

PRE-PUBLICATION NOTICE

On March 8, 2021, **Michal Freedhoff**, the EPA acting Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, signed the following document:

Action: Notice
Title: Regulation of Persistent, Bioaccumulative, and Toxic Chemicals
Under TSCA Section 6(h); Request for Comments
FRL #: 10021-08
Docket ID #: EPA-HQ-OPPT-2021-0202

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For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the Federal Register document.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2021-0202; FRL-10021-08]

**Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h);
Request for Comments**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with the January 21, 2021, Executive Order entitled “Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis” and other Biden-Harris Administration Executive Orders and other direction, the Environmental Protection Agency (EPA) is requesting additional public comments on five final rules recently issued under the Toxic Substances Control Act (TSCA). On January 6, 2021, EPA issued final rules to address its obligations under TSCA for five persistent, bioaccumulative, and toxic (PBT) chemicals that EPA determined met the criteria for expedited action under TSCA. These chemicals are 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP) (CASRN 732-26-3); decabromodiphenyl ether (decaBDE) (CASRN 1163-19-5); phenol, isopropylated phosphate (3:1) (PIP (3:1)) (CASRN 68937-41-7); pentachlorothiophenol (PCTP) (CASRN 133-49-3); and hexachlorobutadiene (HCBd) (CASRN 87-68-3). PBT chemicals are of particular concern in the Agency’s efforts to protect human health and the environment because they are toxic and remain in the environment for long periods of time and can build up or accumulate in the body. As a first step in its efforts to immediately review these rules to determine whether they are consistent with the Administration policy to limit exposure to dangerous chemicals (and to determine whether and how these rules should be revised), EPA invites public comment on the final rules, including

whether there are further exposure reductions that could be achieved, including exposure reductions for potentially exposed or susceptible subpopulations and the environment; implementation issues associated with these final rules; and whether to consider additional or alternative measures or approaches. In particular, EPA is seeking comment on specifics of recently raised issues regarding the compliance date for the prohibition on the processing and distribution of PIP (3:1) for use in articles, and PIP (3:1)-containing articles.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2021-0202, through the Federal eRulemaking Portal at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room were closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Cindy Wheeler, Existing Chemicals Risk Management Division (Mail Code 7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave.,

NW., Washington, DC 20460-0001; telephone number: (202) 566-0484; email address: *TSCA-PBT-rules@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this apply to me?

This notice is directed to the public in general and may be of interest to persons who currently or may manufacture (including import), process, distribute, use, and/or dispose of the five PBT chemicals: 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP) (CASRN 732-26-3); decabromodiphenyl ether (decaBDE) (CASRN 1163-19-5); phenol, isopropylated phosphate (3:1) (PIP (3:1)) (CASRN 68937-41-7); pentachlorothiophenol (PCTP) (CASRN 133-49-3); and hexachlorobutadiene (HCBd) (CASRN 87-68-3). The action may also be of interest to persons who currently or may manufacture (including import), process, distribute, use, and/or dispose of products and articles containing these PBT chemicals. Non-governmental organizations in the environmental and public health sectors, state and local government agencies, and members of the public may also be interested in this action. Since other entities may also be interested, EPA has not attempted to describe all the specific entities that may be affected by this action.

B. What is EPA's authority for taking this action?

EPA issued the final rules under TSCA section 6(h), 15 U.S.C. 2601 *et seq.*, for five persistent, bioaccumulative, and toxic (PBT) chemical substances that met the statutory criteria. More specifically, under TSCA section 6(h), EPA must take expedited action on those chemical

substances identified in the 2014 Update to the TSCA Work Plan for Chemical Assessments (Ref. 1) that, among other factors, EPA has a reasonable basis to conclude are toxic and that with respect to persistence and bioaccumulation score high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals: Methods Document (Ref. 2). The chemical substances that meet these criteria are 2,4,6-TTBP, decaBDE, PIP (3:1), PCTP, and HCBd. Under TSCA, if EPA determines that exposure is likely to a chemical meeting these criteria, EPA must issue a rule that addresses the risks of injury to health or the environment that the Administrator determines are presented and reduces exposure to the chemical to the extent practicable. Based on the “Exposure and Use Assessment of Five Persistent, Bioaccumulative and Toxic Chemicals Assessment” (Ref. 3), EPA determined that exposure was likely to all five of the PBT chemicals. On January 6, 2021, EPA issued a final rule for each of the five chemicals under TSCA section 6(h), meeting the Agency’s obligation to promulgate the rules within 18 months of issuance of the proposed rules (Refs. 4-8). With the obligation to promulgate these rules, the Agency also has the authority to amend them if circumstances change, including in relation to the receipt of new information.

