Children's Health Protection Advisory Committee

December 6, 2006

Administrator Steven Johnson
United States Environmental Protection Agency
1200 Pennsylvania Avenue
Washington, D.C.

Subject: PBDE Project Plan

Dear Administrator Johnson:

The Children's Health Protection Advisory Committee (CHPAC) has been tracking Agency activities on polybrominated diphenyl ethers (PBDEs). We read with great interest USEPA's Project Plan for PBDEs dated March 2006, and Agency staff briefed us on PBDE toxicity and the Project Plan at our June 2006 meeting. We commend USEPA for developing a plan to address health concerns raised by this class of brominated flame-retardants. We note that the project plan covers a number of the issues discussed in the CHPAC's December 2004 letter to you. The CHPAC recognizes that the need to protect children from the acute hazards posed by fire is a high priority. Finding appropriate flame-retardants that do not present chronic health risks and developing design features that minimize fire retardant use are critical tasks.

While the Project Plan, which describes activities EPA plans to initiate or consider, is a step in the right direction, improvements are needed to make it comprehensive, timely, and adequately protective of the developing fetus, infants and children. This letter describes the CHPAC's concerns with the Plan and provides the following recommendations: 1) increase the Plan's focus on risks to children; 2) increase the Plan's focus on deca-PBDE; 3) improve screening methods of PBDE replacement chemicals to better predict children's exposures; 4) elevate EPA's role in shaping the use of less hazardous replacement flame retardants and design features that minimize the use of flame retardants, and 5) broaden stakeholder involvement in the Furniture Flame Retardancy Partnership.

Concerns with the current PBDE Plan

Based on toxic effects of PBDE in animals, exposures to PBDEs may have toxic effects on the developing endocrine, immunologic and nervous systems of fetuses, infants and children.

Exposure to PBDEs has been increasing in recent decades, and biomonitored levels in the U.S. are greater than in other countries (Schecter, et al., 2005). Pregnant women, nursing infants, and children are routinely exposed to this group of persistent and bioaccumulative toxicants for which there has been inadequate characterization of sources of exposure and risk. Public health officials cannot provide answers to basic questions such as the amount of risk associated with early life exposure, and how such exposures can be decreased.

The Project Plan describes the types of PBDE research planned or underway, noting the anticipated EPA analyses on metabolism, toxicity and exposure assessment. However, EPA could improve the Plan to present a strategic, integrated approach to provide timely scientific information needed to answer key public health questions and inform risk management decisions. The CHPAC is very concerned that the Plan does not recognize the potential for heightened exposure and risk in early life and the challenge this presents for risk assessment and risk avoidance.

With the phase-out of penta- and octa-PBDEs, two major questions remain: 1) should the uses of deca-PBDE also be limited; and 2) how can replacement chemicals be selected to ensure that future exposure and health risks are prevented? These concerns are not theoretical but immediate and ongoing, leading to an urgency, not currently evident in the Project Plan, to obtain data and develop prudent actions.

1) Should uses of deca-PBDE be limited?

The Project Plan does not provide firm time lines for completing key research studies, developing Agency risk assessments, and determining the need for EPA action regarding deca-PBDE. Deca-PBDE breaks down in the environment and within wildlife to lower brominated congeners (tetra thru octa congeners), which existing data show are more toxic. It is therefore unclear why deca-PBDE isn't receiving the regulatory attention given to penta- and octa- formulations, including a phase-out and Significant New Use Rule (SNUR). This represents a major gap in the PBDE Project Plan.

2) How can replacement chemicals be selected to ensure prevention of future exposure and risk?

The CHPAC commends EPA for entering into a partnership with stakeholders to evaluate alternatives to penta- and octa-PBDE to be used in furniture. The Furniture Flame Retardancy Partnership (FFRP) includes industry, governmental, and non-governmental groups that can work together to evaluate the risks and benefits of replacement flame-retardants and give manufacturers some direction. This is, however, still a voluntary program and one in which EPA's role is merely advisory. This is insufficient given revelations in recent years that children are exposed to ingredients (e.g., phthalates, PFOA) in consumer and commercial products through unexpected and still ill-defined pathways.

