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VIA Electronic Mail  
USEPA, CBIC  
Room 6428  
Washington, DC 20004

**RE: Docket No. EPA-HQ-OPPT-2008-0319**

Dear Sir/Madam:

The Brominated Flame Retardants Panel (BFRIP)<sup>1</sup> of the American Chemistry Council is pleased to submit the following comments on the *Supporting Documents for Initial Risk-Based Prioritization of High Production Volume Chemicals for Hexabromocyclododecane (HBCD; CAS# 3194-55-6 and 25637-99-4)*.<sup>2</sup> Comments are provided on Section 2, Physical-Chemical Properties and Environmental Fate; Section 3, Hazard Characterization; Section 4, Exposure Characterization; and Section 5, Risk Characterization. The Panel encourages EPA to consider these comments in prioritizing and identifying any data needs for this chemical. Our key concerns include the following:

- HBCD is degradable and is not persistent when tested at environmentally relevant concentrations.
- In assessing potential for developmental neurotoxicity, EPA should consider the *Ema et al.* 2007 study.
- In assessing worker exposure characterizations, EPA should evaluate existing industrial hygiene practices prior to assuming that worker exposures are taking place via inhalation and dermal contact.
- In evaluating exposure to the public and children, EPA should interpret the findings of *Abdallah et al.* in context, given that detection is not equivalent to a chemical being present at sufficient levels to present a risk.
- It is recommended that EPA consider the NAS' conclusions of no risk when evaluating exposures to commercial workers and consumers.

BFRIP appreciates the opportunity to comment on the *Supporting Documents for Initial Risk-Based Prioritization of High Production Volume Chemicals*. If you have any

<sup>1</sup> BFRIP members are Albemarle Corporation, Ameribrom-ICL and Chemtura Corporation

<sup>2</sup> EPA (2008) *Supporting Documents for Initial Risk-Based Prioritization of High Production Volume Chemicals* (Chemical/Category: Hexabromocyclododecane), pp. 1-16.  
<http://www.epa.gov/hpvis/hazchar/HBCD.3194556.Web.SupportDocs.31408.pdf>

questions or need additional information, please contact Nancy Sandrof, the BFRIP Manager at 703-741-5605 or [nancy\\_sandrof@americanchemistry.com](mailto:nancy_sandrof@americanchemistry.com)

Sincerely,

Nancy Sandrof  
BFRIP Panel Manager

cc: BFRIP  
C. Franz, ACC

**BFRIP Comments on *Supporting Documents for Initial Risk-Based Prioritization of High Production Volume Chemicals for Hexabromocyclododecane***

**SECTION 2: Physical and Chemical Properties and Environmental Fate**

**Solubility:** The solubility values for HBCD provided in the Supporting Documents for Initial Risk-Based Prioritization of High Production Volume chemicals are 3.4 and 8.6  $\mu\text{g/L}$ . Please note that in a water solubility study performed using the column generator method,<sup>1</sup> the solubility values for the three individual isomers  $\alpha$ ,  $\beta$  and  $\gamma$ , were determined to be 49  $\mu\text{g/L}$ , 15  $\mu\text{g/L}$  and 2  $\mu\text{g/L}$  for  $\alpha$ ,  $\beta$  and  $\gamma$ , respectively.

**Environmental Fate:** HBCD is degradable and is not persistent when tested at environmentally relevant concentrations. In addition, it should be noted that cyclododecatriene (CDT), the product of complete dehalogenation of HBCD is also degradable and not persistent. In an enhanced ready biodegradation test, CDT showed mineralization under stringent test conditions.

