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Dear Sir, Dear Madam,

I am writing to you on behalf of EBFRIIP – the European Brominated Flame Retardant Industry Panel - in the context of the ongoing Öko Institut consultation regarding substances to be potentially added to the RoHS Directive.

We understand that the tender issued by the European Commission requested the Öko Institut to identify potential new substances based on “*whether the substance would be regarded as a substance of very high concern in the sense of REACH*”. The criteria that would therefore be taken into account are: CMR, PBT, vPvB. The Öko Institut added endocrine disruptors as another criterion. The flame retardant Tetrabromobisphenol-A (TBBPA), which is for the moment included in your draft high priority list, does not meet any of the criteria outlined above.

We believe that TBBPA should not be added to the revision of the RoHS Directive as the EU has just finalised an 8-year Risk Assessment (Existing Substances Regulation 793/93), with more than 200 studies reviewed to evaluate its effects on human health and the environment, which did not foresee any legislative restriction. TBBPA is therefore approved for use by the EU for all its applications and it will subsequently go through pre-registration under REACH.

The health part of the EU Risk Assessment concluded that TBBPA presents no risk to human health. It also concluded no risk with regards to endocrine disruption effects. In addition, EBFRIIP has been contributing to further studies under an EU project entitled FIRE (Flame retardants Integrated Risk Assessment for Endocrine effects) set up by the European Union Research Cluster on endocrine disruption (CREDO), which has analysed the potential for endocrine disruption effects for many substances, including TBBPA. The final results of this project have not been published yet.

The EU Risk Assessment has also concluded that there is no risk to the environment when TBBPA is used as a reactive component in the production of printed circuits boards. When reacted, TBBPA is integrated into the polymer of printed circuit boards and therefore it does not exist as a free chemical anymore in the product life cycle. TBBPA is compatible with end of life scenarios as defined by EU regulations.

TBBPA is not found widely spread in the environment. Monitoring studies indicate that TBBPA is only found at low levels, or not detected at all in the environment. A product stewardship programme -VECAP- is being implemented in Europe. VECAP sets new standards on chemicals management in the workplace, helps better understand supply chain processes

and creates awareness on substances management. 100% of additive users of TBBPA in Europe have committed to VECAP.

For the additive use of TBBPA in E&E plastics casings, a low environmental risk was identified under the environmental risk assessment report in one production plant in Europe only. After reviewing all possible EU legislative measures in the context of the Risk Reduction Strategy EU Member States concluded that the Integrated Pollution Prevention Control system (IPPC) was the most effective and proportionate measure to address the risk identified.

Task 1 of the Commission's tender outlines that substances classified in Annex I of Directive 67/548 but which do not meet the criteria for CMR, PBT or vPvB should be included in an inventory of substances used in E&E. This would be the case for TBBPA which is classified R50/53 under Directive 67/548 but it does not meet any of the other above mentioned criteria.

Furthermore, the Öko Institut has included in the draft high priority list a number of other Brominated Flame Retardants (BFRs) simply on the grounds that their use in E&E equipment or in other consumer products is "intensively discussed" (see Table 2). We object to this criterion as it is discriminatory and not based on science. Some of the BFRs listed are not even used in E&E equipment (some are wood preservatives and some are used in foams).

The list of BFRs is based on the JIG list, which was put together for declaration purposes only and was not meant for regulatory purposes. We currently request this table 2 list of BFRs to be removed completely from your priority list as it is targeted without specifying whether they meet the criteria set out by the Commission for a priority substance.

Finally, we would like to draw your attention to another BFR, HBCD. Although it is included in your priority list for being classified as a PBT, the other criteria mentioned in your interim report are not accurate, as HBCD is not classified as R33 or R64. We request you to rectify these references.