Recommendations
The Project Plan can be improved in the following areas:

1) **Increase the Emphasis on Children.** The Project Plan states in several places (Page 10 for deca-; Page 12 for penta- and octa-; Page 34 for calculation of Margin of Exposure - MOE) that PBDE body burden will be used to evaluate exposure and risk, as understood from human biomonitoring data. However, existing biomonitoring data are unlikely to capture exposure information on infants and children as such data are not typically collected from the very young. Infants and children are likely to be highly exposed due to PBDE in human milk and in house dust (Schecter, et al., 2003; Jones-Otazo, et al., 2005; Furst, 2006). Therefore, any body burden-based risk assessments of deca- or other PBDEs should be based upon biomonitoring data collected from breast milk or biological medium in young children, or on modeling of early life exposure pathways to assess children's risks. It is crucial that future Agency risk assessments for PBDEs have a special focus on exposures and risks during early life stages (*in utero* and postnatally). The postnatal period is critical because young children are likely to receive relatively high exposures, have an immature capacity to clear PBDEs (Staskal, et al., 2006), and are at a vulnerable stage of life for the neuroendocrine, immunologic and other effects of PBDEs.

2.) **Fully include deca-PBDEs.** The Project Plan should define the critical data needed to determine whether deca-PBDE should continue to be used, provide a firm time line for obtaining those data, and describe how the data will be used to inform policy. The Agency should consider interim actions on deca-PBDE given the likelihood that deca-PBDE breaks down in the environment into lower-brominated congeners (as noted in the Project Plan) and contributes to body burden and risk.

In addition, the Project Plan does not address replacement flame-retardants for deca-PBDEs. This is in contrast to the Plan's approach to penta- and octa-PBDEs, wherein a major objective is the review of replacements. Evaluation of deca-PBDE alternatives is equally important because replacements should be readily available in the event that deca- is found to present unacceptable health risks either on its own or by degradation to lower brominated congeners. Further, the CHPAC understands that several computer manufacturers have already decided to eliminate deca-PBDE but the replacement chemicals have not undergone any review process. This may lead to new exposures to replacement chemicals and public health concerns that could be avoided by proactive agency review.

3.) **Enhance the standard methods of data evaluation for replacement chemicals to better predict human exposures, particularly children's exposures.** The EPA's Design for the Future Program is evaluating the potential for exposure and health risks from replacement flame retardants based upon physical/chemical properties and a screen of the toxicology database (FFRP document, Volume 1, undated). The method is similar to the standard approach used to screen for persistent, bioaccumulative, and toxic (PBT) chemicals released into the environment from manufacturing and waste disposal. However, these indicators are insufficient to predict human exposure to flame retardants

from consumer and commercial products as exemplified by the following points, and elaborated upon in the attachment.

- Exposure modeling based upon chemical properties is simplistic and does not capture children's exposure pathways.
- The FFRP screen for replacement chemicals is qualitative and does not distinguish well amongst alternatives.
- There is special concern about the formation of brominated dibenzo-p-dioxins and furans from PBDEs and other brominated flame retardants during a fire (Weber and Kuch, 2003; Ebert and Bahadis, 2003; Wichmann et al., 2002).
- The framework for evaluation of flame retardant replacements should be subject to external review.

4.) Elevate EPA's role in shaping use of suitable replacement fire retardants and influencing product designs. The CHPAC appreciates the need for stakeholders to be involved in screening new flame-retardants and the need for EPA to advise industry about the safest chemicals. However, the Project Plan describes a process in which EPA's role is merely to provide information to furniture manufacturers, who then have the option to consider the safety information along with several other factors (cost, feasibility) in determining what to use. Further, as stated above, EPA's screening evaluation (summarized in Table 4-1, Vol. 1, FFRP, undated) does not provide clear recommendations on which chemicals are acceptable and which are to be avoided. As recommended in our December 2004 letter, we believe the EPA can provide incentives for technological innovations that protect children from fire that avoid the use of harmful chemicals. We encourage the EPA to work with the Consumer Product Safety Commission on ways to redesign products to use inherently flame retardant and non-flammable materials and thus minimize the need for flame retardant chemicals while protecting children from injury and death from fire.

