Environmental Defense Fund

Initial Comments on EPA's Documents for its

Letter Peer Reviews for Exposure and Use Assessment and Human Health

and Environmental Hazard Summary for Five PBT Chemicals under § 6(h) of the Toxic Substances Control Act

Docket ID: EPA-HQ-OPPT-2018-0314

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Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on the following documents released for its Letter Peer Reviews for Exposure and Use Assessment and Human Health and Environmental Hazard Summary for Five PBT Chemicals. The specific documents are:

- Peer Review Draft of the Exposure and Use Assessment of Five Persistent, Bioaccumulative and Toxic Chemicals (hereinafter "draft exposure and use assessment");
- Peer Review Draft of the Environmental and Human Health Hazards of Five Persistent, Bioaccumulative and Toxic Chemicals (hereinafter "draft hazard summary");
- Peer Review Draft of the Supplemental Information for the Exposure and Use Assessment of Five Persistent, Bioaccumulative and Toxic Chemicals (hereinafter "draft supplemental document");
- Exposure and Use Assessment Peer Review Charge Questions; and
- Environmental and Human Health Hazard Summary Peer Review Charge Questions

We provide the following comments for consideration by both EPA and the peer review. EDF expects to file additional comments by the August 17, 2018 deadline.

Key points for peer reviewers when reviewing EPA's PBT documents

Exposure reduction is a key driver: The data and analyses need to support EPA's promulgation of rules that meet the requirement to "reduce exposure to the extent practicable" as well as to eliminate unreasonable risk. For many uses, meeting the exposure reduction requirement can and should drive deeper cuts in use of PBT chemicals than simply eliminating unreasonable risk, up to and including bans on some or all uses. For example, where a viable alternative exists, a ban would be necessary to comply with the requirement that EPA "reduce exposure to the chemical substance to the extent practicable."

Need to identify potentially exposed or susceptible subpopulations: EPA has not included, and should add, a section to each document identifying the relevant potentially exposed or susceptible subpopulations it can now identify based on the information it has already provided in the documents, and EPA should update these as more information is developed.

Exposure is likely to each of the five PBTs: The draft exposure and use assessment confirms that exposure "is likely" for each of the five PBT chemicals EPA has identified. Each of these chemicals is, by definition, persistent and bioaccumulative, which means people and other organisms can remain exposed to it for a very long time, with those higher up the food chain more heavily exposed. All five of these PBT chemicals appear to still be active in commerce. And monitoring data show that exposure is likely to each of the five chemicals.

EPA must consider all conditions of use: This includes so-called legacy-related use and disposal as well as conditions of use related to recycling and imported articles.

EPA statements suggesting certain exposures are low lack sufficient evidence: Certain EPA statements invoking existing regulations (sometimes in countries other than the U.S.), suggesting reductions in use over time, or characterizing specific scenarios suggest that some exposures to PBT chemicals are low or have declined. For reasons discussed in our comments, these statements are questionable or lack sufficient evidence.

EPA can and should use its authorities to address gaps in available information: TSCA gives EPA ample authority to require testing or monitoring and to collect existing information in order to fill gaps in hazard and exposure or use information. EPA should use these authorities where needed to inform robust exposure reduction rules for the five PBT chemicals.

EPA has inappropriately excluded reasonably available information, including through its literature search strategy: EPA has not yet summarized relevant information it already received on the PBT chemicals under its TSCA sections 4 and 8 authorities. EPA has also excluded large numbers of studies due to "time constraints" (see draft supplemental document). EPA should immediately provide a list of references to all excluded studies to peer reviewers and the public in advance of the upcoming peer review. EPA should also promptly initiate efforts to acquire and make public copies of the full studies as soon as possible.

EPA needs to identify all types of acute and subacute as well as chronic hazards: EPA's focus only on repeated-dose studies is overly narrow, given EPA's mandate to reduce human risks from all hazards.

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I. EPA's documents need to accurately reflect TSCA's requirements for regulating chemical substances subject to section 6(h).

Section 6(h)(4) of TSCA reads:

> SELECTING RESTRICTIONS.—In selecting among prohibitions and other restrictions promulgated in a rule under subsection (a) pursuant to paragraph (1), the Administrator shall address the risks of injury to health or the environment that the Administrator determines are presented by the chemical substance and shall reduce exposure to the chemical substance to the extent practicable.

This provision imposes two requirements on EPA for any risk management rule it promulgates pursuant to section 6(h). First, the rule "shall address the risks of injury to health or the environment that the Administrator determines are presented by the chemical substance." This requirement is further elucidated by the provision's cross-reference to subsection (a), which states that, in addressing any unreasonable risk identified by the agency, "the Administrator shall by rule *** apply one or more of the following requirements to such substance or mixture *to the extent necessary so that the chemical substance no longer presents such risk*." (emphasis added)

Second, the rule "*shall reduce exposure to the chemical substance to the extent practicable*." (emphasis added)

Both standards apply and must be met: The rule must eliminate any unreasonable risk posed by the chemical substance identified by EPA and it must reduce exposure to the chemical substance to the extent practicable.

