

PRE-PUBLICATION NOTICE

On Friday, June 21, 2019, Andrew R. Wheeler, the EPA Administrator, signed the following document:

Action: Proposed Rule.
Title: Regulation of Persistent, Bioaccumulative, and Toxic Chemicals
under TSCA Section 6(h)
FRL #: 9995-76
Docket ID #: EPA-HQ-OPPT-2019-0080

EPA is submitting this document for publication in the *Federal Register* (FR). EPA is providing this document solely for the convenience of interested parties. It is not the official version of the document for purposes of public notice and comment under the Administrative Procedure Act. This document is not disseminated for purposes of EPA's Information Quality Guidelines and does not represent an Agency determination or policy. While we have taken steps to ensure the accuracy of this Internet version of the document that was signed, the official version will publish in a forthcoming FR publication, which will appear on the Government Printing Office's govinfo website (<https://www.govinfo.gov/app/collection/fr>) and on Regulations.gov (<https://www.regulations.gov>) in the docket identified above. Notwithstanding the fact that EPA is posting a pre-publication version, the final rule will not be promulgated until published in the *Federal Register*.

Once the official version of this document is published in the *Federal Register*, this version will be removed from the Internet and replaced with a link to the official version. At that time, you will also be able to access the on-line docket for this *Federal Register* document at <http://www.regulations.gov>.

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.

This page is intentionally left blank.

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA-HQ-OPPT-2019-0080; FRL-9995-76]

RIN 2070-AK34

Regulation of Persistent, Bioaccumulative, and Toxic Chemicals under TSCA Section 6(h)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a rule to address certain persistent, bioaccumulative, and toxic chemicals identified pursuant to section 6(h) of the Toxic Substances Control Act (TSCA). These five chemicals are: decabromodiphenyl ether; phenol, isopropylated phosphate (3:1), also known as tris(4-isopropylphenyl) phosphate; 2,4,6-tris(tert-butyl)phenol; hexachlorobutadiene; and pentachlorothiophenol. This proposed rule would restrict or prohibit manufacture (including import), processing, and distribution in commerce for many uses of four of these five chemical substances. EPA has evaluated the uses of hexachlorobutadiene and is proposing no regulatory action. For the other four, this proposal includes recordkeeping requirements. Additional downstream notification requirements are proposed for phenol, isopropylated phosphate (3:1).

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Under the Paperwork Reduction Act, comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before [INSERT DATE THIRTY DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-

HQ-OPPT-2019-0080, by one of the following methods:

- *Federal eRulemaking Portal*: <https://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.

- *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Cindy Wheeler, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number (202) 566-0484; email address: wheeler.cindy@epa.gov; or Peter Gimlin, National Program Chemicals Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-0515; email address: gimlin.peter@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:

Table of Contents

The information presented in this preamble is organized as follows:

I. Executive Summary

- A. Does this Action Apply to Me?
- B. What is the Agency's Authority for Taking this Action?
- C. What Action is the Agency Taking?
- D. Why is the Agency Taking this Action?
- E. What are the Estimated Incremental Impacts of this Action?
- F. What Should I Consider as I Prepare My Comments for EPA?

II. Background

- A. Why PBT Chemicals are of Concern
- B. Overview of TSCA Sections 6(c) and 26 Considerations
- C. TSCA Section 6(h) and the 2014 Update to the TSCA Work Plan for Chemical

Assessments

- D. Overview of the Chemicals Subject to this Proposed Action
- E. Exposure and Use Assessment and Hazard Summary

III. Regulatory Assessment of the PBT Chemicals

- A. Regulatory Approach
- B. DecaBDE
- C. PIP (3:1)
- D. 2,4,6-TTBP
- E. HCB

F. PCTP

IV. Reasonably Ascertainable Economic Consequences of the Proposed Rule

A. Overview of Cost Methodology

B. Estimated Costs of Proposed and Primary Alternative Regulatory Actions

C. Benefits

V. References

VI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563:

Improving Regulation and Regulatory Review

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

C. Paperwork Reduction Act (PRA)

D. Regulatory Flexibility Act (FRA)

E. Unfunded Mandates Reform Act (UMRA)

F. Executive Order 13132: Federalism

G. Executive Order 13175: Consultation and Coordination with Indian Tribal

Governments

H. Executive Order 13045: Protection of Children from Environmental Health Risks and

Safety Risks

I. Executive Order 13211: Actions Concerning Regulations that Significantly Affect

Energy Supply, Distribution or Use

J. National Technology Transfer and Advancement Act (NTTAA)

K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority

Populations and Low-Income Populations

I. Executive Summary

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture (including import), process, distribute in commerce, or commercially use decabromodiphenyl ether (DecaBDE); phenol, isopropylated phosphate (3:1) (PIP (3:1)), also known as tris(4-isopropylphenyl) phosphate; 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP); hexachlorobutadiene (HCBD); or pentachlorothiophenol (PCTP) or products containing these chemicals, especially electronics, plastic products, additives, hydraulic fluids, or other industrial fluids. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- Pipe, Duct and Boiler Insulation (NAICS Code 238290);
- Nonwoven Fabric Mills (NAICS Code 313230);
- Fabric Coating Mills (NAICS Code 313320);
- Petroleum Refineries (NAICS Code 324110);
- Petroleum Lubricating Oil and Grease Manufacturing (NAICS Code 324191);
- Petrochemical Manufacturing (NAICS Code 325110);
- Other Basic Inorganic Chemical Manufacturing (NAICS Code 325180);
- All Other Basic Organic Chemical Manufacturing (NAICS Code 325199);
- Plastics Material and Resin Manufacturing (NAICS Code 325211);
- Paint and Coating Manufacturing (NAICS Code 325510);
- Adhesive Manufacturing (NAICS Code 325520);
- Polish and Other Sanitation Good Manufacturing (NAICS Code 325612);

- Custom Compounding of Purchased Resins (NAICS Code 325991);
- All Other Miscellaneous Chemical Product and Preparation Manufacturing (NAICS Code 325998);
- Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing (NAICS Code 326113);
- Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing (NAICS Code 326130);
- Urethane and Other Foam Product (except Polystyrene) Manufacturing (NAICS Code 326150);
- All Other Plastics Product Manufacturing (NAICS Code 326199);
- All Other Rubber Product Manufacturing (NAICS Code 326299);
- Cement Manufacturing (NAICS Code 327310);
- Copper Rolling, Drawing, Extruding, and Alloying (NAICS Code 331420);
- Machinery Manufacturing (NAICS Code 333);
- Computer and Peripheral Equipment Manufacturing (NAICS Code 3341);
- Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing (NAICS Code 334220);
- Other Communications Equipment Manufacturing (NAICS Code 334290);
- Audio and Video Equipment Manufacturing (NAICS Code 334310);
- Other Communication and Energy Wire Manufacturing (NAICS Code 335929);
- Motor Vehicle Manufacturing (NAICS Code 3361), *e.g.*, automobile, aircraft, ship, and boat manufacturers and motor vehicle parts manufacturers;
- Other Motor Vehicle Parts Manufacturing (NAICS Code 336390);

- Aircraft Manufacturing (NAICS Code 336411);
- Guided Missile and Space Vehicle Manufacturing (NAICS Code 336414);
- Household and Institutional Furniture Manufacturing (NAICS Code 33712);
- Surgical Appliance and Supplies Manufacturing (NAICS Code 339113);
- Sporting and Athletic Goods Manufacturing (NAICS Code 339920);
- Doll, Toy, and Game Manufacturing (NAICS Code 33993);
- Automobile and Other Motor Vehicle Merchant Wholesalers (NAICS Code 423110);
- Motor Vehicle Supplies and New Parts Merchant Wholesalers (NAICS Code 423120);
- Furniture and Home Furnishing Merchant Wholesalers (NAICS Code 4232);
- Insulation Materials (except Wood) Merchant Wholesalers (NAICS Code 423330);
- Household Appliances, Electric Housewares, and Consumer Electronics Merchant Wholesalers (NAICS Code 423620);
- Sporting and Recreational Goods and Supplies Merchant Wholesalers (NAICS Code 423910);
- Toy and Hobby Goods and Supplies Merchant Wholesalers (NAICS Code 423920);
- Other Chemical and Allied Products Merchant Wholesalers (NAICS Code 424690);
- Farm Supplies Merchant Wholesalers (NAICS Code 424910);
- New Car Dealers (NAICS Code 441110);
- Boat Dealers (NAICS Code 441222);
- Automotive Parts and Accessories Stores (NAICS Code 441310);
- Furniture Stores (NAICS Code 442110);
- All Other Home Furnishing Stores (NAICS Code 442299);
- Gasoline Stations with Convenience Stores (NAICS Code 447110);

- Other Gasoline Stations (NAICS Code 447190);
- Children's and Infant's Clothing Stores (NAICS Code 448130);
- Sporting Goods Stores (NAICS Code 451110);
- Hobby, Toy, and Game Stores (NAICS Code 451120)
- General Merchandise Stores (NAICS Code 452);
- Aircraft Maintenance and Repair Services (NAICS Code 488190);
- All Other Consumer Goods Rental (NAICS Code 532289);
- Hazardous Waste Treatment and Disposal (NAICS Code 562211);
- Solid Waste Combustors and Incinerators (NAICS Code 562213);
- Marinas (NAICS Code 713930);
- General Automotive Repair (NAICS Code 811111).

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the technical information contact listed under FOR FURTHER INFORMATION CONTACT.

B. What is the Agency's Authority for Taking this Action?

Section 6(h) of TSCA, 15 U.S.C. 2601 *et seq.*, directs EPA to issue a proposed rule under TSCA section 6(a) on certain persistent, bioaccumulative, and toxic (PBT) chemical substances. More specifically, EPA must take action on those chemical substances identified in the 2014 Update to the TSCA Work Plan for Chemical Assessments (Ref. 1) that, with certain exceptions, 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) EPA published in 2012 (or a successor scoring system), and exposure to which is likely under the conditions of use. For the

purposes of this proposed rule, these specific chemical substances are hereinafter collectively referred to as the PBT chemicals. TSCA section 6(a) regulatory requirements include: (1) Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of such substances; (2) Prohibit or otherwise restrict manufacturing, processing, or distribution in commerce of such substances for particular uses or for uses in excess of a specified concentration; (3) Require minimum warning labels and instructions; (4) Require recordkeeping or testing; (5) Prohibit or regulate any manner or method of commercial use; (6) Prohibit or otherwise regulate any manner or method of disposal by a manufacturer, processor, or any other person who uses or disposes of the chemical for commercial purposes; and (7) Direct manufacturers and processors to give notice of the determination to distributors and the public and replace or repurchase substances. EPA must apply one or more of these requirements to the extent necessary to meet the TSCA section 6(h)(4) statutory standard, which is discussed in Unit II.C.

C. What Action is the Agency Taking?

EPA is proposing to restrict or prohibit certain actions with respect to four of the five PBT chemicals subject to this rulemaking. As of the effective date of the final rule, affected persons would be required to maintain, for three years from the date the record is generated, ordinary business records that demonstrate compliance with the restrictions, prohibitions, and other requirements.

The extent of exposure, the severity of the hazard, and thus the likely risk of these chemicals varies significantly. For example, the evidence suggests that human exposure to hexachlorobutadiene is very limited due in large part to the high waste treatment efficiencies achieved by the chemical manufacturers. Additionally, the amount and type of hazard

information varies substantially, from relatively well studied chemicals (e.g. decabromodiphenyl ether) to data-sparse chemicals (e.g. pentachlorothiophenol).

1. Decabromodiphenyl ether. DecaBDE (Chemical Abstracts Registry Service Number (CASRN) 1163-19-5) is a flame retardant that has been widely used in textiles, plastics, adhesives, and polyurethane foam. For DecaBDE, this proposal would prohibit the manufacture (including import), processing, and distribution in commerce of DecaBDE, and articles and products to which DecaBDE has been added except for the following:

- Manufacture, processing, and distribution in commerce for use in parts for new aircraft and aerospace vehicles, and distribution in commerce of the new vehicles containing such parts, for a period of three years;

- Manufacture, processing, and distribution in commerce for use in curtains in the hospitality industry, and the distribution of the curtains themselves, for a period of 18 months;

- Manufacture, processing, and distribution in commerce for use in replacement parts for the automotive and aerospace industries, and distribution in commerce of the replacement parts themselves;

- Processing for recycling and distribution in commerce for recycling of plastic that contained DecaBDE before the plastic was recycled (*i.e.*, the plastic to be recycled is from articles and products that were originally made with DecaBDE), so long as no new DecaBDE is added during the recycling process; and

- Processing and distribution in commerce of articles and products made from recycled plastic that contained DecaBDE before the plastic was recycled, so long as no new DecaBDE was added during the recycling process or to the articles and products made from the recycled plastic.

2. *Phenol, isopropylated phosphate (3:1)*. PIP (3:1) (CASRN 68937-41-7) is a flame retardant, a plasticizer, and an anti-compressibility and anti-wear additive. It is used in lubricants and hydraulic fluids and in the manufacture of other compounds. For PIP (3:1), which is also known as tris(4-isopropylphenyl) phosphate, this proposal would prohibit processing and distribution in commerce of the chemical substance, and products containing the chemical substance except for the following:

- Processing and distribution in commerce for use in aviation hydraulic fluid;
- Processing and distribution in commerce for use in lubricants and greases; and
- Processing and distribution in commerce for use in new and replacement parts for automobiles and other motor vehicles, and the distribution in commerce of the parts to which PIP (3:1) has been added.

In addition, this rule would prohibit releases to water from the non-prohibited processing, distribution in commerce, and commercial use activities. Persons manufacturing, processing, and distributing PIP (3:1), and products containing PIP (3:1), in commerce would be required to notify their customers of these restrictions.

3. *2,4,6-tris(tert-butyl)phenol*. 2,4,6-TTBP (CASRN 732-26-3) is an antioxidant that can be used as a fuel additive or lubricant additive, as an intermediate in the manufacture of other compounds, and as a waste fuel. For 2,4,6-TTBP, this proposal would prohibit the distribution in commerce of 2,4,6-TTBP and products containing 2,4,6-TTBP in any container with a volume of less than 55 gallons for any use, in order to effectively prevent 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). It is EPA's intent that the 55-gallon container restriction will ensure the continued fuel additive or fuel injector cleaner use of this PBT only by commercial operators

who have the capacity to protect their workers who may come into contact with 2,4,6-TTBP and whose workplaces are generally subject to the standards promulgated by the Occupational Safety and Health Administration (OSHA). This restriction also would prohibit 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, regardless of container size.

4. *Hexachlorobutadiene*. HCBD (CASRN 87-68-3) is produced as a byproduct in the production of chlorinated solvents and has also been used in the past as an absorbent for gas impurity removal and as an intermediate in the manufacture of rubber compounds. For HCBD, EPA has evaluated the uses of hexachlorobutadiene and is proposing no regulatory action for the reasons described in Unit III.E.

5. *Pentachlorothiophenol*. PCTP (CASRN 133-49-3) is used in the manufacture of rubber compounds. For PCTP, this proposal would prohibit the manufacture (including import), processing, and distribution in commerce of PCTP, and products containing PCTP, unless in concentrations at or below 1% by weight.

D. Why is the Agency Taking this Action?

EPA is issuing this proposed rule to fulfill EPA's obligations under TSCA section 6(h) to take timely regulatory action on PBT chemicals – specifically, “to address the risks of injury to health or the environment that the Administrator determines are presented by the chemical substance and [. . .] to reduce exposure to the substance to the extent practicable.” PBT chemicals remain in the environment for a significant period of time and can accumulate in biota. Congress directed EPA in TSCA section 6(h) to take expedited regulatory action for certain PBT chemicals. As required by the statute, the Agency is proposing risk management actions to reduce exposures to the PBT chemicals to the extent practicable for the general population,

potentially exposed or susceptible subpopulations, and the environment. Although EPA did not make an affirmative determination that risks are presented by the five PBT chemicals due to the language of TSCA section 6(h), this proposal nevertheless meets the standards of TSCA section 6(h)(4).

E. What are the Estimated Incremental Impacts of this Action?

EPA has evaluated the potential costs of these proposed restrictions and prohibitions and the associated reporting and recordkeeping requirements. The “Economic Analysis for Proposed Regulation of Persistent, Bioaccumulative, and Toxic Chemicals under TSCA section 6(h)” (Economic Analysis) (Ref. 3), which is available in the docket, is discussed in Unit IV, and is briefly summarized here. Total quantified annualized social costs for the proposed rule under the proposed option are approximately \$43.5 million (at both 3% and 7% discount rates). As discussed in more detail in Unit II.C., EPA did not perform risk evaluations for these chemical substances, nor did EPA develop quantitative risk estimates. Thus, EPA was not able to quantify the benefits of reducing human and environmental exposures to these PBT chemicals; therefore, the Economic Analysis (Ref. 3) qualitatively discusses the benefits of reducing exposure under the proposed option and the primary alternative regulatory action for the five PBT chemicals.

F. What Should I Consider as I Prepare My Comments for EPA?

See the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets> when preparing and submitting your comments. Do not submit CBI to EPA through *regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be 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.

EPA requests comment on all aspects of this proposal, including the proposed regulatory actions for each of the PBT chemicals, the primary alternative regulatory actions, and any other options that EPA has considered or should consider. In particular, EPA is requesting comment on its proposed determinations with respect to whether exposure is likely and whether EPA's proposed regulatory actions achieve the statutory directives to "address the risks of injury to health and the environment that the Administrator determines are presented by the chemical substance and [. . .] reduce exposure to the substance to the extent practicable." EPA also requests comment on all aspects of the Economic Analysis (Ref. 3) accompanying this action. In taking final action on this proposal, following review of comments, EPA may require exposure reductions beyond those proposed here, or may reduce the scope of the proposed exposure reductions.

II. Background

A. Why PBT Chemicals are of Concern

Toxic chemicals that persist and bioaccumulate are of concern because they remain in the environment for long periods of time and accumulate in the organisms exposed to them (*i.e.*, can build up or concentrate in body tissue). A chemical's persistence refers to the length of time the chemical can exist in the environment before being degraded at rates that prevent substantial buildup of the parent chemical in the environment. Bioaccumulation is the net accumulation of a chemical by an aquatic organism as a result of uptake from all environmental sources. The term refers to both uptake of chemicals by aquatic species from water (bioconcentration) and from ingested food and sediment residues. PBT chemicals are toxic chemicals that are not removed from the environment at rates adequate to prevent exposure to aquatic or terrestrial organisms.

Following exposure, PBT chemicals increase in concentration in the exposed organism's tissues relative to the concentrations in environmental media to which they are exposed. Chemicals that persist and bioaccumulate have been found in humans, other aquatic and terrestrial mammals, fish, shellfish, and birds.

Biomagnification is the increase in concentration of a chemical in the tissue of organisms along a series of predator-prey associations, primarily through the mechanism of dietary accumulation and can be an additional characteristic of PBT chemicals. Biomagnification in food webs results in apex predators (*e.g.*, eagles and orcas) being subject to higher exposures of PBT chemicals via food. When humans consume organisms from higher trophic levels (*e.g.*, predator fish like tuna or swordfish), humans often have increased tissue concentrations of PBT chemicals due to biomagnification and therefore are exposed to increased concentrations of the chemical.

B. Overview of TSCA Sections 6(c) and 26 Considerations

1. TSCA section 6(c)(2) considerations. TSCA section 6(c)(2) requires EPA to consider and publish a statement based on reasonably available information with respect to the:

- Health effects of the chemical substance or mixture and the magnitude of human exposure;
- Environmental effects of the chemical substance or mixture and the magnitude of exposure of the environment;
- Benefits of the chemical substance or mixture for various uses; and
- Reasonably ascertainable economic consequences of the rule, including: The likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; the costs and benefits of the proposed and final rule and of the one or more primary alternative regulatory actions that EPA considered; and the cost

effectiveness of the proposed rule and of the one or more primary alternative regulatory actions that EPA considered.

In addition, in selecting among prohibitions and other restrictions available under TSCA section 6(a), EPA must factor in, to the extent practicable, these considerations. Further, in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, EPA must also consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment would be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

EPA's summary of the health and environmental effects of and the potential for exposure to the five chemical substances subject to this action can be found in Unit II.E., which discusses the Exposure and Use Assessment (Ref. 4) and the Hazard Summary (Ref. 5)

With respect to the costs and benefits of this proposal and the alternatives EPA considered, as well as the impacts on small businesses, the full analysis is presented in the economic analysis document (Ref. 3). Due to the lack of risk information, EPA was not able to quantify the benefits of this proposal and the alternatives. A qualitative discussion of the potential benefits associated with the proposed option for each chemical is provided in Unit IV.C. EPA requests comment on all aspects of the benefits attributable to this proposed action, including the impacts that the selection of substitutes for those uses proposed to be restricted or prohibited may have on the anticipated benefits.

EPA considered the estimated costs to regulated entities as well as the cost to administer and enforce the options. EPA took into account reasonably available information about the functionality and performance efficacy of the regulatory options and the ability to implement the

use of chemical substitutes or other alternatives. A discussion of the costs EPA considered can be found in Units IV.A. and IV.B., along with a discussion of the alternatives that EPA considered. In addition, a discussion of the impacts on small businesses can be found in Unit VI.D.

With respect to the cost effectiveness of the proposed regulatory action and the primary alternative regulatory action, EPA is unable to perform a traditional cost-effectiveness analysis of the proposed actions and alternatives for the PBT chemicals. The cost effectiveness of a policy option would properly be calculated by dividing the annualized costs of the option by a final outcome, such as cancer cases avoided, or to intermediate outputs such as tons of emissions of a pollutant curtailed. Without the supporting analyses for a risk determination, EPA is unable to calculate either a health-based or environment-based denominator. Thus, EPA is unable to perform a quantitative cost-effectiveness analysis of the proposed and alternative regulatory actions. However, by evaluating the practicability of the proposed and alternative regulatory actions, EPA believes that it has considered elements related to the cost effectiveness of the actions, including the cost and the effect on exposure to the PBT chemicals of the proposed and alternative regulatory actions.

With respect to the anticipated effects of this proposal on the national economy, EPA considered the number of businesses and workers that would be affected and the costs and benefits to those businesses and workers (Ref. 3).

The benefits of the five PBT chemicals subject to this proposal for their various uses are discussed in Unit II.D. The technical feasibility, economic feasibility, and reasonable availability of alternatives that benefit health or the environment is discussed in Unit III., in the Economic Analysis (Ref. 3), and in the document entitled “Persistence, Bioaccumulation, Environmental Hazard and Human Health Hazard Ratings for Alternatives to PBT Chemicals Proposed for

Regulation” (Ref. 5).

The dates that the proposed restrictions would take effect are discussed in Unit III.

Finally, with respect to this proposal’s effect on technological innovation, EPA expects this action to spur innovation, not hinder it (Ref. 3). In most cases, a wide variety of alternatives are available for the uses that this proposal would prohibit or restrict.

2. TSCA section 26 considerations. EPA has used scientific information, technical procedures, measures, and methodologies that are fit for purpose and consistent with the best available science. For example, EPA based its proposed determination that human and environmental exposures are likely to the five PBT chemicals subject to this action on the Exposure and Use Assessment (Ref. 4) discussed in Unit II.E.1, which underwent a peer review and public comment process, as well as using best available science and methods sufficient to make that determination. The extent to which the various information, procedures, measures, and methodologies, as applicable, used in EPA’s decision-making have been subject to independent verification or peer review is adequate to justify their use, collectively, in the record for this rule. Additional information on the peer review and public comment process, such as the peer review plan, the peer review report, and the Agency’s response to comments, can be found in the public docket for this action (EPA-HQ-OPPT-2019-0080). In addition, in accordance with TSCA section 26(i), EPA has made scientific decisions based on the weight of the scientific evidence.