EPA's role in shaping flame retardant use should be elevated in the following ways:

- EPA needs to develop strong child-centered criteria to judge replacement fire retardants. These criteria should include but not be limited to: potential for release from consumer and commercial products; fate in the indoor environment; exposure pathways in infants and children (including human milk); potential for persistence and bioaccumulation; and toxicity in early life stages.

- EPA should enhance their current efforts to partner with the Consumer Product Safety Commission (CPSC) and establish a child-centered framework to evaluate fire retardants and approve their replacements. Such an enhanced partnership would bring children's health concerns about flame-retardants to the forefront.

- EPA should develop clear statements about the safety of each replacement flame retardant relative to the chemical it is replacing (e.g., penta-PBDE). A chemical with inadequate information on critical human health endpoints, or that has

toxicity, environmental, or exposure concerns should be flagged (and perhaps subject to regulatory action such as SNURs, mentioned as a possible consideration on page 10 of the Project Plan) so that it will not be used by industry without more extensive study.

- EPA should gather information from manufacturers regarding the flame retardants actually in use, their quantities and market share, and use this information to make recommendations to CDC regarding their inclusion in upcoming biomonitoring studies. This will promote the generation of baseline and temporal trend biomonitoring data that can be used to identify emerging exposure issues early in the process. Further, it will improve the coordination between EPA and CDC in gathering and interpreting biomonitoring data.

5.) Broaden the Partnership to ensure that children's interests are represented. The FFRP lacks public health officials, academic researchers, pediatricians, parents and other community members who can make important contributions to the direction of new flame retardant usage. Including these groups will lead to better protection of children's health.

In summary, we commend the USEPA for developing a plan to address health effects from exposure to brominated flame retardants. However, the plan needs to be improved. We are at a critical juncture as we work to prevent children's exposures and health risks from flame-retardants while protecting children from fire-related injury and death. The critical evaluation of the potential for exposure and health risks from PBDE replacements provides an excellent opportunity for EPA to institute a solid child-centered framework to protect public health. For this to occur, the PBDE Project Plan needs to be strategic, more comprehensive and proactive, invoke strong partnership with CPSC, and ascribe a greater leadership role to EPA. These improvements will yield an approach that can serve as an example for other chemicals to which children are and will be routinely exposed. We would be happy to discuss these comments with you or your designee.

Sincerely,

Melanie A. Marty

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Children's Health Protection Advisory Committee

Ccs: Charles M. Auer, Director, Office of Pollution Prevention and Toxics
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Daniel Axelrad, PBDE Workgroup Chair, Office of Policy, Economics, and Innovation

Enclosure

Attachment

Evaluating the potential for exposure and risk from replacement flame retardants as outlined in the FFRP and briefly described in the PBDE Project Plan, is simplistic and does not capture children's exposure pathways. This problem is exemplified by the following:

- Persistence in the environment as assessed by soil and sediment half-life may have little to do with persistence indoors in house dust where there is little UV light, biota, or moisture to degrade the chemical. It may or may not be related to how persistent a chemical will be in human tissues where clearance depends upon many metabolic and elimination factors. These factors may be immature in young children, resulting in accumulation that would not occur in other receptors and that cannot be predicted from soil or water half-life. More comprehensive models than those described in the FFRP document should be used. These models need to take into account chemical behavior in the indoor environment and its metabolism and clearance from human receptors, particularly in infants and children.

- The disposition of a chemical in mothers and children will have a large effect on its potential to bioaccumulate in humans. Bioaccumulation based upon a fish bioconcentration factor (BCF) may not predict how a toxicant will concentrate in human milk, resulting in exposure of nursing infants. Chemical properties that influence transfers of chemicals into human milk include not only lipophilicity, which BCF reflects, but also the pKa of ionizable compounds, extent of plasma protein binding, and structural or physical similarity to endogenous compounds that are actively transported into human milk (Findlay, 1983). Thus, the fish BCF assay alone is inadequate to screen for potential bioaccumulation from exposures early in life.

