



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA-HQ-OPPT-2019-0080; FRL-10018-90]

RIN 2070-AK59

2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals under TSCA Section 6(h)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing a rule under the Toxic Substances Control Act (TSCA) to address its obligations under TSCA for 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP) (CASRN 732-26-3), which EPA has determined meets the requirements for expedited action under TSCA. This final rule prohibits the distribution in commerce of 2,4,6-TTBP and products containing 2,4,6-TTBP at concentrations above 0.3% in any container with a volume of less than 35 gallons for any use, in order to effectively prevent the use of 2,4,6-TTBP as an antioxidant in fuel additives or fuel injector cleaners by consumers and small commercial operations (e.g., automotive repair shops, marinas). This final rule also prohibits the processing and distribution in commerce of 2,4,6-TTBP, and products containing 2,4,6-TTBP at concentrations above 0.3 percent by weight, for use as an oil or lubricant additive, regardless of container size. These requirements will reduce the exposure to humans and the environment, by reducing the potential for consumer exposures to 2,4,6-TTBP and potential occupational exposure in certain industries where workers are unprotected, as well as potential releases to the environment from consumer and small commercial operations use.

DATES: This final rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. For purposes of judicial review and 40 CFR 23.5, this rule shall be promulgated at 1 p.m. (e.s.t.) on [INSERT DATE 14 DAYS AFTER

DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2019-0080, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

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

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Peter Gimlin, Existing Chemicals Risk Management 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:

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 use products containing this chemical, 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP), especially fuel additives, fuel injector cleaners and oil and lubricants. 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:

- Petroleum Refineries (NAICS Code: 324110);
- Petrochemical Manufacturing (NAICS Code: 325110);
- All Other Basic Organic Chemical Manufacturing (NAICS Code: 325199);
- Polish and Other Sanitation Good Manufacturing (NAICS Code: 325612);
- All Other Miscellaneous Chemical Product and Preparation Manufacturing (NAICS Code: 325998);
- Lawn and Garden Tractor and Home Lawn and Garden Equipment Manufacturing (NAICS Code: 333112);
- Aircraft Manufacturing (NAICS Code: 336411);
- Motor Vehicle Supplies and New Parts Merchant Wholesalers (NAICS Code: 423120);
- Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals) (NAICS Code: 424720);
- Farm Supplies Merchant Wholesalers (NAICS Code: 424910);
- Boat Dealers (NAICS Code: 441222);
- Automotive Parts and Accessories Stores (NAICS Code: 441310);
- Gasoline Stations with Convenience Stores (NAICS Code: 447110);
- Other Gasoline Stations (NAICS Code: 447190);
- General Merchandise Stores (NAICS Code: 452);
- Aircraft Maintenance and Repair Services (NAICS Code: 488190);
- Marinas (NAICS Code: 713930); and
- General Automotive Repair (NAICS Code: 811111).

If you have any questions regarding the applicability of this 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 final 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, among other factors, EPA has a reasonable basis to conclude are toxic and that with respect to persistence and bioaccumulation score high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals: Methods Document (Ref. 2). 2,4,6-TTBP is one such chemical substance. TSCA section 6(h) directs EPA to take expedited action on these chemical substances, regardless of whether that substance is primarily found as an impurity or byproduct, to reduce exposure to the substance, including to exposure to the substance as an impurity or byproduct, to the extent practicable. This final rule is final agency action for purposes of judicial review under TSCA section 19(a).

C. What action is the Agency taking?

EPA published a proposed rule on July 29, 2019 to address the five PBT chemicals EPA identified pursuant to TSCA section 6(h) (84 FR 36728; FRL-9995-76). After publication of the proposed rule, EPA determined to address the five PBT chemicals in separate final actions. This final rule prohibits the distribution in commerce of 2,4,6-TTBP and products containing 2,4,6-TTBP at concentrations above 0.3% (i.e., present as a functional additive instead of as impurity) in any container with a volume of less than 35 gallons for any use, beginning on January 6, 2026, 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). This final rule also prohibits the processing and distribution in commerce of 2,4,6-TTBP, and products

containing 2,4,6-TTBP at concentrations above 0.3%, for use as an oil or lubricant additive, regardless of container size, beginning on January 6, 2026. Beginning on January 6, 2026, affected persons are required to maintain, for three years from the date the record is generated, ordinary business records related to compliance with these restrictions. For this specific chemical, ordinary business records that include the name of the purchaser and the sizes of the containers supplied would be sufficient. This provision is not intended to require subject companies to retain records in addition to those specified herein, except as needed pursuant to normal business operations.

D. Why is the Agency taking this action?

EPA is issuing this final 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.” Consistent with that requirement, the Agency is finalizing this rule to reduce exposures to 2,4,6-TTBP to the extent practicable.

E. What are the estimated incremental impacts of this action?

EPA has evaluated the potential costs of these final restrictions and prohibitions and the associated reporting and recordkeeping requirements. The “Economic Analysis for Final Regulation of 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP) Under TSCA Section 6(h)” (Economic Analysis) (Ref. 3) is available in the docket and is briefly summarized here.

- *Benefits.* EPA was not able to quantify the benefits of reducing the potential for human and environmental exposures to 2,4,6-TTBP. As discussed in more detail in Unit II.A., EPA did not perform risk evaluations for 2,4,6-TTBP, nor did EPA develop quantitative risk estimates. Therefore, the Economic Analysis (Ref. 3) qualitatively discusses the benefits of reducing the exposure under the final action and the primary alternative regulatory action for 2,4,6-TTBP.

- *Costs.* Total quantified annualized social costs for this final rule are approximately \$5.6

million at a 3% discount rate and \$4.9 million at a 7% discount rate. Potential unquantified costs are those associated with testing, reformulation, importation of articles, foregone profits, and indirect costs. The limited data available for those costs prevents EPA from constructing a quantitative assessment.

- *Small entity impacts.* This rule will impact approximately three small businesses of which none are expected to incur cost impacts of 1% or greater of their revenue.

- *Environmental Justice.* This rule will increase the level of protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population or children.

- *Effects on State, local, and Tribal governments.* This rule does not have any significant or unique effects on small governments, or federalism or tribal implications.

F. Children's Environmental Health

Executive Order 13045 applies if the regulatory action is economically significant and concerns an environmental health risk or safety risk that may disproportionately affect children. This final rule is not subject to Executive Order 13045 because it is not an economically significant regulatory action as defined by Executive Order 12866. While the action is not subject to Executive Order 13045, the Agency's Policy on Evaluating Health Risks to Children (<https://www.epa.gov/children/epas-policy-evaluating-risk-children>) is to consider the risks to infants and children consistently and explicitly during its decision making process. This regulation will reduce the exposure that could occur from activities now prohibited under this final rule to 2,4,6-TTBP for the general population and for potentially exposed or susceptible subpopulations such as children. More information can be found in the Exposure and Use Assessment (Ref. 4).

II. Background

A. History of this Rulemaking: TSCA sections 6(h) and the TSCA Work Plan

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 (Ref. 1). As required by the statute, EPA issued a proposed rule to address five persistent, bioaccumulative, and toxic chemicals identified pursuant to TSCA section 6(h) (84 FR 36728, July 29, 2019). The statute required that this be followed by promulgation of a final rule no later than 18 months after the proposal. While EPA proposed regulatory actions on each chemical substance in one proposal, in response to public comments requesting these five actions be separated, EPA is finalizing five separate actions to individually address each of the PBT chemicals. EPA intends for the five separate final rules to publish in the same issue of the *Federal Register*. More discussion on these comments is in the response to comments document (Ref. 5). The details of the proposal for 2,4,6-TTBP are described in more detail in Unit II.D.

Under TSCA section 6(h)(1)(A), chemical substances subject to expedited action 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 TSCA was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Pub. L. 114-182, 130 Stat. 448).

