ORGALIME

The Director General

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RoHS2: Study for the Review of the List of Restricted Substances - Consultation on the draft RoHS Annex2 Dossiers for HBCDD, DEHP, BBP and DBP

Dear Mrs Karigl,

Orgalime thanks you for the possibility to provide comments on the draft RoHS Annex II Dossiers for HBCDD, DEHP, BBP and DBP and welcomes the extension of the consultation deadline.

While we acknowledge that there was considerable time pressure for both developing your draft methodology and evaluating the four substances under this new methodology, the recent stakeholder meeting of 28 October 2013 has confirmed that there is no consensus amongst regulators and stakeholders on the draft substance evaluation methodology in its present form. Orgalime also considers the present draft methodology is insufficiently mature to provide a reliable and comprehensible basis for the future revisions of annex II of the RoHS2 Directive.

Orgalime regrets to see the insufficiencies of the UBA draft substance methodology clearly mirrored in the detailed assessment reports on the four substances, which we specify in the annex to this letter. This is particularly true for the suggested assessment that, despite the explicit requirement of article 6 RoHS, remains insufficiently coherent with REACH.

A recent judgment of the European Court of Justice concerning a REACH restriction on the use of cadmium pigments in plastic materials confirms that before tightening substance bans, a thorough assessment is required.[1] In the light of this judgement, we see the need for a substantial redraft of the draft methodology in its present form to satisfy the Court's requirements, especially for an inclusive evaluation with sufficient evidence base in its evaluation of the risks of an envisaged substance restriction.

We thank you in advance for taking these comments into account and remain available for any further information that you or your team may wish to obtain.

Yours sincerely,
Adrian Harris (signed electronically)

ANNEX

Cc:
DG Environment: Mr Garcia Burgues, Mr Hansen, Mrs De Avila, Mr Langendorff, Mr Eberl
DG Enterprise: Mrs Rogalska, Mr Berend, Mr Girao, Mrs Ekroth-Manssila, Mrs Stefanescu, Mrs Luvarra, Mr Forsyth, Mr Buhagiar

[1] EU General Court judgment in case T-456/11

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ANNEX: INSUFFICIENCIES OF THE DETAILED ASSESSMENT REPORTS ON THE FOUR SUBSTANCES FOLLOWING THE DRAFT UBA SUBSTANCE EVALUATION METHODOLOGY

Orgalime does not object to any new substance restrictions per se; however, new restrictions need to be scientifically evaluated and assessed on the basis of a mature, comprehensive, consistent and reliable methodology before they are introduced.

Ensuring that any shift to alternatives provides better performance in environmental, health and worker and consumer safety terms is, in our view, an essential element of such a reliable methodology.

Setting new restrictions bears unforeseeable risks and negative consequences, especially at the level of product reliability and safety. In particular considering the enlarged scope of RoHS following the recast, new restrictions bring with them specific risks to companies manufacturing long-lasting infrastructure and building technology.

Where it is technically feasible, companies are already taking a proactive approach today in shifting to what they see as reliable alternatives and they are communicating this to regulators. However, such individual approaches for specific applications are different from setting legally binding new restrictions for the vast variety of different product categories covered by the RoHS Directive.

During the RoHS recast, the EP's own impact assessment, including in its revised form of May 2010, confirms that there is no evidence today that the phase-outs for PVC and associated plasticisers or halogenated flame retardants, would outweigh the costs related to such restrictions.

Notwithstanding certain progress made, none of these elements is in our view satisfactorily addressed in the draft UBA methodology in its present form and the subsequent detailed assessment reports on the four substances HBCDD, DEHP, BBP or DBP.
We substantiate the insufficiencies of the UBA detailed assessment reports as follows:

1. **The substance reports are based on numerous assumptions and estimates that are difficult to understand and misleading**

Instead of providing evidence of risk and evidence of uses and the significance of these uses, with the four substance reports are primarily based on estimates and assumptions that are somewhat incomprehensible. The calculations used to provide the exposure levels and thereby to make assumptions on the risk are not validated by any measurement. Besides, the report lacks reliable data or very limited data on the quantity of these four substances that are actually present in EEE. As a consequence, the conclusions drawn and recommendations made are hardly supported by the findings of the assessment, which appear too uncertain and unjustified.