- The reliance upon general physical properties (volatility, water solubility) to characterize exposure potential is inadequate, as it does not necessarily predict the chemical's release from a consumer or commercial product and its ability to become entrained in house dust. House dust exposure may be particularly important for young children who play and breathe close to the ground and normally exhibit hand-to-mouth and object-to-mouth behavior. The ranking system in the Plan judges the potential for ingestion exposure based on a chemical's water solubility, and exposure potential is categorized by a simplistic "yes" or "no" rating. A more robust and refined exposure screening approach is needed to adequately assess prenatal, infant and children's exposures. In addition, EPA needs to research release mechanisms from consumer and commercial products to understand the physical and chemical factors and patterns of use that lead to a high potential for human exposure. Direct measurements of environmental release under actual or simulated environmental conditions may be necessary if adequately predictive models of release cannot be developed.

- There is no screening category for evaluating combustion byproducts. Given the significant combustion of waste materials in the U.S. and the potential for structural fires, more thought should be given to life cycle issues and fate upon combustion of the chemical. PBDE's in products can become brominated dioxins and furans during uncontrolled combustion. The Agency should consider ways to evaluate whether the chemical structure of halogenated flame-retardants presents unique concerns for formation of halogenated dioxins and furans when combusted.

- The summary screening table for replacement flame retardants (Table 4-1, Volume 1, FFRP, undated) assembles many toxicology and environmental fate properties into general low ("L"), medium("M"), or high("H") rankings, and exposure categories into Yes ("Y") or No ("N") categories. All replacement chemicals have Y's under exposure potential and at least some M's in the health and environmental categories. This qualitative ranking approach does not distinguish well between possible alternatives, making it difficult to choose a replacement based upon potential health and environmental impacts. For each proposed replacement, a synthesis of the information is needed to provide a summary recommendation and highlight critical data gaps, uncertainties, life-stage specific health or exposure concerns, and other relevant issues.

- External public and peer review of the method used to evaluate flame retardant replacements is needed. New chemicals in consumer and commercial products may result in unexpected and widespread children's exposure. For the screening process to be robust, it is critical for it to be subject to external review.

References

Ebert J, Bahadir M. (2003) Formation of PBDD/F from flame-retarded plastic materials under thermal stress. Environ Int 29:711-6.

Findlay, JWA. (1983) The distribution of some commonly used drugs in human breast milk. Drug Metab Rev 14:653-84.

Furst P. (2006) Dioxins, polychlorinated biphenyls and other organohalogen compounds in human milk. Levels, correlations, trends and exposure through breastfeeding. Mol Nutr Food Res 50:922-33.

FFRP (undated) Environmental Profiles of Chemical Flame-retardant Alternatives for Low-density Polyurethane Foam, Vol 1. Available at http://www.epa.gov/oppt/dfe/pubs

Jones-Otazo, HA, Clarke, JP, Diamond, ML, et al. (2005) Is house dust the missing exposure pathway for PBDEs? An analysis of the urban fate and human exposure to PBDEs. Environ Sci Technol 39: 5121-5130.

Schecter, A., Pavuk, M, Papke, O., et al. (2003) Polybrominated diphenyl ethers (PBDEs) in US mothers' milk. EHP 111: 1723-1729.

Schecter, A., Papke, O., Tung, KC, et al. (2005) Polybrominated diphenyl ether flame retardants in the US population: current levels, temporal trends, and comparison with dioxins, dibenzofurans, and polychlorinated biphenyls. J Occup Environ Med 47: 199-211.

Staskal, DF, Diliberto, JJ and Birnbaum, LS (2006) Disposition of BDE 47 in developing mice. Toxicol Sci 90: 309-316.

USEPA, OPPTS (2006) PBDE Project Plan. March, 2006.

Weber R, Kuch B. (2003) Relevance of BFRs and thermal conditions on the formation pathways of brominated and brominated-chlorinated dibenzodioxins and dibenzofurans. Environ Int 29:699-710.

Wichmann H, Dettmer FT, Bahadir M. (2002) Thermal formation of PBDD/F from tetrabromobisphenol A – a comparison of polymer linked TBBP A with its additive