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 the Administrator. TSCA section 6(h)(2) 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).

Based on the criteria set forth in TSCA section 6(h), EPA proposed to determine that five chemical substances meet the TSCA section 6(h)(1)(A) criteria for expedited action, and 2,4,6-TTBP is one of these five chemical substances. In addition, and in accordance with the statutory requirements to demonstrate that exposure to the chemical substance is likely under the conditions of use, EPA conducted an Exposure and Use Assessment for 2,4,6-TTBP. As described in the proposed rule, EPA conducted a review of available literature with respect to 2,4,6-TTBP to identify, screen, extract, and evaluate reasonably available information on use and exposures. This information is in the document entitled “Exposure and Use Assessment of Five Persistent, Bioaccumulative and Toxic Chemicals” (Ref. 4). Based on this review, which was subject to peer review and public comment, EPA finds that exposure to 2,4,6-TTBP is likely, based on information detailed in the Exposure and Use Assessment.

B. Other Provisions of TSCA Section 6

1. EPA’s approach for implementing TSCA section 6(h)(4).

TSCA section 6(h)(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 reads this text to require action on the chemical, not specific conditions of use.

The approach EPA takes is consistent with the language of TSCA section 6(h)(4) and its distinct differences from other provisions of TSCA section 6 for chemicals that are the subject of required risk evaluations. First, the term “condition of use” is only used in TSCA section 6(h) in the context of the TSCA section 6(h)(1)(B) finding relating to likely exposures under “conditions of use” to “the general population or to a potentially exposed or susceptible subpopulation ... or

the environment.” In contrast to the risk evaluation process under TSCA section 6(b), this TSCA section 6(h)(1)(B) threshold criterion is triggered only through an Exposure and Use Assessment regarding the likelihood of exposure and does not require identification of every condition of use (Ref. 4). As a result, EPA collected all the information it could on the use of each chemical substance, without regard to whether any chemical activity would be characterized as “known, intended or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of,” and from that information created use profiles and then an Exposure and Use Assessment to make the TSCA section 6(h)(1)(B) finding for at least one or more “condition of use” activities where some exposure is likely. EPA did not attempt to precisely classify all activities for each chemical substance as a “condition of use” and thus did not attempt to make a TSCA section 6(h)(1)(B) finding for all chemical activities summarized in the Exposure and Use Assessment. Second, TSCA section 6 generally requires a risk evaluation under TSCA section 6(b) for chemicals based on the identified conditions of use. However, pursuant to TSCA section 6(h)(2), for chemical substances that meet the criteria of TSCA section 6(h)(1), a risk evaluation is neither required nor contemplated to be conducted for EPA to meet its obligations under TSCA section 6(h)(4). Rather, as noted in Unit II.B.3., if a previously prepared TSCA risk assessment exists, EPA would have authority to use that risk assessment to “address risks” under TSCA section 6(h)(4), but even that risk assessment would not necessarily be focused on whether an activity is “known, intended or reasonably foreseen,” as those terms were not used in TSCA prior to the 2016 amendments and a preexisting assessment of risks would have had no reason to use such terminology or make such judgments. It is for this reason EPA believes that the TSCA section 6(h)(4) “address risk” standard refers to the risks the Administrator determines “are presented by *the chemical substance*” and makes no reference to “conditions of use.” Congress did not contemplate or require a risk evaluation identifying the conditions of use as defined under TSCA section 3(4). The kind of analysis required to identify and evaluate the conditions of use for a chemical substance is only contemplated in the context of a TSCA section

6(b) risk evaluation, not in the context of an expedited rulemaking to address PBT chemicals.

Similarly, the TSCA amendments require EPA to “reduce exposure *to the substance* to the extent practicable,” without reference to whether the exposure is found “likely” pursuant to TSCA section 6(h)(1)(B).

Taking this into account, EPA reads its TSCA section 6(h)(4) obligation to apply to the chemical substance generally, thus requiring EPA to address risks and reduce exposures to the chemical substance without focusing on whether the measure taken is specific to an activity that might be characterized as a “condition of use” as that term is defined in TSCA section 3(4) and interpreted by EPA in the Risk Evaluation Rule, 82 FR 33726 (July 20, 2017). This approach ensures that any activity involving a TSCA section 6(h) PBT chemical, past, present or future, is addressed by the regulatory approach taken. Thus, under this final rule, EPA grouped all activities with 2,4,6-TTBP into four general categories, and addressed the practicability of specific standards for each group. As described in detail in Unit II.F., EPA has considered the uses of 2,4,6-TTBP in these four general categories: (1) domestic manufacture and use as an intermediate/reactant in processing at chemical facilities; (2) use in formulations and mixtures for fuel treatment in refineries and fuel facilities; (3) use in formulations intended for the maintenance or repair of motor vehicles and machinery at small commercial entities and for retail sale, and (4) use in formulations and mixtures for liquid lubricant and grease additives/antioxidants additives. This final rule prohibits distribution of 2,4,6-TTBP and products containing 2,4,6-TTBP in any container with a volume of less than 35 gallons for any use, as well as processing and distribution of 2,4,6-TTBP and products containing 2,4,6-TTBP for use as an oil or lubricant additive, and thus reduces the exposures that will result with resumption of past activities or the initiation of similar or other activities in the future. Therefore, EPA has determined that prohibiting these activities will reduce exposures to the extent practicable. The approach taken for this rulemaking is limited to implementation of TSCA section 6(h) and is not relevant to any other action under TSCA section 6 or other statutory actions.

2. EPA's interpretation of "practicable."

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, such as TSCA section 6(c)(2)(A) which requires the Administrator to consider health effects, exposure, and environmental effects of the chemical substance; benefits of the chemical substance; and the reasonably ascertainable economic consequences of the rule. In addition, pursuant to TSCA section 6(c)(2)(B), in selecting the appropriate TSCA section 6(a) regulatory approach to take, the Administrator is directed to "factor in, to the extent practicable" those same considerations.

EPA received comments on the proposed rule regarding this interpretation of "practicable." EPA has reviewed these comments and believes the interpretation described previously within this Unit is consistent with the intent of TSCA and has not changed that interpretation. EPA's interpretation of an ambiguous statutory term receives deference. More discussion on these comments is in the Response to Comments document for this rulemaking (Ref. 5).

3. EPA did not conduct a risk assessment.

As EPA explained in the proposed rule, EPA does not interpret the "address risk" language to require EPA to determine, through a risk assessment or risk evaluation, whether risks are presented. EPA believes this reading gives the Administrator the flexibility Congress intended for issuance of expedited rules for PBTs and is consistent with TSCA section 6(h)(2) which makes clear that a risk evaluation is not required to support this rulemaking.

EPA received comments on the proposed rule regarding its interpretation of TSCA section 6(h)(4) and regarding EPA's lack of risk assessment or risk evaluation of 2,4,6-TTBP. A number of commenters commented that, while EPA was not compelled to conduct a risk

evaluation, EPA should have conducted a risk evaluation under TSCA section 6(b) regardless. The rationales provided by the commenters for such a risk assessment or risk evaluation included that one was needed for EPA to fully quantify the benefits to support this rulemaking, and that without a risk evaluation, EPA would not be able to determine the benefits, risks, and cost effectiveness of the rule in a meaningful way. As described by the commenters, EPA would therefore not be able to meet the TSCA section 6(c)(2) requirement for a statement of these considerations. Regarding the contradiction between the mandate in TSCA section 6(h) to expeditiously issue a rulemaking and the time needed to conduct a risk evaluation, some commenters argued that EPA would have had enough time to conduct a risk evaluation and issue a proposed rule by the statutory deadline.