Unfortunately, none of EPA's documents – neither its draft hazard summary or its associated charge questions, nor its exposure and use assessment or its associated charge questions – accurately describes these dual requirements. In fact the draft hazard summary and associated charge questions provide only a selective rendition, including only the first of the two requirements and never mentioning the second. On page 4 of the draft hazard summary and page 1 of hazard summary charge questions, EPA states that its "document[s] and the data cited for each PBT will support the development of a proposed rule that *addresses the risks of injury to the environment and health that the EPA determines are presented by the subject PBT chemicals*." (emphasis added)

Furthermore, EPA misstates the regulatory decisions it must make with regard to substances subject to TSCA section 6(h). On page 4 of the draft hazard summary, and page 1 of the associated charge questions, EPA states: The document is intended to provide an overview of the nature and extent of hazards for use in making *risk-based regulatory decisions*." (emphasis added)

While other provisions of section 6 call on EPA to make risk-based regulatory decisions, section 6(h) is decidedly and intentionally different. While Congress directed EPA to identify chemicals subject to expedited action based on consideration of their hazards and exposures, EPA's regulatory mandate is not solely to be risk-based. If anything, *reducing exposure* is the main charge. Section 6(h)(4).

It is important that peer reviewers, when reviewing the data and analyses EPA has provided them, understand that the data and analyses need to support EPA's promulgation of rules that meet the requirement to "reduce exposure to the extent practicable" as well as the requirement to eliminate unreasonable risk. For many conditions of use of such chemicals, meeting the exposure reduction requirement can and should drive deeper cuts in production and use of the chemicals than simply eliminating unreasonable risk, up to and including bans on some or all such production and use. For example, for any use for which a viable alternative exists, a ban would be necessary to comply with the requirement that EPA "reduce exposure to the chemical substance to the extent practicable." Section 6(h)(4).

II. EPA needs to more explicitly identify potentially exposed or susceptible subpopulations relevant to each of the five PBTs.

TSCA section 6(h)(1)(B) calls on the Administrator to identify chemicals for which "exposure *** under the conditions of use is likely to the general population or to a *potentially exposed or susceptible subpopulation* identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator." (emphasis added)

And the rules that TSCA section 6(h) requires EPA to promulgate under section 6(a) must protect potentially exposed or susceptible subpopulations. *See* section 6(a) and section 6(b)(4), which it cross-references.

Yet neither the draft exposure and use assessment nor the draft hazard summary explicitly identifies potentially exposed or susceptible subpopulations relevant to each of the five PBTs. EPA should do so in finalizing these documents. For example, women of childbearing age, pregnant women, infants, and children should be considered susceptible subpopulations for at least four of the five PBTs, given that the evidence EPA has included in the draft hazard summary demonstrates developmental toxicity:

- DecaBDE: p. 12
- HCBD: p. 17
- PIP (3:1): p. 24
- 2,4,6 TTBP: p. 28
- PCPT: p. 32 (analogous chemicals)

Similarly, evidence EPA has included in the draft exposure and use assessment points to greater than average exposure potential for certain subpopulations. For example, EPA cites evidence that exposures to DecBDE for infants and children differ from and can be higher than those experienced by adults. (p. 67) Evidence cited by EPA for surrogate chemicals EPA employed for PIP (3:1) and 2,4,6 TTBP showed higher exposure in children than in adults. (pp. 124 and 141, respectively)

EPA should add a new section to each document identifying the relevant potentially exposed or susceptible subpopulations it can identify based on the information it has already provided in the documents, and update these as more information is developed.

III. The evidence clearly demonstrates that these five PBT chemicals have met the criteria in TSCA section 6(h)(1).

TSCA section 6(h)(1) specifies that EPA must, no later than three years after the date of enactment (June 22, 2019), propose rules for certain PBTs under section 6(a). EPA has clearly indicated that the five chemicals listed below meet the criteria laid out in TSCA section 6(h)(1), and EPA has acknowledged that it must propose rules for these chemicals by June 2019. EPA's website states:[1]

> EPA must propose a rule to reduce exposures from these PBT chemicals to the extent practicable no later than June 22, 2019, with a final rule to follow no more than 18 months later. *** As a first step in the TSCA section 6(h) process, five PBT chemicals were identified for action by EPA according to statutory criteria. These five PBT chemicals will be the subject of the rule discussed in the preceding section. EPA first looked to chemical substances identified in the 2014 update of the TSCA Work Plan for Chemical Assessments that met the criteria for persistence and bioaccumulation described in the statute and based on the 2012 TSCA Work Plan Chemicals Methods Document.*** The following five PBT chemicals are identified under the conditions specified in TSCA section 6(h):
>
> - **Decabromodiphenyl ethers (DecaBDE)**, used as a flame retardant in textiles, plastics, wiring insulation, and building and construction materials;
> - **Hexachlorobutadiene (HCBD)**, used as a solvent in the manufacture of rubber compounds and as hydraulic, heat transfer or transformer fluid;
> - **Pentachlorothiophenol (PCTP)**, used as a mercaptan (sulfur) cross-linking agent to make rubber more pliable in industrial uses;
> - **Phenol, isopropylated, phosphate (3:1)**, used as a flame retardant in consumer products and as lubricant, hydraulic fluid, and other industrial uses; and
> - **2,4,6-Tris(tert-butyl) phenol**, an antioxidant that can be used as a fuel, oil, gasoline or lubricant additive.

TSCA section 6(h)(1)(B) calls on the Administrator to identify chemicals for which "exposure *** under the conditions of use is likely to the general population or to a potentially exposed or susceptible subpopulation identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator."

