

Examples of Regulatory Determinations Demonstrating That Specific Organohalogen Flame Retardants Do Not Present a Risk

The following are specific examples of where an expert body has determined that the use of specific organohalogen flame retardant does not present a significant health hazard. In evaluating these examples and other expert body evaluations regarding the potential hazards of a chemical, it is critical to distinguish between studies that describe a chemical's hazard properties and more comprehensive assessments that incorporate exposure to evaluate the potential for any risk to human health or the environment. Consideration of both hazard and actual exposure to understand risk is a fundamental tenant of effective chemical management as recognized by the FHSA.

These examples of formal risk assessments by recognized national authorities reinforce our view that the Petition should be denied on its merits.

The Canadian Environmental Protection Act requires the Minister of the Environment and the Minister of Health to conduct screening assessments of substances of potential concern to determine whether they present or may present a risk to the environment or to human health.¹ Following an extensive review of available hazard and exposure data for TBBPA, TBBPA bis(allyl ether), and TBBPA bis(2-hydroxyethyl ether), they concluded that the three substances

- *“[A]re not entering the environment in quantities or concentrations or under conditions that constitute or may constitute a danger in Canada to human life or health . . .”² and*
- *“[A]re not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.”³*

In 2006, the ECB published a risk of assessment of TBBPA.⁴ The analysis examined multiple endpoints—acute toxicity, irritation, corrosivity, sensitization, repeated dose toxicity, mutagenicity, carcinogenicity, and reproductive toxicity—from inhalation, ingestion, dermal exposure routes. The Bureau's conclusions were as follows:

¹ Government of Canada. 1999. Canadian Environmental Protection Act, 1999 (S.C. 1999, c. 33). Available at URL: <http://laws-lois.justice.gc.ca/eng/acts/C-15.31/index.html>. Accessed Jan. 16, 2016.

² Environment Canada and Health Canada. 2013. Screening Assessment Report Phenol, 4,4'-(1-methylethylidene) bis[2,6-dibromo-, Ethanol,2,2' [(1-methylethylidene)bis[(2,6-dibromo-4,1-phenylene)oxy]]bis, Benzene, 1,1'-(1-methylethylidene)bis[3,5-dibromo-4-(2-propenyloxy)-, Available at: http://ec.gc.ca/ece-ees/BEE093E4-8387-4790-A9CD-C753B3E5BFAD/FSAR_TBBPA_EN.pdf. Page 6.

³ *Id.* at 43.

⁴ European Chemicals Bureau. 2006. European Union Risk Assessment Report. 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (tetrabromobisphenol-A or TBBP-A) Part II – human health, Available at URL: <http://echa.europa.eu/documents/10162/32b000fe-b4fe-4828-b3d3-93c24c1cdd51>.

- Regarding human health, “No health effects of concern have been identified for TBBPA.”⁵
- Regarding workers, “No health effects of concern to adults have been identified.” Furthermore, “There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.”⁶ This conclusion applied “in relation to all endpoints and for all exposure scenarios.”⁷
- Regarding consumer exposure, “consumer exposure is negligible” and the findings were identical to those for workers for all endpoints.⁸

In 2011, the European Commission directed EFSA’s CONTAM Panel to deliver a scientific opinion on potential risks from TBBPA and its derivatives in food. The panel produced a comprehensive aggregate assessment that also included consideration of exposure to breast-fed infants with average or high milk consumption, as well as exposure to TBBPA in dust in homes, classrooms, and cars. They concluded that:

- For consumers of fish and consumers of cow’s milk (i.e., infants and small children), the margin of exposure (MOE) in the worst case exposure scenarios was several orders of magnitude below the default margin of exposure (100), “indicating that current dietary exposure to TBBPA for these population groups in the EU does not raise a health concern.”⁹
- More generally, given the extremely low levels of TBBPA in food (below the level of quantification), “it is unlikely that current dietary exposure of the general population to TBBPA raises a health concern.”¹⁰
- Regarding breast-fed infants, “Exposure of breast-fed infants to TBBPA via human milk also shows very high MOEs . . . and therefore does not raise a health concern.”¹¹
- And finally, “combined exposure to TBBPA from food and dust, particularly for children, is unlikely to raise a health concern.”¹²

The European Chemicals Bureau’s (ECB) 2008 assessment of Tris (1-chloro-2-propyl) phosphate (TCPP) examined multiple endpoints—acute toxicity, irritation, corrosivity, sensitization, repeated dose toxicity, mutagenicity, carcinogenicity, and reproductive toxicity—from inhalation, ingestion, dermal exposure routes. For TCPP, ECB found:

- Regarding risk to the environment, “There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being

⁵ *Id.* at VI.

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ CONTAM (European Food Safety Authority Panel on Contaminants in the Food Chain). 2011. Scientific Opinion on Tetrabromobisphenol A (TBBPA) and its derivatives in food. EFSA Journal 9(12):2477. Page 54.

¹⁰ *Id.* at 4.

¹¹ *Id.* at 55.

¹² *Id.*

applied already.”¹³ The study also noted that TCPP meets neither the bioaccumulation nor toxicity criteria for persistent, bioaccumulative, and toxic (PBT) designation.

- *ECB made the same conclusion with respect to potential risk to workers, consumers, humans exposed via the environment. The conclusion held even when ECB combined consumer and environmental exposures.¹⁴*

¹³ European Chemicals Bureau. 2008. European Union Risk Assessment Report Tris(2-chloro-1-methyl ethyl) phosphate (TCPP). Page 8. Available at: http://echa.europa.eu/documents/10162/6434698/orats_summary_tris2-chloro-1-methylethylphos_en.pdf (accessed Jan. 7, 2016).

¹⁴ *Id.* at 14.