C. What action is EPA taking?

EPA is inviting public comment on the provisions of the final rules. The Agency is broadly re-examining TSCA section 6(h) requirements and other provisions of amended TSCA, including determining how the new Executive Orders and other direction provided by the Biden-Harris Administration (Refs. 9-13) will be addressed, as well as new information received from stakeholders. As part of this process, EPA will review and consider revising the final PBT rules with an eye towards reducing exposure to the extent practicable, environmental justice, scientific integrity, and EPA’s mission of protecting human health and the environment, taking into

consideration information received while the rules were under development as well as any new information submitted since the rules were finalized and information received in response to this notice. EPA is also aware of and plans to consider revisions in response to implementation issues that have been raised by a range of stakeholders. In particular, EPA is seeking comment on newly-raised issues associated with the March 8, 2021, compliance date in the PIP (3:1) rule for certain regulated articles.

D. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Summary of the Final PBT Rules

This unit provides a summary of the five TSCA section 6(h) final rules that published in the Federal Register of January 6, 2021. However, each rule should be consulted for additional details on the requirements adopted and the rationale for those requirements.

A. 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h) (RIN 2070-AK59)

Uses of 2,4,6-TTBP may be grouped into four general categories: (1) Domestic manufacture and use as an intermediate/reactant in processing at chemical facilities; (2) use in formulations and mixtures for fuel treatment in refineries and fuel facilities; (3) use in formulations intended for the maintenance or repair of motor vehicles and machinery at small commercial operations and for retail sale, and (4) use in formulations and mixtures for liquid lubricant and grease additives/antioxidants additives. 2,4,6-TTBP is toxic to aquatic plants, aquatic invertebrates, and fish. Surveyed animal data indicate the potential for liver and developmental effects. The final rule for 2,4,6-TTBP (Ref. 4) prohibits the distribution in commerce of 2,4,6-TTBP and products containing 2,4,6-TTBP at concentrations above 0.3% by weight in any container with a volume of less than 35 gallons in order to minimize the use of 2,4,6-TTBP as a fuel additive or fuel injector cleaner by consumers and small commercial operations (e.g., automotive repair shops, marinas). The final rule also prohibits the processing and distribution in commerce of 2,4,6-TTBP, and products containing 2,4,6-TTBP, for use as an oil or lubricant additive in concentrations above 0.3% by weight regardless of container size. The final rule includes a number of broad exclusions or definitions intended to apply to each of the five PBT rules, including definitions of article and product and exclusions for research and development, disposal, and the resale of products and articles previously sold to an end user.

B. Decabromodiphenyl Ether (DecaBDE); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h) (RIN 2070-AK34)

DecaBDE (Ref. 5) is used as an additive flame retardant in plastic enclosures for televisions, computers, audio and video equipment, textiles and upholstered articles, wire and cables for communication and electronic equipment, and other applications. DecaBDE is also used as a flame retardant for multiple applications for aerospace and automotive vehicles,

including replacement parts for aircraft and cars. DecaBDE is toxic to aquatic invertebrates, fish, and terrestrial invertebrates. Data indicate the potential for developmental, neurological, and immunological effects, general developmental toxicity, liver effects, and carcinogenicity. The final rule for decaBDE (Ref. 5) prohibits the manufacture (including import) and processing of decaBDE, and products and articles containing decaBDE, as of March 8, 2021. Distribution in commerce of products and articles to which decaBDE has been added is prohibited as of January 6, 2022. Different compliance dates or exclusions include:

- Manufacture, processing, and distribution in commerce for use in curtains in the hospitality industry after July 6, 2022;
- Processing and distribution in commerce for use in wire and cable insulation in nuclear power generation facilities after January 6, 2023;
- Manufacture, processing, and distribution in commerce for use in parts for new aerospace vehicles after January 8, 2024;
- Manufacture, processing, and distribution in commerce for use in replacement parts for aerospace vehicles until the end of the vehicles' service lives;
- Manufacture, processing, and distribution in commerce for use in replacement parts for motor vehicles until the end of the vehicles' service lives or 2036, whichever is earlier;
- Distribution in commerce of plastic shipping pallets manufactured prior to the publication of the final rule that contain decaBDE until the end of the pallets service lives; and
- Processing and distribution in commerce for recycling of plastic that contained decaBDE before the plastic was recycled, and the articles and products made from such recycled plastic so long as no new decaBDE is added during the recycling or production process.