The draft exposure and use assessment confirms that exposure "is likely" for each of the five PBT chemicals EPA has identified.

[1] EPA's PERSISTENT, BIOACCUMULATIVE, AND TOXIC (PBT) CHEMICALS UNDER TSCA SECTION 6(H), https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/persistent-bioaccumulative-and-toxic-pbt-chemicals-under#identified (last visited July 19, 2018).

First, each of these chemicals are, by definition, persistent and bioaccumulative. As EPA recently stated:

> Persistent and bioaccumulative chemicals present special issues because organisms can remain exposed to them for a very long time and organisms higher up the food chain may be exposed to larger quantities of the chemicals through their food supply.[2]

In other words, these chemicals will remain in the environment and in people's and other organisms' bodies for a long time – even long after the chemicals' production or use has ceased.

Second, all five of these PBT chemicals appear to still be active in commerce, as each was reported as active in the TSCA inventory reset currently underway.[3]

Third, the draft exposure and use assessment itself lays out monitoring data supporting that exposure is likely to each of the five chemicals:

- **DecaBDE:** EPA found that DecaBDE was detected in 66% of human blood serum samples from 30 datasets, and DecaBDE was detected in 87% of samples from other types of human matrices from 36 datasets. EPA also found exposure to animals to be ubiquitous. (p. 46)

- **HCBD:** While EPA found limited human biomonitoring data, EPA demonstrated that exposure is occurring to ecological receptors. For example, EPA's review found that HCBD was detected in 48% of 25 datasets in fish and 37% of 17 datasets in aquatic invertebrates. (p. 88)

- **PIP (3:1):**
    - PIP (3:1) is a component of a common flame retardant formulation (Firemaster 550[4]). EPA notes that "production and use of PIP (3:1) may have increased since the flame retardant pentabromodiphenylether was banned and phased out of production in 2013." (p. 115) While not explicitly discussed in the draft exposure and use assessment, use of Firemaster 550 is widespread.[5] And because PIP (3:1) is an additive, not reactive, component, it can easily migrate out of products.

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[2] OPPT, TSCA Work Plan Chemicals: Methods Document at 14 (Feb. 2012), https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf.

[3] EPA's LIST OF SUBSTANCES REPORTED UNDER THE TSCA INVENTORY NOTIFICATION (ACTIVE-INACTIVE RULE), https://www.epa.gov/tsca-inventory/list-substances-reported-under-tsca-inventory-notification-active-inactive-rule (last visited July 23, 2018).

[4] EPA does not mention the commercial name of this formulation in its draft exposure and use assessment.

[5] Firemaster 550 is the most ubiquitous Firemaster product, as it was the primary replacement for PBDEs in polyurethane foam (PUF). Recent estimates indicate that Firemaster 550 is the second most common flame retardant added to PUF products and is the most common flame retardant used in products sold in California. Sources: 1) Peng, H., et al., "Detection, identification, and quantification of hydroxylated bis(2-ethylhexyl)-tetrabromophthalate isomers in house dust." 2015. *Environmental Science and Technology*. Available at: https://www.ncbi.nlm.nih.gov/pubmed/25621784; 2) LaGuardia M.L., and Hale, R. C., "Halogenated flame

- EPA found limited monitoring data for PIP (3:1), so it also included data on TPP – a closely related chemical also used in Firemaster 550 – as a surrogate. EPA found clear evidence of exposure: 85% human biomonitoring samples (non-blood) from five datasets had detections of TPP (p. 121); and 95% of indoor dust samples from 29 datasets had detections of PIP (3:1) and/or TPP. (p. 161)
- EPA also describes a UK modeling assessment on PIP (3:1), which "predicted occupational exposures on the order of 0.1 mg/kg/day and general population exposures on the order of 3 × 10-4 mg/kg/day driven by consumption of contaminated fish." (p. 127)

- **2,4,6 TTBP:** EPA evaluated data both for 2,4,6 TTBP and BHT, a structural and physical-chemical surrogate. While EPA identified limited monitoring data, there was 100% detection frequency of 2,4,6 TTBP and/or BHT in each of the indoor dust and indoor air samples based on two datasets and 97% detection frequency in surface/ground water based on two datasets. Further, one study that modeled the average daily dose of the sum of seven synthetic phenolic antioxidant analogues (surrogates for 2,4,6 TTBP) found that "[u]rban environments resulted in higher dose estimates than rural environments, and children also had higher dose estimates than adults," with urban children having an average daily dose of over 6 ng/kg/day. Children constitute a potentially exposed or susceptible subpopulation under TSCA. Beyond the current document, it is clear from the most recent Chemical Data Reporting (CDR) rule information that workers – another potentially exposed or susceptible subpopulation – are "likely exposed" to 2,4,6 TTBP. According to the 2016 CDR data, at least 125 – 550 industrial workers are "likely exposed" to 2,4,6 TTBP.[6]

- PCTP: While EPA only identified two human biomonitoring studies, both studies detected PCTP. (p. 150) EPA aptly explains that "this is potentially caused by a lack of monitoring data for PCTP, rather than an absence of PCTP in biomonitoring media." (p. 150) While the dataset is limited, the fact that 100% of available studies demonstrate PCTP in human matrices indicates that exposure is likely.

