



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 751

[EPA-HQ-OPPT-2019-0080; FRL-10018-89]

RIN 2070-AK60

### **Pentachlorothiophenol (PCTP); 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 is finalizing a rule under the Toxic Substances Control Act (TSCA) to address its obligations under TSCA for pentachlorothiophenol (PCTP) (CASRN 133-49-3), which EPA has determined meets the requirements for expedited action under TSCA. This final rule prohibits all manufacturing (including import), processing, and distribution in commerce of PCTP and PCTP-containing products or articles for any use, unless PCTP concentrations are at or below 1% by weight. This rule will result in lower amounts of PCTP being manufactured, processed, and distributed, which will impact the amount that will be available for use or disposal, thus reducing the exposures to humans and the environment.

**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. eastern standard time 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:* Brooke Porter, Existing Chemical Management Division, Office of Pollution Prevention and Toxics, (7404T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-6388; email address: [porter.brooke@epa.gov](mailto:porter.brooke@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](mailto: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 pentachlorothiophenol (PCTP) or products or articles that contain PCTP, especially rubber products. 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:

- Sporting and Athletic Goods Manufacturing (NAICS Code 339920);
- Sporting and Recreational Goods and Supplies Merchant Wholesale (NAICS Code 423910);
- Sporting Goods Stores (NAICS Code 451110);
- All Other Rubber Product Manufacturing (NAICS Code 326299).

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. PCTP (CASRN 87-86-5), primarily found as an impurity in the zinc salt of PCTP, is one such chemical substance. 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). 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 each of the five PBT chemicals in separate final actions. This final rule prohibits the manufacture (including import), processing, and distribution

in commerce of PCTP and products and articles containing PCTP, unless PCTP concentrations are at or below 1% by weight. Specifically, all persons are prohibited from all manufacturing and processing of PCTP or PCTP-containing products or articles, unless PCTP concentrations are at or below 1% by weight after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and all persons are prohibited from all distribution in commerce of PCTP or PCTP-containing products or articles, unless PCTP concentrations are at or below 1% by weight after January 6, 2022. In addition, after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], persons manufacturing, processing, and distributing in commerce PCTP and articles and products containing PCTP must maintain, for three years from the date the record is generated, ordinary business records related to compliance with the prohibitions and restrictions that include the name of the purchaser and list the products or articles. 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, including PCTP, "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." As required by the statute, the Agency is finalizing this rule to reduce exposures to PCTP to the extent practicable.

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

EPA has evaluated the potential costs of these restrictions and prohibitions and the associated reporting and recordkeeping requirements. The "Economic Analysis for Regulation of Pentachlorothiophenol (PCTP) 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 PCTP. As discussed in more detail in Unit II.A., EPA did not

perform a risk evaluation for PCTP, nor did EPA develop quantitative risk estimates. Therefore, the Economic Analysis (Ref. 3) qualitatively discusses the benefits of reducing the exposure under the final rule for PCTP, as summarized in Unit III.B.2.

- *Costs.* Total quantified annualized social costs for this final rule are approximately \$108,000 (at both 3% and 7% discount rates). 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 final rule will impact approximately one small business of which the one small entity is not expected to incur impacts of 1% of their revenue or greater.

- *Environmental Justice.* This final 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 final rule will 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. 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 final rule will reduce the exposure to PCTP that could occur from activities now prohibited under this final rule 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. 5).

## II. Background

### A. History of this Rulemaking

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 PBT 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. Although EPA proposed regulatory actions on each chemical substance in one proposal, in response to public comments (EPA-HQ-OPPT-2019-0080-0544), (EPA-HQ-OPPT-2019-0080-0553), (EPA-HQ-OPPT-2019-0080-0556), (EPA-HQ-OPPT-2019-0080-0562) 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 which is available in the docket (Ref. 4). The details of the proposal for PCTP are described in more detail in Unit II.D.