C. Phenol, Isopropylated Phosphate (3:1) (PIP 3:1); Regulation of Persistent, Bioaccumulative,

and Toxic Chemicals Under TSCA Section 6(h) (RIN 2070-AK58)

PIP (3:1) (Ref. 6) is used as a plasticizer, a flame retardant, an anti-wear additive, or an anti-compressibility additive in hydraulic fluid, lubricating oils, lubricants and greases, various industrial coatings, adhesives, sealants, and plastic articles. PIP (3:1) is toxic to aquatic plants, aquatic invertebrates, sediment invertebrates and fish. Data indicate the potential for reproductive and developmental effects, neurological effects and effects on systemic organs, specifically adrenals, liver, ovary, heart, and lungs. The PIP (3:1) final rule (Ref. 6) prohibits processing and distribution in commerce of PIP (3:1), and products or articles containing the chemical substance, for all uses, except for the following different compliance dates or exclusions:

- Use in photographic printing articles after January 1, 2022;
- Use in aviation hydraulic fluid in hydraulic systems and use in specialty hydraulic fluids for military applications;
- Use in lubricants and greases;
- Use in new and replacement parts for the aerospace and automotive industries;
- Use as an intermediate in the manufacture of cyanoacrylate glue;
- Use in specialized engine air filters for locomotive and marine applications;
- Use in sealants and adhesives after January 6, 2025; and
- Recycling of plastic that contained PIP (3:1) before the plastic was recycled, and the articles and products made from such recycled plastic, so long as no new PIP (3:1) is added during the recycling or production process.

In addition, the final rule requires manufacturers, processors, and distributors of PIP (3:1) and products containing PIP (3:1) to notify their customers of these restrictions. Finally, the rule

prohibits releases to water from the remaining manufacturing, processing, and distribution in commerce activities, and requires commercial users of PIP (3:1) and PIP (3:1)-containing products to follow existing regulations and best practices to prevent releases to water during use.

D. Pentachlorothiophenol (PCTP); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h) (RIN 2070-AK60)

PCTP was used in rubber manufacturing as a peptizer, or a chemical that makes rubber more amenable to processing. Although it is likely that PCTP is no longer used as a peptizer, it can be found as an impurity in the zinc salt of PCTP (zinc PCTP) (CASRN 117-97-5) after zinc PCTP manufacturing. PCTP is toxic to protozoa, fish, terrestrial plants, and birds. Data for analogous chemicals (pentachloronitrobenzene and hexachlorobenzene) indicate the potential for liver and reproductive effects. However, no animal or human hazard data has been identified. The final rule for PCTP (Ref. 7) prohibits all manufacturing (including import) and processing of PCTP, and products or articles containing PCTP, unless PCTP concentrations are at or below 1% by weight. A prohibition on the distribution in commerce of PCTP or PCTP-containing products or articles, unless PCTP concentrations are at or below 1% by weight, will take effect on January 6, 2022.

E. Hexachlorobutadiene (HCBD); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h) (RIN 2070-AK61)

HCBD is a halogenated aliphatic hydrocarbon that is produced as an unintentional byproduct during the manufacture of chlorinated hydrocarbons, particularly perchloroethylene, trichloroethylene, and carbon tetrachloride, and is subsequently burned as a waste fuel. HCBD is toxic to aquatic invertebrates, fish, and birds, and has been identified as a possible human carcinogen. Data indicate the potential for renal, reproductive, and developmental effects. The

final rule for HCBd (Ref. 8) prohibits the manufacture (including import), processing, and distribution in commerce of HCBd and HCBd-containing products or articles, except for the unintentional production of HCBd as a byproduct during the production of chlorinated solvents, and the processing and distribution in commerce of HCBd for burning as a waste fuel.

