AmCham EU's response to the second stakeholder consultation on RoHS II

CONSULTATION RESPONSE

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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 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.

The need for a RoHS –specific methodology

In the context of recent regulatory developments, in particular in the framework of REACH, it is legitimate to question the need for maintaining RoHS. The co-existence of the two legal instruments creates a complex regulatory environment with different obligations regarding substances used in the production process and/or incorporated in electric and electronic equipment (EEE). We disagree with the conclusion of the Austrian Environmental Agency that there is no overlap between RoHS and REACH, as REACH 'generally regulates substances', while RoHS is a sector specific directive. REACH introduces very specific requirements that impact EEE in the same way RoHS does. We strongly recommend that the Austrian Environmental Agency makes a detailed analysis of the overlaps between REACH and RoHS, using the recent REACH review report by the Commission.

Although the coexistence of the two pieces of legislation is a great challenge for our members, we are of the opinion that RoHS has its place in the EU regulatory landscape:

- The RoHS model, regarding scope, exclusions and exemptions, addresses industry specific needs for the continued use of a substance. This is particularly important for EEE, where new technologies and applications are constantly developed.
- Both industry and national authorities have invested in developing RoHS compliance programmes and enforcement practices that have been largely accepted across Europe. The CE marking and an EN standard developed under RoHS are very helpful in reducing red tape and avoiding different requirements in every MS.
- RoHS has now become a global legislation standard, with similar versions introduced in 40 jurisdictions outside the EU, including important markets such as China and India.

To maximise the necessary synergies with REACH, we strongly suggest that the information generated under REACH on substances, their classification, uses, exposure, are fully taken into consideration in the context of RoHS.

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One should also take into account regulatory decisions and practices that were developed under REACH and other regulatory instruments since the recast of RoHS II took place. Risk assessment and socio-economic analysis performed in the context of restriction decisions under REACH should be taken into consideration under RoHS, when these cover uses in EEE.

As RoHS should focus mainly on risks arising in the end of life phase, we welcome the development of these specific criteria for the review and amendment of RoHS Annex II:

- Possible impact during WEEE management operations, including substandard practices;
- Possible release of substances into the environment that could give rise to hazardous residues; and
- Possible exposure to waste industry workers.

These criteria should be further refined and elaborated. As listed, they focus essentially on EEE processing plants. WEEE goes through several steps once it is collected (collection facility, transport, treatment, recycling) and these other steps should be taken into consideration.

The RoHS Directive requires assessing substitutes or alternative technologies with less negative impacts. We want to stress that it is critical to assess the economic availability of substitutes and other socio-economic impacts.

Procedure for identification and assessment of substances

The Directive foresees the introduction of new substances by delegated acts. The past experience with comitology has shown that it is not a transparent process allowing stakeholders to contribute input. It is questionable if this is the most appropriate and most science-based procedure for RoHS.

Right of initiative

According to the proposed methodology, the Commission, or a Member State, can propose substances for restriction under RoHS. In addition, it is indicated that if the proposal is made by the Commission, it should follow the methodology for identification of candidate list substances, while if the proposal is made by a Member State, it will go straight to the second phase of pre-assessment.[1]

We see several issues with this approach: the initiative of both Commission and Member States make the system very similar to REACH and could lead to a large number of proposals. In the context of REACH, many of the proposals made for authorisation or restriction of substances were very much driven by Member States' specific national priorities and considerations. The proposals by Member States in the context of RoHS should follow the same process and comply with the methodology for the identification of substances that is

[1] 'Study for the Review of the List of Restricted Substances under RoHS2', p. 13

required for the Commission. This will ensure an objective and transparent approach regarding substance prioritisation.

Frequency

The Austrian Agency does not make any suggestions regarding the frequency of proposals. 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. 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. Given the RoHS Directive allows for more than one substance to be added to Annex 2 by a delegated act, if this occurs, it should happen in one batch, with the necessary transition (minimum of 2 years) period per substance. This is in line with the need for predictability and effective supply chain management and

Assessment 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, Oeko Institute was commissioned to run a study. Given the important consequences of substance restrictions, we strongly recommend that the assessment of the candidate substances should be made by a scientific body. The methodology should integrate this as a key step in the process.

