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REVISING THE RoHS SUBSTANCE METHODOLOGY: ESTABLISHING A COMMON RoHS-REACH METHODOLOGY FOR A MUTUALLY REINFORCING, COHERENT AND CONSISTENT IMPLEMENTATION OF REACH AND RoHS

[Orgalime](#), representing Europe's Technology Industries, including European manufacturers of electrical and electronic equipment (EEE), **thanks the Öko-Institut for the opportunity to comment** on the [draft of the revised manual methodology](#) for identification and assessment of substances for inclusion in the list of restricted substances (Annex II) under the RoHS 2 Directive 2011/65/EU prepared in the framework of the Study to support the review of the list of restricted substances and to assess a new exemption request under RoHS (RoHS Pack 15).

We reiterate our **support to the objective of the RoHS Directive** laying down rules on the restriction of the use of hazardous substances in EEE with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE.

We welcome the re-evaluation of the methodology for identification and assessment of substances for inclusion in the list of RoHS restricted substances (Annex II) as published in 2013 by the Austrian Umweltbundesamt (AUBA 2013) considering its serious shortcomings. The present AUBA methodology indeed does not provide a reliable and comprehensible basis for the future revisions of Annex II of the RoHS Directive.

For a proper implementation of both RoHS and REACH, a thorough substance identification and evaluation methodology is a prerogative. Any new substance restriction under RoHS, and any other legislation on chemicals must be based on a robust, science-based and consistent substance evaluation methodology.

We are seriously concerned that the current [draft of the revised manual methodology](#) could result in a revised **RoHS standalone methodology widely decoupled from the existing REACH methodology**. For example, on page 13 the draft states that *“Article 6 particularly requires coherence with chemical legislation and REACH. Moreover, the Directive in its Article 2(3) sets the obligation to observe Union legislation on safety and health as well as waste management. There is however, neither a legal mandate nor an obligation to copy the procedure of substance restriction developed under REACH nor to involve ECHA and its scientific committees (RAC, SEAC) in the assessment process of substances under RoHS. Coherence is interpreted to mean that amendments of Annex II shall not result in contradictions, duplication and uncertainties between RoHS and other chemical legislation and in particular between RoHS and REACH. The*

Orgalime representing the European Technology Industries speaks for 45 trade federations of the mechanical, electrical, electronic, metalworking & metal technology industries of 23 European countries. The industry employs nearly 11 million people in the EU and in 2017 accounted for some €2,000 billion of output. The industry represents over a quarter of the output of manufactured products and over a third of the manufactured exports of the European Union.

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relation between these two legislations has been established and published in the document “REACH and Directive 2011/65/EU (RoHS) - A Common Understanding” (COM 2014). This document provides guidance for various scenarios in which substances are regulated under these legislations in various ways. A summary of the considerations and action courses to be taken during an assessment of a substance for restriction under RoHS, in cases where regulation already exists under REACH is provided in Table I.”

In our view, this approach does not suffice for a proper implementation of Article 6.1 of the RoHS Directive and its explicit requirement of ensuring coherence. We have the following recommendations for ensuring a truly complementary, coherent and consistent implementation of the horizontal REACH Regulation (EC) No 1907/2006 and the product specific RoHS Directive 2011/65/EU:

- We believe that the best way is striving for a **holistic, common methodology between REACH and RoHS**. Whenever a substance is assessed - whether under REACH or RoHS - there should be only one common methodology. The implementation of the REACH Regulation and RoHS methodology should lead to this one holistic and commonly accepted scientific and technical evaluation per substance that should be valid for implementation under both legal acts in application of the [REACH and RoHS common understanding](#).
- **The main source and primary vehicle for gathering information about substances, including for the further implementation of RoHS, should be the REACH Regulation.** The RoHS methodology for determining the hazardousness of substances should rely on the existing REACH methodology to identify substances with hazardous properties. The RoHS methodology shall be based for example on the following main “REACH lists of substances”:
 1. Candidate List of substances of very high concern
 2. Information gathered in the context of Annex XV dossiers for the identification of substances of very high concern
 3. Substances restricted in articles listed in Annex XVII

The implementation of Article 6.1 of RoHS “shall be in coherence with REACH” should in our view mean at least:

- RAC and SEAC opinions to be taken into account, or where not yet existing, to be sought for any substance restriction under either RoHS or REACH
- Proper implementation of ECHA Guidance R.18, and its results to be taken into account under RoHS
- (Additional) results REACH evaluation process, notably for substance aspects in waste phase, to be sought and taken into account
- The RoHS methodology shall specify the information needed for proper RoHS implementation – this information shall be gathered via REACH
- Objective: **one common scientific conclusion per substance**, which will be relevant for RoHS and REACH implementation according to the [Common Understanding](#)

The RoHS review/amendment proposal for a substance restriction according to Article 6.2 of RoHS should in our opinion contain the minimum information requirements of Article 6.2 RoHS and the missing elements of an Annex XV REACH dossier:

- A Member State’s RoHS proposal should equal an annex Annex XV REACH dossier
- Risk Management Options should be included (as part of preparation process of the dossier)
- The Commission document “[REACH and Directive 2011/65/EU \(RoHS\) - A Common Understanding](#)” (COM 2014) must be applied systematically. Its added value could be further increased by including in an updated version other risk management measures such as Waste Incineration, Industrial Emissions or WEEE Directives.

More information about the **RoHS-REACH consistency and complementarity** is available in the Annex of this document with the two flowcharts about the RoHS-REACH consistency from the RoHS perspective and from the REACH perspective.

We have the following **additional comments**:

- Regarding the **Figure 1-1 workflow of identifying substances** used in EEE with a potential negative impact during use, and/or on or during waste management (on page 21 of the [draft revised manual methodology](#)), we believe that **the prioritization of substances should indeed tackle RoHS specific priorities and in particular focus first on the main substances that really hinder good quality recycling of EEE and the transition towards a circular economy**. This is why we suggest that the methodology will **first** address the main substances/ substance groups that are on the REACH Candidate List and are used in EEE, which are of concern during use and/or during WEEE management (proposed Step P I-3b) **before** creating/updating the very large inventory of hazardous substances (proposed Step P I-1 in the workflow. Furthermore, as there is already the list of 21 priority substances in EEE identified by the Austrian Umweltbundesamt in the past, we do not see the need to repeat this identification step.
- We note in the summary of the [draft of the revised manual methodology](#) that “*the draft is based on a revision of the manual published in 2013 by the Austrian UBA*” (page 7). **The revised methodology should not be based only on a revision of the manual published in 2013 by the Austrian UBA but also take into account the documents produced by the Commission's Expert Group** accompanying future substance reviews under the RoHS Directive 2011/65/EU **and other inputs received from stakeholders** to update the methodology, as mentioned in the “Specific terms of reference” for the study. The [summary](#) from the Öko-Institut of the 27.03.2018 meeting of the [Commission expert group](#) accompanying future substance reviews under Directive 2011/65/EU (Restriction of certain Hazardous Substances in electrical and electronic equipment; Recast Directive (RoHS 2)) states on page 2 that “*some of the suggestions made for the study included to take into consideration the previous work of the Substance Working Group (SWG). Prior activities of the Substance Working Group were mentioned and it was discussed how these could be taken into consideration in the tasks at hand. The Substance Working Group meetings took place between 2013-2016. A number of sub-groups were nominated during this period and documents discussing the various opinions of the group members in relation to thematic areas of relevance to substance review and restriction were prepared on: Dealing with data quality and data gaps; Substitution; Member State submissions; Grouping of substitutes, Aspects related to restrictions, Article 5 and Article 6.*”
- Related to the extract on to the **Waste Framework Directive** in the section about the coherence with other legislation required in Article 6 (page 13 of the [draft revised manual methodology](#)) we would like to highlight that the final wording - which is securing the functioning of the internal market - of the Waste Framework [Directive](#) (EU) 2018/851 states in its Article 9.1(i) that “*Member States shall take measures to prevent waste generation. Those measures shall, at least promote the reduction of the content of hazardous substances in materials and products, without prejudice to harmonised legal requirements concerning those materials and products laid down at Union level...*” In this context, **for a mutually reinforcing implementation of RoHS and the Waste Framework Directive, a proper implementation of WEEE treatment standards will be critical**. We support the Commission to implement Article 8.5 of the WEEE Directive and adopt implementing acts laying down minimum quality WEEE treatment standards based on the existing WEEE treatment standards developed by European standardization organisations. This is particularly important also in the light of the discussions about the setting up of the new ECHA waste database for which recyclers have recently stated that they will not adjust their treatment processes for waste streams subject to sector specific obligations, such as WEEE, since specific treatment requirements exist (please see EURIC position paper of September 2018 [here](#)).