Under TSCA section 6(h)(1)(A), the 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 (e.g., 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 PCTP 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 PCTP. As described in the proposed rule, EPA conducted a review of available literature with respect to PCTP 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. 5). Based on this review, which was subject to peer review and public comment, EPA proposed to find that exposure to PCTP 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 final 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. 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 (Ref. 4) 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 (Ref. 4). 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 all of 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, manufacturing, processing, and distribution in commerce activities that are not specifically excluded are prohibited. The specified excluded activities are those which EPA determined were not appropriate to regulate under TSCA section 6(h)(4) standard. Consistently, based on the Exposure and Use Assessment, activities associated with PCTP are that are no longer occurring are addressed by this rule and thus the prohibitions adopted in this rule reduce 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 final rule is limited to implementation of TSCA section 6(h) and is not relevant to any other action under TSCA section 6 or other TSCA 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 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, 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 can be found in the Response to Comments document for this rulemaking (Ref. 4).

## *3. EPA did not conduct a risk evaluation or 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 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 PCTP. A number of commenters asserted 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 stated that EPA would have had enough time to conduct a risk evaluation and issue a proposed rule by the statutory deadline.

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 evaluations to determine risks are now addressed through the TSCA section 6(b) risk evaluation process and 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(1)(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.” 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. More discussion on the issue raised is in the Response to Comments document (Ref. 4).

#### *4. Replacement parts and articles.*

In the preamble to the proposed rule, EPA explained that it did not read provisions of TSCA that conflict with TSCA section 6(h) to apply to TSCA section 6(h) rules. Specifically, TSCA sections 6(c)(2)(D) and (E) require a risk finding pursuant to a TSCA section 6(b) risk evaluation to regulate replacement parts and articles. Yet, TSCA section 6(h) neither compels nor contemplates a risk evaluation to precede or support the compelled regulatory action to “address the risks...” and “reduce exposures to the substance to the extent practicable”. TSCA section 6(h)(2) makes clear no risk evaluation is required, and the timing required for conducting a risk evaluation is not consistent with the timing compelled for issuance of a proposed rule under TSCA section 6(h). Moreover, even assuming a prior risk assessment might allow a risk determination under the TSCA section 6(h)(4) “address risk” standard, such assessment would still not satisfy the requirement in TSCA section 6(c)(2)(D) and (E) for a risk finding pursuant to a TSCA section 6(b) risk evaluation. Because of the clear conflict between these provisions, EPA determined that those provisions of TSCA section 6(c) that assume the existence of a TSCA section 6(b) risk evaluation do not apply in the context of this TSCA section 6(h) rulemaking. Instead, EPA resolves this conflict in these provisions by taking into account the TSCA section 6(c) considerations in its determinations as to what measures “reduce exposure to the substance to the extent practicable”.

Commenters contended that TSCA section 6(c)(2)(D) and (E) bar a TSCA section 6(h) rule in the absence of a risk evaluation, representing Congress’s recognition of the special burdens associated with regulating replacement parts and articles and the difficulty importers face in knowing what chemicals are present in the articles they import. As noted earlier in this Unit and further discussed in the Response to Comment document, while EPA determined that provisions of TSCA section 6(c)(2)(D) and (E) do not apply because they conflict with the

requirements of TSCA section 6(h), EPA interpreted the “practicability” standard in TSCA section 6(h)(4) to reasonably contemplate the considerations embodied by TSCA section 6(c)(2)(D) and (E). As a result, EPA disagrees with any suggestions that the clear conflict between Congress’ mandates in TSCA section 6(h) and TSCA section 6(c)(2)(D) and (E) must be read to bar regulation of replacement parts and articles made with chemicals that Congress believed were worthy of expedited action under TSCA section 6(h) and in the absence of a risk evaluation. The statute does not clearly communicate that outcome. Instead, Congress left ambiguous how best to address the conflict in these provisions, and EPA’s approach for taking into consideration the TSCA section 6(c)(2)(D) and (E) concepts in its TSCA section 6(h)(4) “practicability” determinations is a reasonable approach. In addition, with respect to comments that TSCA section 6(c)(2)(D) and (E) were intended to address Congress’s concerns regarding burdens associated with regulation of replacement parts and articles, EPA agrees that these concerns are relevant and takes them into account in its implementation of the TSCA section 6(h)(4) mandate, with respect to the circumstances for each chemical. Finally, EPA does not believe that Congress intended, through the article provisions incorporated into the TSCA amendments, to absolve importers of the duty to know what they are importing. Importers can and should take steps to determine whether the articles they are importing contain chemicals that are prohibited or restricted. Therefore, as discussed earlier in this Unit and in the Response to Comment document, EPA is continuing to interpret TSCA sections 6(c)(2)(D) and 6(c)(2)(E) to be inapplicable to this rulemaking. While this interpretation has not changed, EPA has reviewed the practicability of regulating replacement parts and articles in accordance with the statutory directive in TSCA section 6(h)(4) to reduce exposures to the PBT chemicals to the extent practicable. This is discussed further in Unit III.A.

