

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families on Persistent, Bioaccumulative, and Toxic (PBT) Chemicals Subject to Regulation under Section 6(h) of the Toxic Substances Control Act

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Decabromodiphenyl ethers (DecaBDE): EPA-HQ-OPPT-2016-0724

Hexachlorobutadiene (HCBD): EPA-HQ-OPPT-2016-0738

Pentachlorothiophenol (PCTP): EPA-HQ-OPPT-2016-0739

Phenol, isopropylated, phosphate (3:1): EPA-HQ-OPPT-2016-0730

2,4,6-Tris(tert-butyl) phenol: EPA-HQ-OPPT-2016-0734

Safer Chemicals Healthy Families (SCHF), Alaska Community Action on Toxics, Center for Environmental Health, Earthjustice, Environmental Health Strategy Center, Natural Resources Defense Council, and Toxic-Free Future submit these comments on the five Persistent, Bioaccumulative, and Toxic (PBT) chemicals identified by the Environmental Protection Agency (EPA) for regulation under section 6(h) of the recently amended Toxic Substances Control Act (TSCA).

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. 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.

These comments focus on the broad goals and requirements of TSCA section 6(h). Additional comments by our groups and related organizations provide specific use and exposure information on the five PBTs that will enhance EPA's understanding of their presence in products, workplaces and the environment.

Section 6(h) is one of several improvements in health and environmental protection from chemical risks that Congress made in TSCA through the 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA). This provision reflects the long-standing recognition by EPA and international bodies of the special dangers that PBTs pose to people and ecosystems as a result of their long-term presence, wide distribution and accumulation in living organisms and the natural environment. To address these dangers, section 6(h) creates a fast-track process for stringently restricting manufacture, use and disposal of chemicals previously determined by EPA to possess PBT properties. These restrictions must reduce exposure to the extent practicable, thereby preventing further build-up of the PBTs in the environment and biota and the harmful consequences that result. Reflecting this sense of urgency, rules imposing these restrictions must be proposed no later than June of 2019 and finalized 18 months thereafter.

We strongly urge EPA to interpret and implement section 6(h) in a manner that achieves the goals of section 6(h). Congress framed its requirements so that EPA could act expeditiously, based on the presumption that chemicals determined to be PBTs are harmful to the health and the environment and must be restricted without further risk evaluation or analysis of costs and benefits. As discussed below, in implementing section 6(h), EPA should not create unnecessary roadblocks but should focus on the overriding Congressional objective of achieving the maximum possible reduction in human exposure and environmental release. This objective compels EPA, subject only to constraints on feasibility, to impose requirements under section 6(a)(1) that eliminate manufacturing, processing, distribution in commerce and disposal of the five PBTs. In addition, use and unsafe disposal of legacy PBT-containing products should be prohibited under sections 6(a)(5) and (6), and manufacturers and processors should be required to repurchase or replace these products under section 6(a)(7).

EPA Has on Numerous Occasions Highlighted the Serious and Unique Threats Posed by PBTs to Human Health and the Environment

In its 1989 PBT strategy, EPA noted that:¹

“EPA has a long history of successful programs in controlling PBT pollutants -- pollutants that are toxic, persist in the environment, and bioaccumulate in food chains, and thus pose risks to human health and ecosystems. The challenges remaining on PBT pollutants stem from the fact that they transfer rather easily among air, water, and land, and span boundaries of programs, geography, and generations, making single-statute approaches less than the full solution to reducing these risks. To achieve further reductions, a multi-media approach is necessary.”

“PBTs are associated with a range of adverse human health effects, including effects on the nervous system, reproductive and developmental problems, cancer, and genetic impacts. People who eat large amounts of fish from local waters contaminated with certain PBTs are at risk for adverse effects. The developing fetus and young child are at particular risk for developmental problems. Birds and mammals at the top of the food chain are also at risk. The most famous example is the serious decline of the bald eagle in the 1960's because the fish they ate contained DDT.”

In its presentation at the September 7, 2017 Webinar on section 6(h),² EPA further underscored that:

“EPA believes that, as a general matter, the release to the environment of toxic chemicals that persist and bioaccumulate **is of greater concern than the release of toxic chemicals that do not persist or bioaccumulate.**”

Since PBT chemicals can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues, even relatively small releases of such chemicals from individual facilities have the potential to accumulate over time to higher levels and cause significant adverse impacts on human health and the environment.”

¹ <https://archive.epa.gov/p2/archive/web/pdf/pbtstrat.pdf>

² https://www.epa.gov/sites/production/files/2017-09/documents/pbt_public_webinar_-_9-5-17.pdf (emphasis in original).

As EPA has recognized, the special characteristics of PBTs dictate a comprehensive, multi-media strategy to reduce exposure and release – and thus potential accumulation in biological systems and the environment – to the lowest levels possible. This is the goal of section 6(h).