III. Request for Comment

During the comment period, the public may submit comments and information relevant to any aspect of the final PBT rules. The public is encouraged to provide comments and information relating to EPA's statutory obligations under TSCA section 6(h) and the extent to which there are further exposure reductions that could be achieved, including exposure reductions for potentially exposed or susceptible subpopulations and the environment. EPA is particularly interested in information relating to the impacts of the final rules on human health, including potentially exposed or susceptible subpopulations, and the environment. EPA is also requesting comment on implementation issues associated with these final rules. EPA specifically invites public comment on additional measures or approaches that EPA could take in addition to the provisions in the final rules.

In particular, EPA is seeking comment on newly-raised issues associated with the March 8, 2021 compliance date in the PIP (3:1) rule for certain regulated articles. Stakeholders recently informed EPA that the prohibition on processing and distribution of PIP (3:1) could impact articles used in a wide variety of electronics, from cell phones, to robotics used to manufacture semiconductors, to equipment used to move COVID-19 vaccines and keep them at the appropriate temperature. Stakeholders note that the complexity of international supply chains makes locating the presence of, and finding alternatives to, PIP (3:1) in components challenging. They assert that an extension to the compliance deadline is necessary to avoid significant

disruption to the supply chain for a wide variety of articles. It was clearly not EPA's intent during the development of the rule to have such a broad disruptive impact. Nonetheless, compliance deadlines for the PBT rules must be in place "as soon as practicable" and provide reasonable transition periods, pursuant to the requirements of TSCA section 6(d)(1). Thus, for EPA to amend the existing deadline, the Agency needs additional information regarding the impact of the deadline. EPA specifically asks commenters to specify the articles that need the alternative deadline; the basis for the alternative deadline, taking into consideration the reasons supporting alternative deadlines in the final rule already issued, such as the January 1, 2022, date for photographic printing articles and the January 6, 2025, date for adhesives and sealants, with supporting documentation; and the additional time needed for specific articles to clear channels of trade. EPA plans to address the compliance deadline in the PIP (3:1) rule as part of the broader re-examination of these rules and will take into account comments received during this comment period when deciding upon future action involving this matter. In the meantime, the Agency will exercise its enforcement discretion to not pursue enforcement actions for violations of the prohibitions on the processing and distribution of PIP (3:1) for use in articles, or articles containing PIP (3:1) for up to 180 days, while this review and agency action to address this matter are pending.

III. References

1. EPA. TSCA Work Plan for Chemical Assessments: 2014 Update. October 2014.
<https://www.epa.gov/assessingandmanaging-chemicals-under-tsca/tscawork-plan-chemical-assessments-2014-update>. Accessed March 1, 2019.
2. EPA. TSCA Work Plan Chemicals: Methods Document. February 2012.
<https://www.epa.gov/sites/production/files/2014->

03/documents/work_plan_methods_document_web_final.pdf. Accessed March 1, 2019.

3. EPA. Exposure and Use Assessment of Five Persistent, Bioaccumulative, and Toxic Chemicals. December 2020.

4. EPA. 2,4,6-Tris(tert-butyl)phenol (2,4,6- TTBP); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h); Final Rule. **Federal Register** (86 FR 866, January 6, 2021) (FRL-10018-90).

5. EPA. Decabromodiphenyl Ether (DecaBDE); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h); Final Rule. **Federal Register** (86 FR 880, January 6, 2021) (FRL-10018-87).

6. EPA. Phenol, Isopropylated Phosphate (3:1) (PIP 3:1)); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h); Final Rule. **Federal Register** (86 FR 894, January 6, 2021) (FRL-10018-88).

7. EPA. Pentachlorothiophenol (PCTP); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h); Final Rule. **Federal Register** (86 FR 911, January 6, 2021) (FRL-10018-89).

8. EPA. Hexachlorobutadiene (HCBd); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h); Final Rule. **Federal Register** (86 FR 922, January 6, 2021) (FRL-10018-91).

9. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. **Federal Register** (86 FR 7009, January 25, 2021).

10. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. **Federal Register** (86 FR 7037, of January 25, 2021).

11. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. **Federal Register** (86 FR 7619, February 1, 2021).

12. Presidential Memorandum. Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. **Federal Register** (January 27, 2021).

13. Fact Sheet: List of Agency Actions for Review (January 21, 2021).

Authority: 15 U.S.C. 2601 *et seq.*

Dated: March 8, 2021.

Michal Freedhoff,

Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.