In the context of the REACH restriction procedure, scientific and socio-economic analyses of the substances are run for substances for which restriction is proposed. These are performed by the European Chemical Agency's (ECHA) Committee for Risk Assessment (RAC) and Committee for Socio-Economic Analysis (SEAC). This process includes several consultations with stakeholders, and allows for industry representation during RAC and SEAC discussions. The finding and work by ECHA committees should be used as well when assessing substances used in EEE. If a restriction proposed under REACH is broadly formulated and covers uses in EEE, RAC and SEAC will make a detailed assessment of the risk, the substitutes and the socio-economic impacts, which will also cover EEE. If ECHA concludes that there are no grounds for restriction in EEE, no further actions should be taken under REACH and no

restrictions should be envisaged under RoHS. If ECHA concludes that a restriction including in EEE should be introduced, this may trigger a RoHS specific assessment taking into account waste criteria.

Data sources for substance identification

We are concerned that the substance identification approach selected by the Austrian Environment Agency is too broad and very much focused on hazard classification. It uses a mixture of official classification lists and purely voluntary listings. Moreover, the screening method used is questionable as it is based on a purely quantitative analysis, the relevance of the substance being approximated from the frequency of referencing.

- The source lists should be authoritative lists based on comprehensive expert review by recognised authoritative bodies. Screen lists developed using less comprehensive review, or compiled by an organisation that is not considered authoritative, or developed using exclusively estimated data, should not be used for RoHS substance identification purposes
- The criteria and methodology regarding substance identification should take into consideration the need for predictability. EEE manufacturers face great challenges regarding product design as the choice and the availability of materials has been substantially limited with the recent listing of substances under different REACH procedures (Restrictions, SVHC, Authorisation) and other sector specific legislation. Clear indication about the criteria and the priorities will be very important as it will create more logical and predictable environment.
- As mentioned in our previous submission, the use of substitution databases is questionable. Substitutes are not necessarily suitable for all EEE applications especially in the context of an open RoHS scope. Moreover, the substitutes should be assessed for their technical and economic availability, which is very much an application specific assessment. Most importantly, the prioritisation of substances under RoHS should be based on risk identification and not on the existence of substitutes.
- Using the SVHC list is not appropriate for the purposes of RoHS. The substances are included in the candidate list on the basis of their hazard properties (CMR, PBT, vPvB or equivalent concern), which is not sufficient for a restriction under RoHS, which should be risk, not hazard, based, as the criteria under Art. 6(1) a-d imply.
- Voluntary restrictions and company or NGOs specific listings cannot be a valid source for substance identification. Other than purely risk driven, other reasons (market requirements, etc.) could be important drivers for inclusion of certain substances in the lists.

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- Endocrine disruptors: The Commission is working on identification criteria at the moment. This means any identification of substances for RoHS restriction will be premature before these criteria are finalised.
- Nanomaterials: We are concerned that the Austrian Environmental Agency is targeting nanomaterials specifically as substances to be examined under the RoHS substance review. This approach is contradictory with the Commission view laid out in the Second Regulatory Review on Nanomaterials[2], which concludes that nanomaterials should be addressed under REACH, using the regulation's tried and tested substance-by-substance risk management approach.
- Proposing to assess the nanoform of all substances that may be found in the waste phase under RoHS creates a climate where hazard considerations outweigh scientific risk assessment. This trend is very worrisome for industry, particularly in the field of nanomaterials, where much R&D is ongoing and a stable regulatory framework is needed. REACH should be the framework where the risk assessment of substances in the nano form takes place. In addition, AmCham EU members share the Commission view that 'current knowledge about nanomaterials does not suggest risks which would require information about all products in which nanomaterials are used'. The proposal by the Austrian UBA to assess the nano form of substances as a class for restriction in the substance review of a sectoral legislation such as RoHS is therefore also at odds with the ongoing Commission impact assessment to firsty identify if an information gap on nanomaterials exists. The Commission approach will guarantee that the potential needs for information are properly defined, and that the most cost-effective policy measures are implemented while taking into account the proportionality principle.

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[2] COM(2012) 572), http://ec.europa.eu/nanotechnology/pdf/second_regulatory_review_on_nanomaterials_-_com(2012)_572.pdf