EDF strongly believes that the evidence laid out in the current document demonstrates that exposure is likely to each of the five PBT chemicals.

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retardant concentrations in settled dust, respirable and inhalable particulates and polyurethane foam at gymnastic training facilities and residences." 2015. *Environment International*. Available at: http://www.ncbi.nlm.nih.gov/pubmed/25812808. 3) California Office of Environmental Health Hazard Assessment (OEHHA), "Brominated and Chlorinated Organic Chemical Compounds Used as Flame Retardants." 2008. Available at: http://oehha.ca.gov/multimedia/biomon/pdf/120408flamedoc.pdf.

[6] See CDR data for 2,4,6 TTBP in Chemview: https://chemview.epa.gov/chemview/?tf=0&ch=732-26-3&su=2-5-6-7&as=3-10-9-8&ac=1-15-16-6378999&ma=4-11-1981377&tds=0&tdl=10&tas1=1&tas2=asc&tas3=undefined&tss=&modal=template&modalId=122990&modalSrc=4&modalDetailId=&modalCdr=122990.

IV. EPA must consider all conditions of use, including legacy uses, associated disposal, and legacy disposal as well as uses related to recycling and imported articles in its exposure and use assessment.

The text, structure, and purpose of TSCA section 6(h) all indicate that EPA must address each of these PBT substances as a whole. EPA has no legal basis for ignoring any conditions of use or sources of exposure. For example, TSCA section 6(h)(4) expressly requires that EPA "shall reduce exposure to the substance to the extent practicable," and to achieve that goal of reducing exposure, EPA will have to identify and address all potential exposure to the extent practicable. Thus, as a matter of law, EPA must consider all conditions of use and all sources of exposure to fulfill its statutory obligations.

a. Legacy uses, associated disposal, and legacy disposal

In the context of risk evaluation, EPA has adopted an approach to "conditions of use" that is contrary to law. For example, EPA asserts that it can ignore so-called "legacy uses," "associated disposal," and "legacy disposal."[7] As EDF has explained, there is no legal or logical basis for ignoring legacy uses or associated uses, and there is also no legal or logical basis for ignoring any conditions of use. *See* EDF Comments on the First Ten Scopes (Sept. 19, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0107. EDF incorporates and reiterates the points made in those comments here.

In addition, as a practical matter, it is particularly inappropriate to ignore so-called legacy uses, associated disposals, or legacy disposals in the context of PBTs under TSCA section 6(h). TSCA section 6(h) required expedited action on these chemicals precisely because they were both "persistent" and "bioaccumulative."[8] Thus, these chemicals are particularly likely to result in heightened exposure for lengthy periods of time even if their active production, use and disposal has ceased. Congress focused on these chemicals because of their long legacy; it would be absurd to ignore exposure resulting from those legacy uses and associated disposals in determining exposure to and regulating these chemicals.

The draft exposure and use assessment is somewhat ambiguous on the issue of legacy use, associated disposal, and legacy disposal. For example, in the lifecycle diagram for each chemical, EPA has usefully identified past/legacy uses. While not explicitly stated, however, it seems that the agency may not be planning to address these uses in developing the requisite TSCA section 6(a) rule, as they are not captured in the Representative Exposure Scenarios section for each chemical. It is unclear whether EPA considers that these are past uses it believes no longer result in exposure, or if this is an oversight. Given the absence of comprehensive bans on these uses, they need to be addressed in the TSCA section 6(a) rule.

[7] *See* 82 Fed. Reg. at 33,729-30

[8] 15 U.S.C. section 2605(h)

Notably, EPA aptly describes some of the legacy issues concerning DecaBDE elsewhere:

> DecaBDE was produced and released at higher levels in the past, but continues to be released under current conditions of use. Across the lifecycle, while releases from manufacturing and processing may be declining over time, releases associated with use, disposal, and recycling are likely to increase over time until the stock of available materials with DecaBDE is depleted. This depletion may take several years because of how long articles are typically used before being disposed and/or recycled. (p. 68)

However, in the Representative Exposure Scenarios section that follows, it is unclear if all such exposures are captured. For example, it is unclear whether the consumer exposure pathway (p. 69) is intended to address exposures from articles manufactured earlier (or newly manufactured from recycled materials; see subsection b below) and still in use (as described above), or only new imported articles. EPA should clarify that consumers may be exposed to DecaBDE through either route, and it must address both in developing the rule required under section 6(h).

The environmental monitoring and biomonitoring data on which the agency relies in the draft exposure and use assessment provide only limited means to quantitatively attribute the observed exposures to specific sources. There is every reason to expect, however, that much or most of this exposure to DecaBDE is coming from continued use of articles manufactured in the past. EPA must address such exposures moving forward.

b. Disposal and reasonably foreseen conditions of use arising from recycling

In the case of DecaBDE, the agency explicitly states that it "plans to analyze the use of DecaBDE in recycled plastic pallets, as the flame retardant properties of DecaBDE are still utilized for this particular use. EPA does not expect to consider recycled articles, where those articles do not have intended flame retardant applications." (p. 24) The decision only to address chemical exposure when the chemical subject to disposal serves its original function makes little sense and has no basis in the law.

