ORGALIME

The Director General

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RoHS2: Study for the Review of the List of Restricted Substances Consultation on the draft methodology manual

Dear Mrs Karigl,

Thank you for the possibility to provide comments on the draft methodology manual, which we substantiate in the "*Excel sheet commenting table*" annexed to this letter.

Orgalime welcomes a number of important modifications brought to the draft methodology manual in comparison to the draft first interim report, such as the inclusion of certain references to the ECHA Guidance documents, improved wording regarding nanomaterials and certain terminologies such as "candidate substances". We also welcome the clarification given at the stakeholder meeting to work on the basis of a working list that would not be publically available.

However, we regret seeing that our core concerns which we consider vital for ensuring a workable future substance restriction process have not been addressed in the draft methodology manual, notably for ensuring that the methodology properly implements articles 1 and 6 of the RoHS Directive.

Regarding the requirement of article 6.1 that RoHS "shall be coherent with" the REACH Regulation, we uphold our earlier general requests:

- The implementation of the REACH Regulation and RoHS methodology should lead to one holistic and commonly accepted scientific and technical evaluation per substance that should be valid under both legal acts.
- The REACH Regulation should be the primary vehicle to gather information on substances.
- The RoHS methodology should specify what information needs to be gathered for a proper implementation of the RoHS Directive.

In practical terms, we kindly request you to take into account the following comments:

- Member States' RoHS restriction proposals should not be required to be made in parallel to REACH Annex XV dossiers.
- (Long and short) RoHS candidate lists should not be drawn up in parallel to the REACH candidate list that currently encompasses some 138 substances. The 4 priority substances referred to in RoHS Recital 10 are already included on both the REACH candidate list and the REACH Annex XIV list of substances subject to authorisation. International developments, such as the Stockholm Convention on Persistent Organic Pollutants, which voted for a global ban of HBCDD, should be taken into account.

- The RoHS restriction process needs to be sufficiently risk-based.
- The RoHS restriction process needs to take into account all relevant life cycle stages: Article 1 of the RoHS Directive spells out that "*This Directive lays 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, <u>including</u> the environmentally sound recovery and disposal of waste EEE*". Therefore, RoHS follows life cycle thinking, including the waste phase however, not the environmentally sound recovery and disposal of waste EEE **<u>alone</u>**. This fundamental aspect needs to be reflected in the draft methodology manual.
- The opinions of the REACH Risk Assessment and Socioeconomic Committees need to be sought and taken into account for the implementation of both legal acts, RoHS and REACH.
- The identification of the criteria that shall apply for identifying a candidate substance and the relevant information requirements for proposals for reviewing/amending annex II should already form part of such a methodology. We therefore support that the methodology should provide for common principles in this respect, especially in the case of article 6.2 RoHS.
- Proposals by Member States for additional substance restrictions and the periodical assessment by the European commission should follow all the steps of the methodology. In case of article 6.2 RoHS, the methodology should clarify the procedure and criteria upon which the Commission would check a Member State's proposal.
- The definition of "hazardous substances" is harmonised at EU level via article 3 of the CLP Regulation. This should be the starting point for the substance identification process. In general, any definition used in the methodology should be taken from the relevant pieces of EU chemicals legislation, in particular from the REACH and CLP Regulations (e.g. hazardous according to the CLP, PBT, vPvB or of equivalent concern as defined under REACH, nanomaterials according to the Commission Recommendation of 18 October 2011 and endocrine disruptors can only be referred to once the Commission adopts its proposal).
- Reassessment of previously assessed substances or new substances should only occur in case of new solid scientific evidence to ensure legal certainty and predictability.
- The currently applicable legal regime, such as workers' protection legislation, Industrial Emissions Directive (IED), Water Framework Directive or EU waste legislation needs to be taken into consideration in the methodology, especially for the identification of the proper risk management measure.
- Stakeholder consultation needs to be foreseen throughout the assessment and the procedure to adopt additional restrictions.

A copy of this letter has been sent to the European Commission.

We thank you in advance for your consideration and remain at your disposal for any further information that you and your team may require.

Yours sincerely,

Adrian Harris
(signed electronically)