For similar reasons, EPA does not believe that TSCA section 6(c)(2) requires a quantification of benefits, much less a specific kind of quantification. Under TSCA section 6(c)(2)(A)(iv), EPA must consider and publish a statement, based on reasonably available information, on the reasonably ascertainable economic consequences of the rule, but that provision does not require quantification, particularly if quantification is not possible. EPA has reasonably complied with this requirement by including a quantification of direct costs and a qualitative discussion of benefits in each of the preambles to the final rules. EPA was unable to quantify the indirect costs associated with the rule. Further discussion on these issues can be found in the Response to Comment document. (Ref. 5)

EPA disagrees with the commenters' interpretation of EPA's obligations with respect to chemicals subject to TSCA section 6(h)(4). TSCA section 6(h)(4) 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." With respect to the first requirement, that standard is distinct from the "unreasonable risk" standard for all other chemicals for which a section 6(a) rule might be issued. EPA does not believe that TSCA section 6(h) contemplates a new evaluation of any kind,

given that evaluations to determine risks are now addressed through the TSCA section 6(b) risk evaluation process and that TSCA section 6(h)(2) explicitly provides that no risk evaluation is required. Moreover, it would have been impossible to prepare a meaningful evaluation under TSCA and subsequently develop a proposed rule in the time contemplated for issuance of a proposed rule under TSCA section 6(h)(1). Although EPA does not believe the statute contemplates a new evaluation of any kind for these reasons, EPA reviewed the hazard and exposure information on the five PBT chemicals EPA had compiled. However, while this information appropriately addresses the criteria of TSCA section 6(h)(1)(A) and (B), it did not provide a basis for EPA to develop sufficient and scientifically robust and representative risk estimates to evaluate whether or not any of the chemicals present an identifiable risk of injury to health or the environment.

Rather than suggesting a new assessment is required, EPA reads the “address risk” language in TSCA section 6(h)(4) to contemplate reliance on an existing EPA assessment under TSCA, similar to a risk assessment that may be permissibly used under TSCA section 26(l)(4) to regulate the chemical under TSCA section 6(a). This interpretation gives meaning to the “address risk” phrase, without compelling an evaluation contrary to TSCA section 6(h)(2), and would allow use of an existing determination, or development of a new determination based on such an existing risk assessment, in the timeframe contemplated for issuance of a proposed rule under TSCA section 6(h). However, there were no existing EPA assessments of risk for any of the PBT chemicals. Thus, because EPA had no existing EPA risk assessments or determinations of risk, the regulatory measures addressed in this final rule focus on reducing exposures “to the extent practicable.”

In sum, because neither the statute nor the legislative history suggests that a new evaluation is compelled to identify and thereby provide a basis for the Agency to “address risks” and one could not be done prior to preparation and timely issuance of a proposed rule, and no existing TSCA risk assessment exists for any of the chemicals, EPA has made no risk

determination finding for any of the PBT chemicals. Instead, EPA implements the requirement of TSCA section 6(h)(4) by reducing exposures of each PBT chemical “to the extent practicable.”

More discussion on these comments is in the response to comments document (Ref. 5).

C. 2,4,6-TTBP Overview, Health Effects and Exposure

1. Uses of 2,4,6-TTBP.

The use information presented in this Unit is based on the EPA’s review of the reasonably available information, as presented in the rulemaking record, including public comments on the use documents, proposed regulation and other stakeholder input.

Uses of 2,4,6-TTBP may be grouped into four general categories: (1) domestic manufacture and use as an intermediate/reactant in processing at chemical facilities; (2) use in formulations and mixtures for fuel treatment in refineries and fuel facilities; (3) use in formulations intended for the maintenance or repair of motor vehicles and machinery at small commercial operations and for retail sale, and (4) use in formulations and mixtures for liquid lubricant and grease additives/antioxidants additives. EPA summarizes below these uses and its conclusions regarding the exposures and the practicability of reducing such exposures.

i. Manufacture and use as an intermediate/reactant.

SI Group is currently the only large volume domestic manufacturer of 2,4,6-TTBP. Historical CDR data indicate that in the 1986 to 1998 reporting years, the aggregate range of production of 2,4,6-TTBP was between one 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 confidential business information (CBI) in the 2016 CDR (Ref. 6). There have not been any indications of substantial importation of 2,4,6-TTBP into the United States from other countries.

2,4,6-TTBP is predominantly created in chemical reactions as a co-product with a closely related alkylphenol, 2,6 di(tert-butyl)phenol (2,6-DTBP). Neither chemical can be effectively

produced commercially without co-production of the other. The chemical is produced as 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. (Ref. 7, EPA-HQ-OPPT-2019-0080-0537). SI Group notes that while the reaction profile for this trans-alkylation process can be shifted based on temperature of the reaction and ratio of isobutylene to phenol, there is no feasible way to eliminate the production of 2,4,6-TTBP in this reaction chemistry.

Approximately 94% of the 2,4,6-TTBP produced by SI Group is consumed by the company in internal chemical processes as a feedstock for further production of other alkylphenol chemicals. This quantity of the chemical is not sold to other chemical processors; it is used by SI Group itself. 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.

As noted, approximately 94% of the 2,4,6-TTBP produced by SI Group is consumed by the company in internal processes, being used as a feedstock for further production of alkylphenol chemical products. The chemical reactions that use 2,4,6-TTBP as a chemical feedstock consume (destroy) the feedstock during the process, on site within the facility. An additional 4% of 2,4,6-TTBP produced by SI Group, which is in excess of what it requires for chemical feedstock use, is sold as a waste fuel for energy use. This excess material stream containing 2,4,6-TTBP is used as a waste fuel for energy value, which is burned and destroyed during use (Ref. 8). A hydrocarbon, 2,4,6-TTBP has a high energy value and can be sold as a fuel. (The remaining 2% manufactured is used as a fuel additive, discussed later in this document.)

SI Group notes that in the course of normal operations, the manufacturing stream of the

2,4,6-TTBP containing product is as a liquid, eliminating the possibility of fugitive and stack air (dust) emissions and therefore inhalation or exposure to dust (EPA-HQ-OPPT-2018-0314-0018). Based on the low vapor pressure of 2,4,6-TTBP, 6.6×10^{-4} mg Hg, EPA expects minimal chance of exposure by inhalation of vapor from such liquid (Ref. 4). Dermal exposure resulting from manufacturing and processing conditions of use at chemical production facilities is expected to be minimal due to use of specified engineering controls and required personal protective equipment (PPE) identified by the SI Group. For example, at the manufacturer/processing facilities, required 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).

EPA has not identified releases, or potential releases from SI Group's operations, that are posing an exposure to the environment and that can be targeted for reduction with practicable measures under TSCA section 6(a). Similarly, EPA has not identified exposure or potential exposures to workers (or the general population from chemical facility production and use) that can be targeted for reduction with specific measures in this rule. As discussed in Unit II.F., EPA believes that in industrial settings worker protection measures used by employers reduce exposures to the extent practicable and EPA has determined that it is not practicable to regulate worker exposures in this rule through engineering or process controls or PPE requirements.

The production and use of 2,4,6-TTBP as a chemical intermediate has significance for other alkylphenol chemical products beyond the immediate uses of 2,4,6-TTBP itself, as a result of the difficulty in commercially producing these other chemicals without generating or using 2,4,6-TTBP (EPA-HQ-OPPT-2018-0314-0018), EPA did not propose to prohibit the manufacture of 2,4,6-TTBP or processing and use of 2,4,6-TTBP as a chemical intermediate.

During the public comment period, EPA received no specific information addressing these issues as it might related to 2,4,6-TTBP chemical facility operations. EPA therefore is not imposing any additional regulatory controls for the manufacture of 2,4,6-TTBP for any use.

ii. Use for fuel treatment in refineries and fuel facilities.