Figures on DBP are quoted from the Danish Environmental Protection Agency (DEPA) for its usage in EEE in the EU. There is no analysis and evidence given over what volumes would actually constitute a risk. Instead, a large range between 50 and 500 tons per year is given as an estimate which we believe is not sufficiently accurate to provide a reliable assessment of the substance as results can be very far-ranging and diverse.

Figures on DEHP are quoted from the Danish Environmental Protection Agency (DEPA) report of 2009, which are themselves based on estimates. Nonetheless, the use of DEHP in the Nordic countries has dropped substantially from 2009 to 2011. Therefore, the figures from Denmark cannot be properly used for the detailed assessment, as there must have been some errors in the reporting. In Norway, Sweden and Finland the use has significantly dropped as a minimum to 25% of the consumption in 2009. For example, the total consumption of DEHP for the use "Softeners for plastic, rubber, paint and adhesive" has dropped from 1025 tons in 2009 to 348 tons in 2011 in Sweden. Again, there is no analysis and evidence given over what volume would actually constitute a risk.

A number of assumptions are made concerning the treatment of cables. For example, it is assumed that not all treatment facilities would be equipped with efficient dust prevention techniques. This is one of the main routes of emissions being considered and the implementation of the methodology should not rely on an assumption. We remind that RoHS is not the vehicle to combat illegal waste management practices (see section 2 of this paper).

The DEHP report, "Section 5.1.2, Monitoring of human exposure at WEEE waste managing plants", presents exposure data from Chinese workers, which showed a higher risk to those workers and to the environment around the plant. As was pointed out at the stakeholder meeting, such data from non-EU facilities are not necessarily relevant for the EU. The report should recognise this dissonance and that the value of the Chinese data lies solely to inform the risk from substandard treatment of DEHP, but does not represent the actual situation in the EU (unless further EU-specific data is available which would support such a conclusion). We again remind UBA and regulators that RoHS is not the vehicle to combat illegal waste management practices (see point 2).

Finally, the recent judgement of the European General Court[2] concerning a REACH restriction on the use of cadmium pigments in plastic materials confirms that, before tightening substance bans, a thorough assessment is required. On 14 November 2013 the General Court explicitly mentions in a ruling that: "the file does not show that the Commission evaluated all the relevant factors and circumstances" and that "by concluding, on the basis of the scientific evidence mentioned {…}, that there was a risk to human health or the environment which needed to be addressed on a European Union-wide basis, the Commission therefore committed a manifest error of assessment." What we would like to show with this case is that in order to recommend a restriction on any substances, the European Commission must provide an inclusive evaluation with sufficient evidence base in its evaluation of the risks. Considering article 6 RoHS that requires that RoHS implementation "shall be coherent with REACH", we ask to strive for a RoHS implementation methodology that qualifies in the light of the given Court ruling.

2. Inappropriate management of risks already adequately covered by European legislation

The assessments are still building on the concept that RoHS would be the instrument to combat illegal waste shipments and waste treatment processes. However, the Commission has made the explicit statement, at the previous stakeholder meeting and in Mr Potočnik's letter to the EEB[3] that: "*RoHS is not the appropriate legal instrument to fight illegal waste treatment in the EU and abroad, this problem is addressed inter alia in the revised WEEE Directive as well as in a recent Commission proposal to reinforce inspections in the context of the EU Waste Shipment Regulation."*

Indeed, for the assessment of DBP, 41% of WEEE is estimated to be exported and then dumped or improperly treated. Apart from the question on where this figure comes from, RoHS is not the appropriate risk management option. Moreover, the recommendation for the DBP and DEHP restrictions refer to the condition of insufficient dust removal during WEEE recycling. Again, RoHS is not the appropriate RMO. This is rather an issue of WEEE treatment standards.

These issues are related to the EU's waste regulation and its proper enforcement/market surveillance (for example the Waste Shipment Regulation, Waste Incineration Directive, Waste Directive, WEEE Directive, and Industrial Emissions Directive). Such aspects cannot in our view be addressed under RoHS and should not be considered for the detailed assessment of the current four substances, nor for the assessment of future substances.