ANNEX: FLOWCHARTS ON THE CONSISTENCY BETWEEN RoHS AND REACH

Flowchart 1:

Consistency RoHS-REACH from the perspective of RoHS

Step 1: RoHS review/amendment proposal for a substance restriction (Art. 6.2 RoHS2)

- To contain the minimum information requirements of Article 6.2 RoHS and missing elements of an Annex XV REACH dossier:
- A Member State's RoHS proposal should equal an Annex XV REACH dossier
- Risk Management Options to be included (as of preparation process of the dossier)
- The Commission document "REACH and Directive 2011/65/EU (RoHS) - A Common Understanding" (COM 2014) must be applied systematically. Its added value could be further increased by including in an updated version other risk management measures such as Waste Incineration, Industrial Emissions or WEEE Directives

Step 2: Preparatory Substance Assessment (Methodology art. 6.1 RoHS2)

- Implementation of Article 6.1 RoHS2 "shall be in coherence with REACH", shall mean at least:
- RAC and SEAC opinions to be taken into account, or where not yet existing, to be sought for any substance restriction under either RoHS or REACH
- Proper implementation of ECHA Guidance R.18, and its results to be taken into account under RoHS
- (Additional) results REACH evaluation process, notably for substance aspects in waste phase, to be sought and taken into account
- The RoHS2 methodology shall specify the information needed for proper RoHS implementation - this information shall be gathered via REACH
- Objective: **one common scientific conclusions per substance**, which will be relevant for RoHS and REACH implementation

Step 3: Stakeholder Consultation

- Minimum 8 weeks and announcement and results to be made available publically

Step 4: Commission decision

- On the basis of Commission document "REACH and Directive 2011/65/EU (RoHS) - A Common Understanding" (COM 2014) - what procedure in what case - whereby:
- In case of an existing RoHS restriction - RoHS as *lex specialis* sets relevant restriction (no REACH authorisation for RoHS scope in application of Article 58.2 REACH)
- In case of setting a new restriction - either in RoHS2 (if case specific) or REACH Annex XVII (but not twice for the same equipment); no REACH authorisation process
- Where RoHS grants an exemption, no REACH authorisation should become necessary in application of Article 58.2 REACH
- Sufficient timelines for industry to ensure compliance with any new restriction

Flowchart 2:

Consistency RoHS-REACH from the perspective of REACH

Step 1: Registration

- Registration dossiers (Chemical Safety Reports, Exposure Scenarios) to properly implement ECHA Guidance R.18, and its results to be taken into account under RoHS2
- The RoHS Article 6 Methodology shall specify, which information would be needed to ensure a proper RoHS implementation; this information should be generated via REACH
- Objective: **One common scientific conclusion per substance**, which will be relevant for REACH and RoHS implementation

Step 2: Evaluation

- Where data and information gaps should exist (especially on substance aspects in the waste phase, including on the information required by Article 6 of RoHS methodology), these should be filled by REACH, including during evaluation process
- Objective: **one common scientific conclusions per substance**, which will be relevant for RoHS and REACH implementation

Step 3: Authorisation

- Annex XV dossiers (and their preparation) to include Risk Management Options
- The Commission document "REACH and Directive 2011/65/EU (RoHS) - A Common Understanding" (COM 2014) must be applied systematically. Its added value could be further increased by including in an updated version other risk management measures such as Waste Incineration, Industrial Emissions or WEEE Directives
- Where RoHS grants an exemption, Article 58.2 REACH shall be applied
- Prior to setting any authorisation requirement, the opinions of RAC and SEAC need to be sought

Step 4: Restriction

- Annex XV dossiers to include Risk Management Options
- On the basis of Commission document "REACH and Directive 2011/65/EU (RoHS) - A Common Understanding" (COM 2014) - what procedure in what case - whereby:
- In case of an existing RoHS restriction - RoHS as *lex specialis* sets relevant restriction (no REACH authorisation to apply following Article 58.2 REACH; no new REACH restriction to be set for Electrical and Electronic Equipment)
- In case of setting a new restriction - either in RoHS (if case specific) or in REACH Annex XVII (but not twice);
- Where RoHS grants an exemption, Article 58.2 REACH shall be applied
- Prior to setting any restriction, under RoHS or REACH, the opinions of RAC and SEAC need to be sought
- Sufficient timelines for industry to ensure compliance with any new restriction