C. TSCA Section 6(h) and the 2014 Update to the TSCA Work Plan for Chemical Assessments

1. TSCA sections 6(h) and 6(a). TSCA section 6(h) requires EPA to take expedited regulatory action under TSCA section 6(a) for certain PBT chemicals identified in the 2014 Update to the TSCA Work Plan for Chemical Assessments. More specifically, under TSCA section 6(h)(1)(A), the subject chemical substances are those that:

- 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 2012 TSCA Work Plan Chemicals: Methods Document or a successor scoring system;

- Are not a metal or a metal compound; and

- Are chemical substances for which EPA has not completed a TSCA Work Plan Problem Formulation, initiated a review under TSCA section 5, or entered into a consent agreement under TSCA section 4, prior to June 22, 2016, the date that the Frank R. Lautenberg Chemical Safety for the 21st Century Act became law.

In addition, in order for a chemical substance to be subject to expedited action, TSCA section 6(h)(1)(B) states that EPA must find that exposure to the chemical substance under the conditions of use is likely to the general population or to a potentially exposed or susceptible subpopulation identified by the Administrator (such as infants, children, pregnant women, workers or the elderly), or to the environment on the basis of an exposure and use assessment conducted by EPA. EPA also considers consumers to be a potentially exposed or susceptible subpopulation for the purposes of this rule in addition to the groups identified in the statutory definition at TSCA section 3(12), such as workers.

For chemical substances subject to TSCA section 6(h), EPA must issue a proposed rule by June 22, 2019, and a final rule no later than 18 months after the proposal is issued. The statute further provides that the Administrator shall not be required to conduct risk evaluations on chemical substances that are subject to TSCA section 6(h)(1).

TSCA section 6(a) prohibitions and other restrictions can include one or more, or a combination of, the following actions:

- A requirement either prohibiting or otherwise restricting the manufacturing, processing,

or distribution in commerce of such substance or mixture, or limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce (TSCA section 6(a)(1)).

- A requirement either prohibiting or otherwise restricting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement (TSCA section 6(a)(2)).

- A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate minimum warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities (TSCA section 6(a)(3)).

- A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture or monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection (TSCA section 6(a)(4)).

- A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture (TSCA section 6(a)(5)).

- A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial

purposes (TSCA section 6(a)(6)).

- A requirement directing manufacturers or processors of such substance or mixture to give notice of such determination to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, to give public notice of such determination, and to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed. Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of such substances (TSCA section 6(a)(7)).

TSCA section 6(h)(4) directs EPA, in selecting among the prohibitions and restrictions in section 6(a), to “address the risks of injury to health or the environment that the Administrator determines are presented by the chemical substance and [. . .] reduce exposure to the substance to the extent practicable.” EPA interprets the directive in TSCA section 6(h) regarding issuance of a TSCA section 6(a) rule to require EPA to issue a rule to satisfy TSCA section 6(h) requirements, using the regulatory prohibitions and other restrictions identified in TSCA section 6(a)(1) – (7), applying other provisions of TSCA section 6 applicable to TSCA section 6(a) rules consistent with the direction in TSCA section 6(h), but not applying those provisions of TSCA section 6(c) that conflict with TSCA section 6(h), in the sense that those provisions assume the existence of a TSCA section 6(b) risk evaluation, whereas TSCA section 6(h)(2) specifically provides that EPA is not required to conduct a risk evaluation. EPA invites public comment on this interpretation and seeks input on other possible interpretations.

2. Address risks and reduce exposure to the extent practicable. TSCA section 6(h)(1) through (4) requires EPA to issue a TSCA section 6(a) rule to “address the risks of injury to health or the environment that the Administrator determines are presented by the chemical

substance and [. . .] reduce exposure to the substance to the extent practicable.”

EPA began by compiling use information on each of the five PBT chemicals that EPA preliminarily determined met the criteria for expedited action. Separate use documents were developed for each of the five PBT chemicals and made available for public comment in August of 2017 (Refs. 6, 7, 8, 9, and 10).

EPA then conducted a review of available literature with respect to the PBT chemicals discussed in this proposal to identify, screen, extract, and evaluate exposure information reasonably available for each. The information gathered is presented in the document entitled “Exposure and Use Assessment of Five Persistent, Bioaccumulative and Toxic Chemicals” (Exposure and Use Assessment) (Ref. 4). The exposure information presented in the Exposure and Use Assessment document was not intended to comprehensively discuss all possible nor use-specific exposure scenarios presented by the PBT chemicals evaluated, but rather to describe a broad range of potential exposures that would enable EPA to determine whether exposure to these PBT chemicals is likely for the purposes of TSCA section 6(h)(1)(B). The Exposure and Use Assessment was peer reviewed; the peer review comments and the Agency’s responses can be found in the public docket at EPA-HQ-OPPT-2018-0314.

In addition, EPA compiled hazard information on the five PBT chemicals discussed in this proposal. The information is presented in the document entitled “Environmental and Human Health Hazards of Five Persistent, Bioaccumulative, and Toxic Chemicals” (Hazard Summary) (Ref. 5). To create this document, which presents a limited summary of the hazards of these chemical substances, environmental and human health hazard data were compiled from various primary and secondary sources of reasonably available information. The information in the Hazard Summary does not represent an exhaustive literature review nor is it an analysis of

relative importance or comparative dose-response among hazards. The hazard data are reported from the literature with no additional analysis or assessment.

The information compiled by EPA in the Exposure and Use Assessment is useful in characterizing the exposures by these PBT chemicals. EPA identified and included available information about potentially exposed and susceptible subpopulations during the development of both the Exposure and Use Assessment (Ref. 4) and the Hazard Summary (Ref. 5).

The statute provides that EPA shall: (1) “address the risks of injury to health or the environment that the Administrator determines are presented by the chemical substance“ and (2) “reduce exposure to the substance to the extent practicable.” (TSCA section 6(h)(4)). With respect to the first requirement, EPA reviewed the hazard and exposure information on the five PBT chemicals as described previously. While this information identified hazards and exposures for the PBT chemicals, the information for these five chemicals did not provide a basis for EPA to develop scientifically robust and representative risk estimates to evaluate whether or not any of the chemicals present a risk of injury to health or the environment. EPA does not interpret TSCA section 6(h)(4), specifically the language directing EPA to “address the risks of injury to health or the environment that the Administrator determines are presented,” to require EPA to determine, through a risk assessment or risk evaluation, whether risks are presented. EPA believes this reading gives EPA the flexibility Congress intended for issuance of an expedited rule for PBTs without compelling a risk evaluation to support this rulemaking. EPA did not perform a systematic review or a weight of the scientific evidence assessment for the hazard characterization of these chemicals. As a result, the characterization is not definitive or comprehensive. Other information on these chemicals may exist in addition to the studies summarized in the Hazard Summary that could refine the characterization. EPA does not believe

that a systematic review would change our proposed risk management determinations as TSCA section 6(h)(4) requires EPA to reduce exposure to the substance to the extent practicable, regardless of risk. EPA is seeking public comment on the decision not to pursue a systematic review for these five chemicals and the impact of this decision on the PBT rulemaking.

As required by the statute, the Agency is proposing risk management actions to reduce exposures to the PBT chemicals to the extent practicable. Although EPA did not make an affirmative determination that risks are presented by the five PBT chemicals due to the language of TSCA section 6(h), this proposal nevertheless meets the standards of TSCA section 6(h)(4).

With respect to the second requirement, the term “practicable” is not defined in TSCA. EPA interprets this requirement as generally directing the Agency to consider such factors as achievability, feasibility, workability, and reasonableness. In addition, EPA’s approach to determining whether particular prohibitions or restrictions are practicable is informed in part by a consideration of certain other provisions in TSCA section 6. For example, TSCA section 6(c)(2)(A) provides a list of factors that EPA must consider in promulgating a rule under TSCA section 6(a), and EPA’s statement on those factors can be found in Unit II.B. Those factors include the costs and benefits of the rule, along with the effects on health and the environment, the magnitude of human and environmental exposure, the benefits of the chemical substance for various uses, and other factors, such as the effect of the rule on the national economy, small business, and technological innovation. In addition, pursuant to TSCA section 6(c)(2)(B), in selecting the appropriate TSCA section 6(a) regulatory approach to take, EPA is directed to “factor in, to the extent practicable” those same considerations. EPA invites public comment on the factors that should be considered in determining whether a particular prohibition or restriction is practicable.

3. *The TSCA Work Plan for Chemical Assessments.* The 2012 TSCA Work Plan

Chemicals identified a list of chemicals for assessment by EPA (Ref. 11). The screening process for identifying these chemicals is described in the TSCA Work Plan Chemicals: Methods Document (Ref. 2). Chemicals were evaluated and received a score through the application of a numerical algorithm. This score was based on three characteristics: hazard, exposure, and potential for persistence/bioaccumulation. Using this system, chemicals were sorted into one of four bins. Chemicals able to be scored on all three characteristics were scored as High (3), Moderate (2), or Low (1) based on their available information. The data used to determine the hazard score for each chemical were obtained through specified data sources (Ref. 2, Appendix A). The hazard data reviews on each chemical were not exhaustive and did not rise to the level of assessments. Chemicals were scored on the basis of readily available data, and no judgment was made concerning gaps in or completeness of the available data set for a given chemical. The hazard score was determined based on three hazard levels, and each hazard level had a corresponding hazard rank (High-3, Moderate-2, and Low-1). The concentration ranges or characteristics corresponding to each hazard level are identified in the TSCA Work Plan Chemicals: Methods Document (Ref. 2, pp. 8-9). The highest hazard rank score a chemical received for any single human health or environmental toxicity endpoint became its hazard score (Ref. 2).

Persistence scoring consisted of the evaluation of the potential half-life in air, water, soil, and sediment while considering the expected partitioning characteristics of the chemicals and all potential removal pathways based on standard physical-chemical properties and environmental fate parameters. Specified data sources (Ref. 2, Appendix B) were searched to locate studies on biotic and abiotic transformation (*e.g.*, biodegradation, hydrolysis, photolysis) to estimate half-

lives for the chemicals in the environment. Bioaccumulation scoring consisted of evaluation of bioaccumulation/bioconcentration (measured or estimated BAF/BCF) data. When BAF data were not available, bioconcentration data (measured or estimated) were used to evaluate the potential for a chemical to bioaccumulate in organisms in the environment. In the absence of test data establishing the chemical's measured persistence or bioaccumulation potential, EPA used its EPI Suite™ model to derive a ranking for the chemical (Ref. 2).

Scores were assigned independently for persistence potential and bioaccumulation potential; the independent scores were added together to derive a single score for persistence/bioaccumulation. Chemicals with a combined score of 5-6 were scored as High (3) for persistence/bioaccumulation, a combined persistence and bioaccumulation score of 3-4 was scored as Moderate (2), and a combined score of 1-2 was scored as Low (1). Chemicals with High or Moderate hazard or persistence/bioaccumulation scores that could not be scored for exposure because of an absence of data, together with chemicals that could not be scored for hazard, were identified separately as potential candidates for information gathering. In 2014, EPA applied the screening process for exposure information described in the TSCA Work Plan Chemicals: Methods Document (Ref. 2) to update its list of chemicals on the TSCA Work Plan for Chemical Assessments. This update focused primarily on updating the exposure score to reflect updated industry data submitted to EPA through the Toxics Release Inventory (TRI) (40 CFR part 372) in 2011 and the TSCA Chemical Data Reporting (CDR) rule (40 CFR part 711) in 2012 on chemical releases and potential exposures, respectively. The 2014 Update to the TSCA Work Plan for Chemical Assessments included a list of 90 chemicals and chemical categories; the TSCA amendments passed in 2016 as part of the Frank R. Lautenberg Chemical Safety for the 21st Century Act reference the 2014 Update to the TSCA Work Plan for Chemical

Assessments in several places, including TSCA section 6(h).

In accordance with TSCA section 6(h)(1), chemical substances that meet the criteria described therein are subject to expedited rulemaking without the risk evaluations required for other TSCA Work Plan chemicals prior to initiating TSCA section 6(a) risk management actions. EPA interprets the TSCA section 6(h)(1)(A) provision pertaining to chemical substances “that the Administrator has a reasonable basis to conclude are toxic,” as referring to the toxicity score identified in the 2014 Update to the TSCA Work Plan for Chemical Assessments, and likewise focused on toxicity scores of high or moderate. In addition, EPA conducted the screening level literature search described in the peer-reviewed Hazard Summary to provide additional information and support for the hazard score assigned to these five chemicals in the 2014 Update to the TSCA Work Plan for Chemical Assessments. The information EPA has collected and reviewed in developing this proposal provides no basis to call into question the scoring for persistence, bioaccumulation, and toxicity performed in 2014 for these five PBT chemicals pursuant to the screening process described in the TSCA Work Plan Chemicals: Methods Document.

EPA is proposing to determine that five chemical substances meet the TSCA section 6(h)(1)(A) criteria for expedited action. These substances are: DecaBDE; PIP (3:1); 2,4,6-TTBP; HCBD; and PCTP.

A manufacturer of two other chemical substances on the 2014 Update to the TSCA Work Plan for Chemical Assessments submitted a timely request to EPA for risk evaluations pursuant to TSCA section 6(h)(5). As a result of the request, these two chemicals: Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthalenyl) and Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl) are excluded from this proposed rule (Ref. 12).

D. Overview of the Chemicals Subject to this Proposed Action

The use information presented in this Unit is based on the EPA's review of the available information, as presented in the use documents developed for each of the PBT chemicals (Refs. 6, 7, 8, 9, and 10), as well as public comments on the use documents and other stakeholder input.

1. Decabromodiphenyl ether (DecaBDE). (i) *Use background:* DecaBDE 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 communications and electronics, and other applications (Ref. 6). DecaBDE is also used as a flame retardant for multiple applications in the aerospace and automotive industries, including replacement parts for aircraft and cars (Refs. 13 and 14). Examples of products that have been made with DecaBDE as a flame retardant include:

- Consumer products made of both hard and soft plastics, such as furniture and furnishings, foam in furniture or mattresses, computer casings, and other plastic products including toys and other children's products (such as play structures);
- Fabrics and textiles, such as apparel, furniture and furnishings, curtains, and construction and building materials;
- Rubber articles, such as wire casings and other rubber articles; and
- Complex articles in road vehicles and other vehicles for passengers and goods, such as cars, trucks, and airplanes; and machinery and mechanical appliances.

DecaBDE can also be found in plastic materials recycled from plastic products originally made with DecaBDE.

EPA presented its initial research into DecaBDE uses in the August 2017 "*Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal*" document on

DecaBDE (Ref. 6). EPA received comments from 12 entities on the Preliminary Information document. EPA also communicated with dozens of companies, industry groups, chemical users, academic experts, states, and other stakeholders to identify and verify uses of DecaBDE (Ref. 6). These interactions and comments further informed EPA's understanding of the current status of uses for DecaBDE. Public comments and stakeholder meeting summaries are available in the public docket at EPA-HQ-OPPT-2016-0724.

In 2009, based on the EPA-Industry DecaBDE Phase-Out Initiative, domestic manufacturers and importers of commercially available DecaBDE agreed to voluntarily phase out the manufacture and import of the chemical no later than December 31, 2013 (Ref. 15). For the 2012 and 2016 CDR periods, data reported to EPA indicate that five sites manufactured (including imported) DecaBDE in the United States between 2011 and 2015 (Refs. 16 and 17). The total volume of DecaBDE manufactured (including imported) in the United States in 2011 was 18,110,827 lbs (Ref. 16). For the 2016 reporting period, the total volume of DecaBDE manufactured (including imported) in the United States was 16,696,951 lbs in 2012, between 1,000,000 and 10,000,000 lbs in 2013, between 100,000 and 500,000 lbs in 2014, and between 500,000 and 1,000,000 lbs in 2015. Actual production volume for years 2013 through 2015 is claimed in CDR as confidential business information (Ref. 17). Data reported to EPA from TRI show a general decline of DecaBDE releases, with 259,102 lbs of total on- and off-site reported releases of DecaBDE from 24 sites in 2016, and 67,248 lbs of total on- and off-site reported releases of DecaBDE from 17 sites in 2017. Of these 17 sites, one site reported import of the chemical, 14 reported processing of DecaBDE, and at the other two sites the specific activities are unknown (Refs. 18 and 19). EPA requests comment as to why some companies are still processing and using DecaBDE despite phase-out initiatives and the availability of relatively

inexpensive substitutes.

(ii) What are the beneficial properties of DecaBDE for various uses? DecaBDE is a brominated flame retardant that has been added to plastics, textiles, and other materials. When fire occurs, DecaBDE and other polybrominated diphenyl ethers (PBDEs), are part of vapor-phase chemical reactions that interfere with the combustion process, thus delaying ignition and inhibiting the spread of fire. DecaBDE has been considered an economical flame retardant because relatively small quantities are necessary to be effective (Ref. 6).

(iii) What are the 2014 Update to the TSCA Work Plan for Chemical Assessments scores for DecaBDE? DecaBDE scored high (3) for hazard (based on developmental effects in mammals and aquatic toxicity); high (3) for exposure (based on its use in textiles, plastics, and polyurethane foam; and information reported to CDR and TRI); and high (3) for persistence and bioaccumulation (based on high environmental persistence and high bioaccumulation potential). The overall screening score for DecaBDE was high (9).

(iv) Regulatory actions pertaining to DecaBDE. DecaBDE is regulated as a PBT chemical by federal, state, and international agencies. They are briefly summarized in this unit. More detailed information can be found in the Economic Analysis (Ref. 3). In addition, the OSHA regulations discussed in Unit III.A apply to commercial and industrial workplaces.

At the Federal level, under TSCA, DecaBDE was one of the chemical substances required to be tested for dioxin/furan contamination as outlined in 40 CFR part 766. DecaBDE manufacturing, processing, and use information is reportable under CDR (40 CFR part 711). Under the CDR rule, EPA collects basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the U.S. Under TSCA section 8(e), manufacturers (including importers), processors, and distributors must immediately

notify EPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment. Four such notifications were received for DecaBDE between 1996 and 2002. Under the Emergency Planning and Community Right-to-Know Act (EPCRA), DecaBDE has been on the TRI list of reportable chemicals since 1988 (Ref. 20). TRI tracks the management of certain toxic chemicals that may pose a threat to human health and the environment. U.S. facilities in different industry sectors must report annually how much of each chemical is released to the environment or managed through recycling, energy recovery and treatment. A release of a chemical for TRI purposes means that it is emitted to the air or water, or placed in some type of land disposal.

Several states have taken action on DecaBDE. In California, DecaBDE is listed as a candidate chemical by the Department of Toxic Substances Control and as a priority chemical through the California Environmental Contaminant Biomonitoring Program. Starting in 2020, California will also prohibit the use of flame retardants (including DecaBDE) above 1000 parts per million (ppm) in children's products, mattresses, and upholstered furniture. Hawaii prohibits the manufacture, use, sale, and distribution of televisions, computers, upholstered furniture, mattresses, and mattress pads containing DecaBDE greater than 0.1% by weight. In Maine, DecaBDE is listed as a chemical of high concern; it is banned in the use of new shipping pallets (though recycled pallets are exempted), and manufacturers or distributors who use DecaBDE in certain children's products are required to report to the Department of Environmental Protection. In Maryland, the sale of products that contain more than 0.1% DecaBDE by mass is prohibited, though the recycling of articles containing DecaBDE is exempted. New Jersey and Pennsylvania include DecaBDE on their hazardous substances lists under right-to-know legislation. DecaBDE is one of Oregon's 66 high priority chemicals of concern for children's health. Vermont prohibits

DecaBDE in certain home products and manufacturers using DecaBDE must report to the Vermont Health Department. Washington prohibits the use of DecaBDE in children's products, mattresses, electronics, and residential furniture (Ref. 3).

International actions on DecaBDE include Australia listing it as a priority existing chemical, which requires the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) to fully assess the human health and environmental risks of DecaBDE. The draft NICNAS report on DecaBDE was completed in May 2019. Canada added DecaBDE to its Prohibition of Certain Toxic Substances Regulation, which prohibits the manufacture, use, sale, offer for sale, or import of DecaBDE unless present in a manufactured article. The European Member State Committee has identified DecaBDE as a Substance of Very High Concern due to its PBT chemical properties. The European Chemical Agency (ECHA) has prohibited the manufacture and use of DecaBDE (including in most articles at concentrations greater than 0.1% by weight) as of March 2019 under Annex XVII to the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) regulation. DecaBDE is also listed as a persistent organic pollutant (POP) under the Stockholm Convention, which requires parties to take measures to eliminate production and use of the chemical (Ref. 3).

2. Phenol, isopropylated phosphate (3:1) (PIP (3:1)). (i) Use background: PIP (3:1) is used as a plasticizer, a flame retardant, an anti-wear additive, and/or an anti-compressibility additive in hydraulic fluid, lubricating oils, lubricants and greases, epoxy coatings for decks of marine shipping vessels, coatings for pipes and insulation in construction, adhesives and sealants for insulation, and articles. For example, in lubricating oils, PIP (3:1) acts as a flame retardant, an anti-wear additive, anti-compressibility additive, or some combination of the three, while in adhesives and sealants PIP (3:1) acts as a plasticizer and flame retardant (Ref. 4).

PIP (3:1) has been identified as a possible component in plastic products and articles, including children's products, automotive, and aerospace products (Ref. 7).

PIP (3:1) also is added to articles as a plasticizer or flame-retardant additive in plastic components, adhesives and sealants, and paints and coatings. Use of PIP (3:1) in complex articles (such as in casings of electronics or components of automobiles), plastic articles including furniture and furnishings, and toys intended for children's use, has been identified (Ref. 7). PIP (3:1) is sold as a plastic flame-retardant additive and is a component of some flame-retardant additives for flexible polyurethane foam (Ref. 7). EPA is aware that PIP (3:1) is used in antifouling paint; however, EPA does not consider this a TSCA use because any pesticide, when manufactured, processed, or distributed in commerce as a pesticide does not meet the definition of "chemical substance" under TSCA section 3. To ensure that this is clear, EPA is proposing to incorporate the statutory definition of "chemical substance" into 40 CFR part 751, subpart E.

EPA presented its initial research into PIP (3:1) uses in the August 2017 *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal* document on PIP (3:1) (Ref. 7). EPA received comments from 15 entities on the Preliminary Information document. EPA also communicated with companies, industry groups, chemical users, states, and other stakeholders to identify and verify uses of PIP (3:1) (Ref. 4). These interactions and comments further informed EPA's understanding of the uses for PIP (3:1). Public comments and stakeholder meeting summaries are available in EPA's docket at EPA-HQ-OPPT-2016-0730.

For the 2012 CDR period, data indicate that four sites manufactured (including imported) PIP (3:1) in the United States. For the 2016 CDR period, data indicate nine sites manufactured (including imported) PIP (3:1) in the United States (Ref. 17). The total volume of PIP (3:1) manufactured (including imported) in the United States was 14,904,236 lbs in 2011, 3,191,017

lbs in 2012, 2,968,861 lbs in 2013, 5,632,272 lbs in 2014, and 5,951,318 in 2015 (Ref. 17).

