UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families, et al. on Exposure and Use Assessment and Environmental and Human Health Hazards of Five PBT Chemicals under Section 6(h) of the Toxic Substances Control Act

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Safer Chemicals Healthy Families, Environmental Health Strategy Center, Earthjustice and Center for Environmental Health submit these comments on two documents developed by the Environmental Protection Agency (EPA) on five Persistent, Bioaccumulative and Toxic (PBT) chemicals identified for restriction under section 6(h) of the amended Toxic Substances Control Act (TSCA). The two documents are entitled *Exposure and Use Assessment of Five Persistent, Bioaccumulative and Toxic Chemicals* (Exposure and Use Assessment) and *Environmental and Human Health Hazards of Five Persistent, Bioaccumulative and Toxic Chemicals* (Environmental and Human Health Hazard Summary). The 5 PBTs they address are decabromodiphenyl ether (DecaBDE); hexachlorobutadiene (HCBD); pentachlorothiophenol (PCTP); phenol, isopropylated, phosphate (3:1) (PIP (3:1)); and 2,4,6-Tris(tert-butyl) phenol) (2,4,6 TTBP). The two documents were released for public comment on May 25, 2018 (83 Federal Register 24305). EPA also convened a preparatory meeting for experts selected to serve as letter peer reviewers for the two documents on June 25, 2018 and invited input by members of the public.

The signatory organizations are national and grassroots groups committed to assuring the safety of chemicals used in our homes, workplaces and the many products to which our families and children are exposed each day, and to ensuring an environment free from toxic pollution. They took a leadership role during the TSCA legislative process, advocating the most protective and effective legislation possible to reduce the risks of toxic chemicals in use today.

We filed both general and chemical-specific comments on the 5 PBTs on January 12, 2018 and then discussed the use and exposure information provided in our comments by conference call with the EPA staff. Patrick MacRoy, Deputy Director of Environmental Health Strategy Center, offered oral comments at the June 25 public meeting.

Our principal concern is that neither the two documents nor EPA's remarks at the meeting provide a clear explanation of the role the documents will play in restricting the 5 PBTs under TSCA section 6(h). This lack of clarity may have confused the peer reviewers and could point to uncertainty regarding EPA's plans to use the documents for regulatory decision-making. As EPA revises and finalizes the two documents and continues with its regulatory development process, it's critical that the Agency has a clear understanding of the goals and requirements of section 6(h) and how the two documents will contribute to meeting them.

As we explained in our January 12 comments, Section 6(h)(2) is explicit that EPA is not "required to conduct risk evaluations" on PBTs identified under section 6(h)(1). In lieu of a risk determination, section 6(h) requires two simple findings that EPA has already made for each of the five chemicals.

First, under section 6(h)(1)(A), EPA must have a "reasonable basis to conclude" that a chemical meeting the criteria for persistence and bioaccumulation is also "toxic." To meet this requirement, EPA must simply identify data or another basis to conclude that the chemical can cause one or more acute or chronic adverse effects in people or animal species.[1] Using the criteria and methodology in its 2012 Work Plan Methods Document, EPA screened all the chemicals under review for "hazard" based on human health and environmental toxicity concerns and assigned each chemical a score reflecting the type and level of toxicity reported in the literature. Chemicals selected for inclusion in the final 2014 Work Plan list necessarily received "high" or "moderate" hazard scores based on this screening process. Thus, EPA has already concluded that the five PBTs under consideration for restriction under section 6(h) are "toxic."

Second, under section 6(h)(1)(B), EPA must also determine that the general population, a potentially exposed or susceptible population or the environment is "likely" to be exposed to the chemical under the conditions of use. Again, however, the analysis EPA conducts need not be extensive or comprehensive, in contrast to the assessment of exposure that TSCA requires for risk evaluations conducted under section 6(b). Since EPA must only show that the occurrence of exposure is "likely," it is not required to characterize the nature, magnitude and duration of exposure in any detail or even to document actual exposure. The probability of exposure by people or presence in the environment based on the nature of the PBT's manufacture, processing and use will be sufficient. Under the Work Plan Methods Document, the five PBTs have already been screened and scored for "exposure" and this constitutes sufficient evidence of "likely exposure" under section 6(h)(1)(B).[2]

Although not a prerequisite for applying section 6(h), the two documents confirm that the requirements of "likely exposure" and "toxicity" have been met for the five chemicals. As described in the Exposure and Use Assessment, EPA's literature review variously documented these chemicals in the indoor and outdoor environment, people and wildlife, as shown in the table below:[3]

[1] The severity of these effects, the exposure levels at which they occur and their underlying biological mechanism should be irrelevant because these considerations relate to "risk" rather than "toxicity."