Yours sincerely,



Veronique Steukers – Chair

Detailed information

1. TBBPA

TBBPA has been approved by an EU Risk Assessment and it has no restrictions to its marketing and use

- An EU Risk Assessment concluded in 2005 that TBBPA presents no risk to human health. This report included a part on endocrine disruption and identified no risk.
- It has also concluded that there is no risk to the environment when TBBPA is used as a reactive component in the production of epoxy resins for printed circuits boards for E&E appliances.
- For the additive use of TBBPA in E&E plastics casings, a low environmental risk was identified in one production plant in Europe only.
- After reviewing all possible EU legislative measures, the rapporteur and the Commission recommended controlling this risk under the Integrate Pollution Prevention Control (IPPC) as the most effective and proportionate measure to address the risk identified.
- TBBPA is therefore approved for use by the EU for all its applications and it will subsequently go through REACH pre-registration.

TBBPA is an in-depth tested flame retardant with a large volume of scientific data available

- The EU has just finalised an 8-year Risk Assessment (Reg 793/93) followed by a Risk Reduction Strategy and a SCHER review, to evaluate the effects of TBBPA on human health and the environment
- The EU Risk Assessment and Risk Reduction Strategy did not foresee any legislative restriction on the continued use of TBBPA in E&E.
- Over 200 studies have been produced in the context of the Risk Assessment
- TBBPA has been used for more than 40 years by the industry and its proven performance makes it a trusted basis for future innovative electronic products.

TBBPA does not meet any of the criteria for the Öko priority substances list.

- In the tender sent to the Öko Institut the European Commission specified the criteria to identify high priority substances. These criteria are: CMR, PBT, vPvB and endocrine disruptors.
- The recently finalised EU Risk Assessment of TBBPA confirms that TBBPA does not meet any of the above criteria.
- Furthermore, in its reactive use, TBBPA is integrated into the polymer of printed circuit boards and therefore it does not exist as such anymore in the product life cycle.
- TBBPA is compatible with end of life scenarios as defined by EU regulations.

TBBPA should only be listed under the inventory of substances (indicated in Task 1 of the Commission's tender)

- Task 1 of the Commission's tender outlines that substances classified in Annex I of Directive 67/548 (Classification & Labeling Directive) but which do not meet the criteria for CMR, PBT, vPvB or endocrine disruptors should be included in an inventory of substances used in E&E
- TBBPA will be classified R50/53 under Directive 67/548 but it does not meet any of the other criteria above mentioned.
- When TBBPA is reacted into printed circuit boards it does no longer exist as such as it forms part of the polymeric backbone of the resin. Therefore the R50/53 classification does not apply anymore in that case.
- In addition, EU Member States, in the context of the Risk Reduction Strategy, concluded that restricting TBBPA under EU legislation would be disproportionate.

Potential alternative substances should be as well tested as TBBPA

- Based on TBBPA Risk Assessment conclusions, there is no need to switch to other chemicals than TBBPA.
- However, to be considered potential substitutes to TBBPA, other flame retardants should be subject to the same or similar scientific review process. They should also be able to demonstrate that their impact on the environment and health is lower than TBBPA.
- Suitable alternatives should be as cost-effective as TBBPA
- Alternatives should also be compatible with end of life scenarios as defined by EU regulations

2. All other BFRs listed in Table 2

Listing of all other BFRs by Öko Institut is not based on science

- The Öko Institute has included in the draft high priority list a number of other BFRs whose use in E&E equipment or in other consumer products is "intensively discussed".
- This criterion is discriminatory and not based on science.
- Some of the BFRs listed are not even used in E&E equipment (some are wood preservatives others are used in foams & in construction, or are not used any longer).
- The Öko Institut has not indicated any criteria to justify the addition of all the BFRs to the priority list.
- These BFRs do not actually meet the criteria set by the Öko Institut for priority substances.
- The list is based on the JIG list, which is a voluntary list intended for declaration purposes only. This list should not be used for regulatory purposes. It is not a black list.
- Consequently Table 2 listing these BFRs should be removed completely and the references to it in the priority list should be deleted accordingly.

3. HBCD

HBCD is classified PBT, but the other criteria mentioned by Öko Institut are not accurate

- HBCD is included in the Öko draft priority list for being classified as a PBT
- However, HBCD is not classified as R33 nor R64.
- We request you to rectify this reference.