



1 May 2014

Dear Sir/Madam,

I am writing to you on behalf of the member companies of the Bromine Science and Environmental Forum (BSEF) who manufacture brominated flame retardants including four specified in the draft Danish EPA [strategy for brominated flame retardants](#): Decabromodiphenyl ethane (CAS N°: 84852-53-9), Decabromodiphenyl ether (CAS N°: 1163-19-5), Hexabromocyclododecane (CAS N°: 25637-99-4) and Tetrabromobisphenol A (CAS N°: 79-94-7). We would like to take this opportunity to submit comments to the consultation on the draft [strategy](#), as developed on the basis of the review of LOUS substances.

First, we would draw your attention to an important error on page 7 where, contrary to LOUS report and the extensive data available, it is implied that TBBPA could meet the PBT criteria. Based on the LOUS report, which correctly states that TBBPA does not meet the PBT criteria (p. 13)¹, and an 8-year EU Risk Assessment², which concluded that TBBPA is persistent, but that it does not meet the criteria for bioaccumulation and toxicity, we would urge rapid correction of the relevant sentence on page 7.

Second, the Danish EPA notes concerns for a potential risk of TBBPA on the basis of endocrine activity and that this should be further looked into in the context of REACH substance Evaluation. BSEF member companies support the REACH processes but would like to take this opportunity to stress that:

- TBBPA was placed on the market following extensive toxicological, behavioural and environmental testing, including long term reproductive studies conducted in line with GLP (good laboratory practice). Results confirming the absence of endocrine disrupting properties of TBBPA as defined by the WHO definition for endocrine disruptors³ have been reported in studies by both international and EU agencies^{4 5}.
- According to the 8-year EU Risk Assessment, TBBPA has no significant endocrine potential. Specifically, it was concluded that “the weight of evidence from [existing] studies indicates that TBBPA has no significant oestrogenic potential”.
- Following the publication of the EU Risk Assessment, an independent review of additional new data on TBBPA⁶ was conducted by Professor Wolfgang Dekant (former member of the EU Scientific Committee on Health and Environmental Risks) which confirmed the EU Risk Assessment conclusion including oestrogenic potential.
- A 2013 literature review on TBBPA prepared by Thomas Colnot, Sam Kacew and Wolfgang Dekant concluded that TBBPA does not produce “adverse effects that might be considered to be related to

¹ The Danish LOUS Survey of brominated flame retardants can be found here: <http://www2.mst.dk/Udgiv/publications/2014/01/978-87-93026-90-2.pdf>

² TBBPA risk assessment publication can be found at: <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:152:0011:0020:EN:PDF>

³ According to the WHO definition, an endocrine disruptor is “an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or sub-populations”. The WHO definition is the most widely accepted definition and used in scientific literature.

⁴ Scientific Opinion on Tetrabromobisphenol A (TBBPA) and its derivatives in food (2011) available at: <http://www.efsa.europa.eu/en/efsajournal/doc/2477.pdf>

⁵ WHO report, “Endocrine disruptors and child health: Possible developmental early effects of endocrine disruptors on child health”, 2012 http://apps.who.int/iris/bitstream/10665/75342/1/9789241503761_eng.pdf

⁶ Risk assessment of TBBPA: Updating the EU Risk Assessment Reports, Wolfgang Dekant, Dr., http://www.ebfrp.org/uploads/Press/documents/TBBPA%20review%2012042010_Dekan%20Report.pdf, 2010

disturbances in the endocrine system". Therefore, in accordance with internationally accepted definitions, TBBPA should not be considered an endocrine disruptor⁷.

Finally, regarding the report's point (page 16) on a potential restriction for regulating all brominated flame retardants under the Directive for the Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS), BSEF member companies would like to note that the emerging RoHS methodology for considering substances supports an evaluation of substances on an individual basis in line with REACH principles and practice.

We hope the above provides some useful information with respect to the outcome of the LOUS review. We remain at your disposal for any further questions you may have on the science behind flame retardants and would be happy to set up a meeting to discuss any of those points in greater detail.

Yours Sincerely,



Robert Campbell
Chairman of BSEF

⁷ "Mammalian toxicology and human exposures to the flame retardant 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (TBBPA): implications for risk assessment" can be accessed here: <https://www.readbyqxd.com/read/24352537/mammalian-toxicology-and-human-exposures-to-the-flame-retardant-2-2-6-6-tetrabromo-4-4-isopropylidenediphenol-tbbpa-implications-for-risk-assessment>