### *C. PCTP Overview, Health Effects, and Exposure*

Historically, PCTP was used in rubber manufacturing as a peptizer, or a chemical that makes rubber more amenable to processing. As described in the proposed rule, there are few data

on end-use products and articles that contain PCTP. For years, PCTP was produced in the United States, but domestic manufacture appears to have ceased (Ref. 6). Although it is likely that PCTP is no longer used as a peptizer, it can be found as an impurity in the zinc salt of PCTP (zinc PCTP) (CASRN 117-97-5) after zinc PCTP manufacturing (Ref. 7). As shown by a number of patents, zinc PCTP can be used as a peptizer in rubber manufacturing and as an ingredient in the rubber core of golf balls to enhance certain performance characteristics of the ball, such as spin, rebound, and distance (Ref. 8, 9, and 10). EPA considers the presence of PCTP in rubber during manufacturing, whether as a peptizer or an impurity, to be processing under TSCA. Zinc PCTP is imported into the United States, with approximately 65,000 lbs. imported in 2017 (Ref. 3). EPA believes that some or all of the zinc PCTP could contain PCTP. The importation of PCTP, including as an impurity with zinc PCTP, is considered manufacturing under TSCA.

There is likely exposure to the general population, workers, and the environment, including water releases from process water and from cleaning the processing area and equipment, and worker exposure during unloading and transfer of the chemical. Women of childbearing age exposed in the workplace may transfer PCTP to infants via breastmilk. Exposure information for PCTP is detailed in EPA's Exposure and Use Assessment (Ref. 5) and the proposed rule.

PCTP is toxic to protozoa, fish, terrestrial plants, and birds. Data for analogous chemicals (pentachloronitrobenzene and hexachlorobenzene) indicate the potential for liver effects in mammals and systemic (body weight) effects for PCTP in mammals (no repeated-dose animal or human epidemiological data were identified for PCTP) (Ref. 11). The studies presented in the document entitled "Environmental and Human Health Hazards of Five Persistent, Bioaccumulative and Toxic Chemicals (Hazard Summary) (Ref. 11) 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), PCTP scored high (3) for hazard (based on toxicity for acute and chronic exposures); low (1) for exposure (based on 2012 CDR data); and high (3) for persistence and bioaccumulation (based on high environmental persistence and high bioaccumulation potential). The overall screening score for PCTP was high (7).

In consideration of the production and use of PCTP, the environmental and human health hazards of PCTP, and the public comments on the proposed rule that are further discussed in Unit III.A., EPA determines that PCTP 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 PCTP under the conditions of use is likely 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 throughout the lifecycle of PCTP, including the potential for consumer exposures. EPA did not receive any significant comments or information to call the exposure finding into question.

#### *D. EPA's Proposed Rule Under TSCA Section 6(h) for PCTP*

In the proposed rule, EPA proposed to prohibit all manufacturing, processing, and distribution of PCTP and PCTP-containing products and articles for any use, unless PCTP concentrations are at or below 1% by weight.

In addition, EPA proposed to require, that all persons who manufacture, process, or distribute in commerce PCTP and articles and products containing PCTP maintain ordinary business records, such as invoices and bills-of-lading, that demonstrate compliance with the prohibitions and restrictions. EPA proposed that these records will 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 a 30-day extension provided (Ref. 4). 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. 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.

In this preamble, EPA has responded to the major comments relevant to the PCTP final rule. Of the comment submissions, 10 directly addressed EPA's proposed regulation of PCTP. Additional discussion related to this final action can be found in the Response to Comments document (Ref. 4).