[2] Q&A 43 of its general TSCA Q&As confirms that: "In identifying these chemicals in the Work Plan, EPA considered the uses and potential for exposures."

[3] We acknowledge with gratitude preparation of this Table by the Program on Reproductive Health and the Environment of the University of California, San Francisco, which is also including the Table in separate comments it is filing with other scientists and public health experts.

	Chemical detected?					
Chemical	**Indoor environment (air or dust)**	**Ambient air**	**Water**	**Vegetation/ Diet**	**People**	**Wildlife**
DecaBDE	X	X	X	X	X	X
HCBD	X	X	X	X		X
PIP (3:1)	X	X			X	X
2,4,6-TTBP	X	X	X			X
PCTP					X	

Similarly, although it does not address all available studies, the Environmental and Human Health Hazard Summary provides sufficient evidence of ecological and human toxicity for the 5 PBTs for the purposes of section 6(h).

Although not required to support the threshold requirements for regulation under section 6(h), compiling further exposure, use and hazard information on the 5 PBTs, as EPA has done in the two draft documents, will be useful in informing EPA's decisions on which of the authorized restrictions in section 6(a) should be imposed to limit exposure to the 5 PBTs. Unfortunately, EPA has done a poor job of explaining how it will use the documents for this purpose, making it difficult for commenters and reviewers to assess their completeness and relevance.

However, we do believe that section 6(h)(4) provides touchpoints that can be used to evaluate the adequacy of the two documents. First, this provision requires that "in selecting among prohibitions and other restrictions" in the required risk management rule for these substances, EPA must "address the risks of injury to health or the environment that [it] determines are presented by the" PBT. Second and in addition, EPA must impose requirements that "reduce exposure to [the PBT] to the extent practicable." Importantly, neither of these goals requires EPA to make a determination of "unreasonable risk," conduct an analysis of costs, benefits and other economic consequences of its rule, or consider the availability of alternatives to the PBT.

As discussed in our January 12 comments, to satisfy the first requirement, EPA must consider and seek to reduce all risks that are attributable to the PBT as a result of its adverse effects on health or the environment from near-term exposure and release and/or its potential for long-term buildup and accumulation in biological systems or the biosphere. Thus, EPA should have a sufficient understanding of the PBT's pathways of exposure and release and its associated risks of harm so it can show that the requirements it imposes are likely to provide meaningful long-term protection against known or suspected adverse effects to people, animals and plant species. EPA cannot do this unless it has identified all the plausible risk scenarios involving the PBT's conditions of use. However, the two documents are incomplete in this regard.

First, EPA states that "[d]ue to time constraints," it chose not to evaluate studies lacking data in text or tables, and that "studies that had fewer than 10 observations were not extracted or evaluated."[4] Overall, this resulted in over 600 studies being excluded from EPA's evaluation because they were "not able to be extracted." This exclusion of studies has the potential consequence of overlooking hazard or exposure scenarios that show the PBT's "risk of injury." EPA should therefore expand the universe of studies included in the Environmental and Human Health Hazard Summary.

Second, EPA indicates that it will evaluate the "quality" of the studies referenced in the Environmental and Human Health Hazard Summary and Exposure and Use Assessment using its TSCA systematic review document. This document is unsound, has not been peer reviewed and conflicts with the consensus of the scientific community on how systematic review should be conducted. Use of the document for any purpose at this time would be contrary to the best available science.[5]

In addition, in the Exposure and Use Assessment, EPA made no effort to identify "potentially exposed or susceptible subpopulations" under TSCA beyond the broad categories of "occupational," "general public," and "consumers." Since potentially exposed or susceptible subpopulations are at greater risk than the general population, they must be identified with some specificity to assure that they are protected from any "risk of injury." As Patrick MacRoy noted at the public meeting, EPA has failed to accomplish this in several respects:

- For four of the PBTs, DecaBDE, HCBD, PIP(3:1), and TTBP, EPA presents evidence and models indicating that children are likely to receive higher doses. EPA also identifies unique uses for some of the substances in children's products. (See attached appendix for specific examples.) In the Environmental and Human Health Hazard Summary, the Agency highlights developmental hazards that may be more applicable to children. Children are clearly a susceptible subpopulation whose pathways of exposure need to be more clearly detailed.
- EPA has also largely ignored exposures to people eating contaminated fish or other food products. In our comments on the initial use documents in January, we noted that that ATSDR previously stated that: "Individuals who consume large amounts of fish from contaminated waters may also be exposed to above-average levels of HCBD." While EPA does note for HCBD that the "potential for ecological exposure remains as some current releases still occur," it does NOT include the fish-to-human pathway of exposure for HCBD. Given that bioaccumulation in the food chain is a major exposure route for PBTs, these pathways should be more carefully explored and included.
- EPA's exposure pathways also continue to ignore accidental releases. We can clearly learn from history that such exposures are both foreseeable and likely and must be considered if the agency is to actually reduce exposure to the extent practicable. As we established in our January comments, TRI data documented accidental releases of HCBD in Lake Charles, LA in both 2015 and 2016. A plant producing TBBP in Freeport, TX flooded during Hurricane Harvey. To fail to consider such exposure pathways is to deny the reality of how a "potentially exposed or susceptible subpopulation" – the fenceline communities – is actually put at risk of harm.

[4] The explanation of this selection process is provided in the EPA document entitled "Supplemental Information for the Exposure and Use Assessment of Five Persistent, Bioaccumulative and Toxic Chemicals" (June 2018), which can be found in the docket.

[5] These concerns were amplified in the August 16 comments on the TSCA systematic review document filed by SCHF and several other groups.

Similarly, EPA should not write off exposures that are theoretically, but demonstrably not in fact, addressed by other environmental regulations. EPA chose to ignore, for example, the release of waste oil containing TBBP to water since most waste oil is properly disposed. It's reasonable and foreseeable that, especially when used in consumer fuel and oil additives, some amount will end up poured down drains, dumped, etc. This exposure pathway should not be ignored in developing restrictions on known PBTs where the goal of regulation is reducing exposure to the extent practicable.

The second requirement in section 6(h)(4) (which is independent of the first) is that EPA's regulation should assure that the selected restrictions achieve the largest possible reduction in exposure by humans, plant and animal species and environmental media (air, water and waste) that is "practicable." To achieve this objective, EPA must have a comprehensive understanding of all pathways of exposure so none is outside the scope of its regulation. This should include ongoing exposure and environmental release related to discontinued (what EPA calls "legacy") manufacturing, processing and use activities. It should also include reasonably foreseeable reintroduction of legacy products in the future since this could create new unregulated exposures that defeat the goal of regulation under section 6(h). We believe that EPA's Exposure and Use Assessment devotes insufficient attention to ongoing human exposure and release from legacy uses and the potential for legacy products to reappear in the stream of commerce.[6] For example, the Exposure and Use Assessment states that: "EPA does not expect to consider recycled articles, where those articles [containing DecaBDE] do not have intended flame retardant applications" (page 69). This exclusion cannot be squared with the broad focus of section 6(h) on *all* exposure pathways: DecaBDE in recycled articles will contribute to environmental release and human exposure whether or not it is intended as a flame retardant in those articles. Since the presence of DecaBDE in recycled articles is a known and reasonably foreseen exposure pathway, it would be inconsistent with TSCA section 6(h) for EPA to exclude this pathway from its exposure and use assessment.

We appreciate the opportunity to submit these comments. Please contact SCHF counsel Bob Sussman at bobsussman1@comcast.net with any questions.

Respectfully submitted,

Liz Hitchcock
Acting Director
Safer Chemicals, Healthy Families

Patrick MacRoy
Deputy Director
Environmental Health Strategy Center

Eve Gartner
Staff Attorney
Earthjustice

Ansje Miller
Director of Policy and Partnerships
Center for Environmental Health

[6] The requirement to reduce exposure under section 6(h)(4) is not limited to a PBT's "conditions of use" but applies to the substance broadly. EPA has argued (erroneously in our view) that it need not conduct risk evaluations on non-PBTs for exposures to legacy products on the ground that they are outside the definition of "conditions of use." But whatever the merits of EPA's position may be, it has no application under section 6(h)(4), which does not limit required reductions in exposure to regulation of activities that fall within the definition of this term.