As noted, of the 2,4,6-TTBP it produces, SI Group itself consumes 94% as a chemical intermediate and sells off another 4% as waste fuel. The remaining 2% of 2,4,6-TTBP produced by SI Group is sold for use in fuel as an antioxidant. 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 (primarily two proprietary chemical mixtures, Isonox® 133 and Ethanox® 4733) (Ref. 7). SI Group also stated that it does not sell, supply, or distribute into commerce 2,4,6-TTBP in a pure (neat) form.

Most of SI Group's antioxidant product goes to use at refineries: after refining, petroleum products such as fuels quickly begin to degrade due to oxidation. A small portion of its sales volume goes to processors of aftermarket fuel treatment products (discussed in the next section). SI Group does not sell its mixtures containing 2,4,6-TTBP directly to consumers. 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. Once blended into fuel, the resultant concentration of 2,4,6-TTBP in fuel is low, in the five to 50 ppm range.

As summarized in the proposed rule, the 2,4,6-TTBP mixture is a widely used antioxidant for jet, automotive, and marine fuels. 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 Aerospace Industries Association identified critical uses of 2,4,6-TTBP as a fuel 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 five and 50 parts per million to reduce gasoline deposits in engines and subsequently reduce emissions (EPA-HQ-OPPT-2016-0734-0006). With respect to use as an antioxidant in the general fuel supply, EPA has received comment supporting 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. 8), notably jet fuel that is supplied to and used by the U.S. military. 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 (Ref. 8 and 9). 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. 9). 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. 8).

Once blended into fuel, the resultant concentration of 2,4,6-TTBP in fuel is low, in the five to 50 ppm range. Treated fuel is distributed through the nation's fuel supply chain (pipeline or vehicle transportation, storage and distribution to end points such as airports, gas stations and military facilities). 2,4,6-TTBP, a hydrocarbon, is destroyed (burned) as the fuel to which it is added is consumed during end use (Ref. 7).

SI Group typically ships its product to refineries in tankers or other large containers. Fugitive air releases of 2,4,6-TTBP are expected to be minimal (due to the low vapor pressure)

from unloading and transfer operations. Releases may possibly occur from spills and leaks from loading operations, but exposure would be addressed at these industrial sites through spill control measures. 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; however, dermal exposure at fuel production facilities is expected to be minimal due to the required use of engineering controls and personal protective equipment (PPE) noted above (EPA-HQ-OPPT-2018-0314-0018). Refineries, fuel distribution and fuel storage facilities also operate with the same or similar engineering controls, PPE (gloves, slickers, boots, respirators, etc.), worker training, leak detection and spill control measures; vapor recovery systems are used during distribution and storage (EPA-HQ-OPPT-2016-0734-0006), similar to procedures used at the manufacturing facility. Once blended into fuel, the resultant concentration of 2,4,6-TTBP in fuel is low, in the five to 50 ppm range, limiting the exposure resulting from handling and spills or leaks.

EPA has not identified releases, or potential releases from the use of 2,4,6-TTBP for fuel treatment at refineries and fuel facilities that can be targeted for reduction with practicable measures under TSCA section 6(a). Similarly, EPA has not identified exposure or potential exposures to workers (or the general population from refinery and fuel facility use) that can be targeted for reduction with practicable measures under TSCA section 6(a). As discussed in Unit II.F., EPA believes that in industrial settings worker protection measures used by employers reduce exposures to the extent practicable and EPA has determined that it is not practicable to regulate worker exposures in this rule through additional engineering or process controls or PPE requirements.

The benefit to continuing the use of existing antioxidants containing 2,4,6-TTBP is a result of the necessity of antioxidants to the nation's fuel supply and the difficulties inherent in removing 2,4,6-TTBP in terms of standards and performance specifications. Given the absence

of and difficulty with identifying and adopting alternatives, EPA did not propose to prohibit the manufacturing, processing, or distribution for use of 2,4,6-TTBP as an additive at refineries and fuel facilities.

iii. Formulations intended for the maintenance or repair of motor vehicles and machinery.

SI Group does not sell its Isonox or Ethanox mixtures directly to consumers. However, a portion (approximately 6%) of the 2,4,6-TTBP mixtures SI Group sells for use in fuels 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, which contain a percentage of Isonox or Ethanox as an antioxidant component, 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).

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. As discussed in Unit III.B, EPA has identified a number of substitute chemicals and substitute products in the Exposure and Use Assessment for this rule for this specific use.

Use of retail fuel additive products which are sold in small containers to mechanics and consumers to service cars, boats, small engines, etc., present opportunities for release and dermal exposure during transfer activities if users are unprotected. Use of the product involves pouring it from the bottle either into a fuel storage container, such as a gas can that is used to refill equipment such as lawn mowers, or it may be poured directly into the fuel tank of the lawn equipment, or car, boat, etc.

EPA believes that the general public does not routinely use PPE while using this product

in these mundane activities, and has not received special training in the handling of the product. No PPE is specified for the use of retail fuel additive products and EPA has no information to indicate that the general public takes any further protective measures when adding this product to fuel containers. Similarly, EPA received no comment that workers who use these fuel additive products, such as mechanics or lawn care workers, routinely use PPE that would provide protection against chemical exposure, such as nitrile gloves, slickers or respirators, while using these products, or have received any special training in the handling of the products or use of PPE with the product. Therefore, this scenario is in contrast to the assumed use of PPE in industrial settings discussed in Unit II.C.1.i and II.C.1.ii. As discussed in Unit II.F., while EPA assumes compliance with other federal requirements, including the OSHA standards and regulations, it would be difficult to support broadly applicable and safe additional measures for each specific activity without a risk evaluation and in the limited time for issuance of this regulation under TSCA section 6(h), but imposing such measures without sufficient analysis could inadvertently result in conflicting or confusing requirements and make it difficult for employers to understand their obligations. Such regulations would not be practicable.

Spillage may occur when the product is being poured into fuel tanks and storage cans. Retail product containers may also leak during transportation, handling, storage and disposal. After use by mechanics and consumers, used retail product 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 K_{oc} (soil organic carbon/water partitioning coefficient).

EPA believes these identified releases and potential releases can be targeted for reduction with practicable measures under TSCA section 6(a). Accordingly, EPA proposed to prohibit the

distribution in commerce of 2,4,6-TTBP in formulations intended for the maintenance or repair of motor vehicles and machinery through a container size restriction. EPA is finalizing these regulations, with changes based on public comments discussed elsewhere in this notice.

iv. Oil/lubricant uses.

The Agency is addressing the use of 2,4,6-TTBP in liquid lubricant and grease additives/antioxidants. Although EPA has not identified 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.

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. 8). 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. No commenters during this rulemaking identified uses without substitutes.

While no releases were specifically identified, EPA believes potential for exposure can be targeted for reduction with practicable measures under TSCA section 6(a). Given this and the general availability of substitutes, EPA is prohibiting the use of 2,4,6-TTBP in oil and lubricant additives.

2. Health Effects, Exposure and TSCA section 6(h)(1) findings.

Exposure information for 2,4,6-TTBP is detailed in EPA's Exposure and Use Assessment (Ref. 4). Based on reasonably available information, 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.

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 the document entitled “Environmental and Human Health Hazards of Five Persistent, Bioaccumulative and Toxic Chemicals (Hazard Summary) (Ref. 10) demonstrate these hazardous endpoints. 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, this hazard characterization is not definitive or comprehensive. Other hazard information on these chemicals may exist in addition to the studies summarized in the Hazard Summary that could alter the hazard characterization. In the 2014 Update to the TSCA Work Plan for Chemical Assessments (Ref. 1), 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).

Taking all this into account, EPA determines that 2,4,6-TTBP meets the TSCA section 6(h)(1)(A) criteria. In addition, EPA determines, in accordance with TSCA section 6(h)(1)(B), that, based on the Exposure and Use Assessment and other reasonably available information, exposure to 2,4,6-TTBP is likely under the conditions of use to the general population, to a potentially exposed or susceptible subpopulation, or to the environment. EPA’s determination is based on the opportunities for exposure to 2,4,6-TTBP including the potential for consumer exposures.