(ii) What are the beneficial properties of PIP (3:1) for the various uses? PIP (3:1) has multiple functional uses, including as a plasticizer, flame retardant, anti-wear additive, or as an anti-compressibility additive (Ref. 4). When PIP (3:1) is included in a formula, it is often for a combination of these functional uses, for example as flame retardant and an anti-wear additive. Additionally, PIP (3:1) is an isomer mixture, and through manufacturing, the proportion of various isomers can be manipulated to achieve specific properties which can affect the performance of a formula (Ref. 21).

PIP (3:1) is a component of additives to help lubricating oils and hydraulic fluids meet safety and specific performance standards from both military and industry, particularly in the aviation sector (EPA-HQ-OPPT-2016-0730-0009) (Refs. 22, 23, 24, 25 and 26). It is present in lubricating fluids which need to perform at extreme temperatures, both hot and cold, as a flame retardant and anti-wear additive (Ref. 4). Some lubricants containing PIP (3:1) are formulated to the military performance specifications such as MIL-PRF-32014 for use in a multipurpose, water resistant, high speed grease in a wide temperature range (Refs. 22 and 23). In aviation hydraulic fluid, some phosphate ester-based hydraulic fluids contain PIP (3:1) as a flame retardant, anti-wear additive, and anti-compressibility additive. While multiple hydraulic fluids meet industry performance standards for most commercial and military airplanes, for some commercial models, the information reasonably available to EPA indicates that only hydraulic fluids containing PIP (3:1) can meet safety and air worthiness standards. This includes those models which are designed to operate at higher pressure systems, that is, 5,000 pounds per square inch (PSI) or greater (Ref. 23, 24, and 25). For these systems, additives containing PIP (3:1) allow the fluid to remain functional under this high pressure at various temperatures and minimize wear in

the hydraulic system (Refs. 22, 23, 24 and 25).

(iii) What are the 2014 TSCA Work Plan for Chemical Assessments scores for PIP (3:1)?

While not among the chemicals screened in 2012, PIP (3:1) came to the Agency's attention as part of EPA's analysis of flame-retardant chemicals and was subsequently scored using the TSCA Work Plan Chemicals: Methods Document (Ref. 2) and added to the 2014 Update to the TSCA Work Plan for Chemical Assessments. PIP (3:1) scored high (3) for hazard (based on neurotoxicity in mammals and aquatic toxicity); high (3) for exposure (based on use as a flame retardant in industrial and consumer products); and high (3) for persistence and bioaccumulation (based on high environmental persistence and high bioaccumulation potential). The overall screening score for PIP (3:1) was high (9).

(iv) Regulatory actions pertaining to PIP (3:1). PIP (3:1) is regulated by federal, state, and international agencies. They are briefly summarized in this unit. More detailed information can be found in the Economic Analysis (Ref. 3). In addition, the OSHA regulations discussed in Unit III.A. apply to commercial and industrial workplaces.

PIP (3:1) was added to the Priority Testing List by the TSCA Interagency Testing Committee in May 2012 (77 FR 30855). In addition, a high-volume use of PIP (3:1) is in aviation and industrial hydraulic fluid and lubricants and greases. If such fluids, lubricants, and greases meet the definition of "used oil" under 40 CFR 279.1, they are subject to Resource Conservation and Recovery Act (RCRA) regulations for managing used oil (40 CFR part 279) (Ref. 3).

With respect to state regulations, PIP (3:1) is listed as a candidate chemical and identified as a potential priority monitoring chemical in California, and Washington has identified PIP (3:1) as a Chemical of High Concern to Children (Ref. 3).

Internationally, PIP (3:1) is included in the ECHA Classification and Labeling Inventory. The ECHA Classification and Labeling Inventory is in line with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS); OSHA has also incorporated the GHS in its Hazard Communication Standard. In Canada, PIP (3:1) was placed on the Domestic Substance List (DSL) in 1994 as an Existing Substance not subject to the New Substance Notification Regulations. The inclusion of PIP (3:1) on the DSL designates it as an existing, rather than a new, substance in Canada, the equivalent of being included on the TSCA inventory as an active chemical (Ref. 3).

3. *2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP)*. (i) *Use background*: Uses of 2,4,6-TTBP include domestic manufacture, use as an intermediate/reactant in processing, incorporation in formulations and mixtures destined for fuel and fuel related additives, as well as formulations intended for the maintenance or repair of motor vehicles and machinery. Although EPA has not identified current users of 2,4,6-TTBP for liquid lubricant and grease additives/antioxidants, it found indications of current use, and a manufacturer has reported that, it is aware that some customers may use its products for this end use, although it does not actively market products with 2,4,6-TTBP for lubricant applications. Therefore, the Agency proposes, for purposes of this rulemaking, to address the use of 2,4,6-TTBP in liquid lubricant and grease additives/antioxidants.

2,4,6-TTBP is an alkylphenol whose primary value is as an antioxidant. It is a widely used antioxidant for jet, automotive, and marine fuels. Several stakeholders submitted comments to the public docket following posting of the document, “*Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: 2,4,6-Tris(tert-butyl)phenol, August 2017*” (Ref. 8), which presented EPA’s initial research into the uses of 2,4,6-TTBP. One

chemical processor stated that they sell 2,4,6-TTBP as part of an antioxidant in fuel additives for use in gasoline fuels with a concentration of one to 15% 2,4,6-TTBP; the gasoline fuels, after blending, are packaged and sold in mild steel drums (55-gallon volume) or stainless-steel totes (350-gallon volume) (EPA-HQ-OPPT-2016-0734-0015). The Aerospace Industries Association also identified critical uses of 2,4,6-TTBP as a fuel, lubricant, and oil additive/antioxidant in formulations designed to meet specific technical performance requirements that are documented in a number of engineering specifications over the service life of complex aerospace products (EPA-HQ-OPPT-2016-0734-0010). The American Petroleum Institute also confirmed that their members use 2,4,6-TTBP as an antioxidant in gasoline, diesel, and aviation fuels at concentrations of between 5 and 50 parts per million to reduce gasoline deposits in engines and subsequently reduce emissions (EPA-HQ-OPPT-2016-0734-0006).

Based on EPA's research and public comments submitted, the only large volume domestic manufacturer, and the only manufacturer currently reporting to the EPA's CDR with production volumes of 2,4,6-TTBP that meet the CDR threshold, is SI Group. Historical CDR data indicate that in the 1986 to 1998 reporting years, the aggregate range of production of 2,4,6-TTBP was between 1 and 10 million pounds per year, and increased to a range of 10 to 50 million pounds per year in reporting years 2002 and 2006. The range of production in 2012, 2013, 2014, and 2015 was claimed as CBI in the 2016 CDR (Ref. 3). There have not been any indications of substantial importation of 2,4,6-TTBP into the United States from other countries.

SI Group stated that proprietary chemical mixtures (primarily two, Isonox® 133 and Ethanox® 4733) contain detectable percentages of 2,4,6-TTBP and are used to meet several military specifications for use in jet fuel that is supplied and used by the U.S. military (Ref. 27). SI Group also stated that they do not sell, supply, or distribute into commerce 2,4,6-TTBP in a

pure (neat) form, and none of their proprietary blended chemical mixtures containing 2,4,6-TTBP are sold directly to consumers; however, SI Group customers use these mixtures to formulate other products containing 2,4,6-TTBP that are intended for consumer applications (Ref. 27). SI Group also stated that none of its proprietary chemical mixtures containing 2,4,6-TTBP are actively marketed for use as a lubricant additive; however, some of SI Group's customers may use the proprietary chemical mixtures for this use (Ref. 27). SI Group also confirmed the sale of an excess material stream containing 2,4,6-TTBP, that is used as a waste fuel for energy value, which is burned and destroyed during use (Ref. 27).

2,4,6-TTBP is a co-product with a closely related alkylphenol, 2,6 di(tert-butyl) phenol (2,6-DTBP), which is also a primary substitute for it. Neither chemical can be effectively produced commercially without co-production of the other. Approximately 94% of the 2,4,6-TTBP produced by SI Group is consumed by the company in internal processes (feedstock for further production of alkylphenols). An additional 4% is sold as a waste fuel for energy use. Both uses result in the destruction of the chemical.

The remaining 2% of 2,4,6-TTBP produced by SI Group is sold as an antioxidant primarily for use in fuel for all uses: aviation, military, industrial, commercial, and consumer use. The chemical is sold in a mixture with its co-products, primarily 2,6-DTBP, at a concentration of approximately 85% 2,6-DTBP and 12% 2,4,6-TTBP. The 2,4,6-TTBP is destroyed when the fuel is consumed in the combustion process when the fuel is burned (Ref. 8).

Antioxidant additives are essential to the storage and transport of fuel, as without them, fuel quickly begins to degrade and form harmful sludge and varnish. The 2,4,6-TTBP mixtures are the primary antioxidants used in aviation, marine, and automotive fuel streams in the United States. Many current performance specifications for fuel require their use; including for specialty

fuels for aviation and the military. The majority of the 2,4,6-TTBP mixtures sold are blended into the fuel at the refinery or soon after at tank farms prior to commercial distribution of the fuel.

A portion (approximately 6%) of the 2,4,6-TTBP mixtures are sold to processors who blend and distribute antioxidant products that are intended to be added to the fuel tanks/systems in vehicles or machinery by repair shops or the owner/operators of the equipment themselves. These fuel stabilizer products are sold to consumers at various retail locations, as well as online. These additives are typically sold in small bottles containing up to 32 ounces; gallon containers are available through some retailers. Specialty products are also sold for cleaning fuel injectors or use in 2-stroke engines (pre-blended with oil).

Other countries have reported that 2,4,6-TTBP is, or has been, used as an additive in oils and lubricants (EPA-HQ-OPPT-2016-0734-0002). SI Group states that it does not actively market products containing 2,4,6-TTBP for lubricant applications, but that it is aware that some customers may use these products in lubricant applications (Ref. 27).

(ii) What are the beneficial properties of 2,4,6-TTBP for various uses? Regarding the benefit of manufacture, beyond its use as an antioxidant, 2,4,6-TTBP has value as a chemical intermediate in the production of dialkylphenol chemicals. Moreover, SI Group reports it is not possible to significantly suppress the formation of 2,4,6-TTBP without severely constraining the yield of other desired dialkylphenol products, therefore its manufacture has impacts beyond the commercial use of 2,4,6-TTBP itself. The production of other dialkylphenol products, including alternative antioxidants, is therefore a benefit of ongoing 2,4,6-TTBP manufacture.

With respect to use as an antioxidant in the general fuel supply, EPA has received comment regarding the beneficial properties of 2,4,6-TTBP as an antioxidant component blended

in fuel. SI Group identified numerous U.S. military and ASTM standards that its proprietary blended products containing 2,4,6-TTBP satisfy for the antioxidant requirements in fuel (Ref. 27). Although particular specifications do not list 2,4,6-TTBP by CASRN or trade name, 2,4,6-TTBP is the preferred antioxidant component for fuel standards due to its chemical reaction potential and physical property characteristics (Refs. 27 and 28). According to the manufacturers and processors, any substitution of 2,4,6-TTBP with another alkylphenol or antioxidant compound would materially change the performance characteristics of that fuel and compliance with mandatory reference standards could not be assured (Ref. 28). Introducing a new jet fuel component into use involves the fuel component supplier, engine manufacturers, airplane makers and regulators in a complicated process that may take several years and involve significant cost. New fuel additives must be tested and approved to ensure they would have no negative impact on engine safety, durability or performance (Ref. 27).

Regarding the retail sale of fuel additives and fuel injector cleaners, EPA was unable to find any specifications or standards for retail fuel antioxidants or additives that explicitly require the use of 2,4,6-TTBP.

Regarding the use of 2,4,6-TTBP as an antioxidant additive in oil and lubricants, EPA was unable to find any specifications or standards for oil, lubricant, or grease additives that require the use of 2,4,6-TTBP.

(iii) What are the 2014 Updates to the TSCA Work Plan for Chemical Assessments scores for 2,4,6-TTBP? 2,4,6-TTBP scored moderate (2) for hazard (based on toxicity following chronic exposure including liver effects); moderate (2) for exposure (based on its wide use in consumer products, presence in indoor environments, and estimation to have moderate releases to the environment); and high (3) for persistence and bioaccumulation (based on moderate

environmental persistence and high bioaccumulation potential). The overall screening score for 2,4,6-TTBP was high (7).

(iv) Regulatory actions pertaining to 2,4,6-TTBP. EPA has no existing regulations expressly identifying 2,4,6-TTBP, and EPA did not identify any existing or developing Federal regulations for 2,4,6-TTBP. However, the OSHA regulations discussed in Unit III.A. apply to commercial and industrial workplaces.

With respect to state regulations, the California Department of Toxic Substances Control (DTSC) lists 2,4,6-TTBP as a Candidate Chemical. A Candidate Chemical must exhibit a hazardous trait and/or an environmental or toxicological endpoint and is found on an authoritative list under California Code of Regulations section 69502.2(a) or is listed by DTSC using criteria specified in section 69502.2(b) (Ref. 3). In Oregon, 2,4,6-TTBP is listed on Oregon Department of Environmental Quality's pollutant profiles (Ref. 3) and 2,4,6-TTBP is listed as a tier 1 persistent pollutant (Ref. 3). With respect to international actions, Japan has prohibited the importation, manufacture, and use of 2,4,6-TTBP as a Class 1 Specified Chemical under the Chemical Substance Control Law (Ref. 3).

Environment Canada's 2008 screening assessment for 2,4,6-TTBP concluded that 2,4,6-TTBP may be entering the environment and meets the criteria set out in section 64 of the Canadian Environmental Protection Act of 1999. Environment Canada has since completed a risk evaluation and in 2016 recommended 2,4,6-TTBP be added to schedule 1 of the environmental emergency regulations, at a threshold quantity of 0.22 tonnes at a concentration of 10%; listing may require persons who own or manage specified toxic and hazardous substances at or above the specified thresholds to provide required information on the substance(s) and their quantities and to prepare and implement environmental emergency plans (Ref. 3).

2,4,6-TTBP is on the European Chemical Agencies (ECHA) Classification and Labeling inventory and the European community inventory. More detailed information on the state and international regulations pertaining to 2,4,6-TTBP can be found in the Economic Analysis (Ref. 3).

4. Hexachlorobutadiene (HCBD). (i) Use background: HCBD is a halogenated aliphatic hydrocarbon that is produced as a byproduct during the manufacture of chlorinated hydrocarbons, particularly perchloroethylene, trichloroethylene, and carbon tetrachloride (Ref. 29). The majority of what is manufactured is destroyed via incineration by the manufacturer. A small percentage of the HCBD is sent off-site for incineration or for burning as a waste fuel by cement manufacturers in cement kilns (EPA-HQ-OPPT-2016-0738-0012). EPA has not identified any uses of HCBD other than burning as a waste fuel. According to TRI data, over 9 million lbs of HCBD were generated by chemical manufacturers in reporting year 2017, with almost 8.9 million lbs treated for destruction on-site via incineration. TRI reports show other waste management activities of HCBD including 58,000 lbs being treated for destruction off-site, 33,000 lbs burned for energy recovery off-site, and 2,400 lbs released to air.

(ii) What are the beneficial properties of HCBD for the various uses? HCBD is manufactured as a waste byproduct by chemical manufacturers. The majority of what is manufactured is destroyed via incineration by the manufacturer. A small percentage of the HCBD is sent off-site for burning as a waste fuel by cement manufacturers.

(iii) What are the 2014 Update to the TSCA Work Plan for Chemical Assessments scores for HCBD? HCBD scored high (3) for hazard (possible human carcinogen); moderate (2) for exposure (based on TRI data); and high (3) for persistence and bioaccumulation (based on high environmental persistence and high bioaccumulation potential). The overall screening score for

HCBD was high (8).

(iv) Regulatory actions pertaining to HCBD. Under EPCRA, HCBD has been listed on the TRI list of reportable chemicals since 1988 (Ref. 20). HCBD is a Hazardous Air Pollutant (HAP) under section 112 of the Clean Air Act (CAA) as amended in 1990. The Agency has promulgated National Emission Standards for Hazardous Air Pollutants (NESHAPs) which require the maximum achievable control technology (MACT) for major sources in Standard Source Categories. Under the Clean Water Act (CWA), HCBD is listed on the Priority Pollutant List and is subject to Effluent Guidelines and the requirements of the National Pollutant Discharge and Elimination System (NPDES). Under the Resource Conservation and Recovery Act (RCRA), HCBD is a hazardous constituent and can be characterized as a toxicity characteristic waste (Hazardous Waste No. D033) or listed hazardous waste (U128) under RCRA when discarded or intended for discard. Under the Comprehensive Environmental Response, Compensation and Liability Act, HCBD is designated as a hazardous substance with a reportable quantity (RQ) of 1 lb. More information on the impact of these existing regulations is in Unit III.E.

With respect to other Federal regulations, the Pipeline and Hazardous Material Safety Administration in the Department of Transportation lists HCBD as a hazardous substance with a reportable quantity of 1 lb. In addition, the OSHA regulations discussed in Unit III.A. apply to commercial and industrial workplaces.

Many states have promulgated regulations applicable to HCBD. State requirements concerning HCBD include regulations of water quality standards, sources of air pollution and management of waste containing the chemical. The following states implemented water quality standards for HCBD: Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia,

Hawaii, Idaho, Indiana, Kentucky, Louisiana, Maine, Maryland, Michigan, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington and Wisconsin. Several states have air pollution requirements for HCBD including Idaho, Illinois, Maryland, New Hampshire and Ohio.

Internationally, Austria banned the use of HCBD in 1992 citing its carcinogenic and mutagenic properties as well as fetotoxicity and negative effects on fertility. In Canada, HCBD is on the Domestic Substance List (DSL) as an Existing Substance not subject to the New Substance Notification Regulations. It was also added to Schedule 1 of the Canadian Environmental Protection Act and to Schedule 1 of the Prohibition of Certain Toxic Substances Regulations. HCBD was also placed on Canada's Virtual Elimination List. In China, HCBD is in the Catalog of Hazardous Chemicals. In the European Union (EU), HCBD is listed on the Annex III inventory based on its bioaccumulative properties and is subject to Annex V Part 1 of Prior Informed Consent (PIC) Regulation. In Germany, HCBD is on the Master List of the German Federal Environment Agency (UBA). Under the Chemical Substances Control Law of Japan, HCBD was designated a Class I Chemical Substance. Swedish Chemicals Agency includes HCBD on a list of phase-out substances. The United Kingdom regulates HCBD through several mechanisms including the Pollution Prevention and Control regulations, the Food and Environmental Protection Act, and the Control of Pesticides Regulations. Under the Stockholm Convention, HCBD is listed as a persistent organic pollutant (POP) under Annex A which requires parties take measures to eliminate production and use of the chemical, and under Annex C which requires parties to reduce the unintentional releases of chemicals.

For more information about regulatory actions pertaining to HCBD, see the Economic

Analysis for this proposed rule (Ref. 3).

5. *Pentachlorothiophenol (PCTP)*. (i) *Use background*: Historically, PCTP was used in rubber manufacturing as a peptizer, a chemical that makes rubber more amenable to processing. There are few data, however, on end-use products that contain PCTP. For years, PCTP was produced in the United States but domestic manufacture appears to have ceased (Ref. 17). While 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 (Ref. 30). As shown by a number of patents, zinc PCTP can be used as a peptizer in rubber manufacturing and as an ingredient in the rubber core of golf balls to enhance certain performance characteristics of the ball, such as spin, rebound, and distance (Refs. 31 and 32). EPA considers the addition of PCTP to rubber during manufacturing, whether as a peptizer or an impurity, to be processing under TSCA.

Zinc PCTP is imported into the United States, with approximately 65,000 lbs imported in 2017 (Ref. 3). EPA believes that some or all of the zinc PCTP could contain PCTP. The importation of PCTP, including as an impurity with zinc PCTP, is considered manufacturing under TSCA. EPA requests comments as to which chemicals would most likely serve as alternatives to ZnPCTP in golf balls, and why golf ball manufacturers may not currently choose to use these alternatives.

(ii) *What are the beneficial properties of PCTP for various uses?* During the manufacture of rubber, PCTP was used as a peptizer to reduce the viscosity of rubber during processing. PCTP has been used as a mastication agent in the rubber industry and, more specifically, a peptizing agent for natural rubber viscosity reduction in the early stages of rubber manufacturing (Ref. 33). Mastication and peptization are processing stages during which the viscosity of rubber

is reduced to a level facilitating further processing (Ref. 34). It is possible to reduce the viscosity of natural and synthetic rubbers through solely mechanical efforts, but peptizers allow this process to be less sensitive to varying time and temperature, which improves the uniformity between batches (Ref. 33).

(iii) What are the 2014 Update to the TSCA Work Plan for Chemical Assessments scores for PCTP? PCTP scored high (3) for hazard (based on toxicity for acute and chronic exposures); low (1) for exposure (based on 2012 CDR data); and high (3) for persistence and bioaccumulation (based on high environmental persistence and high bioaccumulation potential). The overall screening score for PCTP was high (7).

(iv) Regulatory actions pertaining to PCTP. PCTP was added to the TSCA Preliminary Assessment Information Rule (PAIR) Priority Testing List in August 2001 (Ref. 35). The PAIR requires manufacturers (including importers) of the substances identified to report certain production, importation, use, and exposure-related information to EPA. PCTP was removed from the Priority Testing List in 2003 because of low exposure potential (Ref. 36). In addition, the OSHA regulations discussed in Unit III.A. apply to commercial and industrial workplaces.

With respect to state regulations, California's Department of Toxic Substances Control includes PCTP on its Candidate Chemical list based on its bioaccumulation, environmental persistence, and toxicity. Maine includes PCTP on its list of Chemicals of High Concern. Maryland lists PCTP as a Toxic Air Pollutant. The Minnesota Department of Health lists PCTP as a Chemical of High Concern for its PBT properties (Ref. 3).

With respect to international actions, in Canada, PCTP is on the Domestic Substance List (DSL) as an "Existing Substance" as it met the criteria under subsection 73(1) of the Canadian Environmental Protection Act, 1999 (CEPA), because it was already in commerce in Canada

from 1984 to 1986 and thus not subject to the New Substance Notification Regulations. In 2008, PCTP was moved to Part 2 of the DSL to indicate that it is subject to a Significant New Use Activity under subsection 81(3) of CEPA. In the European Union, PCTP is listed on the Annex III inventory based on its bioaccumulative properties and, in Japan, PCTP is listed as an Existing Chemical under the Chemical Substances Control Law (CSCL). More information on the Federal, state and international regulations pertaining to PCTP can be found in the Economic Analysis (Ref. 3).

E. Exposure and Use Assessment and Hazard Summary

1. Summary of the Exposure and Use Assessment. An exposure and use assessment was conducted for the five PBT chemicals using the following information: a) chemical and physical-chemical properties, b) use descriptions, c) expected environmental partitioning, d) lifecycle and potential sources, e) environmental monitoring, f) biomonitoring, g) modeled intake and doses from existing studies, h) trends in the data, i) summary information from completed exposure assessments and review of peer-review articles published at the time of preparation of the exposure and use assessment, j) representative exposure scenarios, and k) information provided by public comment and peer review. This information helps to identify potential exposure scenarios that are the combination of sources/uses, environmental pathways, and receptors.