Appendix: Specific Evidence of Children as a Potentially Exposed or Susceptible Subpopulation

In its Exposure and Use Assessment, EPA documents numerous examples of children's unique exposures for four of the five PBT chemicals examined. As discussed in the main comment, however, the agency has not identified children specifically as a Potentially Exposed or Susceptible Subpopulation nor has it provided exposure scenarios unique to children. This is especially critical given the likelihood of children both having unique susceptibility and having unique and high exposures to the PBTs through multiple pathways (for example, a young child breastfeeding from an occupationally exposed mother whose hand-to-mouth activity is also resulting in a substantial exposure from household dust.)

The following are specific examples from EPA's findings that support the need to specifically consider children as a potentially exposed subpopulation. It is not intended to be an exhaustive listing. All page references are to EPA's Exposure and Use Assessment document.

DecaBDE

The agency charted the results of 11 studies that modeled an estimated average daily dose (ng/kg/day) of DecaBDE. Four of these derived DecaBDE doses for infants, toddlers, and children through ingestion. The doses calculated for these age groups were generally much higher than adult doses. EPA stated the average estimated doses were under 5 ng/kg/day, but two of these studies estimated doses greater than 20 ng/kg/day for infants who drank breast milk and toddlers who ingested household dust. [pages 62-63]

EPA cited to 14 studies that estimated DecaBDE intake, 9 of which provided data for infants, toddlers, and children. One estimated toddlers' intake via inhalation of dust in an e-waste recycling area in southern China at over 4,000 ng/day. [pages 63-64]

EPA discussed previously completed exposure assessments and noted that several identified children as having higher exposures. For example, in 2012, Health Canada evaluated total intakes of DecaBDE for a range of age groups. This agency found those aged 0 to 4 years had the highest total intake (between 41 and 190 ng/kg/bw per day), with the predominant sources being from breast milk and the mouthing of hard plastic toys. [page 67]

HCBD

EPA notes that according to manufacturers' reporting to the State of Washington, HCBD was detected in 5 consumer products: jewelry, surface coatings of headware, underwear (likely the adhesive), and surface coatings of dolls or soft toys. EPA states that consumers may be exposed from wearing or using these products, so children would be among those exposed. [page 78]

As summarized by EPA, in 2000, Environment Canada and Health Canada estimated total intakes from exposures to HCBD in air, drinking water and food for a range of age groups. The agencies calculated higher intakes for infants and children up to age 12 (30 to 200 ng/kg/bw per day) compared with older children and adults (10 to 50 ng/kg/bw per day). [page 104]

PIP (3:1)

EPA discusses one use of PIP (3:1) as a flame retardant or plasticizer in hard or soft plastic products and articles, including articles meant for children such as toys. [pages 109-110]

EPA cited to five studies that modeled an average daily dose of TPP, a close relative of PIP (3:1), for infants, toddlers, children, and adults. Estimated doses across the studies were generally less than 2 ng/kg/day, but nearly all studies estimated higher doses for infants, toddlers, and children. One study calculated infant exposure to be as high as 40 ng/kg/day, assuming ingestion of dust at the highest concentration of TPP included in the model. [pages 123-4]

EPA also discussed one study that estimated intake of TPP by stay-at-home toddlers to be around seven times greater than the highest adult exposure. In the worst-case scenario, assuming high dust ingestion and high TPP levels in dust, the toddlers' estimated dose was 3,100 ng/day, compared with adult exposures of 157-428 ng/day. [pages 124-5]

2,4,6 TTBP

In the absence of studies calculating the average daily dose of 2,4,6 TTBP, EPA cited to a study providing the dose for the sum of seven synthetic phenolic antioxidant analogues in indoor dust. Children in both rural and urban settings had higher estimated average daily doses than adults - potentially up to 10 ng/kg/day compared with under 2 ng/kg/day. [pages 141-142]