25 February 2013

AmCham EU response to the stakeholder consultation on the review of the 'List of Restricted Substances' under Directive 2011/65/EU (RoHS 2)

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.

We have been actively involved in the recast of the Restriction of Hazardous Substances Directive (RoHS) and we have contributed to the various studies and stakeholders' consultations since 2007. We will be interested in participating in the current consultation regarding RoHS substance review, however we would like to express our concerns related to the approach taken by the Austrian Environmental Agency:

- According to RoHS II, the mandate of the Commission should focus primarily on the preparation of a methodology to identify and assess substances, while the on-going consultation launched by the Austrian UBA focuses solely on identification of substances used in EEE;
- The reference to the http://www.subsport.eu cannot be considered as a solid science- based starting point for identifying substances in the context of RoHS;
- The potential overlap between REACH and RoHS have not been analysed; and
- The consultant does not provide any analysis of the regulatory measures taken in the context of REACH since the RoHS recast.

Developing a methodology to identify and assess substances in the context of RoHS is essential

The current consultation focuses only on the identification of hazardous substances with questions related to the presence of such substances in electronics and electronic equipment (EEE).

The main objective of the consultation should be the development of methodology, prior to any substance specific discussions. Targeting substances before establishing clear criteria for identification contradicts the provision of the RoHS directive (article 6) and prevents objective and science-based assessment.

We would like to stress that according to article 6(1), the review of the RoHS substances should be coherent with REACH Authorisation and Restriction.

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Furthermore, any proposals to review and amend the list of restricted substances should be based on scientific evidence, including information on adverse effects and exposure, in particular during waste EEE management operations (article 6[2]). This is also emphasised by recitals 10 and 16 of the RoHS II Directive:

> *The annexes to this Directive should be reviewed periodically to take into account, inter alia, Annexes XIV and XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency* (recital 10).
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> *To this end, the review and amendment of the list of restricted substances in Annex II should be coherent, maximise synergies with, and reflect the complementary nature of the work carried out under other Union legislation, and in particular under Regulation (EC) No 1907/2006 while ensuring the mutually independent operation of this Directive and that Regulation.* (recital 16).

In addition to that, it should be demonstrated that a restriction is the most appropriate measure. This requires analyses of the other possible risk management options that are or could be put in place.

The approach regarding the identification of substance is questionable

Substitution support portal

In its background document, the Austrian Environment Agency specifies that the information for hazardous substances is derived in particular from the substitution support portal (http://www.subsport.eu), 'which constitutes a state-of-the-art resource on safer alternatives to the use of hazardous chemicals and contains a database of hazardous substances, that are legally or voluntarily restricted or the subject of public debates'.

That substances are eligible for identification as substances of very high concern (SVHC) does not automatically make them candidates for restriction under RoHS. Substances should only be considered for restriction under RoHS after they have been fully assessed under the scientific procedures of the REACH Regulation.

In fact, the RoHS Directive is linked to the REACH Authorisation and Restriction procedures, not simply to SVHC status. The inclusion of substances in the Authorisation and Restriction annexes requires additional assessment. Under the Restriction procedure 'unacceptable risk' must be demonstrated, and socio-economic as well as risk management option analyses should be conducted to justify the restriction measure. Under Authorisation, candidates are prioritised according to their volume, their classification and dispersive use.

Moreover, the existence of substitutes, as suggested by the database, cannot be a solid argument for restriction under RoHS. The RoHS scope has been extended to cover all categories of EEE, from consumer goods to complex equipment with high reliability requirements and long lifetimes. Serious research is needed before concluding that a substitute for one application could be suitable for other applications. This is particularly relevant for products in sensitive

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categories (e.g. healthcare), and therefore an approach that takes a holistic view of the socio-economic impact of chemical substitution on different RoHS product categories is critical to any proposed methodology.

In accordance with article 6(2) of RoHS, the information on possible alternatives is not sufficient; their availability and reliability should be proven. The hazardous profile of substitutes should be also subject to assessment, as many of the suggested substances are equally classified, and in this case, the restriction will not prevent the use of harmful substances.

The Oeko Institute study

The study of the Oeko Institute has been suggested as one of the sources for the identification of substances. It is important to stress that the results of this study did not bring any substantial arguments to justify inclusion of new substances during the RoHS recast. In fact, the Commission Impact Assessment concludes that the preferred policy option should be not to change the substance scope because of the 'lack of sufficient scientific and market information to justify adding new substances'[1]. Therefore the results of this study should be carefully 're-investigated' as required by recital 10 of the RoHS Directive.

Further clarification of the relationship between REACH and RoHS is needed

The background document prepared by the Austrian Agency touches briefly upon the relationship between RoHS and REACH, and concludes that 'RoHS does not affect the application of REACH, and vice-versa'. A more serious analysis of this relationship is needed, as this is a critical component of the discussion on what methodology should be used in the context of RoHS.

The Austrian Environmental Agency should revisit the analyses and the conclusions of the report prepared by Milieu in March 2012, which recognises that 'potential double regulation could arise where a substance is listed in REACH Annex XIV, which would then require an authorisation to be obtained for specific uses of the substance, and at the same time restricted in the RoHS Directive, but with the possibility of an exemption for the same specific use'.[2]

This theoretical suggestion became a reality this year when the Swedish authorities proposed adding cadmium to the REACH candidate list for Authorisation. The substance may well be included in Annex XIV, while under RoHS, exemptions have been granted to use cadmium in different applications.

The study also suggests that these overlaps should be resolved with the built-in mechanism laid out in article 58(2) of REACH, which provides that uses or categories of uses may be exempted from authorisation requirements if the risk is properly controlled on the basis of the existing specific Community legislation, imposing minimum requirements relating to the protection of human health or the environment. We strongly suggest that this topic be further analysed and clarified in the current work on the RoHS methodology.

[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2008:2930:FIN:EN:PDF, p. 56
[2] Milieu Report, 2012, p 219

Analysis of the regulatory measures taken in the context of REACH since the RoHS recast

This analysis is explicitly required by the provisions of RoHS, however so far we see no indication that the latest decisions under REACH have been taken into consideration.

Although certain substances were identified as priorities for assessment under RoHS at the time of the adoption of the recast, some of these – e.g. phthalates — have already been subjected to risk management measures, such as additions to the REACH Authorisation annex. The ECHA Risk Assessment Committee recently assessed the possible risks from use of four low molecule weight phthalates in a wide range of articles, including EEE or components thereof. In its opinion of 15 June 2012, the RAC concluded that there is no risk, leading to the decision not to introduce the restrictions proposed by Denmark in the framework of REACH. These regulatory decisions under REACH Authorisation and Restriction should be taken into consideration and should become part of the process and the methodology under RoHS.

Our membership represents a large spectrum of industry sectors, which have all made significant investments to comply with both RoHS and REACH, and will do so in the future. We therefore have a keen interest in ensuring that the application of the RoHS and REACH processes avoids duplication and overlaps and are based on sound science.

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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 U.S. investment in Europe totaled €1.7 trillion in 2010 and directly supports more than 4.2 million jobs in Europe.

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