Lifecycle diagrams were developed and qualitative evaluations describing relative potential for occupational exposure of the five PBT chemicals were performed to assess release to different media from various industrial operations. Though environmental partitioning of chemicals in various media were considered, uses and processes for each of these five PBT chemicals have variations of releases in different media. A comprehensive literature search was performed to collect environmental and bio-monitoring information to assess the likely exposure

of the general population, consumers, occupational populations, potentially exposed or susceptible subpopulations, and the environment from the conditions of use of the PBT chemicals.

Only a few monitoring studies were reported for PIP (3:1) and 2,4,6-TTBP. Thus, a supplemental search was conducted to identify closely related chemicals. Based on EPA scientific review and evaluations, triphenyl phosphate (TPP) and 2,4-di-tert-butylphenol (2,4-DTBP) were considered as surrogate chemicals for PIP (3:1) and 2,4,6-TTBP, respectively. These surrogates were selected based on availability of data, structural similarity, similar use, and reasonably close physical-chemical properties. PCTP was also found to have limited data; however, no surrogate chemicals were identified for PCTP using these criteria.

Multiple approaches were considered to construct non-specific exposure scenarios. Comparison of exposure scenarios revealed source attribution. The relative complexity of source attribution varied depending on the continuum of available uses/sources and the media considered. For example, total dust concentrations in a residence represent contributions from multiple sources. Similarly, internal dose measured in biota represents total exposure from multiple media and sources. This source attribution can be qualitative or quantitative. Qualitative descriptors (*e.g.*, higher, lower potential for exposure) were used to characterize exposures, and uncertainties were acknowledged across the exposure scenarios.

2. Proposed TSCA section 6(h)(1)(B) exposure finding. In this unit EPA provides an overview of the potential exposures for each PBT chemical. The possible exposures are described within the context of the lifecycle of the chemical, *e.g.*, exposures during manufacturing, processing, distribution, use and disposal. However, EPA notes that these exposures are possible, not necessarily probable nor known. This is especially so in instances

where regulatory controls mandated by other statutes are applicable. As discussed in Unit III.A., EPA generally expects there is compliance with Federal and state laws, such as worker protection standards or disposal restrictions, unless case-specific facts indicate otherwise.

EPA is proposing to determine in accordance with TSCA section 6(h)(1)(B) that, based on the Exposure and Use Assessment and other reasonably-available information, exposure to the five PBT chemicals under the conditions of use is likely to the general population, to a potentially exposed or susceptible subpopulation, or the environment, which is the threshold for expedited action under TSCA section 6(h). EPA's proposed determination is based on the opportunities for exposure throughout the lifecycle of each of the five PBT chemicals including, for some, consumer exposures.

(i) *DecaBDE*. Exposure information for DecaBDE is summarized here and is detailed in EPA's Exposure and Use Assessment (Ref. 4).

The most likely sources of releases and occupational exposures during the manufacturing condition of use of DecaBDE are associated with fugitive dust. These include air releases from transfer and packaging operations (fugitive dust to ambient air, as well as dust that is collected and channeled through a dedicated point as a stack release) and solid waste from floor sweepings, disposal of used transfer containers containing residual DecaBDE, and liquid waste from equipment cleaning. Fugitive vapor air releases are not expected due to the chemical's low vapor pressure. Releases to land are possible when floor sweepings and other solid waste are collected and disposed in landfills. Similarly, the collection and disposal of liquid equipment cleaning solutions has the potential of generating liquid waste containing DecaBDE (aqueous waste to surface waters and sent to publicly owned treatment works, and organic waste collected and sent for other disposal or waste treatment such as incineration). Historical and recent TRI

data confirm primary releases are to air, followed by landfill and water (Ref. 4). As noted previously, under TRI, a release of a chemical means that it is emitted to the air or water, or placed in some type of land disposal. These releases may be regulated under other environmental statutes, such as the CAA, CWA, or RCRA. Occupational exposures from inhalation and dermal exposure to dust are possible during transfer and packaging operations and from fugitive dust emissions from process operations if workers are unprotected. The OSHA regulations discussed in Unit III.A. apply to industrial and commercial workplaces. More specifically, the OSHA regulations at 29 CFR 1910.132 require employers to assess a workplace to determine if hazards are present or likely to be present which necessitate the use of personal protective equipment (PPE). If the employer determines hazards are present or likely to be present, the employer must select the types of PPE that will protect against the identified hazards, require employees to use that PPE, communicate the selection decisions to each affected employee, and select PPE that properly fits each affected employee. Thus, EPA would not expect workers in industrial and commercial workplaces to be unprotected.

During processing conditions of use, DecaBDE is combined with other ingredients (*e.g.*, monomers) and then molded, extruded, formed into final products, or applied to a finished article, where curing may occur (Ref. 4). Releases to air, land, and water may occur from DecaBDE and DecaBDE flame-retardant formulations (solids and liquids), as well as from off-specification products containing the additive flame retardant. Air releases (fugitive dust and dust collected and channeled to a stack) may occur from transfer operations. Releases to land may occur during disposal of transfer containers containing residual material, collection and disposal of floor sweepings, and disposal of off-spec product. Equipment and general area cleaning with aqueous cleaning materials may result in releases to water. Current and historical

TRI data indicate the primary releases are to air, followed by landfill and water (Ref. 4).

Occupational exposures from inhalation and dermal exposure to dust may occur during transfer and packaging operations and from fugitive dust emissions from process operations if workers are unprotected. Dermal exposure to liquids is possible from incidental contact of liquid flame-retardant formulations containing DecaBDE during transfer, loading, and mixing operations.

Occupational exposures may occur when the bags of flame retardant are emptied into a hopper prior to mixing if workers are unprotected. Once formulated, DecaBDE is encased in the polymer matrix and the potential for worker exposure is reduced significantly (Ref. 4).

DecaBDE is present in plastic that may be recycled and subsequently reused. Releases from recycling facilities may occur from discarded material that cannot be recycled and reclaimed and is disposed in landfills. Releases to air and water are expected to be minimal during most recycling processes because DecaBDE is entrained in the articles and is not expected to volatilize or migrate readily from the facility during recycling operations. However, there is potential for volatilization and releases to air if recycling involves heating and melting the DecaBDE-containing plastic article, and, thus, inhalation exposures if workers are unprotected. Limited occupational exposure to workers at recycling facilities is possible from dermal contact during handling of plastic material that is received and introduced into recycling operations, and from inhalation exposure to dust from grinding and shredding operations, if workers are unprotected.

DecaBDE is combined with other ingredients and incorporated into the back coating of various textiles, such as curtains, via roll or dip coating processes. Releases may occur from disposal of transfer containers associated with DecaBDE formulations, disposal of waste from equipment and area cleaning, disposal of off-spec product, and disposal of bath dumps.

Historical TRI data indicate most releases during this processing activity are associated with disposal to landfills, with smaller quantities released to air, and with minimal releases to water. If workers are unprotected, inhalation exposures may occur due to: fugitive dust generated from unloading and transfer of the solid flame retardant into mixing vessels; mist generated from the squeezing of the immersed fabric with rollers; from the roll coating application during back coating; and, after the coating operations are complete, during fabric cutting. If workers are unprotected, dermal exposures to solid and liquid DecaBDE mixtures in fabric finishing may occur from unloading operations, mixing finishing baths, equipment cleaning, and spilling (Ref. 4).

DecaBDE is combined with other ingredients and then molded, extruded, formed into final products, or applied to wire or cable (Ref. 4). Releases may occur from transfer operations, volatilization from extrusions, disposal of transfer containers, waste from equipment and area cleaning, and disposal of off-spec product. Historical TRI data indicate most releases during this processing activity are associated with disposal to landfills, with smaller quantities released to air, and with minimal or no releases to water (Ref. 4). If workers are unprotected, inhalation exposure from fugitive dust that is generated from unloading and transfer of the flame retardant into mixing vessels and from vapors generated during extrusion may occur. If workers are unprotected, dermal exposure is most likely during formulation when the bags of flame retardant are emptied into a hopper prior to mixing. Once formulated, DecaBDE is encased in the cured coating and the potential for worker exposure is minimal.

Article components containing DecaBDE, such as fabrics and plastic parts, are incorporated into finished products, such as automobiles and aircraft. Releases to land may occur from disposal of off-spec products that contain DecaBDE. Releases to air and water are expected

to be minimal because DecaBDE is entrained in the articles and is not expected to volatilize or migrate readily under normal use. Occupational exposure from dermal contact with article components during installation is possible if workers are unprotected. Inhalation exposure is not expected due to the low potential for volatilization.

Articles treated with DecaBDE are used in the home, in business settings, and in the transportation sector. DecaBDE has also been found in children's products such as plastic play structures and toys, though DecaBDE is present only in low (below 0.1%) concentrations in many cases. DecaBDE is also found in plastics used as components in electrical appliances and equipment such as stereos, computers, televisions, circuit boards, casings, and cable insulation. Other uses in the transportation and construction sector are in the fabrics of automobiles, aircrafts, and in building materials (Ref. 4). DecaBDE's primary use is in high impact polystyrene-based products that are used in plastics, specifically in plastic enclosures for televisions, computers, and audio and video equipment. It is also used in textiles and upholstered articles (including carpets, upholstery fabric, curtains, and cushions), and wire and cables for communications and electronics (Refs. 4 and 6). The quantity of DecaBDE in these articles is unknown. Releases from these articles may occur when DecaBDE migrates from the articles during use (e.g., in homes and business settings), disposal, and waste management. Occupational dermal exposures are expected to be minimal from handling and repackaging articles. Inhalation and dermal exposures are possible during recycling operations if workers are unprotected (e.g., recycling of plastics) (Ref. 4). The end-of-life disposal and waste handling options for products containing DecaBDE include disposal in landfills, recycling and incineration (Ref. 4).

Exposure assessments on DecaBDE have been conducted by the EPA (including industry-supplied information as part of the Voluntary Children's Chemical Evaluation Program),

the National Academy of Sciences, and international governments. These assessments describe exposure potential for PBDEs, including DecaBDE, through a variety of pathways. Adult and child exposures occur via dust ingestion, dermal contact with dust, and dietary exposures (such as dairy consumption). Household consumer products have been identified as the main source of PBDEs (including DecaBDE) in house dust. The next highest exposure pathways included dairy ingestion, and inhalation of indoor air (via dust). Infant and child exposures occur via breastmilk ingestion and mouthing of hard plastic toys and fabrics. Occupational exposures for breastfeeding women were highest in women engaged in activities resulting in direct contact with DecaBDE (Ref. 4).

Experimental product testing studies suggest that DecaBDE can be emitted from articles during use through abrasion and direct transfer to dust on surfaces. Based on DecaBDE's physical-chemical properties, ingestion of settled dust through routine hand-to-mouth and object-to-mouth contact is likely the primary exposure route for articles. The inhalation pathway also contributes to exposure when suspended particles deposited in the upper airway are subsequently swallowed. The dermal pathway likely contributes a smaller proportion of total exposure.

Numerous monitoring studies have shown that DecaBDE has been detected in a wide variety of media such as indoor dust, air, water, soil, human blood, and fish. Dietary exposure through the food-chain and trophic transfer may contribute to presence in biological matrices (human blood, fish, etc.).

Exposure to ecological receptors has been well documented, with several biomonitoring studies reporting levels in tissues of invertebrates, fish, and birds (Ref. 4). Environmental and biological levels are typically higher near point sources. However, DecaBDE has also been detected in remote areas indicating potential for long-range transport.

DecaBDE was produced and released at higher levels in the past but continues to be released. Releases from manufacturing and processing are declining over time, as are releases associated with use, disposal, and recycling (Ref. 4).

(ii) *PIP (3:1)*. As discussed briefly in Unit II.D.2, PIP (3:1), CASRN 68937-41-7 is a mixture of isomers. The proportion of various isomers within a mixture is often proprietary, and can affect the performance of the product, as well as its hazard and ecological persistence and bioaccumulation. Most of the existing studies of PIP (3:1) represent exposures to whole commercial products; however, the amount of PIP (3:1) within the studied formula varies greatly in content and propylation configurations. In these studies, exposure to other chemicals within the product, such as triphenyl phosphate, which is often present in mixtures of PIP (3:1) in concentrations from 5-10%, may influence the magnitude of exposure to PIP (3:1) from commercial products, and the effects observed.

Exposure information for PIP (3:1) is briefly summarized here and is detailed in EPA's Exposure and Use Assessment (Ref. 4).

PIP (3:1) is manufactured, processed, distributed, and used domestically. There is potential for exposure to PIP (3:1) under the conditions of use at all stages of the lifecycle (*i.e.*, manufacturing, processing, use (industrial, commercial, and consumer), distribution, and disposal) of the chemical (Ref. 4).

During the manufacturing condition of use, fugitive air releases from various process steps, water releases from separation and drying steps as well as equipment and area cleaning, and land releases from disposal of spent filters are possible.

During the processing into formulas conditions of use, releases to air, water, and land are possible from the associated unit operations. The primary sources of release include container

residue, process equipment cleaning, and disposal of off-spec products.

PIP (3:1) is an additive flame retardant that is used in a variety of articles including plastic resins, foam, and synthetic rubber. Flame retardants in general are incorporated into products in one of two manners. They are either chemically bound to the product matrix as “reactive” mixtures, or they are dissolved in the polymer materials as “additives.” Additive flame retardants are not chemically bound and are relatively unattached to the polymer matrix. Therefore, they have the increased potential of migrating from products to the surrounding environment during normal use.

Fugitive air releases of PIP (3:1) are expected to be minimal due to its low vapor pressure. Water and land releases are not expected from waste hydraulic fluids and greases because used fluids and grease are typically collected for reuse or incineration (Ref. 4).

If workers are unprotected, dermal exposure to PIP (3:1) (full or partial hand immersion, splashing, or spraying) is possible from handling hydraulic fluids and lubricants and greases. Inhalation exposure to fugitive vapors is expected to be minimal, but inhalation exposure to mist is possible if the fluid is spray-applied and if workers are not wearing appropriate personal protective equipment. Transportation workers, aside from those who regularly handle these fluids, can also be exposed to hydraulic fluid vapor; for example, airline crews can be exposed to hydraulic or engine oil smoke or fumes (Ref. 4).

PIP (3:1) is also added to coatings, adhesives, and sealants for a variety of industrial uses. Potential application methods of these coatings to industrial substrates may include roll, dip, and spray processes. The quantity of releases and level of occupational exposures varies with each process; however, each presents possible releases to all media (air, water, land) and exposures (inhalation of vapors or mists and dermal exposure to liquids).

While release of PIP (3:1) is possible, the data on PIP (3:1) pathways and endpoints are limited, even when looking at an analogue like triphenyl phosphate. The reasonably available data are generally consistent with the fate summary and reported physical-chemical properties in that PIP (3:1) was detected in indoor dust, soil, ambient air, and sediment in higher concentrations and was not reported in other media.

Triphenyl phosphate, or TPP, is used as an analogue for PIP (3:1) in EPA's Exposure and Use Assessment. TPP is present in formulated products with PIP (3:1), sometimes in concentrations of 5-10%. The larger body of TPP data provides insight into the expected patterns of environmental partitioning and uptake of PIP (3:1), but not as being indicative of the levels of PIP (3:1) that should be expected or the toxicity of PIP (3:1). In the literature search, information was identified showing that TPP or its metabolites were detected or estimated in human blood, dermal wipes, fish, terrestrial invertebrates, birds, and terrestrial mammals.

(iii) 2,4,6-TTBP. Exposure information for 2,4,6-TTBP is briefly summarized here and is detailed in EPA's Exposure and Use Assessment (Ref. 4)

Fuel additive formulations containing 2,4,6-TTBP in solution may be shipped to end users in a variety of container types. Fugitive air releases of 2,4,6-TTBP are expected to be minimal (due to the low vapor pressure) from unloading and transfer operations. It is expected that the majority of 2,4,6-TTBP is destroyed (burned) as the fuel it is added to is consumed. Releases may occur from disposal of empty transport containers and waste absorbents used to clean spills and leaks from loading operations. Waste from equipment cleaning with organic cleaning solutions is anticipated to be collected for incineration. Water releases are possible from equipment and general area cleaning with aqueous cleaning solutions. Dermal exposure to 2,4,6-TTBP to workers may occur from transfer and fuel loading operations. Dermal exposure

resulting from manufacturing and processing conditions of use at manufacturing facilities and fuel production facilities is expected to be minimal due to the use of appropriate engineering controls and personal protective equipment (PPE). At the manufacturer facilities, worker PPE consists of nitrile gloves, chemical-resistant slicker suits, chemical resistant boots, respirators with face shield and hard hats; workers are trained and monitored in the correct use of their PPE. Sampling during production is accomplished using controlled sampling spigots, which prevent aerosol formation, splashing and spillage, minimizing potential worker exposure. Controlled sampling spigots are also used for transfer activities (loading and unloading) (EPA-HQ-OPPT-2018-0314-0018). Refineries, fuel distribution and fuel storage facilities also operate with appropriate engineering controls, PPE, working worker training, leak detection and spill control measures; vapor recovery systems are used during distribution and storage (EPA-HQ-OPPT-2016-0734-0006). Once blended into fuel, the resultant concentration of 2,4,6-TTBP in fuel is low, in the 5 to 50 ppm range, limiting the exposure resulting from handling and spills or leaks.

Use of retail fuel additive products which are sold in small containers by mechanics and consumers to service cars, boats, small engines, etc., present opportunities for release and dermal exposure during transfer activities if workers are unprotected. Spillage may occur when the product is being pouring into fuel tanks and storage cans. Product containers may also leak during transportation, handling, storage and disposal. Used containers are disposed of in the municipal solid waste stream without special handling.

If released to the indoor environment, 2,4,6-TTBP could partition to particulates and dust based on its chemical relationship with organic carbon compared to that of air. If released into a sanitary sewer system or storm water system, 2,4,6-TTBP would likely transport to nearby wastewater treatment plants due to relative mobility in water due to high water solubility and low

KOC (soil organic carbon/water partitioning coefficient).

EPA did not identify any studies with extractable 2,4,6-TTBP data in drinking water or any studies with detectable levels of 2,4,6-TTBP in soil, sludge/biosolids, or vegetation/diet. Additionally, EPA did not identify any studies with detectable levels of 2,4,6-TTBP in human blood (serum), other human organs, aquatic invertebrates, aquatic vertebrates, terrestrial invertebrates, birds, or terrestrial mammals.

(iv) *HCBD*. Exposure information for HCBD is briefly summarized here and is detailed in EPA's Exposure and Use Assessment (Ref. 4).

HCBD is manufactured as a byproduct by chemical manufacturing facilities. Most of the chemical is destroyed by incineration with a small percentage released to air via stack and fugitive emissions. Waste containing HCBD is blended with conventional fuels and burned in cement kilns for energy recovery. EPA has not identified any uses of HCBD other than burning as a waste fuel. The destruction and removal efficiency from incineration of HCBD is expected to be significant but not complete, resulting in air releases from incinerator flue gas and land releases from disposal of ash and slag. Minor water releases from equipment cleaning are possible (Ref. 4).

Multiple studies show that HCBD has been detected in a wide variety of media. Higher concentrations were reported in ambient air, surface water, soil, and sediment. Lower concentrations were reported in drinking water, indoor air, and sludge/biosolids. TRI data show that HCBD is released to air annually from chemical manufacturers, with approximately 2,400 lbs released in 2017. TRI data indicate that the number of reporting facilities and the total domestic release quantities to all media have remained relatively constant since 2000 (Ref. 7).

(v) *PCTP*. Exposure information for PCTP is briefly summarized here and is detailed in

EPA's Exposure and Use Assessment (Ref. 4).

Since PCTP is a dry powder, the most likely sources of releases and occupational exposures from the manufacturing condition of use are associated with fugitive dust, if workers are unprotected. These include air releases from transfer and packaging operations (fugitive dust to ambient air as well as dust that is collected and channeled through a dedicated point as a stack release) and solid waste from floor sweepings, disposal of used transfer containers containing residual PCTP, and liquid waste from equipment cleaning. Fugitive vapor air releases are not expected due to the low vapor pressure. Releases to land are possible when floor sweepings and other solid waste are collected and disposed in landfills. Similarly, the collection for disposal of liquid equipment cleaning solutions has the potential of generating liquid waste containing PCTP (aqueous waste to surface waters and sent to publicly owned treatment works, and organic waste collected and sent for other disposal or waste treatment such as incineration). Occupational exposures from inhalation of fugitive dust and dermal exposure to dust from transfer and packaging operations and from fugitive dust emissions from processing conditions of use are possible if workers are unprotected. However, dermal exposure to liquids is not anticipated. Similarly, inhalation exposure to fugitive vapors is not expected due to PCTP's low vapor pressure (Ref. 4).

Although releases of PCTP after the zinc PCTP is incorporated into rubber are expected to be minimal, releases of additives from rubber manufacturing are possible to water, air, and land (predominantly prior to reaction process completion). Water releases are expected to be most prevalent. Sources include process wastewater from cooling or heating medium and vulcanization, where water has direct contact with the rubber mixture. Releases to water can also occur from equipment and general area cleaning. Releases are possible from the disposal of off-

spec product and empty transfer containers. Air releases are expected to be minimal due to the low vapor pressure of PCTP. Occupational inhalation and dermal exposure to dust is possible from unloading and transfer operations when the PCTP mixture is added to process equipment if workers are unprotected. Once incorporated into the rubber formulation, the potential for worker exposure is not expected (Ref. 4).

3. *Hazard summary.* The purpose of the Hazard Summary is to describe the hazards of the five PBT chemicals. EPA did not perform a systematic review of the literature to characterize the hazards of the five PBT chemicals, and instead performed a limited survey of the reasonably available scientific information. The information in this document does not represent an exhaustive literature review nor is it an analysis of relative importance or comparative dose-response among hazards. Due to Congress' direction in TSCA to expeditiously regulate PBTs on the 2014 Work Plan and because risk evaluations were not required by Congress, EPA prepared a fit-for-purpose summary of the hazards presented by the five PBT chemicals. EPA leveraged previous data compilations and existing information, wherever possible, as the initial data-gathering approach and to survey the environmental and human health hazard data and information. EPA did not evaluate the strengths and weaknesses of individual studies. nor did EPA select studies to inform a point of departure. The hazard data are reported from the literature with no additional analysis or assessment. Reasonably available hazard information is tabulated and briefly summarized within this document; hazard values, unless noted otherwise (*e.g.*, normalized to percent active ingredient or purity), are as reported by authors, and were not selected for use in conjunction with any particular exposure pathway(s), risk assessment scenarios, or dose-response analysis conducted by EPA. The Hazard Summary does take into consideration public and peer review comments. Hazard information that became available after

the beginning of the peer review and public comment process in June 2018 is not captured in the Hazard Summary. EPA requests comments making the Agency aware of any more recent hazard information available.

Environmental and human health hazard data were compiled from various primary and secondary sources of publicly available information. The hazard summaries relevant to environmental hazard data include toxicological information following acute and chronic exposures for both aquatic and terrestrial wildlife. Due to a general lack of data found for 2,4,6-TTBP and PCTP in the primary and secondary sources initially searched, additional literature searches were conducted for environmental hazard data for these chemicals. Generally, more aquatic toxicity data following acute exposures are available for all five PBT chemicals than are available for aquatic toxicity data following chronic exposures. For four of the five PBT chemicals, excluding PCTP, data were available for organisms spanning three trophic levels.

