Melanie A. Marty, Ph.D., Chair  
Children's Health Protection Advisory Committee  
Cal/EPA, Office of Environmental Health  
Hazard Assessment  
1515 Clay St., 16th Floor  
Oakland, CA 94612  

Dear Dr. Marty:

Thank you for your letter of December 8, 2004, to the U.S. Environmental Protection Agency's (EPA's) Administrator Michael O. Leavitt regarding polybrominated diphenyl ethers (PBDEs). The Office of Pollution Prevention and Toxics (OPPT) has been asked to respond to your letter directly. Your letter anticipates the timely release of the EPA Action Plan on PBDEs, provides recommendations for further research on these chemicals, and encourages the Agency to give priority to children's exposures and health risks.

Thank you for your attention to this important issue. We share your concerns and interest in ensuring that children's health issues are addressed in the development of our policy on PBDEs. As you know, we are currently developing a draft Action Plan on PBDEs, which, while not a detailed strategy, will provide information and direction on EPA's overall approach to PBDEs. The Plan will provide a brief summary of relevant information on PBDEs and outline EPA's plans and activities regarding penta-, octa-, and decaBDE, as well as other brominated flame retardants. We are aware that the means by which people are exposed to PBDEs, and the relative contributions of the various routes of exposure (e.g., inhalation, food or dust ingestion, or dermal absorption), are not well known. Furthermore, we are sensitive to the fact that PBDE-associated concerns for thyroid effects and neurodevelopmental toxicity are relevant to children, that children are likely to have differential exposures and exposure pathways (prenatal, breast milk, dust ingestion), and that the importance of different types of exposure will vary for infants, young children, older children, and adults. The Action Plan has been drafted by an intra-agency workgroup and steering committee with broad EPA participation, including the Office of Children's Health Protection. We plan to make the draft Action Plan available for review in the next couple of months.
We understand and appreciate your recommendations for the direction of future research on PBDEs. As you know, PBDEs are also being sponsored by chemical manufacturers in our Voluntary Children’s Chemical Evaluation Program (VCCEP). VCCEP is intended to provide data to enable the public to understand the potential health risks to children associated with exposures to certain chemicals. As part of their sponsorship, companies collect and develop health effects and exposure information on their chemicals, integrate that information in a risk assessment, and prepare a data needs assessment that is discussed at a peer consultation meeting of scientific experts. EPA will consider the results of the Peer Consultations and use them to determine whether and what additional information is needed to fully characterize PBDE risks to children. EPA anticipates releasing its views of both the peer consultation meeting reports and sponsors’ assessments early this year. See http://www.tera.org/peer/VCCEP/OctaPenta/OctaPentaWelcome.html and http://www.tera.org/peer/VCCEP/DecaWelcome.html for more information.

Directly or through grant mechanisms, EPA is also conducting research, managed primarily by the Office of Research and Development, aimed at determining PBDE levels in the residential environment (e.g., house dust), food, and breast milk; developmental and reproductive toxicity of the chemicals, and the environmental fate of the PBDEs. Research includes measurement of PBDE concentrations in umbilical cord blood from newborn U.S. infants and mothers’ blood to assess if the fetus is exposed to PBDEs, studying Great Lakes sediment cores and fish to assess long term trends of PBDEs in the environment, determining whether decaBDE undergoes debromination to lower brominated PBDEs, estimating the potential exposures of very young children (less than 3 years of age) to PBDEs found in their residential environments, and using animal models to determine the relationship between thyroid hormone decreases caused by pentaBDE during development and adverse neurological effects (e.g., learning and motor deficits). EPA has also requested that the Centers for Disease Control and Prevention (CDC) measure blood serum levels of PBDEs in the general U.S. population. These data will be reported in the National Report on Human Exposure to Environmental Chemicals, which is part of CDC’s National Health and Nutrition Examination Survey. The data should be available in 2006 or 2007.

As you may know, the Toxic Substances Control Act (TSCA) is a risk-benefit statute, in which we balance the environmental risks against the benefits afforded by the chemical. In this particular case, as you point out, PBDEs are excellent flame retardants. Their chemical properties save lives every year and this benefit must be weighed against potential health hazards. To complement the voluntary industry phase-out of pentaBDE and octaBDE, EPA recently issued a proposed regulation under TSCA to ensure that no new manufacture or import of these chemicals occurs without first being subject to Agency review. EPA has been working to ensure that following the phase-out of these two chemicals, acceptable alternatives are available to industry.
PentaBDE has historically been the primary chemical flame retardant used in flexible polyurethane furniture foam in the U.S. A number of alternatives have been proposed for pentaBDE and we are engaged in efforts to better understand them. EPA's Design for Environment (DfE) Program has convened a group of stakeholders in its Furniture Flame Retardancy Partnership, including the furniture and chemical manufacturing industries, environmental non-governmental organizations, and other government agencies, such as the Consumer Products Safety Commission (CPSC). EPA's website contains more information on the partnership: http://www.epa.gov/dfe/projects/flameret/index.htm. The initial focus of the Partnership is an evaluation of the available toxicological data on chemical alternatives to pentaBDE. In the coming months, the Partnership will shift its focus to identifying and filling needs in the available data for alternatives to pentaBDE, exploring non-chemical alternatives for fire protection, and recognizing innovation in industry that is resulting in safer flame retardants. The Partnership may also explore flame retardants that are likely to be used to meet planned national flammability standards for residential upholstered furniture (RUF) under consideration by the CPSC.

EPA is also currently developing a regulation under TSCA to complement the planned CPSC RUF flammability standards. The regulation would cover any or all of the 12 chemicals (including decaBDE and another BFR, hexabromocyclododecane) or categories of chemicals identified by CPSC and evaluated by the National Academy of Sciences as candidates for use to meet the RUF standard, and would require persons who intend to manufacture, import, or process those chemicals to notify EPA at least 90 days before commencing such activity. The required notice would provide EPA with the opportunity to evaluate their use as FR chemicals in RUF, and if necessary, to prohibit or limit such activity before it occurs to prevent unreasonable risk of injury to human health or the environment.

Thank you for the opportunity to share the progress we have made thus far on this important issue. Please contact Daniel Axelrad at 202-566-2304, for further information on the status of the PBDE workgroup and the Action Plan. If you have any further questions regarding PBDEs, feel free to contact Kenneth Moss at 303-312-6700.

Sincerely,

Charles M. Auer, Director
Office of Pollution Prevention and Toxics