D. EPA’s Proposed Rule Under TSCA Section 6(h) for 2,4,6-TTBP

In the proposed rule (84 FR 36728), EPA proposed to restrict all distribution in commerce of 2,4,6-TTBP and products containing 2,4,6-TTBP in containers with a volume of less than 55 gallons. This was intended to effectively prevent use of 2,4,6-TTBP as a retail fuel

additive or fuel injector cleaner by consumers and small commercial operations. Exposures to humans and the environment would be reduced by eliminating retail uses of 2,4,6-TTBP that have a higher potential for releases. EPA believed that 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 engineering controls designed to mitigate environmental and human health exposures. EPA proposed a 55-gallon threshold based on a belief 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. EPA also sought comment on the optimal container size limit to impose, e.g., for instance, whether a 35-gallon container size would impact industrial use less while also preventing the sale of retail products with 2,4,6-TTBP.

EPA proposed 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 stated its belief that 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, noting that 2,4,6-TTBP is a co-product and byproduct present in other alkylphenols, including other antioxidants that are potential substitutes for it.

EPA also proposed to prohibit all 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. To support this provision, EPA proposed 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.

Regarding the timing of these prohibitions, EPA stated in the proposed rule that at that

time it had no information indicating 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 proposed 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 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 would have to be maintained for a period of three years from the date the record is generated.

E. Public Comments and Other Public Input

The proposed rule provided a 60-day public comment period, with an additional 30-day extension granted. (84 FR 50809, September 26, 2019). The comment period closed on October 28, 2019. EPA received a total of 48 comments, with three commenters sending multiple submissions with attached files, for a total of 58 submissions on the proposal for all the PBT chemicals. This includes the previous request for a comment period extension (EPA-HQ-OPPT-2019-0080-0526). Two commenters submitted confidential business information (CBI) or copyrighted documents with information regarding economic analysis and market trends. Copies of all the non-CBI documents, or redacted versions without CBI are available in the docket for this action. EPA also communicated with companies, and other stakeholders to identify and verify uses of 2,4,6-TTBP. These interactions and comments further informed EPA's understanding of the current status of uses for 2,4,6-TTBP. Public comments and stakeholder meeting summaries are available in the public docket at EPA-HQ-OPPT-2019-0080.

In this preamble, EPA has responded to the major comments relevant to the 2,4,6-TTBP final rule. Of the comment submissions, 12 directly addressed EPA's proposed regulation of 2,4,6-TTBP. EPA's more comprehensive responses to comments related to this final action are in the Response to Comments document (Ref. 5).

F. Activities Not Directly Regulated by this Rule

EPA proposed not to use its TSCA section 6(a) authorities to directly regulate occupational exposures in industrial settings. As explained in the proposed rule, as a matter of policy, EPA assumes compliance with federal and state requirements, such as worker protection standards, unless case-specific facts indicate otherwise. The Occupational Safety and Health Administration (OSHA) has not established a permissible exposure limit (PEL) for 2,4,6-TTBP. However, under section 5(a)(1) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 654(a)(1), each employer has a legal obligation to furnish to each of its employees employment and a place of employment that are free from recognized hazards that are causing or are likely to cause death or serious physical harm. The OSHA Hazard Communication Standard at 29 CFR 1910.1200 requires chemical manufacturers and importers to classify the hazards of chemicals they produce or 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. The OSHA standard at 29 CFR 1910.134(a)(1) requires the use of feasible engineering controls to prevent atmospheric contamination by harmful substances. Other provisions of 29 CFR 1910.134 require the use of respirators where effective engineering controls are not feasible and spell out details of the required respiratory protection program. The OSHA standard at 29 CFR 1910.132(a) requires the use of personal protective equipment (PPE) when workers are exposed to chemical and other hazards; 29 CFR 1910.133 requires the use of eye and face protection when employees are exposed to hazards from, among other things, liquid chemicals; and 29 CFR 1910.138 requires the use of PPE to protect employees' hands from, among other hazards, skin absorption of harmful substances. The provisions of 29 CFR 1910.132(d) and (f) address hazard assessment, PPE selection, and training with respect to PPE required under 29 CFR 1910.133, 29 CFR 1910.138, and certain other standards. EPA assumes that employers will require, and workers will use, appropriate PPE consistent with OSHA standards, taking into account employer-based assessments, in a manner sufficient to prevent

occupational exposures that are capable of causing injury.

EPA assumes compliance with other federal requirements, including OSHA standards and regulations. EPA does not read TSCA section 6(h)(4) to direct EPA to adopt potentially redundant or conflicting requirements. Not only would it be difficult to support broadly applicable and safe additional measures for each specific activity without a risk evaluation and in the limited time for issuance of this regulation under TSCA section 6(h), but imposing such measures without sufficient analysis could inadvertently result in conflicting or confusing requirements and make it difficult for employers to understand their obligations. Such regulations would not be practicable. Rather, where EPA has identified worker exposures and available substitutes, EPA is finalizing measures to reduce those exposures, e.g., by prohibiting the sale of 2,4,6-TTBP in the small containers that contribute to potential exposures for workers in smaller commercial establishments, as well as to consumers. While some commenters agreed with EPA's approach, others thought that EPA should establish worker protection requirements for those uses not regulated under the final rule. EPA disagrees with those commenters who thought that EPA should establish specific worker protection requirements. Information provided to EPA before and during the public comment period on the proposed rule indicates that employers are using engineering and process controls and providing appropriate personal protective equipment (PPE) to their employees consistent with these requirements. EPA received no information on 2,4,6-TTBP to the contrary. Further, EPA has not conducted a risk evaluation on 2,4,6-TTBP or any of the five PBT chemicals. Without a risk evaluation and given the time allotted for this rulemaking, EPA cannot identify additional engineering or process controls or PPE requirements that would be appropriate to each chemical-specific circumstance. For these reasons, EPA has determined that it is not practicable to regulate worker exposures in this rule through engineering or process controls or PPE requirements.

Under a newly created general provisions section at 40 CFR 751.401(b), EPA is listing three activities to which the prohibitions and restrictions under the PBT regulations at subpart E

of 40 CFR 751 do not apply in general, unless otherwise specified in the individual chemical regulations.

The first activity is distribution in commerce of any chemical substance, or products and articles that contain the chemical substance, that has previously been sold or supplied to an end user, i.e., an individual or entity that purchased or acquired the finished good for purposes other than resale. An example of this is a consumer who resells a product they no longer intend to use through the internet or donates a used article to charity. EPA does not believe it practicable to attempt to regulate such activity, given the small quantities involved in end user resale relative to overall sales, the multitude of potentially affected persons, the difficulties of making consumers and other end users aware of potential compliance obligations, and the difficulties the Agency would have enforcing such resale prohibitions on the general public and other end users.