**SECTION 3: Hazard Characterization**

**Human Health and Environmental Hazard:** This section assigns an overall human health hazard concern of moderate, which is based on data EPA views as suggestive of thyroid effects that might present concerns for potential developmental neurotoxicity. Furthermore, this section mentions potential reproductive effects based on observed reproductive organ effects at high doses during a repeated dose toxicity study with HBCD. More recent and relevant data from the publication of Ema *et al.* (2007)<sup>2</sup> should help alleviate the EPA's expressed concerns for potential developmental neurotoxicity and the indicated reproductive effects at high doses from an earlier repeated dose toxicity study. The Ema 2 generation study is more comprehensive and was performed under GLP conditions using well accepted methodology and is therefore a more appropriate study to use for assessing these endpoints. The study design included behavioral tests of F<sub>1</sub> rats at 4 weeks of age. Sperm parameters were performed in both F<sub>0</sub> and F<sub>1</sub> male adult

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<sup>1</sup> MacGregor and Nixon 2004: Determination of water solubility of HBCD using a generator column method. Wildlife International.

<sup>2</sup> Ema *et al.* (2008) *Two-generation Reproductive Toxicity Study of the Flame Retardant Hexabromocyclododecane in Rats*, REPRODUCTIVE TOXICOLOGY, Vol. 25, pp. 335-351.

rats. In addition, serum hormone levels of T<sub>3</sub>, T<sub>4</sub> and TSH were performed in both F<sub>0</sub> and F<sub>1</sub> male and female adult rats.

#### **SECTION 4: Exposure Characterization**

Under Section 4 Exposure Characterization (Exposure to Workers), EPA concluded, “exposures [to HBCD] may occur through inhalation of dusts and dermal contact... [and] the potential worker exposure is high”.<sup>3</sup> EPA defines *exposure* as “[c]ontact made between a chemical, physical, or biological agent and the outer boundary of an organism. Exposure is quantified as the amount of an agent at the exchange boundaries of the organism (*e.g.*, skin, lungs, gut).”<sup>4</sup> Therefore, inhalation of HBCD-containing dusts and dermal contact with HBCD may be negligible based on work practice controls (*e.g.*, mandating that eating, drinking, *etc.*, in regulated areas be prohibited) and personal protective equipment (*e.g.*, gloves, respirators, *etc.*). Indeed, based on modeling and information provided by users and producers, the European Union (EU) concluded that risks to workers were negligible when standard industrial hygiene measures are employed.<sup>5</sup> The EPA should evaluate existing industrial hygiene practices prior to assuming that worker exposures are taking place *via* inhalation and dermal contact.

For exposures to the general public and the environment, EPA assumed that these exposures would be high because HBCD has uses as an additive flame retardant and thus has the potential to enter the environment.<sup>6</sup> EPA acknowledged the availability of a recent study (Abdallah *et al.*, 2008)<sup>7</sup> that presented concentrations of HBCD in dust from around the world. Abdallah *et al.*'s estimates of exposure *via* dust ingestion for adults were as high as 1100 ng of total HBCDs in dust/day and that estimates of exposure *via* dust ingestion for children were as high as 4400 ng of total HBCD in dust/day. Though Abdallah *et al.*'s findings indicate that exposures to HBCD may occur for the general public and environment, their results must be

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<sup>3</sup> EPA (2008) *supra* note 2, at p. 4.

<sup>4</sup> EPA (2008) IRIS Glossary/Acronyms & Abbreviations, [http://www.epa.gov/ncea/iris/help\\_gloss.htm#e](http://www.epa.gov/ncea/iris/help_gloss.htm#e)

<sup>5</sup> European Commission – Risk Assessment Report of HBCD, CAS# 25637-99-4 in accordance with Council Regulation 793/93 Final draft May 2008.

<sup>6</sup> EPA (2008) *supra* note 2.

<sup>7</sup> Abdallah *et al.* (2008) *Hexabromocyclododecane in Indoor Dust from Canada, the United Kingdom, and the United States*, ENVIRONMENTAL SCIENCE AND TECHNOLOGY, Vol. 42, pp. 459-464.

interpreted in context, given that detection is not equivalent to a chemical being present at sufficient levels to present a risk.