First, EPA must adopt restrictions under section 6(h)(4) that "shall address the risks of injury to health or the environment *** presented by the chemical substance" and "shall reduce exposure to the substance to the extent practicable." Whether a chemical present in a material is serving a particular function or not has no bearing on its risk or exposure potentials, so EPA must address the chemical under section 6(h)(4) regardless of whether the chemical continues to serve its original function.

Second, under section 6(h)(1)(B) EPA must assess exposure "under the conditions of use," and these uses resulting from recycling qualify. Conditions of use is defined under TSCA section 3(4) to extend to known or reasonably foreseen, as well as intended, circumstances, meaning that EPA cannot exclude exposures that are known or reasonably foreseen even if they are not intended. Thus, regardless of the chemical's intended function, EPA must consider the chemical's conditions of use even if they are merely known and reasonably foreseen. In addition, EPA itself acknowledges that recycling is a form of disposal (p.23), falling neatly within the definition of conditions of use. As EPA is aware of other

recycled articles containing DecaBDE (e.g., toys intended for children's use), it must address the associated exposures in the rule mandated under TSCA section 6(h).

c. Imported articles

Where relevant across the five chemicals, EPA must also address exposures from imported articles. This is particularly salient for DecaBDE. As described in the use and exposure draft:

> The 2016 CDR data indicate that DecaBDE is manufactured (including import) in quantities less than 25,000 lbs (U.S. EPA, 2017b). However, significant quantities are also imported as a component of articles, including: plastics in televisions, computers, audio and video equipment; textiles and upholstered articles such as carpets, upholstery fabric, cushions, mattresses, and tents; wire and cables for communications and electronics; and other miscellaneous applications (EPA-HQ-OPPT-2016-0724). The quantity of DecaBDE in these articles is unknown; however, it may be substantial. Potential releases from these articles may occur when decaBDE migrates from the articles during use, disposal, and waste management. (p. 27)

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For the current exposure and use assessment, peer reviewers need to ensure that EPA has adequately identified all past/legacy uses of these chemicals and the extent to which they are or could be present in imported articles, as well as any ongoing exposures from such uses or post-use activities. It is critical that all such exposures are identified so that they can be effectively addressed in the risk management stage.

Moving forward, EPA must address legacy use, associated disposal, and legacy disposal through its section 6(a) rule in a manner sufficient to, as described above, "reduce exposure to the chemical substance to the extent practicable," as well as to eliminate unreasonable risk. Risk management of legacy use, associated disposal, and legacy disposal should include both a) exposure and risk reduction measures to address ongoing exposures from legacy use or disposal, and b) a prohibition on such conditions of use so that they cannot resume in the future. Absent a section 6(a) ban on past conditions of use, the potential for associated exposures remains—as there is nothing barring persons from resuming those activities. Exposure and risk reduction measures imposed through the requisite rules will likely also need to impose a ban on the import of articles containing the PBT chemicals.

V. EPA makes statements that suggest it believes exposure is low – without sufficient evidence.

EPA makes numerous assumptions with little or no backing that suggest a lack of exposure where such a conclusion is not or may not be warranted.

a. Applicability and sufficiency of existing regulations

EPA makes the following assertion: "Monitoring data from developed countries with well-established and enforced environmental regulations may be more relevant for the U.S." (p. 19) However, it provides no evidence that these five chemicals have been regulated in the U.S., under TSCA or other statutes, in a comparable manner to other countries.

In the case of HCBD, EPA asserts that the chemical is highly regulated (see below) – but provides no evidence of its regulation in the U.S. and instead alludes to regulation only in other parts of the world. In fact, EPA later states that the higher HCBD levels observed in the U.S. may be due to differences in regulations:

> "From 1985 through 2008, US sediments reported higher concentrations of HCBD than sediment concentrations from The Netherlands, Germany, Belgium, France, Malta, Spain, and Denmark. The latter group of seven countries are part of the European Union and subject to different regulations than the US, which may contribute to the differences observed." (p. 94)

We caution EPA from relying on data from a country or region where the chemical is more highly regulated than in the U.S. to estimate domestic exposure. The entire purpose of this assessment is to inform the extent of regulation that the U.S. needs to impose on these chemicals under TSCA; regulation in other countries has little bearing on this process. Indeed, relying on information from countries with more regulations governing these chemicals would create an inaccurate picture, since the exposures may be lower in those countries specifically because of their regulations.

Further, neither in the current document nor in the earlier preliminary use and assessment documents has EPA provided a comprehensive summary of existing regulations, akin to those provided in the problem formulation documents. EPA should develop such a summary.

b. Claims of exposure reductions over time

The draft exposure and use assessment states: "Reported monitoring data does not necessarily reflect current or future conditions; but rather the conditions that were present at the time when samples were collected." (p. 20)

While this is a true statement, absent more current evidence, EPA must rely on the data it has. It should not speculate on potential reductions over time without reliable monitoring data to support such assertions, especially since these chemicals are persistent and bioaccumulative.