EPA Has Already Established that the Five Substances Meet the TSCA Criteria for Persistence and Bioaccumulation

6(h) builds on and incorporates previous EPA efforts to identify PBTs under TSCA. Under section 6(h)(1), chemicals subject to restriction are those that (1) are identified in the 2014 update of the TSCA Work Plan for Chemical Assessments and scored high for both persistence and bioaccumulation, or high for one and either high or moderate for another, based on EPA’s 2012 Work Plan methodology; (2) do not fall within statutory exclusions for metals and certain previous regulatory actions; and (3) were not the subject of timely industry requests for risk evaluations as described in section 6(h)(5).

As EPA has explained,³ the five chemicals that EPA has targeted for restriction under section 6(h) reflect a careful application of these criteria, including scoring of their persistence and bioaccumulation properties using the 2012 Workplan methodology. Thus, EPA’s determination that they are PBTs requiring restriction under section 6(h) is not in doubt.

EPA Should not Replace the Workplan PBT Criteria with a New PBT Identification Framework as Proposed by the Chemical Industry

In comments recently submitted to the PBT docket, the American Chemistry Council (“ACC”) has advocated replacing the Workplan criteria with a new “framework” for identifying PBTs and recommended reexamining the PBT properties of the 5 chemicals based on this framework.⁴ This suggestion should be rejected for many reasons.

For EPA to alter its criteria for what constitutes a PBT chemical would require an extensive public process with considerable input from the scientific community and have implications far beyond TSCA. The Workplan PBT criteria are linked to other EPA programs such as the TSCA new chemical review process,⁵ and are consistent with well-established international efforts to restrict PBTs such as the Stockholm Convention on Persistent Organic Pollutants.⁶ Describing provisions that form the basis for section 6(h), the House Report on the TSCA legislation states that “[t]he Committee hopes the Administrator will rely on its TSCA Work Plan Chemicals Methods Document published in February 2012 in identifying PBT candidate substances for listing.”⁷ To now jettison the Congressionally-approved and internationally-accepted Workplan criteria would be not only irresponsible but a reckless reversal of EPA’s determination nearly a year ago that the five PBTs are subject to section 6(h) because they meet these criteria.

³ <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act-0#pbt>; See Q&As 39-44

⁴ <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0724-0006>

⁵ Federal Register, Vol. 64, No 213. Nov 4, 1999. EPA: Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances.

⁶ Stockholm Convention on Persistent Organic Pollutants, Annex D. Information Requirements and Screening Criteria. Available at: <http://chm.pops.int/Portals/0/download.aspx?d=UNEP-POPS-COP-CONVTEXT-D.En.pdf>

⁷ H.R Report 114–176, 114 Cong, 1st Sess, June 23, 2015, at 27.

Finally, even if it made sense for EPA to alter its criteria for what constitutes a PBT, the “framework” proposed by the ACC would not be an acceptable replacement for the TSCA Work Plan Chemicals Method Document. The 2008 Society of Environmental Toxicology and Chemistry (SETAC) Pellston Workshop is not incorporated in a peer-reviewed publication. The version that is peer-reviewed is 4 pages long and very general: It does NOT propose actual criteria for P, B or T. Moreover, the Workshop was industry funded and 6 out of 9 of the workgroups were chaired by industry participants. It strains credulity to suggest that a non-peer-reviewed document published ten years ago in 2008, sponsored by industry, is a “consensus” on the “current science” of PBTs.

Restriction of the Five PBTs under Section 6(h) Does Not Require a Determination of Risk but Simply Calls for Findings of Toxicity and Likely Exposure

Section 6(h)(2) is explicit that EPA is not “required to conduct risk evaluations” on PBTs identified under section 6(h)(1). This evidences Congress’ recognition that the examination of risk that TSCA requires as a condition for restricting other chemicals is inapplicable to PBTs because of the uniquely serious threats that their inherent properties pose to health and the environment.

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.⁸

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.” No additional analysis is necessary to satisfy this element of section 6(h).

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. This determination must be made on the basis of a “use and exposure assessment.” 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. It is sufficient to show that people are likely to be exposed to the PBT or that it is likely to be present in the environment based on the nature of the PBT’s manufacture, processing and use.

Under the Work Plan Methods Document, the five PBTs have already been screened and scored for “exposure” and this should constitute an adequate “use and exposure assessment” under section

⁸ 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.”

6(h)(1)(B).⁹ Moreover, EPA has supplemented the screening conducted under the Work Plan process by developing “use documents” on the five PBTs that summarize available information on the manufacturing (including importing), processing, distribution in commerce, use, and disposal of each chemical. These descriptions of the chemicals’ conditions of use provide further evidence of “likely” exposure and similarly satisfy the requirement of a “use and exposure assessment” under section 6(h)(1)(B).