### *F. Activities Not Directly Regulated by this Rule*

EPA is not regulating all activities or exposures to PCTP, even though the Exposure and Use Assessment (Ref. 5) identified potential for exposures under many conditions of use. One such activity is disposal. EPA generally presumes compliance with federal and state laws and regulations, including, for example, the Resource Conservation and Recovery Act (RCRA) and its implementing regulations and state laws, as well as the Clean Air Act, the Clean Water Act, and the Safe Drinking Water Act (SDWA). As described in the proposed rule, regulations promulgated under the authority of RCRA, govern the disposal of hazardous and non-hazardous wastes. Although PCTP is not a listed hazardous waste under RCRA, it is subject to the requirements applicable to solid waste under Subtitle D of RCRA. This means there is a general prohibition on open dumping, which includes a prohibition on open burning. Wastes containing this chemical that do not otherwise meet the criteria for hazardous waste would be disposed of in municipal solid waste landfills (MSWLFs), industrial nonhazardous, or, in a few instances,

construction/demolition landfills. Non-hazardous solid waste is regulated under Subtitle D of RCRA, and states play a lead role in ensuring that the federal requirements are met. The requirements for MSWLFs include location restrictions, composite liners, leachate collection and removal systems, operating practices, groundwater monitoring, closure and post-closure care, corrective action provisions, and financial assurance. Industrial waste (non-hazardous) landfills and construction/demolition waste landfills are primarily regulated under state regulatory programs, and in addition they must meet the criteria set forth in federal regulations which may include requirements such as siting, groundwater monitoring and corrective action depending upon what type of wastes are accepted. Disposal by underground injection is regulated under both RCRA and SDWA. In view of these comprehensive, stringent programs for addressing disposal, EPA determined that it is not practicable to impose additional requirements under TSCA on the disposal of the PBT chemicals, including PCTP.

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. However, in EPA's view, establishing an entirely new disposal program for PCTP-containing wastes would be expensive and difficult to establish and administer. A requirement to treat these wastes as if they were listed as hazardous wastes would have impacts on hazardous waste disposal capacity and be very expensive for states and local governments, as well as for affected industries. Therefore, EPA has determined that it is not practicable to further regulate PCTP-containing wastes. More information on the comments received and EPA's responses can be found in the Response to Comments document (Ref. 4).

EPA proposed not to use its TSCA section 6(a) authorities to directly regulate occupational exposures. 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 PCTP. 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 and requires the use of respirators where effective engineering controls are not feasible. The OSHA standard at 29 CFR 1910.143(c) details the required respiratory protection program. The OSHA standard at 29 CFR 1910.132(a) requires the use of personal protective equipment (PPE) by workers when necessary due to a chemical hazard; 29 CFR 1910.133 requires the use of eye and face protection when employees are exposed to hazards including liquid chemicals; and 29 CFR 1910.138 requires the use of PPE to protect employees' hands including from 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, 1910.135, 1910.136, 1910.138, and 1910.140. 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. Furthermore, EPA cannot conclude that broadly imposing specific measures is practicable for all of the varied workplaces. Rather, where EPA has identified worker exposures and available substitutes, EPA is finalizing measures to reduce those exposures. As discussed in the proposed rule, EPA assumes that the worker protection methods used by employers, including in response to existing OSHA standards, in addition to the regulatory measures taken for each chemical, meaningfully reduce the potential for occupational exposures. Although some commenters agreed with this approach, others thought EPA should establish worker protection requirements for those uses that would be allowed to continue under the final rule. 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 and EPA received no information on PCTP to suggest this is not the case. Further, EPA has not conducted a risk evaluation on PCTP or any of the other 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 additional engineering or process controls or PPE requirements.

EPA received comments regarding the use of PBT chemicals in research and development and lab use. Lab use is addressed under newly established 40 CFR 751.401(b) as 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 40 CFR part 751, subpart E, 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 40 CFR part, 751 subpart E. 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.

Finally, EPA received comments regarding requirements for recycling and resale of PCTP-containing products and articles, as well as other PBT chemicals undergoing Section 6(h) rulemaking. One commenter stated that because the proposed definition of “person” includes “any natural person,” the proposed prohibitions would seem to apply to anyone selling golf balls containing PCTP above the 1% concentration by weight threshold at a garage or yard sale (EPA-HQ-OPPT-2019-0080-0559). EPA did not intend to impose these final PCTP regulations on yard sales or used golf ball sales and has added a provision in 40 CFR 751.401 to clarify this issue. Distribution in commerce of PCTP, or products and articles that contain PCTP, that have previously been sold or supplied to an end user are excluded. The prohibition and recordkeeping requirements in this final rule exclude PCTP-containing products and articles that have previously been sold or supplied to an end user for purposes other than resale. An individual or entity that purchased or acquired the finished good in good faith for purposes other than resale are excluded; for example, a consumer who resells a product they no longer intend to use or donates a product or article to charity, such as a golf course that resells used PCTP-containing golf balls it no longer intends to use, or donates used PCTP-containing golf balls to charity.