Particularly troubling is the case of HCBD, where EPA appears to be asserting – without adequate evidence – that exposures have declined overtime. EPA states:

- "HCBD is a highly regulated chemical. In tandem with increased regulation, releases of HCBD have declined over time. This is likely due to many factors including improved control

technologies, increased use of processes that minimize waste, and required processing of waste at hazardous waste facilities which have more stringent control technologies to reduce emissions." (p. 104)

- "Human exposure to HCBD has limited documentation from one biomonitoring study. Choudhary (1995) provide a review of HCBD exposure to humans and notes potential for general population and occupational exposure at that time. ***The overall magnitude of exposures has likely decreased*** due to lower releases and control technologies within facilities. However, potential for human exposure remains." (p. 104; emphasis added)

However, the monitoring data themselves do not suggest any clear downward trend. In fact, the evidence laid out in the draft exposure and use assessment indicates that – with the exception of water – environmental level exposures to HCBD have remained constant overtime. For example:

- Air: "One monitoring database (EPA AMTIC) reported HCBD levels in ambient air from 1990 through 2014 (U.S. EPA, 1990). In general, HCBD concentrations spanned three orders of magnitude, from 101 to 104 ng/m3, with ***no strong temporal trends observed***. From 2004 to 2006, greater variability was observed with a larger range of concentrations detected and/or higher maximum concentrations." (p. 92) (emphasis added)
- Soil: "Eleven years of monitoring data were reported in the USGS database for HCBD concentrations in soils. From 1990 to 2015, ***no strong temporal trends were observed***, with concentrations ranging over five orders of magnitude." (p. 93) (emphasis added)
- Sediment: "Four monitoring databases (ICES, IPCHEM, USGS, EPA GLENDA) reported concentrations of HCBD in sediments from 1985 through 2016 (EC, 2018; ICES, 2018; U.S. EPA, 2018b; USGS, 1991). *** ***No strong temporal trends were observed*** when all databases were considered together or when databases were individually considered." (p.94) (emphasis added)
- Influent/Effluent: "One monitoring database (EPA DMR) reported HCBD levels in the influent/effluents of wastewater from 2007 through 2017 (U.S. EPA, 2007). A decrease in concentration was observed between 2007 and 2011, with levels steady between 2011 and 2017." (p. 97)

EPA's assertion that exposures have likely decreased is highly speculative and is not supported even by the data EPA cites. In the absence of reliable human and environmental exposure data showing otherwise – and sufficient to counter the monitoring data not indicating temporal downward trends – it is inappropriate to make such a claim.

c. Additional statements

Additional statements EPA makes in the draft exposure and use assessment without any or sufficient support or even explanation include:

- DecaBDE: Re Industrial/Commercial Use Articles – Complex articles:
    - "Releases to air and water are not expected." (p. 28)
    - "Inhalation exposure is not expected." (p. 29)
- HCBD:
    - "Once incorporated into the plastic formulation, the potential for worker exposure is not expected." (p. 77)
    - "EPA did not identify any studies with extractable HCBD data in indoor dust. There are not expected to be indoor sources of HCBD (e.g. consumer products or building materials). HCBD present in indoor air may be related to HCBD from outdoor air sources. HCBD in indoor air is not likely to adsorb to dust or other particles due to its log KOA. *As a result, HCBD is not expected to be present in indoor dust.*" (p. 80) (emphasis added)
- PCTP:
    - "Once incorporated into the rubber formulation, the potential for worker exposure is not expected." (p. 149)
    - "Once incorporated into the product, the potential for worker exposure is not expected." (p. 149)

VI. EPA's Representative Exposure Scenarios need to be more clearly presented and include all exposures associated with the conditions of use of the five PBT chemicals.

EPA has not adequately explained the purpose and the derivation of the Representative Exposure Scenarios. This problem is exacerbated by the fact that EPA has not captured all exposures under these scenarios, and has provided no explanation for the omissions.

For example, EPA has not included the consumer exposure pathway under the Representative Exposure Scenarios section for HCBD. This directly contradicts EPA's earlier statement that HCBD may lead to consumer exposure:

> "Reports indicate that HCBD was detected in jewelry, surface coatings of headwear, homogenous mixtures (likely adhesive) in underwear, and surface coatings of dolls or soft toys (WSDE, 2018a) *** Use of these products, if HCBD is present, may lead to consumer exposures (inhalation and dermal exposure) when products are worn or used." (p. 78)

In finalizing the exposure and use assessment, EPA should clearly explain the purpose of the Representative Exposure Scenarios and the process it used for identifying such scenarios. If they are intended to inform the "exposure is likely" determination and/or inform exposure reduction and risk management measures in the rules mandated under section 6(h), EPA must ensure that the Representative Exposure Scenarios capture all uses and associated exposures. Without providing a comprehensive picture, EPA may miss critical uses and pathways that need to be addressed through exposure reduction and risk management.

VII. EPA must identify any information gaps and use its authority under TSCA section 4 to the fullest extent possible to fill those gaps.

EPA should use its section 4 authority to fill any gaps in information. EPA has until June 22, 2019, to prepare proposed rules for these chemicals, so EPA has adequate time to require some testing and monitoring as necessary to identify and characterize hazards and sources of exposure to these chemicals.[9] TSCA section 4 provides EPA with authority to require testing and monitoring for chemicals, such as these, that may present an unreasonable risk of injury to health or the environment.[10]

Information that EPA can require to be generated under TSCA section 4 is reasonably available under EPA's own regulation as "information that EPA *** can reasonably generate [and] obtain."[11] Thus, EPA should identify such information gaps and then promptly require relevant parties to conduct all testing and monitoring as necessary for the development of the TSCA section 6(a) risk management rules. In addition, EPA should require testing and monitoring as necessary to implement requirements adopted in the eventual section 6(a) rules, pursuant to TSCA section 4(a)(2)(a)(ii).[12]

While EDF strongly believes that the draft exposure and use assessment provides sufficient support that exposure is likely to each of the five PBT chemicals, EPA should use its authorities to fill information gaps where they exist in order to better inform how those exposures are to be reduced to the extent practicable through the forthcoming TSCA section 6(a) risk management rules.