The hazard summaries relevant to human health focus on repeated-dose studies in laboratory mammals because these chemicals are expected to persist and bioaccumulate in the environment and result in repeated exposures to exposed human populations. In addition, *in vitro* studies in cells and acute studies in mammals were included to characterize the health concerns that were not examined in repeated-dose studies in mammals. Available published and unpublished repeated-dose toxicity data were tabulated according to health endpoints and the identified studies are briefly summarized. Human health hazard data are presented in the context of any available existing toxicological assessments. In some cases, the identified studies did not observe any toxicological effects. EPA did not conduct an analysis of relative importance of the endpoints reported or do a comparative dose-response among hazards.

The environmental and human health hazards of the five PBT chemicals are summarized

here. These hazard statements are not based on a systematic review of the available literature and information may exist that could refine the hazard characterization.

DecaBDE: DecaBDE is toxic to aquatic invertebrates, fish, and terrestrial invertebrates. Data indicate the potential for developmental, neurological, and immunological effects, general developmental toxicity and liver effects in mammals. There was some evidence of genotoxicity. There was some evidence of carcinogenicity. The studies presented in this document demonstrate these hazardous endpoints.

PIP (3:1): 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, and heart in mammals. The studies presented in this document demonstrate these hazardous endpoints.

2,4,6-TTBP: 2,4,6-TTBP is toxic to aquatic plants, aquatic invertebrates, and fish. Data indicate the potential for liver and developmental effects. The studies presented in this document demonstrate these hazardous endpoints.

HCBD: HCBD is toxic to aquatic invertebrates, fish, and birds. Data indicate the potential for renal, liver, and developmental effects in mammals. HCBD has been identified as a possible human carcinogen. The studies presented in this document demonstrate these hazardous endpoints.

PCTP: PCTP is toxic to protozoa, fish, terrestrial plants, and birds. Data for analogous chemicals (pentachloronitrobenzene and hexachlorobenzene) indicate the potential for liver effects in mammals and systemic (body weight) effects for PCTP in mammals (no repeated-dose animal or human epidemiological data were identified for PCTP). The studies presented in this document demonstrate these hazardous endpoints.

III. Regulatory Assessment of the PBT Chemicals

A. Regulatory Approach

1. Developing options: Stakeholder engagement and consultations. In addition to the consultations described in Unit VI, EPA sought comment from experts on and users of the five PBT chemicals. The purpose of these discussions was to create awareness and educate stakeholders on the provisions under TSCA section 6(h); obtain input from manufacturers, processors, distributors, users, academics, advisory councils, and members of the public health community about past and present uses of the PBT chemicals; identify practices related to the use of the PBT chemicals; determine the importance of the PBT chemicals in their various industries; compile knowledge about critical uses, substitute chemicals or processes in various sectors; identify various industry standards and performance specifications; identify health effects; and craft potential risk reduction strategies. To this end, EPA held a public meeting via webinar in September 2017, and attended a “Fire Retardants in Plastics” conference hosted by Applied Marketing Information in April 2018. Where appropriate, EPA followed up on pertinent details or issues raised in comments. EPA has met with, or otherwise communicated with, more than 50 companies, including manufacturers, processors, distributors, and chemical users as well as trade associations and other non-government organizations to discuss the topics outlined in this paragraph, and these discussions are cited throughout this notice where they informed analysis.

2. Potential exposures that EPA is not proposing to regulate. In general, there are some activities or exposures that EPA is not proposing to regulate, even though the Exposure and Use Assessment (Ref. 4) identified exposures or potential exposures. One of these is disposal. Under RCRA, there are comprehensive regulations governing the disposal of hazardous and non-

hazardous wastes. These range from requirements for RCRA Subtitle C hazardous waste incinerators, which must generally meet a destruction and removal efficiency of 99.99% or more, to hazardous waste landfills, which include a double liner, double leachate collection and removal systems, leak detection system, run on, runoff, and wind dispersal controls, and a construction quality assurance program, to municipal solid waste landfills, which must implement certain requirements that are similar to some of the Subtitle C requirements, to industrial nonhazardous and construction/demolition waste landfills. Industrial nonhazardous and construction/demolition waste landfills are primarily regulated under state regulatory programs, but they must meet the criteria set forth in Federal regulations for siting, groundwater monitoring and corrective action and a prohibition on open dumping. Disposal by underground injection is regulated under both RCRA and the Safe Drinking Water Act. In view of this comprehensive, stringent program for addressing disposal, EPA is proposing to determine that it is not practicable to impose additional requirements under TSCA on the disposal of these PBT chemicals.

EPA is also not generally proposing to use its TSCA section 6(a) authorities to regulate commercial use of products containing the PBT chemicals. For example, EPA is not proposing to prohibit the continued commercial use of articles or products that contain DecaBDE or PIP (3:1), such as commercial aircraft. Such a prohibition would not be practicable; to the contrary, it would be extremely burdensome, necessitating the identification of products containing DecaBDE or PIP (3:1), and the disposal of countless products, such as televisions and computers, that would have to be replaced with new products. If the continued commercial use of vehicles containing DecaBDE or PIP (3:1) were prohibited, it would result in widespread economic impacts and disruption in the channels of trade while the prohibited parts or fluids

were identified and replaced. EPA believes that, for most products containing the PBT chemicals, it would be either extremely burdensome, for vehicles, or unreasonable, because of the low concentrations of PCTP in golf balls, for example, and, thus, impracticable to prohibit or otherwise restrict the continued commercial use of the products.

Finally, EPA is not proposing to directly regulate occupational exposure through mandated controls such as engineering controls or use of personal protective equipment (PPE), such as gloves or respirators. EPA expects there is compliance with federal and state laws, such as worker protection standards, unless case-specific facts indicate otherwise, and therefore existing OSHA regulations for worker protection and hazard communication will prevent occupational exposures that are capable of causing injury from occurring. OSHA has not established permissible exposure limits (PELs) for any of the five PBT chemicals. However, under section 5(a)(1) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 654, each employer has a legal obligation to furnish to each of its employees a place of employment that are free from recognized hazards that are causing or are likely to cause death or serious physical harm.

Moreover, the OSHA hazard communication regulations at 29 CFR 1910.1200 require chemical manufacturers and importers to classify the hazards of chemicals they produce/import; and all employers to provide information to employees about hazardous chemicals to which they may be exposed under normal conditions of use or in foreseeable emergencies. Specifically, manufacturers/importers are required to:

- Evaluate and classify chemicals produced in their workplace in accordance with specified hazard categories;
- Ensure that hazardous chemicals are labeled, tagged, marked or have another form of

warning (unless the distributor fulfills this requirement);

- Obtain or develop a safety data sheet (SDS) for each hazardous chemical they produce or import; and

- Ensure that employers and distributors are provided an appropriate SDS with their initial shipment, and with the first shipment after any SDS update.

Employers must:

- Develop, implement and maintain a written hazard communication program at each workplace;

- Have an SDS in the workplace for each hazardous chemical which they use;
- Maintain copies of the SDS for each hazardous chemical and ensure that they are readily accessible to employees; and

- Provide employees with effective information and training on hazardous chemicals in their work area.

The OSHA regulations at 29 CFR 1910.132 through 1910.140 prescribe certain requirements for employers regarding eye, face, respiratory, head, foot and hand protections; electrical protective equipment; and personal fall protection systems. In general, employers must assess a workplace to determine if hazards are present, or are likely to be present, which necessitate the use of personal protective equipment (PPE). If the employer determines such hazards are present, or likely to be present, the employer must:

- Select the types of PPE that will protect against the identified hazards;
- Require affected employees to use that PPE;
- Communicate selection decisions to each affected employee; and
- Select PPE that properly fits each affected employee.

EPA expects that employers will require, and workers will use, appropriate PPE consistent with 29 CFR 1910.132, taking into account employer-based assessments, in a manner sufficient to prevent occupational exposures that are capable of causing injury. Based upon information from and discussions with industry, EPA understands that engineering controls or PPE is routinely used in workplaces where the PBT chemicals are being manufactured, processed, or used. For example, one commenter, an aviation hydraulic fluid formulator, described the precautions taken to minimize employee exposure at its facility. Mandatory PPE includes approved latex/nitrile safety gloves, long-sleeved, flame retardant shirts, flame retardant pants, and eye protection. In addition, employees are instructed to handle aviation hydraulic fluids in a closed system or where adequate exhaust ventilation is provided (EPA-HQ-OPPT-2016-0730-0006, EPA-HQ-OPPT-2016-0730-0007). Another commenter stated that their employees are required to use PPE consisting of nitrile gloves, chemical-resistant slicker suits, chemical resistant boots, respirator with face shield, and a hardhat. This commenter stated that employees were expected to be trained and monitored in the correct use of the PPE (EPA-HQ-OPPT-2018-0314-0018). Because EPA is proposing to, over time, prohibit the manufacture, processing, and distribution in commerce of the PBT chemicals for most uses, thus eliminating potential worker exposures associated with those activities, EPA believes exposures will be reduced to the extent practicable. EPA is not aware of any exposures to unprotected workers for the PBT chemicals, based on information gathered by EPA specific to these chemicals. Therefore, any additional workplace regulations that EPA could impose are unlikely to result in meaningful exposure reductions. Elimination of the hazardous chemical from the workplace, however, is the most preferred and most effective control measure identified in the recommended hierarchy of controls (Ref. 37) to protect workers from workplace hazards.

3. *Request for comment on proposed and alternative regulatory actions.* EPA requests comment on all aspects of the proposed and alternative regulatory actions discussed in this unit, including comment on whether the proposed regulatory actions reduce exposures to the extent practicable and whether there are other actions that EPA should consider taking under TSCA section 6.

In addition, for all of the PBT chemicals other than HCBd, recordkeeping generally consisting of ordinary business records would be required. EPA is proposing to require that the required records be kept for a period of three years. EPA requests comment on whether the recordkeeping time period is appropriate and adequate, considering the supply chains for the PBT chemicals and regulated products and articles made with the PBT chemicals, and the length of time that such chemicals and products may remain in commerce. EPA specifically requests comment on whether the recordkeeping time period should be five years instead of three years. The statute of limitations for violations of TSCA is five years; thus, a five-year record retention period would require the preservation of records for the time period that a matter could be investigated and an enforcement action commenced.

The proposed regulatory action for each PBT chemical is based on the information that EPA has on the chemical. While, as previously noted, EPA generally expects that there is compliance with Federal and state laws, such as worker protection standards or disposal requirements, unless case-specific facts indicate otherwise, EPA has varying amounts of information on how compliance with these legal obligations is accomplished. For example, for 2,4,6-TTBP, EPA received two very informative comments on the PPE in use and the engineering and process controls that reduce occupational and environmental exposures (EPA-HQ-OPPT-2016-0734-0006; EPA-HQ-OPPT-2018-0314-0018). While EPA expects that these or

similar measures are being taken to control exposures for the other 4 PBT chemicals, EPA does not have the same detailed information for them, and therefore requests comment on the extent to which such measures are being taken for the other four PBT chemicals.

B. DecaBDE

1. Description of the proposed regulatory action. EPA is proposing to prohibit, as of 60 days after the publication date of the final rule, the manufacture, processing and distribution in commerce of DecaBDE, and articles and products containing DecaBDE except those described further in this unit.

EPA is not proposing to prohibit the processing for recycling of plastic from articles containing DecaBDE, so long as no new DecaBDE is added during the recycling process. EPA is also not proposing to prohibit the distribution in commerce of such plastic, either before or after recycling. Finally, EPA is not proposing to prohibit the processing and distribution in commerce of DecaBDE in articles and products that are made of plastic that was recycled from articles containing DecaBDE, so long as no DecaBDE was added during the production of the articles and products made of recycled plastic. EPA is aware that many different types of articles that contain plastic are recycled at the end of their useful life, and some of these articles, such as electronic equipment, were originally made with a flame retardant like DecaBDE. As EPA noted on the occasion of “America Recycles Day” on November 15, 2018, EPA recognizes the importance and impact of recycling, which contributes to American prosperity and the protection of our environment. In addition to helping to protect the environment by keeping valuable materials out of landfills, the U.S. recycling industry is an important economic driver and provides more than 757,000 jobs and \$6.7 billion annually in tax revenues. EPA does not want to create disincentives for recycling by increasing the burden on the recycling of plastic. EPA

believes that it would be overly burdensome and not practicable to impose restrictions on the recycling of plastics that may contain DecaBDE, or on the use of recycled plastic in plastic articles, because the DecaBDE is typically present in such articles at low levels (Ref. 38).

EPA is not proposing to regulate the manufacture, processing, or distribution in commerce of DecaBDE-containing replacement parts for the aerospace and automotive industries. TSCA section 6(c)(2)(D) states that replacement parts for complex durable goods and complex consumer goods that are designed before the rule promulgation date must be exempt from a rule issued under TSCA section 6(a), unless EPA finds that the replacement parts contribute significantly to the risk identified in a risk evaluation under TSCA section 6(b). TSCA section 6(h)(2) specifically provides that EPA is not required to conduct section 6(b) risk evaluations when conducting a TSCA section 6(a) rulemaking on PBTs. EPA notes that most of the PBT provisions in TSCA section 6(c) apply to any rulemaking under TSCA section 6(a), but some TSCA section 6(c) provisions cross-reference TSCA section 6(b) and assume the existence of a risk evaluation conducted thereunder. EPA's interpretation is that, where it has not conducted a TSCA section 6(b) risk evaluation, those provisions of TSCA section 6(c) that assume the existence of a TSCA section 6(b) rulemaking do not apply. Specifically, EPA's interpretation is that the following provisions of TSCA section 6(c) do not apply to a TSCA section 6(a) rulemaking conducted to address PBTs under TSCA section 6(h) if EPA has not conducted a TSCA section 6(b) risk evaluation: TSCA section 6(c)(1) (setting deadlines for TSCA section 6(a) rulemakings by reference to the date of issuance of a TSCA section 6(b) risk evaluation), and TSCA section 6(c)(2)(D) and (E) (addressing the regulation of replacement parts for complex durable goods and articles by reference to the findings contained in a risk evaluation under TSCA section 6(b)). EPA invites public comment on this interpretation and

seeks input on other possible interpretations.

According to comments received from the Aerospace Industries Association (AIA) (on the PBDE SNUR), interior non-metallic parts of an airplane must meet the flammability standards in 14 CFR part 25 and in many cases, a flame retardant such as DecaBDE has been used to meet these standards. The aerospace industry expects to have phased out of DecaBDE in new aircraft within three years (Ref. 39). However, because there are many aircraft currently in use with components made with DecaBDE, replacement parts will still be needed for decades.

Aircraft and their replacement parts must be certified by the FAA under 14 CFR part 21. The AIA states that a typical active service life span of aerospace industry products such as aircraft often is 30-40 years or longer. In order to safely maintain and operate these aircraft, certified replacement parts must be available. EPA understands that it can take years to develop, qualify, and certify replacement parts, although, due to the aerospace industry's ongoing phase-out of DecaBDE, suitable alternatives to DecaBDE have likely been identified for many replacement parts. Nevertheless, the replacement parts must meet specified standards and go through the process of being certified by the FAA. Due to the time and expense involved in certifying replacement parts, the AIA asserts that it is not feasible to change the part design and recertify the large number of replacement parts that may contain DecaBDE for aircraft currently in use. In light of this information, EPA believes that requiring the aerospace industry to recertify replacement parts is not practicable, and therefore is not proposing to regulate DecaBDE-containing replacement parts for aerospace industry products for aircraft manufactured prior to the effective/publication date of the rule.

Replacement parts for the automotive industry must also meet specified standards, though there is no similar certification process. The Federal Motor Vehicle Safety Standards, codified at

49 CFR part 571, includes a standard for the flammability of interior materials at 49 CFR 571.302. This standard establishes a test for flammability, including a specific test method for making the determination. EPA understands that DecaBDE has often been used to meet this flammability standard. While EPA expects that the automotive industry will have phased out of DecaBDE for new automobiles by the time a final rule would be issued and take effect (Ref. 13), they will still have to maintain the availability of replacement parts for vehicles manufactured prior to that date. According to the automotive industry, there are customer and legal requirements which generally require the automotive sector to maintain supplies of replacement parts for 15 years, such as the requirement in 42 U.S.C. 30120(g) to provide defect remedies at no charge for a period of 15 years after the affected vehicle was sold to its first purchaser (Ref. 13). The automotive industry asserts that a phase out of DecaBDE for these parts could mean that suppliers and manufacturers must redesign, source, and validate parts for many vehicles no longer in production, ultimately producing new sets of compliant parts (which could require retooling production lines) while scrapping currently retained parts (EPA-HQ-OPPT-2016-0735-0094). Further, economic disruption could occur if the automobile industry were required to rapidly reformulate replacement parts for countless makes, models, and years, especially if this resulted in a period of unavailability of key replacement parts (EPA-HQ-OPPT-2016-0735-0094). In light of this information, EPA believes that requiring the automotive industry to reformulate replacement parts for vehicles no longer being manufactured is not practicable, and therefore is not proposing to regulate DecaBDE-containing replacement parts for motor vehicles manufactured prior to the effective date of the rule.

Most importantly, any restriction on replacement parts for the aerospace and automobile industries could increase costs and safety concerns without meaningful exposure reductions. This

is because, as previously noted, article components containing DecaBDE for finished products in automobiles and aircraft have limited releases. More specifically, releases to air and water are expected to be minimal because DecaBDE is entrained in the articles and is not expected to volatilize or migrate readily under normal use. Additionally, releases to land may occur from disposal of products that contain DecaBDE. Finally, occupational exposure from dermal contact with article components during installation is possible only if workers are unprotected and inhalation exposure is not expected due to the low potential for volatilization.

EPA's proposed practicability determination is not time-limited, in that EPA is not proposing to prohibit the manufacture, processing, and distribution in commerce of DecaBDE for use in replacement parts, and the replacement parts themselves after a certain period of time. As noted, replacement parts for aerospace vehicles will be needed for decades. The automotive industry has commented that replacement parts are generally needed for 15 years, and EPA believes that, in most cases, replacement parts containing DecaBDE will not be manufactured, processed, or distributed in commerce after 15 years. EPA does not believe it is reasonable or practicable to regulate DecaBDE-containing replacement parts for the automotive industry after 15 years, in the unlikely event that such parts are available or needed.

EPA requests comment on the proposed determination that it is not practicable to regulate DecaBDE-containing replacement parts for the aerospace and automotive industries. EPA also requests comment on whether, instead of a determination that it is not practicable to regulate these parts, EPA should consider an exemption under TSCA section 6(g) for them. EPA believes that, for both the aerospace and automotive industries, regulation of replacement parts would result in the disruption of critical infrastructure.

However, EPA is proposing to prohibit the addition of DecaBDE to products and articles,

other than replacement parts for the aerospace and automotive industries. An exploratory analysis indicated that DecaBDE migration from articles like toys does not represent a risk concern due to the mouthing behaviors (e.g., teething), based on the available information (Ref. 40). EPA believes that it is practicable to reduce exposures by prohibiting the addition of DecaBDE to these products and articles during the production process.

EPA is proposing a compliance date of three years for new aerospace parts to align with the Aerospace Industries Association's voluntary phase-out of DecaBDE, and a compliance date of 18 months for ongoing manufacture of curtains used in the hospitality industry to allow for the orderly transition to a replacement coating chemical. These compliance dates are intended to allow the products to clear the channels of trade prior to the compliance date.

EPA has no information indicating that a compliance date of 60 days after publication of the final rule is not practicable for the activities that would be prohibited, other than those for which later compliance dates are being proposed, or that additional time is needed for products to clear the channels of trade.

In addition, EPA is proposing to require, as of 60 days after the date that the final rule is published, all persons who manufacture, process, or distribute in commerce DecaBDE for non-prohibited uses, and non-prohibited articles and products to which DecaBDE has been added, to maintain ordinary business records, such as invoices and bills-of-lading, that demonstrate compliance with the prohibitions and restrictions. These records would have to be maintained for a period of three years from the date the record is generated. This recordkeeping requirement does not apply to the processing and distribution in commerce of plastic for recycling, recycled plastic, and articles and products made with recycled plastic, so long as no DecaBDE is added to the recycled plastic and the articles and products made with recycled plastic.

TSCA authorizes EPA to investigate, through inspections and the use of administrative subpoenas, and to collect information on the imported products and manufactured materials used to produce those products. EPA uses these tools to help ensure compliance with regulatory requirements for manufactured (including imported), processed, or distributed products, including those containing DecaBDE, among other chemicals. EPA's National Program Guidance for the Office of Enforcement and Compliance Assurance identifies the agency's focus on monitoring the compliance of chemical substances and articles imported into the United States in coordination with U.S. Customs and Border Patrol (CBP).

EPA requests comment on ways that importers and others, who do not produce articles, can ensure that they are in compliance with this prohibition. One option would be for these entities to contract with their suppliers to supply only goods that comply with this prohibition. EPA could establish a requirement that persons who import, process, or distribute articles, or certain categories of articles such as consumer electronics, rubber wire casings and plastic children's products, obtain and retain ordinary business records, such as invoices, and that such records must include a written statement from the supplier that the articles were not made with DecaBDE. Compliance with such a recordkeeping requirement would constitute compliance with the prohibition on the addition of DecaBDE to products and articles. EPA requests comment on the merits of this approach and other approaches to achieving compliance.

2. Description of the primary alternative regulatory action considered. EPA considered an alternative regulatory action of prohibiting the manufacture, processing and distribution in commerce of articles containing DecaBDE at levels above 0.1% by weight. The 0.1% level was determined from consultations with academics and experts as a means to differentiate between DecaBDE that was added to the article versus DecaBDE that may have been present in the

plastic from which the article was made, and from existing state regulations on DecaBDE. This option would be in addition to the prohibitions outlined in Unit III.B.2 and would exclude replacement parts for the automotive and aerospace industries. The delayed compliance dates for certain manufacturing and new aerospace parts would also remain for this option. Requiring industry to meet a level of 0.1% in recycled plastic articles would also result in a significant burden by effectively requiring companies manufacturing (including importing) articles out of recycled plastics to test their products for levels of DecaBDE or risk being out of compliance (Ref. 3). In general, EPA understands that most testing methods cannot distinguish between brominated flame retardants, or between polybrominated diphenyl ether (PBDE) congeners, and that more expensive and time-consuming test methods are necessary to determine whether DecaBDE is present (Ref. 41). Therefore, EPA does not believe this option is practicable.

3. Evaluation of whether the regulatory actions address the TSCA section 6(h)(4) standard. This proposal would, over time, eliminate the introduction of new DecaBDE into the supply chain. Cost-effective and technically feasible substitutes are readily available for all uses of DecaBDE (Ref. 3). However, as previously noted, EPA has determined that it would be impracticable to use the TSCA section 6(a) regulatory tools to address DecaBDE that is already in products in commercial use or the disposal of products. For similar reasons, EPA is not proposing to prohibit the recycling of plastic which may contain DecaBDE, such as high-impact polystyrene. An element of practicability is reasonableness. EPA does not believe it is reasonable, and thereby practicable, to impose a large burden on society through the further reduction or elimination of low concentrations of DecaBDE in articles made from recycled materials. The already low content of DecaBDE in recycled plastic would be expected to continue declining, as fewer and fewer products are made with DecaBDE. In order to ensure that

plastics made with DecaBDE are not recycled into any new articles and products, the incoming waste plastic would have to be sorted and tested for articles most likely to contain DecaBDE, such as television cabinets, electronics cases, and most types of high impact polystyrene, which would be rejected for recycling and instead be disposed of in a landfill, or the incoming waste could be tested for DecaBDE content. EPA considered, as a primary alternative regulatory action to the proposed option, a percentage limit on DecaBDE in products. While this option may also reduce exposures in comparison to the proposed option, EPA believes that the testing burden, including the ability to test specifically for DecaBDE that would need to be assumed as a compliance method by processors and distributors, could be considerable and would make that option impracticable (Ref. 3). More information on these testing burdens and the economic impacts of the primary alternative regulatory action in general can be found in Unit IV.B. and in the Economic Analysis (Ref. 3).

