29 November 2013

AmCham EU's response to the Austrian Environmental Agency's consultation on the draft methodology manual for the identification and detailed assessment of substances for a potential restriction under RoHS 2

Introduction

The American Chamber of Commerce to the European Union (AmCham EU) welcomes the improvements made in the latest draft of the Austrian Environmental Agency's draft methodology manual for the identification and assessment of substances for a potential restriction under RoHS 2, such as the focus on waste criteria for prioritisation of substances.

We are, however, still concerned about some fundamental aspects of the methodology. We insist on the need to further explore the relations between REACH and RoHS to avoid inconsistency and overlaps. Regulatory decisions made in the context of REACH and covering electronics and electronic equipment (EEE), should be fully taken into consideration under RoHS to avoid a duplication of analysis and overlapping restrictions.

We urge the Austrian Environmental Agency and the Commission to work on improving the RoHS methodology. Applying RoHS methodology to substances should only be done after the first step of the project is finalised and the RoHS methodology is accepted and supported by a large number of stakeholders, Member States and the Commission. We welcome the intention of the Commission to form a working group to continue and finalise the work on the methodology. AmCham EU has been a constructive stakeholder contributing to the consultation process and we will be pleased to be part of the working group.

The relation between RoHS and REACH (chapter 2, page 8; chapter 5, page 33)

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.

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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, we recommend that all relevant Risk Analysis Committee (RAC), Socio-Economic Analysis Committee (SEAC) opinions and the regulatory decision of the European Commission are taken into account. Taking into consideration the information and analysis provided in the annex XV dossiers (chapter 5, p. 33) will not be sufficient because they may not necessarily lead to regulatory measures, e.g. if unacceptable risk is not proven in the case of restriction. Therefore we strongly recommend to take into account not only proposals (in the form of annex XV dossiers) but also the European Chemicals Agency committees' opinions and the final Commission decisions.

For example, the Austrian Agency uses extensively the information and analysis of annex XV prepared by Denmark in the context of their proposal to restrict the use of four phthalates in indoor equipment. The Austrian Agency does not, however, take into account the fact that this proposal has been rejected by RAC and SEAC, as the risk has not been proven.

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. In cases where RAC and SEAC have assessed or will assess the risk arising from substances relevant for RoHS, the Commission should take their conclusions into consideration.

The current regulatory context offers an ideal opportunity for real coordination between RoHS and REACH. The substances currently assessed under the draft RoHS methodology are also subject to authorisation. The applications for authorisation do include uses in EEE and one of them focuses specifically on the end of life phase. This information will be assessed by RAC and SEAC and opinions will be delivered next year. 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.

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Priority substances (chapter 3)

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.

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 substances is inappropriate; the list should be limited to the substances that are explicitly under consideration for identification and assessment. In our view 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.

Update information available from databases (chapter 3, page 16)

We would like to stress that the substances listed in the IEC 62474 Database include substances that are already covered by legislation, and any further prioritisation under RoHS will bring little additional value and will complicate the regulatory environment.

Table 1 - Criteria for the identification of candidates (chapter 3, page 18)

As per our previous submission, 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. The fact that a substance is identified as a substance of very high concern (SVHC) does not mean that it is used in EEE, or that it poses a risk during the waste phase. We are also concerned about the persistant, 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.

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Prioritisation of substances (chapter 4, page 21)

Regarding the four attributes considered for prioritisation, we believe that the production volume of the substance is irrelevant. A major part of the production could be exported outside EU and/or used in applications that are not EEE. The concern related to waste management should be given higher priority compared to the hazardous properties of the substance.

We would like to strongly emphasise that only substances that are found in EEE should be considered as RoHS relevant and should be subject to assessment.

We are surprised to see that a substantial work was done for the specific assessment of BBP, which concludes at the end that BBP use in EEE is not confirmed. The presence of the substance in EEE should be the starting point for identification and prioritisation, which will help increase the effectiveness of the work.

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 within scientific or regulatory communities. The occurrence of incomplete, unclear or simply erroneous data is not acceptable in documents of this importance, which are intended to inform and justify significant restrictions in 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 etc. 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.

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- 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 compliance costs for no benefit to public health, and diverting attention from actual substances of concern within WEEE.

- **Data relevance, calculations and robustness**: Data sources should be most 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 date 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.

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- 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 NOAE/L rather than 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 TRA 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.

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- **Burden shifting**: The alternatives assessment (section 8.1) does not address burden shifting between various hazard topics. Burden shifting occurs when adopting an alternative would result in an improvement in one hazard topic but worse performance in another. To avoid a regrettable substitution in which the alternative is worse for human health and the environment than the restricted substance, the detailed assessment needs to include a thorough evaluation of possible substitutes. At a minimum, burden shifting must be identified and addressed.

    - For example: triphenyl phosphate (TPP) is listed as an alternative for HBCDD. TPP has lower reproductive and developmental toxicity than HBCDD, but increased aquatic toxicity. Besides, TPP is not a direct alternative to HBCDD as it cannot be used in virgin HIPS, only in alloys (copolymers).

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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 €1.9 trillion in 2012 and directly supports more than 4.2 million jobs in Europe.

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