[2] EU General Court judgment in case T-456/11
[3] Commissioner Potočnik's letter of 28 August 2013 to the EEB.

Assessment of alternatives

The assessment of alternatives is (too) brief and incomplete, in terms of demonstrating that the alternative will indeed bring an environmental benefit. Alternatives have only been considered for the three phthalates, while many other alternatives with less negative properties have been left aside. For the case of DBP, the identified alternatives have lower toxicity, but the risk posed by DBP has been estimated at practically zero.

Moreover, no life cycle perspective has been taken, neither for the evaluation of the substances nor for the assessment of their alternatives. This is, however, important to avoid a transfer of environmental concerns from one life cycle stage to another. This is also the key for providing consistency with the REACH Regulation. Orgalime suggests a specific stakeholder consultation on alternatives and their socio-economic impact should be built into the methodology implementation process before the stage of conclusion of the final draft report.

3. Socio-economic impact

The basis of the total costs to industry, consumers and waste treatment facilities remains unclear to us. Substitution generally constitutes a complicated and costly exercise and would beforehand require solid data to underpin this option.

4. Weight of evidence

The process of weighting of evidence is not documented and not comprehensible to EEE manufacturers. While Orgalime acknowledges that the RoHS Directive refers to the precautionary principle, we would like to recall that: "*the quality and consistency of the data shall be given appropriate weight. It shall be documented and justified in a clear transparent manner*"[4]. Orgalime seriously questions such an approach, since for the four substance reports the assessment is based on the worst case scenarios. Besides, the level of inaccuracy of the data should be also mentioned and weighted accordingly in the most transparent manner as well as subject to stakeholder consultation, giving sufficient time for stakeholders to comment.

5. Definition of "hazardous substances"

Orgalime would like to reiterate its concern that the definition of "hazardous substances" for the substance identification should explicitly refer to the EU-wide and harmonised accepted definition of "hazardous substance" according to Article 3 of the CLP regulation (instead of Annex VI of the CLP only). Indeed, if the definition in RoHS were supposed to be different, we believe that the RoHS Directive would have had to spell this out explicitly in its legal text.

6. Commission Working Group and future guidance document

Orgalime welcomes the Commission's intention to establish a working group to accompany the continuing process of reviewing Annex II RoHS2. Orgalime remains available to proactively contribute to the discussion to help shape a comprehensible and reliable substance evaluation methodology and implementation in the future.

Similarly, we see with great interest the development of a guidance document which should bring further insight into essential missing elements of the methodology. Among other, the following questions should in our view be answered:

- How and how often will the periodical review be undertaken?
- Who and how will the process run in case a Member State initiates the process?
- How to make assumptions, how to document them and how to use references?
- Who/which scientific body will do the risk assessment and how will it be done, especially taking into account article 6 RoHS?
- By whom and how will a peer review be carried out?
- Is there a completeness check?
- Is there an experienced scientific committee of experts installed for assessing a dossier?

[4] UBA draft methodology section on "weight of evidence", page 9.

- Is there a check for overlaps and conflicts with other restriction and authorisation processes?
- Is there a link with other relevant Committees?
- Is a RoHS restriction indeed the most appropriate means of regulating the use of a substance in EEE?
- Is there a public consultation foreseen and will Industry, NGOs and other stakeholders be involved?

To conclude, Orgalime industries see the necessity to seriously rework the draft RoHS methodology in its present form.

EEE manufacturers need a robust and reliable methodology for the future assessment of substances clearly BEYOND the four substances that are in the focus today, which properly implements the requirement of article 6 for coherence with REACH.

Our concern is therefore of fundamental nature: considering the application of the currently proposed assessment on a wider scale and the large number of assumptions that it makes, it appears that the current process would conclude that it is necessary to restrict any substance with hazardous properties rather than adopting a risk-based approach. This is clearly unacceptable.

A mature methodology is needed instead, which can reliably differentiate between substances, which present a real risk, including at the waste management and recycling phase, and those which do not and/or whose risks are therefore better managed solely under other European legislation.

This would in our view also be the proper way forward in the light of the ECJ ruling on case T-456/11of 14.11.2013.