With respect to the recycling of plastics that contain DecaBDE, EPA requests comment on whether one particular situation warrants a different approach. While it is EPA's understanding that plastic pallets are no longer being made with DecaBDE as a flame retardant, they are being recycled back into plastic pallets when they become damaged and are no longer usable. The pallets were made with DecaBDE to begin with, and the pallet producers are aware of the DecaBDE content, which is likely to be higher than that present in general plastics recycling streams. EPA is still proposing to determine that it is not practicable to prohibit the recycling of plastic pallets because, as previously noted, releases from article components are expected to be minimal because DecaBDE is entrained in the articles and is not expected to volatilize or migrate readily under normal use. However, EPA requests comment on this proposed determination and whether there are actions that EPA should consider taking under TSCA

section 6 with respect to the recycling of plastic pallets.

EPA also considered issues with compliance dates, taking into account input from stakeholders. The aerospace industry has been working towards the elimination of DecaBDE in new aircraft and aerospace vehicles. However, the design and certification of new aircraft, for instance, is a complicated and lengthy process and, as a consequence, some additional time is necessary to ensure a reasonable transition for this industry (EPA-HQ-OPPT-2016-0724-0006). The Aerospace Industries Association has volunteered to remove DecaBDE from all new aerospace parts by 2023 (Ref. 39). Thus, EPA believes a compliance date to begin three years from the publication date of the final rule, rather than an a more immediate compliance date, is the soonest practicable timeframe for the aerospace industry to comply with a prohibition on DecaBDE in new aerospace vehicles and new parts for such vehicles, and for products containing DecaBDE to clear the channels of trade.

With respect to curtains used in the hospitality industry, EPA understands that most of the industry has moved away from using DecaBDE as a flame retardant. However, EPA is aware of one small business that is still using DecaBDE while it searches for a replacement flame retardant. EPA believes that 18 months from the date of publication of the final rule, rather than an immediate compliance date, is the soonest practicable date for the small business to redesign or find a substitute for the curtain production process, and for treated curtains to clear the channels of trade.

4. Consideration of chemical alternatives (substitutes) in deciding whether to propose to prohibit or restrict DecaBDE. EPA believes that there are viable substitutes for all uses of DecaBDE. In January 2014, EPA's Design for the Environment (DfE) published an alternatives assessment for DecaBDE (Ref. 42). EPA identified 29 potential functional, viable alternatives to

DecaBDE for use in select polyolefins, styrenics, engineering thermoplastics, thermosets, elastomers, or waterborne emulsions and coatings (Ref. 42).

(i) Health and environmental effects of the chemical alternatives or substitute methods.

The human health endpoints evaluated in EPA's DfE alternatives assessment include acute toxicity, carcinogenicity, genotoxicity, reproductive toxicity, developmental toxicity, neurotoxicity, repeated-dose toxicity, skin sensitization, respiratory sensitization, eye irritation, and dermal irritation (Ref. 42). Acute and chronic aquatic toxicity endpoints and persistence and bioaccumulation potential were also evaluated as part of this assessment. DecaBDE and the identified alternatives were ranked on these endpoints according to the methodology outlined in EPA's DfE alternatives assessment and given a hazard ranking between very low and very high. While some of the available alternatives were found to have hazard profiles similar to DecaBDE, there are other available alternatives that ranked lower than DecaBDE for each hazard endpoint (Ref. 42).

(ii) Technical feasibility, economic feasibility, and reasonable availability of the chemical alternatives or substitute methods. Several potential substitutes for DecaBDE exist, specific to each use. In total, 27 unique chemical substitutes were identified for DecaBDE through EPA's DfE Alternatives Assessment, published in 2014. Two were removed from the original list of 29 for the purposes of this rulemaking since they are synergists without flame-retardant properties and not considered alternatives. An additional six were identified through internet research for a total of 33 substitutes (Ref. 3). Specific substitutes may be favored by industry based on the ability to easily replace DecaBDE, efficacy, price and availability, relative human health or environmental concerns, or other qualities of the substitute that may or may not impact the final product. Appropriate substitutes for DecaBDE vary depending on the material and application

method being used to apply them. However, cost-effective and technically feasible substitutes are generally available for all uses of DecaBDE (Ref. 3).

C. PIP (3:1)

1. Description of the proposed regulatory action. EPA is proposing to prohibit the processing and distribution in commerce of PIP (3:1), and products containing the chemical substance except for the following:

- Processing and distribution in commerce for use in aviation hydraulic fluid; and
- Processing and distribution in commerce for use in lubricants and greases; and
- Processing and distribution in commerce for use in new and replacement parts for the automotive industry, and the distribution in commerce of the parts to which PIP (3:1) has been added.

EPA is not proposing to regulate the processing or distribution in commerce of PIP (3:1) or PIP (3:1)-containing products for use in new or replacement parts for the automotive industry, or distribution in commerce of such parts that contain PIP (3:1). EPA understands that PIP (3:1) may be used to meet anti-flammability standards and for other uses (EPA-HQ-OPPT-2018-0314-0026). Economic disruption could occur if the automotive industry were required to rapidly reformulate replacement parts for countless makes, models, and years, especially if this resulted in a period of unavailability of key replacement parts (EPA-HQ-OPPT-2016-0735-0094). Restrictions on distribution in commerce of replacement parts that contain PIP (3:1) would have a similar effect. As with DecaBDE, EPA believes that requiring the automotive industry to reformulate replacement parts for vehicles no longer being manufactured is not practicable, and therefore is not proposing to regulate PIP (3:1)-containing replacement parts for motor vehicles manufactured prior to the effective date of the rule. Most importantly, any restriction on

replacement parts for the automotive industries could increase costs and safety concerns without meaningful exposure reductions for those same pathways described in Unit III.B.1. For these same reasons, EPA is not proposing to regulate the processing and distribution in commerce of PIP (3:1) or PIP (3:1)-containing products for use in new parts containing PIP (3:1) for the automotive industry, or distribution in commerce of such parts that contain PIP (3:1). EPA has received information from the automotive industry indicating that there are a number of new parts made with PIP (3:1) and that substitutes for PIP (3:1) in these parts have not been identified and tested (Refs. 43 and 44). EPA acknowledges the importance of PIP (3:1) components to the automotive industry and the difficulties of reformulation. As with replacement parts, any restriction on the processing and distribution in commerce of new parts for the automotive industry could increase costs and safety concerns without meaningful exposure reductions. For this proposal, EPA considers new parts to be newly-manufactured parts that are designed for use in automobiles and other vehicles that will be produced for the model year beginning after the effective date of the final rule. Replacement parts are also newly-manufactured parts that are designed for use in automobiles and other vehicles that will have been produced for the model year beginning before the effective date of the final rule and earlier model years.

In addition, EPA is not proposing to restrict the manufacture of PIP (3:1) so that the allowable processing and distribution may continue, but is proposing to impose recordkeeping and downstream notification requirements on manufacturers. Manufacturing occurs in a closed system and generally there is no waste produced in the manufacturing, so existing best practices are expected to mitigate potential releases to the environment (Ref. 4).

EPA is proposing to prohibit releases to water from the processing, distribution in commerce, and commercial use activities that are permitted to occur, *i.e.*, use in aviation

hydraulic fluid, use in lubricants and greases, and use in new and replacement parts for the automotive industry. Persons manufacturing, processing, and distributing PIP (3:1), and products containing PIP (3:1), in commerce would be required to notify their customers of these prohibitions on processing and distribution, and the prohibition on releases. Additionally, EPA requests comment on additional details of how a prohibition on releases to water could best be achieved in the aircraft maintenance space.

In addition, EPA is proposing to require, as of 60 days after the date that the final rule is published, all persons who manufacture, process, or distribute in commerce PIP (3:1) and articles and products containing PIP (3:1) to maintain ordinary business records, such as invoices and bills-of-lading, that demonstrate compliance with the prohibitions and restrictions. These records would have to be maintained for a period of three years from the date the record is generated.

TSCA authorizes EPA to investigate, through inspections and the use of administrative subpoenas, and to collect information on the imported products and manufactured materials used to produce those products. EPA use these tools to help ensure compliance with regulatory requirements for manufactured (including imported), processed, or distributed products, including those containing PIP (3:1), among other chemicals. EPA's National Program Guidance for the Office of Enforcement and Compliance Assurance identifies the agency's focus on monitoring the compliance of chemical substances and articles imported into the United States in coordination with U.S. Customs and Border Patrol (CBP).

EPA has no information indicating that a compliance date of 60 days after publication of the final rule is not practicable for the activities that would be prohibited, or that additional time is needed for products to clear the channels of trade. However, EPA requests comment on whether additional time is needed for products to clear the channels of trade.

EPA acknowledges that PIP (3:1) is an important anti-wear additive in aviation hydraulic fluid for commercial aircraft and commercial derivative military aircraft, including for emerging technologies such as 5,000 PSI hydraulic systems. It is the Agency's understanding that PIP (3:1)-containing hydraulic fluids are currently the only fluids recommended for these high-pressure hydraulic systems. EPA is requesting comment on the degree to which alternative hydraulic fluids without PIP (3:1) are available for aircraft operating at 3,000 PSI, and documented performance differences between phosphate ester based hydraulic fluids with and without PIP (3:1) in the aviation sector.

EPA also acknowledges the degree to which PIP (3:1) is a crucial anti-wear component for aviation lubricants and greases, which need to perform at a wide range of temperatures and pressures. EPA has excluded lubricants and greases for aviation and non-aviation uses from the proposed prohibition on processing and distribution. EPA understands there are some non-aviation uses of these lubricants and greases where PIP (3:1) is a crucial anti-wear component, such as turbines used in power generation or in marine settings (Ref. 23). Therefore, EPA is proposing to determine that it is not practicable to regulate the presence of PIP (3:1) in lubricants and greases in general. However, EPA acknowledges that uses in non-aircraft machinery may not be subject to these same environmental stresses or safety and performance requirements from industry and government as uses in the aviation sector. Therefore, EPA is requesting comment on the degree to which PIP (3:1) is crucial to the safe and effective performance of lubricants and greases in non-aviation industries. This includes information about alternatives with equivalent performance (or lack thereof), safety standards, information about standard use practices and exposure, and any other relevant information, for lubricants and greases used in turbines or other machinery derived from aviation but applied to a stationary technology such as power

generation, and other military or commercial uses.

In addition, EPA is requesting comment on the concentration by weight of PIP (3:1) currently present in products for the excluded uses, as well as the concentration required for critical application in aviation and other industries, and trends in these concentrations which may accompany changes in technology over time. EPA believes the upper bounds of the levels present in commerce for use in aviation hydraulic fluids to be 20% concentration by weight and aviation lubricants and greases to be 5% concentration by weight. While EPA does not have reason to believe that uses in excess of these levels are occurring, EPA acknowledges that these products are of significant importance in commercial and military aviation, including for emerging technologies such as 5,000 PSI hydraulic systems. EPA does not want to unnecessarily inhibit the development of more efficient aircraft, but large increases in the concentrations of PIP (3:1) in the non-prohibited hydraulic fluids and lubricants and greases could result in greater exposures. EPA requests comment on whether a concentration limit should be imposed on these non-prohibited uses. The uses of PIP (3:1) containing products in these sectors is discussed further in Unit III.C.3.

In addition, EPA is specifically requesting comment on the extent to which plastic articles that contain PIP (3:1) are recycled and whether the recycling of such plastic, and the manufacture, processing, and distribution in commerce of plastic items made from such recycled plastic, should be specifically excluded from this rule. The exclusion would be similar to the exclusion discussed in Unit III.B.1. for recycled plastics that contain DecaBDE. While EPA is aware that many of the plastics in the recycling stream contain DecaBDE, EPA does not have information on the content of PIP (3:1) in articles being recycled. As noted in Unit II.D.2.i., PIP (3:1) has been identified as a possible component in plastic products and articles, including

children's products and automotive and aerospace products. In addition, PIP (3:1) has also been used as a component of flame retardants used in polyurethane foam. EPA also requests comment on the extent to which polyurethane foam that contains PIP (3:1) is recycled, the amount of PIP (3:1) that remains in the recycled material, and whether an exclusion should be considered for recycling of polyurethane foam.

2. *Description of the primary alternative regulatory action considered.* EPA considered an alternative regulatory action for PIP (3:1) of prohibiting the processing and distribution in commerce of PIP (3:1), and products containing the chemical substance except for the following:

- Processing and distribution in commerce for use in aviation hydraulic fluid for aircraft hydraulic systems designed to operate at pressure equal to or greater than 3,000 pounds per square inch (PSI) for a period of 20 years;
- Processing and distribution in commerce for use in aviation lubricants and greases for a period of 20 years; and
- Processing and distribution in commerce for use in new and replacement parts for the automotive industry, and the distribution in commerce of the parts to which PIP (3:1) has been added.

A 20-year time-limited exemption would be proposed under TSCA section 6(g)(1)(B) for use in aviation hydraulic fluids for aircraft hydraulic systems operating at equal to or greater than 3,000 PSI at the currently present in commerce, and aviation lubricants and greases at concentration currently present in commerce. Under the primary alternative action, like with the proposed action, EPA would prohibit releases to water from the processing, distribution in commerce, and commercial use activities that are not prohibited. In addition, like with the proposed action, persons manufacturing, processing, and distributing in commerce PIP (3:1), and

products containing PIP (3:1), would be required to notify their customers of each of these restrictions.

The primary alternative regulatory action differs from the proposed action in that specified allowed uses in aviation would be subject to an exemption under TSCA section 6(g) rather than excluded from the prohibition of uses under TSCA section 6(a). The proposed time-frame for this exemption would be 20 years, after which time the exemption would expire or be extended via rulemaking.

3. Evaluation of whether the regulatory actions address the TSCA section 6(h)(4) standard. As discussed here, there are readily available alternatives for all uses except the specific uses described in Unit II.D.2.i and Unit II.D.2.ii, namely in aviation hydraulic fluids lubricants and greases. Additionally, as previously mentioned, EPA is not proposing regulatory controls on the manufacturing of PIP (3:1) beyond recordkeeping and downstream notification requirements. As stated in Unit III.C.1., manufacturing occurs in a closed system and generally there is no waste produced in the manufacturing, so existing best practices are likely to mitigate potential releases to the environment (Ref. 4).

Lubricants, greases, and aviation hydraulic fluids are excluded from the proposed regulation because they are necessary to maintain the airworthiness of aircraft, no other substitutes are currently available, and the burden of creating and testing new formulations which can meet the equivalent safety and performance standards is high (Ref. 3). Aviation fluids are approved by major aircraft manufacturers who work closely with the FAA, and any change in formula composition results in a full requalification process. This process is a joint effort between the fluid manufacturer and aircraft manufacturer, and resulting fluids are subject to extensive laboratory and field testing. At the end of this iterative evaluation process, there is no

guarantee that a technically equivalent alternative will be developed (Refs. 3, 23 and 24). These aviation lubricants and greases are sometimes used for other machinery such as turbines used in power generation. For lubricants and greases in other industries, EPA has included a request for comment outlining additional information that would be useful in Unit III.C.1. Thus, EPA is not proposing to prohibit manufacture, processing, or distribution for the aviation uses described in Unit II.D.2 because doing so is not practicable. By prohibiting the majority of processing and distribution of the chemical, and placing certain restrictions on processing, distribution, and use for hydraulic fluid and lubricants and greases in aviation, including a prohibition on release to water, the regulatory approach reduces exposures to the extent practicable.

Manufacturers have described alternative chemicals that are available for the functional applications of PIP (3:1) as a plasticizer, flame retardant, and anti-wear additive (Ref. 4). In many sectors, this claim by manufacturers is supported by stakeholder engagement. While possible chemical alternatives or alternative products exist in many sectors, these alternatives lack field testing in formulation for key uses in aviation, including emerging technologies of high-pressure aviation hydraulic systems. (Refs. 23 and 24, and 25). Therefore, EPA believes that prohibitions on processing, distribution, and use, including the alternative approach which could take effect upon the expiration of an exemption, are not practicable for certain uses of PIP (3:1) important to airworthiness in commercial aviation and aerospace.

4. Consideration of chemical alternatives (substitutes) in deciding whether to prohibit or restrict PIP (3:1). Based on an analysis of likely alternatives, EPA believes that there are viable substitutes for all uses of PIP (3:1), except for uses in aviation hydraulic fluids and aviation lubricants and greases.

(i) Health and environmental effects of the chemical alternatives or substitute methods.

EPA conducted an analysis of three identified likely substitutes for PIP (3:1) based on the process described in the TSCA Work Plan Chemicals: Methods Document (Ref. 2). Those substitutes all scored lower than PIP (3:1) in at least one criterion. For example, 2-ethylhexyl diphenyl phosphate ester (CAS 1241-94-7) and isodecyl, diphenyl phosphate (CAS 29761-21-5) both scored lower than PIP (3:1) in persistence, bioaccumulation, and human hazard. In addition, phenol, isobutylenated, phosphate (3:1) (CAS 68937-40-6) scored lower than PIP (3:1) in human and environmental hazard (Ref. 45).

(ii) Technical feasibility, economic feasibility, and reasonable availability of the chemical alternatives or substitute methods. As discussed in Unit II.D.4, viable substitutes are available for many of the uses of PIP (3:1). In their comment, the Israel Chemical Limited (ICL) company stated that there are readily available alternatives for many of the functional uses of PIP (3:1), including as a plasticizer, flame retardant, and anti-wear additive. These alternative chemicals could act as replacements for PIP (3:1) within formulas in various industries. In sectors such as paints and coatings, adhesives and sealants, and plastics, PIP (3:1) containing products represent a small market share, and the elimination of said products would not have a significant effect on small businesses (Ref. 3). For industrial hydraulic fluids (excluding aviation), various alternative products to those containing PIP (3:1) are already in commerce.

PIP (3:1) is used in the aviation industry in hydraulic fluid to achieve the necessary anti-wear and anti-compressibility performance for formulas maintaining the airworthiness of commercial and military aircraft. While alternative formulas have been identified for use in several models of aircrafts, there are no feasible alternative formulas for hydraulic fluid that meet the requisite performance specification and safety standards for hydraulic systems designed to operate at pressures equal to or greater than 5,000 PSI (Refs. 23 and 24, and 25). Therefore, there

are currently no technically feasible alternative formulas available for some PIP (3:1)-containing hydraulic fluids in the aviation sector for hydraulic systems designed to operate at pressures equal to or greater than 5,000 PSI.

Furthermore, PIP (3:1) is a component of a lubricant additive which is used primarily for its anti-wear properties. There are also currently no technically feasible alternative formulas available for some PIP (3:1)-containing and lubricants and greases in the aviation sector, which are formulated to industry and military specifications (Refs. 22, 23, 24, 26, and 46).

The economic feasibility of alternatives for all uses other than these specialized aviation uses is discussed in the economic analysis for this proposed action (Ref. 3).

D. 2,4,6-TTBP

1. Description of the proposed regulatory action. EPA is proposing to restrict the distribution in commerce of TTBP and products containing 2,4,6-TTBP in containers with a volume of less than 55 gallons. This will effectively prevent use of 2,4,6-TTBP as a retail fuel additive or fuel injector cleaner by consumers.

Exposure to humans and the environment would be reduced by eliminating retail uses of 2,4,6-TTBP that have a high potential for releases. This proposal intentionally would not impact use of this chemical in the nation's fuel supply system (*i.e.*, at refineries and bulk petroleum storage facilities), where the distribution, transfer, blending, and general end use of 2,4,6-TTBP-containing blends/mixtures is managed through highly regulated engineered controls designed to mitigate environmental and human health exposures. EPA believes that much, if not all use of 2,4,6-TTBP containing blends/mixtures at refineries and petroleum storage facilities are sourced in quantities larger than 55 gallons at a time; and are typically sourced by the tanker or batch load in quantities over 500 gallons at a time.

As such, EPA is also taking comment on the optimal container size limit to impose: for instance, whether a 35-gallon container size would impact industrial use less while also preventing the commercial and retail sale of products with 2,4,6-TTBP. EPA would welcome information submitted to the docket for this action that provides data or information related to the proposed restriction on container size.

For this regulation, EPA is proposing to define 2,4,6-TTBP to mean the chemical substance 2,4,6-tris(tert-butyl)phenol (CASRN 732-26-3) at any concentration above 0.01% by weight. EPA believes this concentration limit would distinguish between products which contain 2,4,6-TTBP as a functional additive and those in which it may be present in low concentrations as a byproduct or impurity. 2,4,6-TTBP is a co-product and byproduct present in other alkylphenols, including other antioxidants that are potential substitutes for it. Significantly, this lower limit would also ensure that this prohibition does not unintentionally apply to fuels which have been treated with antioxidant additives containing 2,4,6-TTBP, an outcome EPA does not intend. One commenter stated that the chemical is added to fuels at concentrations of 5 to 50 ppm, approximately 0.0005% to 0.005%, or less than half the concentration limit proposed by EPA (EPA-HQ-OPPT-2016-0734-0006). Thus, EPA is not proposing to regulate fuel after it has been treated with antioxidants containing 2,4,6-TTBP; EPA is only proposing to regulate the retail additives containing 2,4,6-TTBP that are used to treat the fuel. A regulation prohibiting the presence of 2,4,6-TTBP in gasoline and other fuels would effectively prohibit the use of this antioxidant at refineries to treat bulk fuels, because it would prohibit the commercial use of the treated fuel in smaller vehicles including automobiles. As discussed in Unit II.D.3.(i) of this notice, EPA believes this is a critical use in the nation's fuel supply.

EPA is also proposing to prohibit processing and distribution in commerce of 2,4,6-TTBP

for use as an additive in oils and lubricants. There are numerous available substitutes for this use of 2,4,6-TTBP. For clarity, EPA is proposing a definition of *oil and lubricant additive* for this rule to mean any intentional additive to a product of any viscosity intended to reduce friction between moving parts, whether mineral oil or synthetic base, including engine crankcase oils and bearing greases.

EPA has no information indicating that a compliance date of 60 days after publication of the final rule is not practicable for the activities that would be prohibited, or that additional time is needed for products to clear the channels of trade.

EPA is proposing for recordkeeping that after 60 days following the date of publication of the final rule, distributors of 2,4,6 TTBP and products containing 2,4,6-TTBP must maintain ordinary business records, such as invoices and bills-of-lading, that demonstrate that 2,4,6-TTBP is not distributed in containers with a volume less than 55 gallons or for use as an oil and lubricant additive. These records must be maintained for a period of three years from the date the record is generated.