The lowest reported no-observed-adverse-effect-level (NOAEL) for HBCD is 10.2 mg/kg-bw/day.<sup>8</sup> This NOAEL, along with the highest estimated exposure dose for HBCD-containing dust as calculated by Abdallah *et al.* (2008), may be used to develop a margin of exposure (MOE):

$$\text{MOE} = \text{NOAEL} \div \text{Exposure} = 10.2 \div 0.0044 = 2318$$

A MOE of 2318 indicates no concern for exposures to the general public. This value can be placed into context based on the following. The EPA recommends limiting the total uncertainty factors (UFs) applied to any chemical to no more than 3000 when deriving a reference dose (RfD).<sup>9</sup> Therefore, if the NOAEL approach were applied to the data from Ema *et al.* (2007) along with a composite UF of 3000 (*i.e.*, RfD = NOAEL  $\div$  UFs), the resulting RfD would be equivalent to 255,000 ng/day for a 75-kg adult and 51,000 ng/day for a 15-kg child. These values are approximately 232 times and 11.6 times higher than the highest, most conservative exposure levels calculated by Abdallah *et al.* (2008). EPA should consider the foregoing information when evaluating exposures to the general public and exposures to children.

EPA determined that exposures to commercial workers and consumers are high.<sup>10</sup> However, there is nothing to show that EPA considered the U.S. National Academy of Sciences' (NAS) conclusion that "HBCD used as an upholstery fabric flame retardant is not likely to pose a noncancer risk *via* the dermal exposure route"<sup>11</sup> and "under the worst-case scenario, HBCD used as an upholstery flame retardant, is not likely to pose noncancer risk *via* inhalation of HBCD in the particulate phase."<sup>12</sup> Further, the EU concluded that there were no identifiable risks to

<sup>8</sup> Ema *et al.* (2008) *supra* note 4.

<sup>9</sup> EPA (2002) *A Review of the Reference Dose and Reference Concentration Processes*, EPA/630/P-02/002F, pp. 1-192, at p. 4-41, [http://www.epa.gov/ncea/iris/RFD\\_FINAL\[1\].pdf](http://www.epa.gov/ncea/iris/RFD_FINAL[1].pdf)

<sup>10</sup> EPA (2008) *supra* note 2, at p. 5.

<sup>11</sup> NAS (2000), *Chapter 4 Hexabromocyclododecane*, IN: TOXICOLOGICAL RISKS OF SELECTED FLAME-RETARDANT CHEMICALS, pp. 53 - 71, at p. 66, [http://books.nap.edu/openbook.php?record\\_id=9841&page=53](http://books.nap.edu/openbook.php?record_id=9841&page=53)

<sup>12</sup> *Id.* at p. 67.

consumers when using HBCD-containing products.<sup>13</sup> EPA should consider the conclusions of the NAS and EU when evaluating exposures to commercial workers and consumers.

## **SECTION 5: Risk Characterization**

**5.1. Risk Statement and Rationale:** EPA concluded there is a potential for exposure to the general population from environmental releases; however, EPA's conclusion fails to capture the U.S. NAS' conclusions about risk for dermal and inhalation exposures. For dermal exposures, the U.S. NAS concluded "[t]he hazard index of  $6.67 \times 10^{-6}$  indicates that HBCD used as an upholstery fabric flame retardant is not likely to pose a noncancer risk via the dermal exposure route."<sup>14</sup> Note that a hazard index of less than or equal to 1.0 will likely not result in adverse noncancer health effects over a lifetime of exposure. For inhalation exposure to particulates containing HBCD, the U.S. NAS concluded "under the worst-case exposure scenario, HBCD, used as an upholstery flame retardant, is not likely to pose noncancer risk via inhalation of HBCD in the particulate phase."<sup>15</sup> The same conclusion was reached for exposures to HBCD occurring in the vapor phase.<sup>16</sup> It is recommended that EPA consider the NAS conclusions during the Risk Statement and Rationals Section.

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<sup>13</sup> European Commission *supra* note 7.

<sup>14</sup> NAS (2000), *supra* note 13.

<sup>15</sup> *Id.* at p. 67.

<sup>16</sup> *Id.* at p. 68.