The second activity is disposal of any chemical substance, or products and articles that contain the chemical substance, including importation, processing and distribution-in-commerce for purposes of disposal. EPA explained in the proposed rule the basis of its determination that, as a general matter, disposal is adequately regulated under the authority of the Resource Conservation and Recovery Act (RCRA) which governs the disposal of hazardous and non-hazardous wastes, and it is not practicable to impose additional requirements under TSCA on the disposal of the PBT chemicals in the proposed rule. (84 FR 36744.) EPA received a number of comments on this aspect of its proposal. Some commenters agreed with EPA's proposed determination that it is not practicable to regulate disposal, while others disagreed. Comments specific to other PBT chemicals, are addressed in those chemicals' final rule notices. More information on the comments received and EPA's responses can be found in the Response to Comments document (Ref. 5). One commenter noted that, while EPA proposed to not regulate disposal of the PBT chemicals under TSCA, the effect of EPA's proposed prohibition on manufacturing, processing, and distribution in commerce would prohibit the processing and distribution in commerce of the PBTs and articles and products containing the PBT chemicals for

disposal. EPA did not intend such an effect, and is including a general provision in the final regulatory text in the new section 40 CFR 751.401(b) to address disposal of any chemical substance, or products and articles that contain the chemical substance, including importation, processing and distribution in commerce for purposes of disposal. In regard to the disposal of 2,4,6-TTBP, use of the chemical as a feedstock, use as a waste fuel, and use as a fuel additive all result in the destruction of the chemical through combustion. This final rule will ultimately eliminate releases from the use of 2,4,6-TTBP-containing retail fuel additive products which are sold in small containers, such as spillage which may occur when the product is poured into fuel tanks or fuel cans, as well as releases from the disposal of used small containers that held those products in the municipal solid waste stream.

EPA also received comments regarding the use of PBT chemicals in research and development and lab use. The final activity addressed under newly established 40 CFR 751.401(b) is the manufacturing, processing, distribution in commerce and use of any chemical substance, or products and articles that contain the chemical substance, for research and development, as defined in new 40 CFR 751.403. *Research and Development* is defined in new 40 CFR 751.403 to mean laboratory and research use only for purposes of scientific experimentation or analysis, or chemical research on, or analysis of, the chemical substance, including methods for disposal, but not for research or analysis for the development of a new product, or refinement of an existing product that contains the chemical substance. This will allow, for example, for samples of environmental media containing PBTs, such as contaminated soil and water, to be collected, packaged and shipped to a laboratory for analysis. Laboratories also must obtain reference standards containing PBTs to calibrate their equipment, otherwise they may not be able to accurately quantify these chemical substances in samples being analyzed. However, research to develop new products that use PBTs subject to subpart E of 40 CFR 751, or the refinement of existing uses of those chemicals, is not included in this definition, and those activities remain potentially subject to the chemical specific provisions in subpart E of

40 CFR 751. EPA believes it is not practicable to limit research and development activity as defined, given the critical importance of this activity to the detection, quantification and control of these chemical substances.

III. Provisions of This Final Rule

A. Scope and Applicability

EPA carefully considered all public comments related to the proposal. This rule finalizes EPA's proposal to prohibit all distribution in commerce of 2,4,6-TTBP and products containing 2,4,6-TTBP in small containers, and prohibit all 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, with changes being made from the proposal to the container size limit, the concentration limit for 2,4,6-TTBP, and the compliance date for the prohibitions.

1. Container size.

In the proposed rule, EPA solicited comment from the public on the optimal container size limit to impose: specifically, whether a 35-gallon container size would impact industrial use less than a 55-gallon container size while also preventing the sale of retail products with 2,4,6-TTBP. Two comments were received on this issue. SI Group recommended EPA adopt a 35-gallon size limit, commenting that: "Industrial users of chemicals occasionally ship materials in the non-standard 55-gallon drum size. This slight decrease in container size will not impact the intent or outcome of the original proposal – consumer access to 2,4,6-TTBP will be restricted" (EPA-HQ-OPPT-2019-0080-0537). API stated that: "A 35-gallon container size would be more appropriate, because it would impact industrial use less while also preventing the commercial and retail sale of products with 2,4,6-TTBP." Based on this information EPA is adopting a 35-gallon container size limit in the final regulation, which will still reduce the exposure to consumers to the same extent (EPA-HQ-OPPT-2019-0080-0539).

2. Concentration limit for 2,4,6-TTBP.

EPA proposed 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 for the purpose of distinguishing 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, noting that 2,4,6-TTBP is a co-product and byproduct present in other alkylphenols, including other antioxidants that are potential substitutes for it.

In response to EPA's concentration proposal to distinguish between products that contain 2,4,6-TTBP as a functional additive and those with low concentrations as a byproduct or impurity, SI Group (EPA-HQ-OPPT-2019-0080-0537) provided more detailed information:

- Impurity levels of 2,4,6-TTBP are typically very low, but may range up to 0.3%.

SI Group's engineering staff recently conducted modeling studies of its processes and the output suggests the company is unable to decrease impurity levels of 2,4,6-TTBP with current manufacturing operations.

- These models indicate there is no way to achieve a zero residual value for 2,4,6-TTBP as an impurity due to numerous factors.

- The hindered phenolic antioxidant 2,6-di-tert-4-secbutylphenol contains an average 2,4,6-TTBP impurity concentration of 0.3%, the highest in SI's portfolio. This substance is the predominant antioxidant technology utilized in automotive brake fluid in the United States.

Given these detailed comments from the manufacturer of 2,4,6-TTBP, EPA believes adopting a 0.3% concentration limit in the final regulation will better achieve the distinction between functional additives and impurities EPA seeks to establish, and thereby avoid unintended and unassessed impacts on other alkylphenols used in products such as brake fluid. For clarity, EPA is stating this concentration limit within the prohibitions for 2,4,6-TTBP under 40 CFR 751.409(a) in the final regulation; EPA believes this will reduce opportunity for the concentration limit to be overlooked by readers of the regulation.

3. Compliance date for the prohibitions.

The proposed rule did not delay the compliance date beyond the rule's effective date; the

processing and distribution bans would come into effect 60 days after publication of the final rule notice. EPA stated in the proposed rule that at that time it had 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. The phrases “as soon as practicable” and “reasonable transition period” as used in TSCA section 6(d)(1) are undefined, and the legislative history on TSCA section 6(d) is limited. Given the ambiguity in the statute, for purposes of this expedited rulemaking, EPA presumed a 60-day compliance date was “as soon as practicable,” unless there was support for a lengthier period of time on the basis of reasonably available information, such as information submitted in comments on the Exposure and Use Assessment or in stakeholder dialogues. Such a presumption is consistent with the general effective date often adopted for rulemakings and ensures the compliance schedule is “as soon as practicable,” particularly in the context of the TSCA section 6(h) rules for chemicals identified as persistent, bioaccumulative and toxic, and given the expedited timeframe for issuing a TSCA section 6(h) proposed rule did not allow time for collection and assessment of new information separate from the comment opportunities during the development of and in response to the proposed rule. Such presumption also allows for submission of information from the sources most likely to have the information that will affect an EPA determination on whether or how best to adjust the compliance deadline to ensure that the chosen final compliance deadline is both “as soon as practicable” and provides a “reasonable transition period.”

On this issue, SI Group provided comment and recommended a 5-year delay in implementation, commenting that “...there could be significant implications to the current aftermarket fuel additives and oil/lubricant value chains with enactment of this rule and the very short time for implementation. Complying with this rule will likely require a considerable amount of time given the requirements of Federal, State, standardization bodies, Original Equipment Manufacturers (OEMs), and brand holders in reformulating and requalifying products

as well as managing current inventory” (EPA-HQ-OPPT-2019-0080-0537). EPA also received comment on this issue from Gold Eagle Company, which identifies itself as the maker of the #1 selling fuel stabilizer in the United States, and produces several brands of fuel stabilizer under various brand names; it commented that “over 100 OEMs [original equipment manufacturers] endorse this fuel stabilizer in their owners manual and/or sell the product in their dealerships, or buy a private label product from Gold Eagle.” (EPA-HQ-OPPT-2019-0080-0533). It states that 2,4,6-TTBP is an essential component of its fuel stabilizers; that it has used the same antioxidant chemistry since 1988; that evaluated alternative antioxidant chemistries do not provide equivalent fuel stability; and that “even if an effective substitute could be found, ASTM approval would likely take about six years.” (EPA-HQ-OPPT-2019-0080-0533). Gold Eagle comments that an alternative antioxidant must be evaluated using ASTM D525 Fuel Stability test referenced in ASTM D4814, Standard Specification for Automotive Spark-Ignition Engine Fuel, used to test refinery gasoline for compliance to fuel specifications for automotive use.