2. Description of the primary alternative regulatory action considered. EPA considered an alternative regulatory action of prohibiting the distribution in commerce of 2,4,6-TTBP in fuel additives and fuel injector cleaners intended for consumer/retail use. Like the proposed action, this approach would define 2,4,6-TTBP with a concentration of 2,4,6-TTBP; a level of 0.01% by weight. This alternative would include defining the end uses for which distribution of 2,4,6-TTBP is prohibited: retail sale of fuel additives and fuel injector cleaners. Distributors of chemical mixtures containing 2,4,6-TTBP above the specified level would be required to notify purchasers of the presence of 2,4,6-TTBP in the product and the prohibition on its sale for retail use. Records of sales and notification to customers would be maintained by distributors. Should

the Agency not finalize provisions related to the container size threshold, downstream notification would need to be a regulatory requirement. While this approach would achieve the same or similar exposure reduction as the limit on container sizes proposed in this rule, EPA believes this alternative approach would potentially impact more retail sellers and users, be more difficult to enforce, and impose a greater compliance burden on the regulated community for notification and recordkeeping requirements. This approach would potentially also affect distribution of large volumes of 2,4,6-TTBP to industrial users, such as refineries, who are not engaged in processing and distribution of fuel additive products for commercial and consumer sales.

3. Evaluation of whether the regulatory actions address the TSCA section 6(h)(4) standard. The proposed approach allows for the processing and distribution for use in the industrial/commercial fuel sector where prohibitions or restrictions on 2,4,6-TTBP mixtures would not be practicable due to its essential use in the nation's fuel supply system. As discussed in Unit II.D.3.(i) of this notice, this chemical is a component of antioxidant mixtures that are widely used in this country and essential for the storage and transport of fuel, and these mixtures cannot be substituted without affecting numerous commercial and military fuel specifications for stability and quality. Although not quantified for this proposed rule, the expense of certifying a new alternative fuel additive would be significant and take years, particularly for aviation applications. In addition, as discussed in Unit II.E.2.(iii) of this notice, the potential for exposure from the manufacturing, processing, and distribution for commercial use and the commercial use is significantly mitigated by use of industrial engineering controls and safeguards. Releases of 2,4,6-TTBP from retail additive use and disposal are more likely than in industrial settings where engineered controls are highly likely to be in place. In contrast, EPA believes the

proposed restriction on the processing and distribution for use of 2,4,6-TTBP in the retail products is practicable because alternative antioxidants are readily available for those products and can be substituted in those products without undue burden. Thus, EPA does not believe a complete prohibition on 2,4,6-TTBP is practicable given its essential use in the nation's fuel supply. Furthermore, its co-production with other alkylphenols is significant, in that prohibiting the manufacture of 2,4,6-TTBP would restrict, if not prevent, the production of other dialkylphenol products, including alternative antioxidants.

4. Consideration of chemical alternatives (substitutes) in deciding whether to propose to prohibit or restrict 2,4,6-TTBP. Based on a screening level analysis of likely alternatives, as noted previously, EPA believes that there are readily available substitutes for the retail fuel additives, as well as oil and lubricant additives containing 2,4,6-TTBP. EPA believes that the overwhelming predominance in the marketplace of oil and lubricant products that do not contain 2,4,6-TTBP is itself sufficient evidence of the availability of those substitute chemicals or products.

(i) Health and environmental effects of the chemical alternatives or substitute methods. EPA conducted a screening level analysis of two possible substitutes for 2,4,6-TTBP based on the TSCA Work Plan Chemicals: Methods Document (Ref. 2). One alternative antioxidant suitable as a fuel additive is 2,4-dimethyl-6-tert-butylphenol, CASRN 1879-09-0, and the other is 2,6-di-tert-butyl-p-cresol, also known as butylated hydroxytoluene or BHT, CASRN 128-37-0. Both chemicals have a lower bioaccumulation potential than 2,4,6-TTBP, but equivalent or higher scores for persistence, environmental hazard and human health hazard (Ref. 45). However, BHT is used as a food additive: it is approved by FDA for use as a food additive (21 CFR 172.115) and in the European Union, its use is permitted in foods by the European Food

Safety Authority under E321 (Ref. 47). BHT is also used in personal care products and cosmetics. EPA seeks public comment on whether the proposed action is practicable given it could result in increased use of alternatives to 2,4,6-TTBP with comparable persistence and hazard scores. EPA did not assess the hazard of the chemical mixtures in commercial products containing 2,4,6-TTBP, nor did it assess the hazard of substitute products that do not contain 2,4,6-TTBP, so no conclusions as to the relative hazard of product substitutes can be drawn.

(ii) Technical feasibility, economic feasibility, and reasonable availability of the chemical alternatives or substitute methods. Alternatives to fuel additives and fuel injector cleaner products containing 2,4,6-TTBP exist. The alternative chemical 2,4-dimethyl-6-tert-butylphenol is currently used as an antioxidant fuel additive in jet fuels, gasolines and aviation gas, among other uses. BHT is used as a fuel additive for its antioxidant properties, and in addition to its uses in fuels, including jet fuels, it is also used in hydraulic fluids, turbine and gear oils, making it a suitable substitute for such uses of 2,4,6-TTBP in oils and lubricants that may be occurring (Ref. 48). While EPA did not identify the specific alternative chemicals used in each product, for the Economic Analysis (Ref. 3), EPA was able to determine 35 product substitutes for commercial fuel stabilizer products and 15 product substitutes for commercial fuel injector cleaner products (for purposes of the analysis, product substitutes are considered those that serve the same purpose but do not contain 2,4,6-TTBP). The appropriate product substitute will vary depending on type of engine for which the use is intended.

E. HCB

1. Description of the proposed regulatory action. EPA is not proposing to regulate HCB under TSCA section 6(h) because the potential for exposure from uses of this chemical is already addressed by actions taken under other statutes and further measures are not practicable.

As stated elsewhere in this preamble, HCBD is regulated under various statutes implemented by the Federal Government, such as the CAA and RCRA, and most states. According to TRI data, most of the HCBD manufactured in the United States is subsequently destroyed via incineration. Of the over 9 million lbs of HCBD in waste reported to TRI, only 2,400 lbs is released to the environment due in large part to the high waste treatment efficiencies achieved by the chemical manufacturers. Most of these releases to the environment are via fugitive and stack air emissions, with little or no quantities released to other media (Ref. 19).

The CAA requires EPA to regulate hazardous air pollutants (HAP) such as HCBD. CAA section 112 requires that the Agency establish National Emission Standards for Hazardous Air Pollutants (NESHAP) for the control of HAP from both new and existing major sources. The CAA requires the NESHAP to reflect the maximum degree of reduction in emissions of HAP that is achievable, taking into consideration the cost of achieving the emissions reductions, any non-air quality health and environmental impacts, and energy requirements. This level of control is commonly referred to as maximum achievable control technology (MACT). The CAA also establishes a minimum control level for MACT standards known as the MACT “floor.” The MACT floor is the minimum control level allowed for NESHAP and is defined under the CAA section 112(d)(3) (Ref. 49).

The chemical manufacturers that produce HCBD are in NAICS group 325 and therefore fall under the NESHAP regulations for miscellaneous organic chemical manufacturing found at 40 CFR part 63 subpart FFFF. These regulations require facilities to treat chemicals in their waste streams at high efficiencies. For example, emissions from process vents must be reduced by greater than or equal to 99% by weight depending on the chemical in the waste stream. According to TRI data, chemical manufacturers that submit reports for HCBD are treating the

chemical via incineration at greater than 99.99% treatment efficiency with some reporting an efficiency greater than 99.9999%.

Under the CAA, facilities in certain industries are required to implement a Leak Detection and Repair (LDAR) program to reduce fugitive air emissions. Included in those industries are synthetic organic chemical manufacturers that produce HCBD. The LDAR program requires these facilities to monitor components such as pumps, valves, connectors and compressors for leaks. When leaks are detected, the facility is required to repair or replace the leaking component.

HCBD is also regulated under RCRA. The statute's implementing regulations, among other things, list HCBD as a hazardous constituent under 40 CFR part 261 (Identification and Listing of Hazardous Waste; specifically, under sections 261.24 and 261.33), which identifies solid wastes which are subject to regulation as hazardous wastes under 40 CFR parts 262 through 265, 268, and parts 270 and 271. HCBD is a hazardous constituent under 40 CFR part 258, Appendix II (Criteria for Municipal Solid Waste Landfills), which establishes criteria for the design and operation of municipal solid waste landfills.

Taking into account the many existing controls on activities that might affect exposures to HCBD, the only meaningful further reductions that might be achieved would be by prohibiting manufacture of HCBD. However, prohibiting the manufacture of HCBD would effectively preclude the manufacture of trichloroethylene, carbon tetrachloride and perchloroethylene. EPA does not believe this would be practicable as explained further in this Unit.

2. Description of the primary alternative regulatory action considered. EPA considered an alternative regulatory action of prohibiting the manufacture of HCBD, but EPA does not believe this would be a practicable regulatory option. HCBD is a byproduct of the manufacture

of the solvents perchloroethylene, trichloroethylene, and carbon tetrachloride (Ref. 29). A prohibition on the manufacture of HCBD would effectively prohibit the manufacture of the three solvents. Because of the extensive use of perchloroethylene, trichloroethylene, and carbon tetrachloride (Ref. 3), EPA believes that it is not practicable to completely prohibit the production of these chemicals by prohibiting the manufacture of HCBD. Additionally, these chemicals are the subject of the risk evaluation process pursuant to TSCA section 6(b). Where unreasonable risks are identified as part of those risk evaluations, EPA is required to take action under TSCA section 6(a) to address unreasonable risk.

3. Evaluation of whether the regulatory actions address the TSCA section 6(h)(4) standard. EPA is not proposing to regulate HCBD under TSCA section 6(h) because releases resulting in exposures have been nearly eliminated through actions under other statutes such as the CAA and RCRA. The Agency does not believe it is practicable to reduce exposures of HCBD further than what has already been done under other statutes. The Agency requests comment on the practicability of further reducing exposures of HCBD.

4. Consideration of chemical alternatives (substitutes) in deciding whether to prohibit or restrict HCBD. EPA has not identified any uses of HCBD other than burning as a waste fuel. Therefore, chemical alternatives were not considered.

F. PCTP

1. Description of the proposed regulatory action. EPA is proposing to prohibit the manufacturing and processing of PCTP for any use in concentrations of above 1% by weight. PCTP can be found in zinc PCTP at concentrations above 1% depending on the yield of the reaction used to create the zinc PCTP (Ref. 30). As a result, this proposal would result in lower amounts of PCTP being manufactured and processed, used or disposed, thus reducing exposures

to human health and the environment.

Zinc PCTP, which may contain PCTP as an impurity, is used in the manufacture of golf balls. Zinc PCTP is sold at varying concentrations, including at a purity of 99% (Ref. 50). According to several patents, golf balls can be made using zinc PCTP at this purity (Ref. 32). Manufacturing or processing zinc PCTP at 99% purity would comply with the proposed concentration limit, as would zinc PCTP at lower purities that contains PCTP at or below 1% concentration. Because of the availability of zinc PCTP at a 99% purity, and the fact that it can be used to manufacture rubber, in particular the rubber in golf balls, EPA believes that the concentration limit for PCTP is a practicable way to reduce exposures to the chemical. The Agency further believes that completely prohibiting the presence of PCTP in zinc PCTP would be overly burdensome and therefore impracticable. EPA requests comment on the proposed concentration limit, including whether the option is practicable, and whether further exposure reductions would be practicable. EPA specifically requests comment on the practicability of a lower limit on the PCTP content in zinc PCTP, and whether it is possible to completely eliminate unreacted PCTP in the manufacture of zinc PCTP.

EPA has no information indicating that a compliance date of 60 days after publication of the final rule is not practicable for the activities that would be prohibited, or that additional time is needed for products to clear the channels of trade.

In addition, EPA is proposing to require, as of 60 days after the date that the final rule is published, all persons who manufacture, process, or distribute in commerce PCTP and articles and products containing PCTP to maintain ordinary business records, such as invoices and bills-of-lading, that demonstrate compliance with the prohibitions and restrictions. These records would have to be maintained for a period of three years from the date the record is generated.

2. Description of the primary alternative regulatory action considered. EPA considered an alternative regulatory action of prohibiting manufacturers and processors from releasing the chemical to the environment. To ensure that no releases occur, manufacturers and processors would have to institute such measures as work practices, emergency procedures, engineering controls, or other measures to eliminate environmental releases. PCTP in waste would have to be collected and destroyed. For example, PCTP in ambient air within the facility would have to be collected and either destroyed onsite or sent offsite for treatment. The prohibition would apply to all releases, including accidental releases, to all environmental media. The Agency requests comment on this alternative approach, including the measures or performance standards that could be implemented to further reduce exposure, and the practicability of the option.

3. Evaluation of whether the regulatory actions address the TSCA section 6(h)(4) standard. The proposed reduction in the concentration of PCTP in mixtures would result in lower amounts of the chemical that may be manufactured and processed and subsequently available for release, resulting in a reduction in exposures.

Historically, PCTP was used in rubber manufacturing as a peptizer, a chemical that makes rubber more amenable to processing. While it is likely that PCTP is no longer intentionally used as a peptizer, it can be found as an impurity in the zinc salt of PCTP (zinc PCTP) (CASRN 117-97-5). Zinc PCTP can be manufactured by reacting PCTP with zinc oxide. Depending on the yield of the reaction, some unreacted PCTP can remain in the mixture as an impurity (Ref. 30). As shown by a number of patents, zinc PCTP can be used as a peptizer in rubber manufacturing including as an ingredient in the rubber core of golf balls (Refs. 31 and 32) to enhance certain performance characteristics of the ball such as spin, rebound, and distance (Ref. 31). Zinc PCTP does not appear to be manufactured domestically (Ref. 17) but rather it is

imported into the United States (Ref. 3).

4. Consideration of chemical alternatives (substitutes) in deciding whether to prohibit or restrict PCTP. Based on a screening level analysis of likely alternatives based on the TSCA Work Plan Chemicals: Methods Document (Ref. 2), EPA believes that there are viable substitutes for PCTP in rubber manufacturing. While EPA is not proposing to prohibit the use of PCTP at concentrations at or below 1%, it is possible that some manufacturers and processors may choose to use alternatives instead of using PCTP at the proposed concentration limit. At this time, EPA does not know whether golf balls are currently being made with halogenated organosulfur compound substitutes. Based on information from patents, EPA believes that use of these substitutes may be occurring in golf ball manufacturing (Refs. 31, 32, 51). Further, only one golf ball manufacturer has confirmed that it incorporates PCTP into its golf balls. EPA believes this limited use of PCTP is sufficient evidence of the availability of substitutes.

(i) Health and environmental effects of the chemical alternatives or substitute methods.

EPA conducted a screening level analysis of several possible substitutes for PCTP based on the TSCA Work Plan Chemicals: Methods Document (Ref. 2). The potential alternatives were evaluated and scored on three characteristics: hazard, exposure and the potential for persistence and/or bioaccumulation. Two chemicals, diphenyldisulfide and 2,2'-dibenzamidodiphenyl disulfide, scored lower for at least one characteristic (Ref. 3). With respect to another chemical, pentafluorothiophenol, there was not enough information available to score each characteristic (Ref. 45).

(ii) Technical feasibility, economic feasibility, and reasonable availability of the chemical alternatives or substitute methods. 2,2'-dibenzamidodiphenyl disulfide (DBD), which is considered to be less toxic and reacts similarly, can be used in place of PCTP (Ref. 33). In golf

ball cores, other halogenated organosulfur compounds can be used as a substitute for PCTP (Ref. 51). EPA requests comment on the extent to which these substitutes are used in the manufacture of golf balls.

IV. Reasonably Ascertainable Economic Consequences of the Proposed Rule

A. Overview of Cost Methodology

EPA has evaluated the potential costs of the proposed and primary alternative regulatory actions for the PBT chemicals. Costs of the proposed rule were estimated based on the assumption that under regulatory limitations on the PBT chemicals, processors that use the regulated chemical in their products would switch to available alternative chemicals to manufacture the product, or to products that do not contain the chemical. Approaches for the analysis of each regulated chemical varied according to whether the focus was on chemical substitutes or product substitutes, depending on the uses for each chemical. For DecaBDE and PCTP, the costs were assessed based on chemical substitutes only. For PIP (3:1) and 2,4,6-TTBP, costs were assessed based on product substitutes where product information was more substantial than information on chemical substitutes alone.

Substitution costs were estimated on the industry level using the price differential between the cost of the chemical (or chemical product) and identified substitutes. Costs for rule familiarization and recordkeeping were estimated based on burdens estimated for other similar rulemakings. Costs were annualized over a 25-year period. Other potential costs include, but are not limited to, those associated with testing, reformulation, release prevention, imported articles, and some portion of potential revenue loss. However, these costs are discussed only qualitatively, due to lack of data availability to estimate quantified costs. More details of this analysis are presented in the Economic Analysis (Ref. 3), which is in the public docket for this

action.

B. Estimated Costs of Proposed and Primary Alternative Regulatory Actions

Total quantified annualized industry costs for the proposed rule is \$43.1 million (at both 3% and 7% discount rates). Total quantified annualized industry costs for the primary alternative regulatory action are \$414 million (at both 3% and 7% discount rates). For DecaBDE, total quantified annualized industry costs for the proposed rule under both the proposed and the primary alternative regulatory actions are zero. For PIP (3:1), total quantified annualized industry costs for the proposed rule are \$34.7 million (at both 3% and 7% discount rates), and \$38.1 million (3% discount rate) or \$37.6 million (7% discount rate) for the primary alternative regulatory action. For 2,4,6-TTBP, total quantified annualized industry costs for the proposed rule under both the proposed and the primary alternative regulatory actions are \$8.4 million (at both 3% and 7% discount rates). For HCBP, the proposed action is not to regulate; therefore, there is no industry cost associated. For HCBP, the annualized costs to industry associated with the primary alternative regulatory action are estimated to total \$368 million (at both 3% and 7% discount rates). For PCTP, total quantified annualized industry costs for the proposed rule are \$0.03 million (at both 3% and 7% discount rates), and negligible for the primary alternative regulatory action. Total annualized Agency costs associated with implementation of the proposed rule were based on EPA's best judgment and experience with other similar rules. For the proposed regulatory action, EPA estimates it will require 3 FTE at \$465,000 per year. For the primary alternative regulatory option, EPA estimates 3.5 FTE at \$543,000 (Ref. 3).

Total quantified annualized social costs for the proposed rule are \$43.5 million (at both 3% and 7% discount rates). Total quantified social costs for the proposed rule under the primary alternative regulatory action are \$415 million (at both 3% and 7% discount rates).

As described in Unit IV.A., potential costs such as testing, reformulation, release prevention, and imported articles, could not be quantified due to lack of data availability to estimate quantified costs. These costs are discussed qualitatively in the Economic Analysis (Ref. 3), which is in the public docket for this action. EPA requests comment on all aspects of the costs that may be incurred as a result of this proposed action. EPA has the following specific requests for comment on costs:

EPA requests comment on potential costs of testing, such laboratory testing, that manufacturers or importers may choose to undertake on articles or components of articles to determine whether they contain the regulated chemical substance, and at what concentration.

EPA requests comment on potential costs of reformulation with substitute chemicals in the uses that are proposed to be restricted or prohibited. Such costs may be incurred by affected entities such as processors and may be related to activities such as research and development, laboratory testing, product re-labeling, and other activities necessary to use substitute chemicals in formulated products. EPA is also interested in soliciting comment on the time it may take for reformulation that would meet the current performance standards.

There are specific requirements to prevent releases to the environment for processors and distributors of PIP (3:1) under the proposed option, and for manufacturers, processors and distributors of PCTP under the primary alternative option. EPA requests comment on potential costs of engineering controls, process changes, or other measures that firms may undertake to prevent releases to the environment for the subject PBT chemicals.

EPA requests comment on potential costs related to ensuring compliance for imported articles affected by the proposed rule. While the rule does not prescribe specific steps that an importer must take to identify specific substances in imported articles, EPA is interested in

understanding potential costs such as testing, communication with suppliers, or other measures that may be incurred at the discretion of any individual importer to ensure compliance.

EPA requests comment on potential costs and firm-level impacts, including possibility of firm closure, related to loss of revenue due to reduced demand for the subject PBT chemicals in the uses that are proposed to be restricted or prohibited. EPA is also interested in information related to the extent to which affected manufacturers (including importers) are willing and able to supply substitute chemicals and the net financial effects for the affected firms.

Finally, EPA requests comment on the likelihood, nature, and extent of potential changes in the domestic and foreign composition of the supply chain for the five PBT chemicals and continued availability for non-restricted uses due to reduced demand in the uses that are proposed to be restricted or prohibited by the proposed rule.

C. Benefits

As discussed in Unit II.C., while EPA reviewed hazard and exposure information for the PBT chemicals, this information did not provide a basis for EPA to develop scientifically robust and representative risk estimates to evaluate whether or not any of the chemicals present a risk of injury to health or the environment. Benefits were not quantified due to the lack of risk estimates. A qualitative discussion of the potential benefits associated with the proposed and alternative actions for each chemical is provided.

DecaBDE is persistent and bioaccumulative and has been associated with developmental neurological effects, developmental immunological effects, general developmental toxicity, and thyroid and liver effects in mammals, as well as with toxicity in aquatic organisms. Under EPA's proposed regulatory action, persons would be prohibited from manufacturing, processing and distributing DecaBDE in commerce and as an intentional component of any articles, with limited

compliance delays and/or exclusions allowed for uses by certain industries (*e.g.*, aerospace).

Exposures to humans and the environment would thus decrease as a result of the proposed regulatory action, and thus there would be benefits to health and the environment.

The primary alternative option would further reduce exposure to DecaBDE by including the prohibition of the manufacture, processing, or distribution in commerce of articles containing the chemical above 0.1 percent of mass weight. In effect, this would include a prohibition of recycled materials that contain above 0.1% DecaBDE. While data on the volume of recycled materials that contain DecaBDE above this threshold are not available, in cases where articles exceed this threshold, there would be an associated reduction of the amount of exposure.

HCBD is persistent, bioaccumulative, and a possible human carcinogen. It is not intentionally manufactured in the United States. Since EPA is not proposing any regulatory action for HCBD, no benefits to health or the environment are expected as a result of the rule. The primary alternative regulatory action considered is a prohibition on the manufacture of HCBD. This would require reducing or eliminating production of the chemicals for which HCBD is produced as a byproduct. While this primary alternative option would further reduce release to the environment, it would require substantial change to the markets for chlorinated solvents that may not be warranted due to the low levels of release of HCBD that have already been realized.

PCTP is persistent, bioaccumulative, and an aquatic toxicant. There are limited data on the potential effects of PCTP in mammals and no data were identified on the potential effects of PCTP in humans. Under the proposed regulatory action, manufacture and processing of PCTP would be limited to concentrations of 1% or lower. With lower concentrations in mixtures, the proposed regulatory action would decrease dermal and inhalation PCTP exposures in workers

involved in the manufacture of golf balls, if the workers are unprotected, and decrease releases of PCTP to the environment. With decreased releases to the environment there would also eventually be a decrease of exposures in the general population generally and as a result of consumption of contaminated food. Thus, by reducing PCTP, the proposed regulatory action would have benefits for the environment and potential benefits to health for workers, if they are unprotected.