EPA should consider promulgating section 4 rules or orders to fill at least the following information gaps:

- Environmental monitoring information for PIP (3:1), 2,4,6 TTBP, and PCTP.
- Indoor dust and human biomonitoring studies for HCBD.
- Repeat-dose animal toxicity studies or human epidemiological studies on PCTP.[13]

[9] 15 U.S.C. section 2605(h)(1)

[10] *Id.* section 2603(a)(1)

[11] 40 C.F.R. section 702.33

[12] 15 U.S.C. section 2603(a)(2)(A)(ii)

[13] EPA states: "For PCTP, no relevant repeated dose animal toxicity studies or human data were available for the chemical. Thus, a search was conducted for analogous chemicals that are known to metabolize or degrade into PCTP using the expanded results feature in the HSDB." (p. 7) While examining data on analogs can be useful, to the extent data gaps in hazard data exist for the specific PBT chemical and are needed to inform the regulation, EPA should be filling them, not solely relying on analogs.

VIII. EPA has excluded reasonably available exposure and use information, including through its literature search strategy.

The draft supplemental document indicates that, for all five PBT chemicals, information EPA has already acquired through TSCA sections 4 and 8 has not been incorporated and will be considered at a later date:

> EPA is aware of information submitted by companies as part of TSCA requirements under sections 4, 8(d), 8(e) or as part of an FYI ("TSCATS Submissions data"). This information was not considered as part of the literature search and screening strategy. EPA plans to consider this information in the future. (pp. 10, 25, 38, 55, 68)

EDF finds this to be wholly unacceptable. Under TSCA section 26(k), EPA is required to consider "reasonably available information" in carrying out sections 4, 5, and 6. EPA regulations now define "reasonably available information" to mean "information that EPA possesses or can reasonably generate, obtain and synthesize for use, considering the deadlines."[14] Information that EPA has acquired under sections 4 and 8 (as well as so-called "FYI submissions") fit squarely within the definition of reasonably available information, as EPA already possesses this information.

While EPA indicates it plans to consider this information in the future, it is inappropriate for EPA to have delayed such consideration. EPA's decision to do so has deprived the peer reviewers and public from the opportunity to consider what may be critical information in their review of the current documents. Even as EPA moves expeditiously to develop the section 6(a) rule, we urge EPA, as soon as possible, to publish a supplemental document that compiles and assesses all information EPA has acquired on these chemicals under TSCA sections 4 and 8. EPA should provide public access to this information, subject to section 14, and accept public comment on the supplemental document.

Additionally, for four of the five PBT chemicals in the assessment (all but PCTP), EPA has excluded reasonably available studies.

> A subset of studies that passed the screening phase were not extracted or evaluated due to the ready availability of the full text and supplemental information. Due to time constraints, studies that did not include data in text or tables, and studies that had fewer than 10 observations were not extracted or evaluated. (e.g., p. 21)

It appears that a large fraction of studies were excluded through this process (e.g., 177 studies on HCBD and 29 studies on 2,4,6 TTBP were excluded because data were not able to be extracted). For chemicals with limited monitoring data (such as 2,4,6 TTBP) in particular, it makes little sense that EPA excluded these data.

[14] 40 C.F.R. sections 702.3, 702.33

While it may be appropriate to assign less weight to or exclude studies if they are of poor quality or are critically deficient, EPA's invoking of time constraints is an inadequate rationale for excluding relevant information. Where EPA has a summary of a study it has excluded because it did not have access to the full study, it should use all of its authorities under TSCA to obtain it. If all attempts to do so have failed, these studies should at least be qualitatively considered in the determination of whether exposure is likely.

We strongly urge EPA to immediately provide a list of references to all of the studies that were excluded through this process and make the list available both to the peer reviewers and the public in advance of the upcoming peer review. Further, EPA should promptly initiate efforts to acquire copies of the full studies for those that it excluded from the analysis on the basis of the inability to access the full text and supplemental information, using its data gathering authorities under TSCA as needed. Once it has acquired the studies, it should make them available to the peer reviewers and the public and integrate them into the final assessment. The studies should be made publicly available no later than when the section 6(a) rule is proposed.

IX. EPA should acquire and make publicly available all health and safety studies and underlying information on which it relies in these documents.

Several statements in EPA's draft hazard summary suggest EPA does not intend to make publicly available all health and safety studies and underlying information it has or will compile and on which it intends to rely in developing proposed rules to restrict these PBT substances pursuant to section 6(h).

First, on page 4 EPA states: "To create this hazard summary, environmental and human health hazard data were compiled from various primary and secondary sources of both *confidential* and publicly-available information." (emphasis added) This statement suggests that EPA considers certain health and safety data it has in its possession to be eligible to be protected from disclosure as confidential business information (CBI). TSCA section 14(b)(2) expressly disallows such protection, subject only to two narrow exceptions. Barring the unlikely explanation that the "confidential" health and safety information EPA possesses qualifies under one of these exemptions, EPA needs to follow the law and ensure such information is publicly available. Peer reviewers also need to understand that they can and should be provided access to all such information in the context of their review of these documents.