Although EPA has already met its obligation to show likely exposure to the five PBTs, we encourage EPA to augment its use documents with any additional information submitted by interested parties. A comprehensive understanding of current use and exposure will help ensure that restrictions imposed by the Agency under section 6(h)(4) target all known or foreseeable pathways of exposure and eliminate them to the extent practicable. This will in turn ensure that EPA’s rules are effective in preventing long-term buildup of the PBTs in the environment and food chain and in preventing the resulting harm to people and biota.

Restrictions on PBTs under Section 6(h) Must Achieve the Greatest Feasible Reduction in Exposure and Environmental Release

Restrictions on PBTs identified in accordance with section 6(h)(1) must comply with section 6(h)(4). Under this provision, EPA must select restrictions on covered PBTs from the list of allowable requirements in section 6(a). However, in all other respects, the risk management provisions of sections 6 do not apply. Thus, EPA need not make a determination of “unreasonable risk,” need not conduct an analysis of costs, benefits and other economic consequences of its rule, and is not required to consider the availability of alternatives to the PBT.

Instead, section 6(h)(4) provides that the selection of restrictions must be based on only two factors. First, 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.”¹⁰

Addressing all Risks of Injury. The first requirement means that, in placing restrictions on the PBT, 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. A formal risk assessment should not be necessary to satisfy this requirement. But EPA should have a sufficient understanding of the PBT’s pathways of exposure and release and 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.

⁹ 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.”

¹⁰ While earlier drafts of the legislation used the phrase “to the maximum extent practicable,” the legislative history indicates that this phrase was considered synonymous with the phrase “to the extent practicable” included in the enacted legislation. Thus, the deletion of “maximum” did not change EPA’s obligations. Congressional Record – Senate 3517 (June 7, 2016).

Reducing Exposure. The second requirement, which is independent of the first, should ensure that the selected restriction achieves the largest possible reduction in exposure by humans, plant and animal species, and environmental media (air, water and waste) that is “practicable.”

According to the Merriam-Webster dictionary, the term “practicable” means “capable of being put into practice or of being done or accomplished.” The dictionary lists as synonyms achievable, attainable, doable, feasible, possible, realizable, viable, and workable. Statutes and regulations using the term “to the extent practicable” have generally been interpreted to require all actions within the limits of available technology and other physical and practical constraints.¹¹ Costs and other economic considerations have generally been excluded from determinations of “practicability” unless they are so great as to make the desired goal impossible to achieve.

These considerations should govern the restrictions that EPA selects from the list of allowable requirements in section 6(a) to reduce PBT exposure. Since exposure must be reduced to the extent “practicable,” EPA must opt for those measures that result in the highest degree of exposure reduction which is technically and economically achievable, without regard to cost-benefit or cost-effectiveness factors. In most cases, the greatest exposure reduction will be obtained from a “requirement prohibiting . . . the manufacturing, processing, or distribution in commerce” of the PBT under section 6(a)(1)(A). Thus, EPA should impose such a prohibition unless the cessation of manufacturing, processing and distribution is not feasible.¹² Since disposal is an additional source of exposure, EPA should also impose a “requirement prohibiting . . . any manner or method of disposal” of the PBT, again subject to limits on feasibility, under section 6(a)(6)(A).¹³

Finally, even if manufacture and processing for a particular use have been discontinued, where “legacy products” containing the PBT remain in use and are a source of ongoing human exposure and release to the environment, EPA must take action to reduce such exposure and release to the extent practicable.¹⁴ Thus, barring feasibility constraints, EPA should invoke section 6(a)(7), under which manufacturers and processors must provide notice of the PBT to exposed persons and the general public and replace or repurchase products containing the PBT. EPA must also take action under section 6(a)(6) to reduce exposure to these “legacy” substances during future disposal and/or recycling.

We appreciate the opportunity to provide our views on section 6(h) of TSCA and look forward to continuing to work with EPA. Please contact SCHF counsel, Bob Sussman, with any questions at bobsussman1@comcast.net.

¹¹ The maximum extent practicable standard “imposes a clear duty on the agency to fulfill the statutory command to the extent that it is feasible or possible.” (*Defenders of Wildlife v. Babbitt*, 130 F. Supp. 2d 121, 131 (D.D.C. 2001); *Friends of Boundary Waters Wilderness v. Thomas*, 53 F.3d 881, 885 (8th Cir. 1995) (“feasible” means “physically possible”).)

¹² This prohibition should cover not just current manufacturing and processing but the resumption of previously discontinued activities in order to prevent future sources of exposure and release.

¹³ Thus, EPA could allow a particular use to continue if there is no available substitute but not if available substitutes are more expensive or provide inferior performance. These considerations would be relevant only in establishing use exemptions from section 6(a) restrictions under section 6(g).

¹⁴ 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 “legacy uses” 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 doesn’t contain this term.

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