Overall, EPA considers these comments to have considerable merit. EPA does not agree with Gold Eagle on the availability of substitute antioxidants for use in fuel additive products; EPA has identified alternative fuel additive products without 2,4,6-TTBP as an active ingredient that are available and can be substituted for fuel additive products with 2,4,6-TTBP that will be removed from the market (Ref. 3). EPA therefore concludes that it is possible for Gold Eagle to reformulate its products to remove the 2,4,6-TTBP component and replace it with other antioxidants. However, EPA does agree with the assertion that it will take time to develop new formulations for various product lines, test them and obtain required approvals. Additionally, as a predominant supplier, Gold Eagle has a complex supply network and relationships with many other companies that supply its product, sell it under other brand names, or endorse its use in their equipment; EPA acknowledges that Gold Eagle’s modifications to the formulation of its product line may require it to engage with these customers and business partners to assure them that its products provide similar performance, a process that will also take time. EPA also agrees

with the comment that managing existing inventory will require time. Like other basic automotive supplies, such as engine oil and windshield wiper fluid, aftermarket fuel additive products are widely available nationally at varied retail outlets, such as auto parts stores, hardware stores, general retail outlets, gas stations and convenience stores. Unopened product is stable and may be stored for several years in the distribution system or on a store shelf before final sale to customers. Products that are unsold as of the compliance date would have to be pulled from the shelf and disposed of. A sudden removal of product from the shelves might also create temporary or spot shortages of fuel additives. Gold Eagle will also incur costs, if it is required to cease sales of its fuel additive products because it can replace them with reformulated products without 2,4,6-TTBP before the compliance date. If its products are off the market for several years, sales losses could be significant.

In consideration of these comments and the issues that they raise, especially in regard to potential unquantified potential costs and market disruption with provision of these needed products, EPA does not believe it is practicable to implement this prohibition without a delay in the compliance date. However, Gold Eagle expresses some uncertainty about its six-year estimate and does not establish the reasoned basis to support that a six-year estimate is "as soon as practicable," compared to the five-year period estimated by SI Group. Therefore, EPA is delaying the compliance date for the prohibition on distribution of 2,4,6-TTBP and products containing 2,4,6-TTBP in any container with a volume of less than 35 gallons for any use, as well as processing and distribution in commerce of 2,4,6-TTBP for use in oil and lubricant additives and of 2,4,6-TTBP-containing oil and lubricant additives, for five years, to give the producers of fuel additives containing 2,4,6-TTBP sufficient time to reformulate their products, requalify them with the necessary entities and clear non-compliant inventory from their distribution chains.

In this final rule, EPA is also establishing a new subpart E of 40 CFR 751 for TSCA section 6(h) PBT chemical provisions, including general provisions at 40 CFR 751.401 as

discussed in Unit II.F. of this document, and definitions applicable to subpart E at 40 CFR 751.403. Terms defined in 40 CFR 751.403 include *article*, *product*, and *research and development*. These definitions are intended to respond to comments requesting additional clarity on the regulatory provisions. (Note the definitions of article and product are not used in 40 CFR 751.409.)

EPA is requiring that 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, related to compliance with the prohibitions and restrictions in this regulation. These records must be maintained for a period of three years from the date the record is generated. EPA revised this language slightly from the proposal to improve clarity.

B. TSCA Section 6(c)(2) Considerations

1. Health effects, exposure, and environmental effects.

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 the Hazard Summary (Ref. 10) demonstrate these hazardous endpoints. These hazard statements are not based on a systematic review of the available literature and information may exist that could refine the hazard characterization.

Additional information about 2,4,6-TTBP health effects, use, and exposure is in Unit II.C. and is further detailed in the Hazard Summary (Ref. 10), and information on use and exposure is also in Unit II.C. and is further detailed in EPA's Exposure and Use Assessment (Ref. 4).

2. The value of the chemical substance or mixture for various uses.

2,4,6-TTBP has value as a chemical intermediate in the production of dialkylphenol chemicals. With respect to use as an antioxidant in the general fuel supply, 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. Antioxidants are also an important component in retail fuel additives and fuel injector cleaners, which are used for engines maintenance. Similarly, antioxidants are also used in oil and lubricants to prevent degradation of the product.

3. The reasonably ascertainable economic consequences of the rule.

i. Overview of cost methodology. EPA has evaluated the potential costs of the final rule and primary alternative regulatory actions for this chemical. Costs of the final rule were estimated based on the assumption that under regulatory limitations on 2,4,6-TTBP, manufactures and processors that use the regulated chemical would switch to available alternative chemicals to manufacture the product, or to products that do not contain the chemical. For 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 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, 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.

ii. Estimated costs of this final rule. Total quantified annualized industry costs for the final rule is \$5.6 million at 3% discount rate and \$4.9 million at 7% discount rate annualized over 25 years. Total annualized Agency costs associated with implementation of the final rule were based on EPA's best judgment and experience with other similar rules. For the final regulatory action, EPA estimates it will require 0.5 FTE at \$77,600 per year (Ref. 3).

4. Benefits

As discussed in Unit II.A., 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. 2,4,6-TTBP is persistent and bioaccumulative, and has been associated with liver toxicity and reproductive and developmental effects in mammals. Under the final regulatory action, 2,4,6-TTBP and products containing 2,4,6-TTBP at concentrations above 0.3% would be prohibited for distribution in containers less than 35 gallons and would be prohibited in processing and distribution for use as an additive to oil/lubricants. Therefore, the rule is expected to reduce the exposure to humans and the environment, by reducing the potential for consumer exposures to 2,4,6-TTBP and potential occupational exposure in certain industries, where workers are unprotected, as well as potential releases to the environment from consumer and small commercial operations use.

5. Cost effectiveness, and effect on national economy, small business, and technological innovation.

With respect to the cost effectiveness of the final regulatory action and the primary alternative regulatory action, EPA is unable to perform a traditional cost-effectiveness analysis of the actions and alternatives for the PBT chemicals. As discussed in the proposed rule, 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 final and alternative regulatory actions. However, by evaluating the practicability of the final 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 final and alternative regulatory actions.

EPA considered the anticipated effect of this rule on the national economy and concluded that this rule is highly unlikely to have any measurable effect on the national economy (Ref. 3). EPA analyzed the expected impacts on small business and found that no small entities are expected to experience impacts of more than 1% of revenues (Ref. 3). Finally, EPA has determined that this rule is unlikely to have significant impacts on technological innovation.

6. Consideration of alternatives.

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. 11). 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.

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. 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 exist for retail fuel stabilizer products and 15 product substitutes exist for retail 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).

C. TSCA Section 26(h) Considerations

In accordance with TSCA section 26(h) and taking into account the requirements of TSCA section 6(h), 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 determination that human and environmental exposures are likely with 2,4,6-TTBP in the Exposure and Use Assessment (Ref. 4) discussed in Unit II.A.2, 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 subjected to independent verification or peer review is adequate to justify their use, collectively, is 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 document, are in the public docket for this action (EPA-HQ-OPPT-2019-0080). In addition, in accordance with TSCA section 26(i) and taking into account the requirements of TSCA section 6(h), EPA has made scientific decisions based on the weight of the scientific evidence.

