysis and the important consequences of substance restrictions, we strongly recommend that a scientific body assist the Commission in the assessment of candidate substances. Stakeholders involvement could also be critical at that stage to ensure that appropriate data are available (e.g. information on alternatives or socio-economic data) in due time. The methodology should integrate this as a key step in the process.

Coherence between RoHS and REACH

AmCham EU welcomes the recognition of the need for coherence between REACH and RoHS. We are pleased that Austrian Environmental Agency recommends using all relevant information generated under REACH for the purposes of RoHS. It is also important that RoHS is recognised as a Risk Management Option (RMO) when assessing a potential SVHC following the European Commission Roadmap, and that the outcome of an RMO analysis conducted by a Member State or ECHA is taken into account in the RoHS process (e.g. action under RoHS should be delayed until the outcome of an RMO is published).

As per our previous submission, we strongly suggest that the information generated under REACH on substances, their classification, uses, exposure and best risk management measures, are fully taken into consideration in the context of RoHS.

To maximise the necessary synergies with REACH and make the best use of analysis already generated, we recommend that all relevant Risk Analysis Committee (RAC), Socio-Economic Analysis Committee (SEAC) opinions and the regulatory decision of the European Commission be taken into account.

The current regulatory context offers an ideal opportunity for real coordination between RoHS and REACH. The substances currently identified under RoHS to be of highest priority (DEHP, DBP, HBCDD) are also subject to authorisation. The applications for authorisation include uses in EEE and one of them focuses specifically on the end of life phase. This information is currently assessed by RAC and SEAC and opinions will be delivered in the coming months. We strongly recommend that the information generated in the context of the authorisation process under REACH and the Commission takes the analysis of RAC and SEAC into consideration before it takes a decision on these substances in the context of RoHS.

Detailed assessment of selected substances

As a matter of principle, we strongly believe that the assessment of specific substances should not be performed before the RoHS substance methodology has been finalised and agreed. Therefore, the assessment of the priority substances is premature. As stressed earlier, to avoid inconsistency and make efficient use of the analysis generated under REACH, RoHS assessment should take into consideration the information submitted in the context of the REACH authorisation procedure and the opinions of RAC and SEAC.

Overall, the current detailed assessment dossiers do not meet the standard of rigour expected by the scientific or regulatory communities. The occurrence of incomplete, unclear or simply erroneous data is not acceptable in documents that are intended to justify significant restrictions on a large industry, such as EEE. We recommend that these dossiers be brought into line with current best practices for peer-reviewed literature and that future dossiers be held to the same standard. Citations used need to be complete and up to date and should meet rigorous standards in the detailed assessments, as they would be applied in peer-review scientific literature.

We have several remarks related to the specific substance assessments:

- The sources of information used for evaluating the suitability of substance for identification under RoHS are rather limited (Danish EPA 2012, KEMI 2011, Oeko Institut 2008). We strongly recommend considering other relevant studies. Information generated by industry should be considered as an important source of information and industry should be involved in the process from the very beginning.

  The relevant regulatory developments under REACH are insufficiently taken into account. The report refers to the annex XV restriction proposal prepared by Denmark, but does not take into consideration the opinion of RAC rejecting the risk.

- **Justification of recommendations**: The supporting evidence for the recommendations is not as strong as it should be in some cases. This weakness is especially pronounced in the BBP dossier. For example, a basic requirement for any recommendation for a RoHS restriction should be that the substance is used within EEE. However, in the BBP dossier, chapter 2.2 explicitly states, '[BBP] usage in EEE has not been confirmed'. No evidence is presented to support the assertion that BBP is actually being used in EEE. Therefore all subsequent estimates of releases are questionable.

- If substances can be recommended for restriction through RoHS regardless of the likely presence in WEEE, it invites the restriction of large numbers of substances unrelated to WEEE, creating additional burden for all involved stakeholders, additional compliance costs for industry with no benefit to public health, and diverting attention from actual substances of concern within WEEE.

- **Data relevance, calculations and robustness**: Data sources should be up-to-date and the relevance of older data must be verified. Any inconsistency or error in the values cited or calculated can undermine the conclusions. In general, we recommend that the most current data be used. Original data for inputs needs to be provided whenever possible and when estimates are used, this must be explicitly stated, and their robustness must be assessed and justified. Cited values are incorrect in some cases within the dossiers, such as the food contact regulation for DBP and BBP in chapter 1.3.

- Older data are used in several places, sometimes even when more recent data are available, or in cases where it is not clear whether the cited data are still relevant. For example, the DBP exposure data used in chapter 6.1 of that dossier is based on a study from 1987, but DBP production is now only 15% of levels at that time. We recommend that the most current source data should be used at all times, and those sources should be properly referenced. The relevance of older data should also be validated and addressed explicitly.

- Another related data relevance issue is around the incorporation of periodically reported data, such as WEEE collection, composition, and treatment statistics, which may be needed for certain estimates and calculations. In chapter 5.2.2 of the DEHP dossier, WEEE data from a 2010 report are used instead of current 2013 data from Eurostat.

There were errors in calculations and certain calculations were not always explicit or clear. For example, the risk characterisation ratio for workplace scenario for DBP is calculated using No Observed, Adverse Effect Level (NOAE/L) rather than Derived No Effect Level (DNEL), rendering the conclusion for the risk to workers incorrect. Any inconsistency or error in the values cited or calculated can undermine the justification for a restriction.

- Estimation will be required in most dossiers; however, the estimations and their bases in these dossiers were inconsistent. For example, in each assessment, there is a calculation of the percent of substance relative to weight of EEE (chapter 2.3). The HBCDD dossier provides this calculation in footnote 30 on page 31, and the DEHP dossier provides a less precise calculation in chapter 2.3. The dossiers for DBP and BBP do not provide justification for this number, which made reviewing the supporting evidence in those dossiers more difficult.

- Another important aspect of creating robust estimations is that it is necessary to explicitly state assumptions. In these dossiers, the Targeted Risk Assessment tool was used to estimate exposure. When estimating exposure using the TRA tool, a fugacity must be selected and justified. We recommend explicitly selecting an appropriate fugacity for the exposure estimates using the TRA tool, and explaining or justifying the choice. Note that an explanation of the differences between 24a, 24b, and 24c can be found in the TRA file ecetoxTRAM.xls in the 'Descriptors' worksheet (Cells G239, G240, G241).

- Assumptions must not only be stated, but also supported and justified. The assumption for quantities in EEE for DBP and BBP is a multiplier of 10 in chapter 2.3, but that multiplier is never explained or justified in the dossier.

- **Socio-economic impact analysis**: The health and environmentally-based economic benefits of restrictions have not been calculated as required in the socio-economic impact analysis in chapter 9.4 (as required in section 5.12 in the methodology). Without these estimates, it is difficult to compare the costs and benefits of enacting a restriction through RoHS. Also, it was not validated whether the recommended maximum concentration levels would be sufficient to successfully achieve the human health and environmental benefits claimed in the socio-economic impact analysis. We recommend that the health and environmental economic benefits of potential restrictions be calculated, and that recommended restriction levels be validated as to whether they would be expected to achieve the desired benefits.