Under the primary alternative regulatory action, EPA would prohibit manufacturers and processors from releasing the chemical to the environment. This would require manufacturers to implement industrial controls that would prevent releases to air, water, or land. If the costs to install and operate such controls are higher than the cost to switch to substitute chemicals for ZnPCTP, then firms would likely switch to substitute chemicals, as they would under the proposed action, and with a similar reduction in exposure to PCTP.

PIP (3:1) is a neurotoxicant and aquatic toxicant with high persistence and high potential for bioaccumulation. It would be prohibited for processing and distribution in all uses under the proposed regulatory action, with the exception of certain uses in aviation and automobile products. Concentrations of PIP (3:1) would be limited in these aviation products, and releases to water as a result of their use would be prohibited. Therefore, occupational exposures, if workers are unprotected, and exposures to the environment would decrease as a result of the proposed regulatory action, and thus there would be benefits to health and the environment.

Under the primary alternative regulatory action, remaining uses of PIP (3:1) in aviation products would also be prohibited following a 10-year exemption. Under this scenario, exposures to PIP (3:1) would be expected to decrease as outlined previously, with additional decreases in exposures for workers in the aviation sector, if they are unprotected.

2,4,6-TTBP is persistent and bioaccumulative, and has been associated with liver toxicity and reproductive and developmental effects in mammals. Under the proposed regulatory action, it would be prohibited for distribution in containers less than 55 gallons and be prohibited in processing and distribution as an additive to oil/lubricants. Therefore, the rule is expected to reduce consumer exposures to 2,4,6-TTBP and occupational exposure in certain industries, if workers are unprotected, as well as releases to the environment from consumer use, and thus, there would be benefits to health and the environment.

Under the primary alternative regulatory action, the container requirement component would be replaced by a limit of 0.01% on the allowable concentration of 2,4,6-TTBP in consumer/retail fuel additive formulations. Since both actions would require reformulation of fuel additives containing 2,4,6-TTBP, decreases in exposures to 2,4,6-TTBP are expected to be similar in each case.

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. TSCA Work Plan for Chemical Assessments: 2014 Update. October 2014.
<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-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-](https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf)

[03/documents/work_plan_methods_document_web_final.pdf](https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf). Accessed March 1, 2019.

3. EPA. Economic Analysis for Proposed Regulation of Persistent, Bioaccumulative, and Toxic Chemicals under TSCA section 6(h). June 2019.

4. EPA. Exposure and Use Assessment of Five Persistent, Bioaccumulative, and Toxic Chemicals June 2019.

5. EPA. Environmental and Human Health Hazards of Five Persistent, Bioaccumulative and Toxic Chemicals. June 2019.

6. EPA. *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Decabromodiphenyl Ether*. August 2017. (EPA-HQ-OPPT-2016-0724-0002).

7. EPA. *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Phenol, isopropylated, phosphate (3:1)*. August 2017. (EPA-HQ-OPPT-2016-0730-0003).

8. EPA. *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: 2,4,6-Tris(tert-butyl)phenol*. August 2017. (EPA-HQ-OPPT-2016-0734-0002).

9. EPA. *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Hexachlorobutadiene*. August 2017. (EPA-HQ-OPPT-2016-0738-0004).

10. EPA. *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Pentachlorothiophenol*. August 2017. (EPA-HQ-OPPT-2016-0739-0003).

11. EPA. TSCA Work Plan Chemicals. June 2012.

[https://www.epa.gov/sites/production/files/2014-](https://www.epa.gov/sites/production/files/2014-02/documents/work_plan_chemicals_web_final.pdf)

[02/documents/work_plan_chemicals_web_final.pdf](https://www.epa.gov/sites/production/files/2014-02/documents/work_plan_chemicals_web_final.pdf), accessed March 2019.

12. EPA. Letter acknowledging receipt of request for risk evaluations under TSCA

section 6(h). Wendy Cleland-Hamnett, Director, Office of Pollution Prevention and Toxics to International Flavors and Fragrances, Inc. September 28, Washington DC.

13. EPA. Stakeholder Comment from Auto Alliance. February 2018.

14. EPA. Stakeholder Comment from iGPS. January 2018.

15. EPA. Certain Polybrominated Diphenylethers; Significant New Use Rule and Test Rule. Proposed Rule. **Federal Register** (77 FR 19862, April 2, 2012) (FRL--8889--3).

16. EPA. Public Database 2012 Chemical Data Reporting. Washington, DC: US Environmental Protection Agency, Office of Pollution Prevention and Toxics.

17. EPA. Public Database 2016 Chemical Data Reporting. Washington, DC: US Environmental Protection Agency, Office of Pollution Prevention and Toxics.

18. EPA. (2016). Toxics Release Inventory (TRI) Basic Plus Data Files.

19. EPA. (2017). Toxics Release Inventory (TRI) Basic Plus Data Files.

20. EPA. Toxic Chemical Release Reporting; Community Right-to-know. Final Rule. **Federal Register** (53 FR 4500, February 16, 1988) (FRL--3298--2).

21. EPA. Stakeholder Meeting with ICL. August 30, 2018. EPA Docket EPA-HQ-OPPT-2019-0080.

22. Boeing Submission Re: Information supporting a Critical Use Exemption Request for phenol, isopropylated, phosphate (3:1) in Aerospace Uses (Docket ID Number: EPA-HQ-OPPT-2016-0730). February 12, 2019.

23. EPA. Stakeholder Meeting with Akin Gump. September 27, 2018. EPA Docket EPA-HQ-OPPT-2019-0080.

24. EPA. Stakeholder Meeting with Boeing. May 2, 2018. EPA Docket EPA-HQ-OPPT-2019-0080.

25. EPA. Stakeholder Meeting with Airbus. February 5, 2019. EPA Docket EPA-HQ-OPPT-2019-0080.
26. EPA. Stakeholder Meeting with Lockheed Martin. March 25, 2019. EPA Docket EPA-HQ-OPPT-2019-0080.
27. SI Group. Comments for the economic impact of 2,4,6-tri-tert-butylphenol (2,4,6-TTBP); letter from Kevin M. Kransler to Doug Parsons, EPA. December 21, 2018.
28. EPA. Afton Chemical conference call with U.S. EPA, regarding 2,4,6-TTBP chemical uses. July 28, 2017.
29. United Nations Environment Program Stockholm Convention on Persistent Organic Pollutants (2012). Risk profile on hexachlorobutadiene. Report of the Persistent Organic Pollutants Review Committee on the work of its eighth meeting.
30. Lucas, CR; Peach, ME. (1970). Reactions of Pentachlorothiophenol. Canadian Journal of Chemistry. 48:1869.
31. Watanabe, Hideo; Kasashima, Atuski, Multi-piece solid golf ball. US Patent Number US7367901B2, filed January 11, 2007, and published May 6, 2008.
32. Kennedy III, Thomas J., Binette, Mark L., Golf ball, US Patent Number 20060019771, filed July 20, 2004, and published January 26, 2006.
33. National Library of Medicine. ToxNet, Hazardous Substance Data Bank. Pentachlorothiophenol: CASRN: 133-49-3. <https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/f?./temp/~ebPHHj:1> Accessed March 4, 2019.
34. Struktol Company of America, LLC. Stow, OH. Rubber Handbook. 2004. <http://www.struktol.com/pdfs/RubberHB.pdf>. Accessed March 4, 2019.
35. EPA. Preliminary Assessment Information Reporting; Addition of Certain Chemicals.

Final Rule. **Federal Register** (66 FR 38955, July 26, 2001) (FRL-6783-6).

36. EPA. Fifty-First Report of the TSCA Interagency Testing Committee to the Administrator; Receipt of Report and Request for Comments. **Federal Register** (68 FR 8975, February 26, 2003) (FRL-7285-7).

37. Department of Labor. Occupational Safety and Health Administration. Recommended Practices for Safety and Health Programs. <https://www.osha.gov/shpguidelines/hazard-prevention.html>. Accessed April 16, 2019.

38. Norwegian Environmental Agency. (2015) Final Report. Literature Study - DecaBDE in Waste Streams.

39. Aerospace Industries Association (AIA). Consultation on Products containing PBDEs. Letter to Environment Canada. December 13, 2013.

40. EPA. Exploratory Analysis for DecaBDE in Children's Toys. April 2019.

41. Tu, Chuanhoing & Prest, Harry F., Agilent Technologies. Determination of Polybrominated Diphenyl Ethers in Polymeric Materials Using the 6890 GC/5973N inert MSD with Electron Impact Ionization. April 5, 2005.

42. EPA. (2014). An Alternatives Assessment for the Flame Retardant Decabromodiphenyl Ether (DecaBDE).

43. Alliance of Automobile Manufacturers and Motor and Equipment Manufacturers Association. Submission RE: Critical Use Exemption Request for Phenol, Isopropylated, Phosphate 3:1 in Automotive Uses. April 5, 2019.

44. Alliance of Automobile Manufacturers and Motor and Equipment Manufacturers Association. Meeting on Phenol, Isopropylated, Phosphate (3:1) (PIP) in Automotive Uses. OIRA EO 12866 Meeting. June 13, 2019.

45. EPA. Persistence, Bioaccumulation, Environmental Hazard and Human Health Hazard Ratings for Alternatives to PBT Chemicals Proposed for Regulation. April 2019.
46. EPA. Stakeholder Meeting with Nye Lubricants. November 14, 2018. EPA Docket EPA-HQ-OPPT-2019-0080.
47. UK Food Standards Agency. (2019). EU Approved Additives and E Numbers (E321 – Butylated Hydroxytoluene (BHT)). https://www.food.gov.uk/business-guidance/eu-approved-additives-and-e-numbers#h_4. Accessed March 11, 2017.
48. Innospec. (2007). Fuel Additives Product Summary. http://login.innospecinc.com/assets/_files/documents/dec_07/cm__1197641587_FS_Product_Summary_US.pdf. Accessed March 18, 2019.
49. EPA. National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing; Final Rule. **Federal Register** (63 FR 63852, Nov. 10, 2003)(FRL-7551-3)
50. American Elements. Los Angeles, CA. Zinc Chlorothiophenolate. <https://www.americanelements.com/zinc-chlorothiophenolate-117-97-5>. Accessed March 3, 2019.
51. Voorheis PR, Rajagopalan M. Golf ball core compositions comprising unsaturated long chain organic acids and their salts. US Patent Number: US6762247B2, filed September 9, 2002, published July 13, 2004.
52. Keweemaw Bay Indian Community. Re: Notification of Consultation and Coordination on a Rulemaking Under the Toxic Substances Control Act: Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h). September 25, 2018.

53. Harper, Barbara and Ranco, Darren, in collaboration with the Maine Tribes.

Wabanaki Traditional Cultural Lifeways Exposure Scenario. July 9, 2009.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review for review under Executive Order 12866 (58 FR 51735, October 4, 1993) and Executive Order 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket. The Economic Analysis (Ref. 3) is available in the docket and is summarized in Unit IV.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is expected to be subject to the requirements for regulatory actions specified in Executive Order 13771 (82 FR 9339, February 3, 2017). Details on the estimated costs of this proposed rule can be found in EPA's analysis of the potential costs and benefits associated with this action (Ref. 3).

C. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to OMB under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2599.01. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

Respondents/affected entities: The entities expected to respond are companies that

manufacture/import, process, or distribute any of the five PBT chemicals included in this proposed rule for the uses covered by this proposed rulemaking. A list of NAICS codes associated with these companies is provided in Unit I.A.

Respondent's obligation to respond: Mandatory.

Estimated number of respondents: A total of 81 companies are expected to be impacted by the proposed option. However, these may be underestimates due to companies that EPA is unaware would be affected.

Frequency of response: Costs are calculated on an annual basis.

Total estimated burden: Total estimated annual paperwork burden for the proposed option is 50.2 hours.

Total estimated cost: The fully loaded wage rate used to estimate these costs is \$78.63. As such, there are expected to be a total of approximately \$3,940 in annual paperwork costs associated with the proposed rule over the three years of the ICR period.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to OIRA_submission@omb.eop.gov, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE

FEDERAL REGISTER]. The EPA will respond to any ICR-related comments in the final rule.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601, et seq. The small entities subject to the requirements of this action are small businesses that manufacture/import, process, or distribute the chemicals subject to this proposed rule. The Agency has determined that 24 of the 81 entities potentially subject to the proposed rule are small entities, including fourteen entities for DecaBDE, zero entities for HCBP, one entity for PCTP, five entities for PIP (3:1) and four entities for 2,4,6-TTBP. None (0%) of the small entities for any of the chemicals assessed are expected to incur impacts of 1% or greater. Details of this analysis are presented in the Economic Analysis (Ref. 3), which is in the public docket for this action.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The requirements of this action would primarily affect manufacturers, processors, and distributors of four PBT chemicals. The total quantified annualized social costs for the proposed rule under the proposed option are approximately \$43.5 million (at both 3% and 7% discount rate), which does not exceed the inflation-adjusted unfunded mandate threshold of \$160 million.

F. Executive Order 13132: Federalism

This action does not have federalism implications, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000) because it does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Thus, Executive Order 13175 does not apply to this action.

Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, the EPA consulted with tribal officials during the development of this action. EPA consulted with representatives of Tribes via teleconference on August 31, 2018, and September 6, 2018, concerning the prospective regulation of these five PBT chemicals under TSCA section 6(h). Tribal members were encouraged to provide additional comments after the teleconferences. EPA received two comments from the Keweenaw Bay Indian Community and Maine Tribes (Refs. 52 and 53). EPA also met with the National Tribal Toxics Council (NTTC) in Washington, DC. During the NTTC meeting, EPA provided background information on the available regulatory options under 6(a) and a summary of the information gathered on the five PBT chemicals. Officials from NTTC expressed support for EPA regulations to reduce exposures to the general population and susceptible subpopulations.

H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not an economically significant regulatory action as defined by Executive Order 12866. As discussed, while EPA believes that the health and environmental risks presented by the PBT chemicals subject to this action may have a disproportionate effect on children and that

this action addresses those risks, EPA did not perform a risk assessment or risk evaluation of these PBT chemicals. However, the proposed requirements would reduce exposure to these PBT chemicals for the general population and for susceptible subpopulations such as workers and children. EPA's evaluation of the exposure potential of these PBT chemicals (Ref. 4) and summary of the health and environmental hazards that may be presented by these chemical substances (Ref. 5) are in the public docket for this action.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a "significant energy action" under Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. While this action proposes to regulate a fuel additive, because the restrictions are limited to fuel additives purchased and used by consumers, it will not significantly affect the nation's fuel supply.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards, and is therefore not subject to considerations under NTTAA section 12(d), 15 U.S.C. 272.

K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this decision is contained in the Economic Analysis (Ref. 3), which is in the public docket for this action.

Proposed Rule; Regulation of Persistent, Bioaccumulative, and Toxic Chemicals under TSCA

Section 6(h) (FRL-9995-79)

Administrator Signature on Page 119 of 126

List of Subjects in 40 CFR Part 751

Environmental protection, Chemicals, Export notification, Hazardous substances, Import certification, Reporting and recordkeeping.

Dated: _____.

Andrew R. Wheeler,

Administrator.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 751--[AMENDED]

1. The authority citation for part 751 continues to read as follows:

Authority: 15 U.S.C. 2605, 15 U.S.C. 2625(1)(4).

2. Add Subpart E to 40 CFR part 751 to read as follows:

Subpart E—Persistent, Bioaccumulative, and Toxic Chemicals

751.401 General.

751.403 Definitions.

751.405 DecaBDE.

751.407 PIP (3:1).

751.409 2,4,6-TTBP.

751.411 PCTP.

§ 751.401. General.

This subpart establishes prohibitions and restrictions on the following persistent, bioaccumulative, and toxic chemicals in accordance with TSCA section 6(h), 15 U.S.C 2605(h): decabromodiphenyl ether; phenol, isopropylated phosphate (3:1), also known as tris(4-isopropylphenyl) phosphate; 2,4,6-tris(tert-butyl)phenol; and pentachlorothiophenol.

§ 751.403 Definitions.

2,4,6-TTBP means the chemical substance 2,4,6-tris(tert-butyl)phenol (CASRN 732-26-3) at any concentration above 0.01 percent by weight.

Chemical substance means any organic or inorganic substance of a particular molecular identity, including:

(i) any combination of such substances occurring in whole or in part as a result of a

chemical reaction or occurring in nature, and

(ii) any element or uncombined radical.

Such term does not include:

(i) any mixture,

(ii) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act)

when manufactured, processed, or distributed in commerce for use as a pesticide,

(iii) tobacco or any tobacco product,

(iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act),

(v) any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code) and any component of such an article (limited to shot shells, cartridges, and components of shot shells and cartridges), and

(vi) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device. The term “food” as used in this subparagraph includes poultry and poultry products (as defined in sections 4(e) and 4(f) of the Poultry Products Inspection Act), meat and meat food products (as defined in section 1(j) of the Federal Meat Inspection Act), and eggs and egg products (as defined in section 4 of the Egg Products Inspection Act).

DecaBDE means the chemical substance decabromodiphenyl ether (CASRN 1163-19-5).

Oil and lubricant additive means any additive to a product of any viscosity intended to

reduce friction between moving parts, whether mineral oil or synthetic base, including engine crankcase and gear oils and bearing greases.

PCTP means the chemical substance pentachlorothiophenol (CASRN 133-49-3)

PIP (3:1) means the chemical substance phenol, isopropylated phosphate (3:1), also known as tris(4-isopropylphenyl) phosphate (CASRN 68937-41-7).

In addition, the definitions in subpart A of this part apply to this subpart unless otherwise specified in this section.

§ 751.405 DecaBDE.

(a) Prohibitions.

(1) After [*date to be calculated at final rule as 60 calendar days after the date of publication of the final rule*], all persons are prohibited from manufacturing, processing and distributing in commerce DecaBDE, or DecaBDE-containing products or articles, except for the following:

(i) Processing and distribution in commerce for recycling of plastic from products or articles containing DecaBDE, where no new DecaBDE is added during the recycling process;

(ii) Processing and distribution in commerce of DecaBDE in finished products or articles made of plastic recycled from products or articles containing DecaBDE, where no new DecaBDE was added during the production of the products or articles made of recycled plastic.

(iii) Manufacture, processing, and distribution in commerce of DecaBDE for use in replacement parts for automobiles and other motor vehicles and aircraft and aerospace vehicles, and the replacement parts, to which DecaBDE has been added, for such vehicles.

(iv) After [*date to be calculated at final rule as 3 years after the date of publication of the final rule*], manufacture, processing and distribution in commerce of DecaBDE for use in parts

installed in and sold as part of new aerospace vehicles, and the parts to which DecaBDE has been added for such vehicles.

(v) After [*date to be calculated at final rule as 18 months after the date of publication of the final rule*], manufacture, processing and distribution in commerce of DecaBDE for use in curtains in the hospitality industry, and the curtains to which DecaBDE has been added.

(b) *Recordkeeping.* (1) After [*date to be calculated at final rule as 60 calendar days after the date of publication of the final rule*], persons who manufacture, process, or distribute in commerce DecaBDE, or Deca-BDE-containing products or articles, must maintain ordinary business records, such as invoices and bills-of-lading, that demonstrate compliance with the prohibitions, restrictions, and other provisions of this section. These records must be maintained for a period of three years from the date the record is generated.

(2) The recordkeeping requirements in subparagraph (b)(1) do not apply to the activities described in subparagraph (a)(1)(i)-(ii) of this section.

§ 751.407 PIP (3:1).

(a) *Prohibitions:*

(1) After [*date to be calculated at final rule as 60 calendar days after the date of publication of the final rule*], all persons are prohibited from processing and distributing in commerce PIP (3:1) or PIP (3:1)-containing products or articles, except for the following:

(i) Processing and distribution in commerce of PIP (3:1) and PIP (3:1)-containing products for use in aviation hydraulic fluid.

(ii) Processing and distribution in commerce of PIP (3:1) and PIP (3:1)-containing products for use in lubricants and greases.

(iii) Processing and distribution in commerce of PIP (3:1) and PIP (3:1)-containing

products for use in new and replacement parts for automobiles and other motor vehicles, and distribution in commerce of the new and replacement parts to which PIP (3:1) has been added for such vehicles.

(2) After [date to be calculated at final rule as 60 calendar days after the date of publication of the final rule], all persons are prohibited from releasing PIP (3:1) to water during manufacturing, processing, distribution in commerce, and commercial use of PIP (3:1).

(b) *Downstream notification.* Each person who manufactures, processes, or distributes in commerce PIP (3:1) or PIP (3:1)-containing products or articles for any use after [date to be calculated at final rule as 60 calendar days after the final rule] must, prior to or concurrent with the shipment, notify companies to whom PIP (3:1) is shipped, in writing, of the restrictions described in this subpart. Notification must occur by inserting the following text in the Safety Data Sheet (SDS) provided with the PIP (3:1) or with any PIP (3:1)-containing product:

(i) *SDS Section 1.(c):* “The Environmental Protection Agency prohibits processing and distribution of this chemical/product for any use other than in aviation hydraulic fluid in aircraft systems lubricants and greases, and new or replacement parts for automobiles and other motor vehicles. In addition, all persons are prohibited from releasing PIP (3:1) to water during manufacturing, processing, distribution in commerce, and commercial use of PIP (3:1).”

(ii) *SDS Section 15:* “The Environmental Protection Agency prohibits processing and distribution of this chemical/product for any use other than in aviation hydraulic fluid in aircraft, lubricants and greases, and new or replacement parts for automobiles and other motor vehicles. In addition, all persons are prohibited from releasing PIP (3:1) to water during manufacturing, processing, distribution in commerce, and commercial use of PIP (3:1).”

(c) *Recordkeeping.* Each person who manufactures, processes, or distributes in commerce

PIP (3:1) or PIP (3:1)-containing products or articles after [*date to be calculated at final rule as 60 calendar days after the date of publication of the final rule*] must maintain ordinary business records, such as invoices and bills-of-lading, that demonstrate compliance with the prohibitions, restrictions, and other provisions of this section. These records must be maintained for a period of three years from the date the record is generated.

§751.409 2,4,6-TTBP.

(a) Prohibitions.

(1) After [*date to be calculated at final rule as 60 calendar days after the date of publication of the final rule*], all persons are prohibited from distributing in commerce 2,4,6-TTBP in containers with a volume less than 55 gallons.

(2) After [*date to be calculated at final rule as 60 calendar days after the date of publication of the final rule*], all persons are prohibited from processing and distributing in commerce 2,4,6-TTBP for use as an oil and lubricant additive.

(b) Recordkeeping. After [*date to be calculated at final rule as 60 calendar days after the date of publication of the final rule*], distributors of 2,4,6 TTBP must maintain ordinary business records, such as invoices and bills-of-lading, that demonstrate compliance with the prohibitions, restrictions, and other provisions of this section. These records must be maintained for a period of three years from the date the record is generated.

§ 751.411 PCTP.

(a) Prohibition. After [*date to be calculated at final rule as 60 calendar days after the date of publication of the final rule*], all persons are prohibited from manufacturing, processing and distributing in commerce PCTP or PCTP-containing products or articles unless in concentrations at or below 1% by weight.

(b) Recordkeeping. After [*date to be calculated at final rule as 60 calendar days after the date of publication of the final rule*], manufacturers, processors and distributors of PCTP or PCTP-containing products or articles must maintain ordinary business records, such as invoices and bills-of-lading, that demonstrate compliance with the prohibitions, restrictions, and other provisions of this section. These records must be maintained for a period of three years from the date the record is generated.