Second, also on page 4, EPA states: "Available published and *unpublished* repeated-dose toxicity data are tabulated according to health endpoints and the identified studies are briefly summarized." (emphasis added) EPA needs to provide public access to the unpublished studies it possesses and intends to rely on. While EPA providing summaries of the information is obviously appropriate in this draft hazard summary, doing so does not obviate EPA's obligation to make the studies and their underlying information publicly available.

Third, the draft hazard summary contains numerous references to information available through the European Chemicals Agency (ECHA), including registration dossiers for two of the five PBT substances

and a "SVHC support document" for a third. It is essential that EPA not rely only on summaries of studies typically included in registration dossiers, but also has access – and provides for public access – to the health and safety studies themselves and any underlying information. For years certain questionable operating procedures by the chemical industry under the EU's REACH Regulation have served to block government and public access to health and safety information on chemicals submitted by companies under REACH. EPA need not and should not simply accept such limited access to information on which it plans to rely. The accuracy and completeness of study summaries prepared by manufacturers or processors of a chemical cannot be relied on absent EPA verification based on access to the studies themselves. EPA needs promptly take steps to obtain the underlying studies and can and should use its information-collection authorities under TSCA section 8 or 11(c) to do so.

X. EPA needs to identify all types of acute and subacute as well as chronic hazards.

On page 4 of EPA's draft hazard summary, and page 1 of its associated charge questions, EPA states: "The hazard summaries relevant to human health *focus on repeated-dose studies* given the PBT nature of the chemicals of interest." (emphasis added)

While such studies certainly should be included, the law provides no basis for EPA to limit its consideration to such studies. EPA needs to summarize all types of hazard data for each of the five chemicals as a basis for fulfilling its obligation to take regulatory action to address all types of associated exposures and risks. Nothing in the text of TSCA section 6(h) limits EPA's consideration of toxicity to repeat-dose toxicity, and chemicals that persist in the environment or bioaccumulate can lead to acute or sub-chronic as well as chronic exposures and effects.

In promulgating the required rules under TSCA section 6(a) and selecting restrictions, EPA is required to address all kinds of risks to human health and the environment as well as reduce all exposures to the relevant chemical substance to the extent practicable. Nothing in the text of TSCA section 6(h)(4) limits these obligations to subsets of hazards, exposures or risks.

Hence, EPA needs to broaden its hazard summaries to encompass all types of hazards presented by the five chemicals.

On related note, EPA appears to have missed a panel of government studies on PIP (3:1). As we noted in our comments on EPA's TSCA Work Plan Chemical Problem Formulation and Data Needs Assessment on the Brominated Phthalates Cluster Flame Retardants,[15] the National Toxicology Program (NTP) selected Firemaster 550 and its four components for further testing in 2013.[16] NTP has completed or initiated a

[15] *See* EDF comments on EPA's TSCA Work Plan Chemical Problem Formulation and Data Needs Assessment on the Brominated Phthalates Cluster Flame Retardants: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0491-0013.

[16] NTP's NOMINATION SUMMARY FOR FIREMASTER 550 (N21305), http://ntp.niehs.nih.gov/testing/noms/search/summary/nm-n21305.html (last visited July 19, 2018).

number of studies, including both short-term and long term, on PIP (3:1).[17] However, EPA has failed to integrate these studies in its summary of the hazards of PIP (3:1). It needs to do so.

XI. EPA's use of hazard data on commercial mixtures containing the PBT chemicals is entirely appropriate.

For two of the PBT chemicals, EPA appears to suggest that it may not rely on or deem as relevant hazard information for commercial mixtures containing the chemical. EPA states:

- DecaBDE: "Most of the available hazard information on DecaBDE are for a product containing DecaBDE, therefore it is important to note that many of the studies cited in Table 4-1 examined effects from the *exposure to a mixture containing DecaBDE*. Commercial mixtures containing DecaBDE (77-98%) also consist of smaller amounts of congeners of nona- and octa-brominated diphenyl ether, although the product composition can vary greatly." (p. 8, emphasis added)
- PIP (3:1): "Most of the studies cited in Table 6-1 *represent exposures to whole commercial products* and the amount of PIP (3:1) varies greatly in content and propylation configurations; the exposure to other chemicals within the product (e.g., triphenyl phosphate) may have influenced the effects observed." (p. 20; emphasis added)

It is not clear why this should be a major concern. The identification of these chemicals as chemicals of concern, and their listing in the Work Plan, relies on such data. In addition, because these are commercial products, the mixtures are the forms in which people and the environment are largely exposed to the chemicals, as opposed to the individual purified substances. Thus, arguably such studies contribute to the best available science for analyzing the hazards presented by these chemicals in the real-world. Moreover, unless EPA is willing to require additional testing using its TSCA section 4 authorities, it must rely on the available data on the commercial mixtures containing these chemicals.

Thank you for the opportunity to provide comment.

[17] NTP's TESTING STATUS OF ISOPROPYLATED PHENOL PHOSPHATE 11037, https://ntp.niehs.nih.gov/testing/status/agents/ts-11037.html (last visited 23 July, 2018).