IV. References

The following is a list 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. All records in docket EPA-HQ-OPPT-2019-0080 are part of the record for this rulemaking. 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/assessingand-managing-chemicals-under-tsca/tsca-work-plan-chemical-assessments-2014-update>. Accessed March 1, 2019.
2. EPA. TSCA Work Plan Chemicals: Methods Document.
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 Regulation of 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP) Under TSCA Section 6(h). December 2020.
4. EPA. Exposure and Use Assessment of Five Persistent, Bioaccumulative, and Toxic Chemicals. December 2020.
5. EPA. Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h); Response to Public Comments. December 2020.
6. EPA. Public Database 2016 Chemical Data Reporting. Washington, DC: US Environmental Protection Agency, Office of Pollution Prevention and Toxics.
7. EPA. Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: 2,4,6-TTBP. August 2017. (EPA-HQ-OPPT-2016-0739-0003).
8. 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.
9. EPA. Afton Chemical conference call with U.S. EPA, regarding 2,4,6-TTBP chemical uses. July 28, 2017.
10. EPA. Environmental and Human Health Hazards of Five Persistent, Bioaccumulative and Toxic Chemicals. December 2020.
11. EPA. Persistence, Bioaccumulation, Environmental Hazard and Human Health Hazard Rating for Alternatives to PBT Chemicals Proposed for Regulation. April 2019.
12. Keweenaw 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.

13. Harper, Barbara and Ranco, Darren, in collaboration with the Maine Tribes. Wabanaki Traditional Cultural Lifeways Exposure Scenario. July 9, 2009.

V. Statutory and Executive Order Reviews

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

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

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Order 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket for this action as required by section 6(a)(3)(E) of Executive Order 12866.

EPA prepared an economic analysis of the potential costs and benefits associated with this action. A copy of this economic analysis *Economic Analysis for Regulation of 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP) Under TSCA Section 6(h)* (Ref. 3) is in the docket and is briefly summarized in Unit III.B.3.

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

This action is considered a regulatory action under Executive Order 13771 (82 FR 9339, February 3, 2017). Details on the estimated costs of this final rule can be found in the Economic Analysis (Ref. 3), which is briefly summarized in Unit III.B.3.

C. Paperwork Reduction Act (PRA)

The information collection activities in this rule have been submitted for approval to the Office of Management and Budget (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 2599.02 and OMB Control No. 2070-0213. A copy of the ICR is available in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

Respondents/affected entities: Entities potentially affected by paperwork requirements of this final rule include one manufacturer and nine processors.

Respondent's obligation to respond: Mandatory.

Estimated number of respondents: 10

Frequency of response: On occasion.

Total estimated burden: Five hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$393(per year), includes \$0 annualized capital or operation & maintenance costs.

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 EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the *Federal Register* and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

D. Regulatory Flexibility Act (RFA)

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 process, or distribute-in-commerce 2,4,6-TTBP. In total, three small businesses are expected to be affected by the rule. Of the small entities assessed, none (0%) are expected to incur impacts of 1% (or greater) of their revenue. Because only three small businesses are directly impacted and impacts are less than 1% for all small entities, EPA presumes no significant economic impact on a substantial number of small entities (no SISNOSE). Details of this analysis are presented in the Economic Analysis (Ref. 3).

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 would not significantly or uniquely affect small governments. The final rule is not expected to result in expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100 million or more (when adjusted annually for inflation) in any one year. Accordingly, this final rule is not subject to the requirements of sections 202, 203, or 205 of UMRA. The total quantified annualized social costs for this final rule under are approximately \$5.6 million at a 3% discount rate and \$4.9 million at a 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 because it is not expected to 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 as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). Thus, Executive Order 13132 does not apply to this action.

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

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

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 the 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 (Ref. 12) and Maine Tribes (Ref. 13).

H. Executive Order 13045: Protection of Children from Environmental Health 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. Although the action is not subject to Executive Order 13045, the Agency considered the risks to infants and children under EPA's Policy on Evaluating Health Risks to Children. EPA did not perform a risk assessment or risk evaluation of 2,4,6-TTBP, however available data indicate the potential for reproductive and developmental effects from 2,4,6-TTBP. More information can be found in the Exposure and Use Assessment (Ref. 4) and the "Environmental and Human Health Hazards of Five Persistent, Bioaccumulative and Toxic Chemicals" (Ref. 10). This regulation will reduce the exposure to 2,4,6-TTBP for the general population and for susceptible subpopulations such as workers and children.

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

This action is not a "significant energy action" as defined in 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 and has not otherwise been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. While this action regulates 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 any technical standards. Therefore, NTTAA section 12(d), 15 U.S.C. 272 *note*, does not apply to this action.

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

Populations and Low-Income Populations

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.

L. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 751

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

Andrew Wheeler,

Administrator.

Therefore, for the reasons stated in the preamble, 40 CFR part 751 is amended as follows:

PART 751—REGULATION OF CERTAIN CHEMICAL SUBSTANCES AND MIXTURES UNDER SECTION 6 OF THE TOXIC SUBSTANCES CONTROL ACT

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

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

2. Add and reserve subpart D.

3. Add subpart E, consisting of §§ 751.401 through 751.413, to read as follows:

Subpart E—Persistent, Bioaccumulative, and Toxic Chemicals

Sec.

751.401 General.

751.403 Definitions.

751.405 [Reserved].

751.407 [Reserved].

751.409 2,4,6-TTBP.

751.411 [Reserved].

751.413 [Reserved].

§ 751.401 General.

(a) This subpart establishes prohibitions and restrictions on the manufacturing, processing, and distribution in commerce of persistent, bioaccumulative, and toxic chemicals in accordance with TSCA section 6(h), 15 U.S.C 2605(h).

(b) Unless otherwise specified in this subpart, prohibitions and restrictions of this subpart do not apply to the following activities:

(1) Distribution in commerce of any chemical substance, or any product or article that contains the chemical substance, that has previously been sold or supplied to an end user, i.e., any person that purchased or acquired the finished good for purposes other than resale. An example of an end user is a consumer who resells a product they no longer intend to use or who donates an article to charity.

(2) Disposal of any chemical substance, or any product or article that contains the chemical substance, as well as importation, processing and distribution in commerce of any

chemical substance or any product or article that contains the chemical substance for purposes of disposal.

(3) Manufacturing, processing, distribution in commerce, and use of any chemical substance, or any product or article that contains the chemical substance, for research and development, as defined in § 751.403.

§ 751.403 Definitions.

The definitions in subpart A of this part apply to this subpart unless otherwise specified in this section.

2,4,6-TTBP means the chemical substance 2,4,6-tris(tert-butyl)phenol (CASRN 732-26-3).

2,4,6-TTBP oil and lubricant additives means any 2,4,6-TTBP-containing 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. 2,4,6-TTBP oil and lubricant additive does not include hydraulic fluid and other oils whose primary purpose is not friction reduction.

Article means a manufactured item:

- (1) Which is formed to a specific shape or design during manufacture,
- (2) Which has end use function(s) dependent in whole or in part upon its shape or design during end use, and
- (3) Which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.

Product means the chemical substance, a mixture containing the chemical substance, or any object that contains the chemical substance or mixture containing the chemical substance

that is not an article.

Research and Development means laboratory and research use only for purposes of scientific experimentation or analysis, or chemical research on, or analysis of, the chemical substance, including methods for disposal, but not for research or analysis for the development of a new product, or refinement of an existing product that contains the chemical substance.

§ 751.405 Reserved]

§ 751.407 Reserved]

§ 751.409 2,4,6-TTBP.

(a) *Prohibitions.* (1) After January 6, 2026, all persons are prohibited from all distribution in commerce of 2,4,6-TTBP, at any concentration above 0.3 percent by weight, in containers with a volume less than 35 gallons.

(2) After January 6, 2026, all persons are prohibited from all processing and distribution in commerce of 2,4,6-TTBP oil and lubricant additives at any concentration above 0.3 percent by weight.

(b) *Recordkeeping.* After January 6, 2026, distributors of 2,4,6-TTBP must maintain ordinary business records, such as invoices and bills-of-lading, related to 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 [Reserved]

§ 751.413 [Reserved]

[FR Doc. 2020-28690 Filed: 1/5/2021 8:45 am; Publication Date: 1/6/2021]