### **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 the manufacturing, processing, and distribution in commerce of PCTP or PCTP-containing products and articles, unless PCTP concentrations are at or below 1% by weight, with changes being made from the proposal to the compliance date of distribution in commerce of PCTP and PCTP-containing products and articles.

##### *1. Banning PCTP.*

EPA received numerous comments regarding the practicability of regulating PCTP. Specifically, commenters expressed concern with EPA's statement that it would be "unreasonable, because of the low concentrations of PCTP in golf balls, for example, and thus, impracticable to prohibit or otherwise restrict the continued commercial use of the products" (84 FR 145). Some commenters stated that a ban would be practicable given that EPA had already identified the sole golf ball manufacturer using PCTP. Commenters also discussed practicability in the context of availability of PCTP alternatives. Other commenters supported EPA's proposed rule and stated that EPA's regulation will allow manufacturers to continue the safe use of zinc PCTP while restricting potentially more dangerous uses of PCTP in greater concentrations or in its pure form.

EPA received comments from one processor of PCTP (i.e., a golf ball manufacturer) stating that its processes are currently within the proposed 1% concentration by weight threshold. This commenter provided data regarding potential exposures, showing little to no exposure to humans or the environment. This commenter stated that even if the PCTP product (e.g., within the rubber of the golf ball's core) is "exposed to the environment through some mechanism, the [zinc-PCTP] compound is bound-up in the solid rubber that makes up the core material" (EPA-HQ-OPPT-2019-0080-0566). This commenter also provided EPA with information from tests assessing leachability of the core material using U.S. EPA Method 1311 (i.e., the toxicity

characteristic leaching procedure (TCLP)). The TCLP test resulted in non-detectable levels of PCTP leaching from the rubber cores of golf balls when they were cut in half or quartered. These study results were provided in EPA Docket EPA-HQ-OPPT-2016-0738.

EPA believes restricting the allowable concentration will result in limited use options for PCTP and will encourage the use of available PCTP alternatives, if other PCTP-related production occurs. EPA does not expect any domestic production of PCTP or domestic use of PCTP to prepare zinc PCTP, which is the only known intermediate use of PCTP. Import of zinc PCTP may occur but only if meeting the concentration threshold of 1% by weight or less of PCTP. As a result, EPA believes these stringent measures will result in limited use of PCTP and encourage the use of alternatives, if that has not already occurred.

To the extent there are continued manufacturing and processing of products and articles, within the permitted 1% threshold, the potential for consumer exposures is not expected from these known activities or products, e.g., as a component of golf ball cores. Therefore, EPA does not believe it is practicable to impose a ban on all manufacture and processing of PCTP at this time.

## *2. 1% Concentration limit.*

EPA requested comment on the proposed concentration limit, including whether the option is practicable, and whether further exposure reductions would be practicable. EPA specifically requested comment on the practicability of a lower limit on the PCTP content in zinc PCTP, and whether it is possible to completely eliminate unreacted PCTP in the manufacture of zinc PCTP. EPA did not receive comments on an alternative or lower concentration limit. However, some commenters did express concern that EPA has not demonstrated that levels below 1% by weight do not present risks. Comments regarding eliminating the concentration limit altogether and issuing a total ban are discussed in Unit III.A.1. Other commenters supported the proposed concentration limit and one commenter provided information on studies to support their opinion that “the 1% concentration threshold provides a more-than-adequate

level of safety for workers and the public, and the available science does not support any further restrictions” (EPA-HQ-OPPT-2019-0080-0566).

As noted earlier, zinc PCTP is manufactured using PCTP, by reacting PCTP with zinc oxide, and depending on the yield of the reaction, zinc PCTP may contain PCTP as an impurity. Zinc PCTP is sold with varying concentrations of zinc salt, including at a purity of 99% (Ref. 12). According to several patents, golf balls can be made using zinc PCTP at this purity (Ref. 9). Since manufacturing or processing zinc PCTP at 99% purity will comply with the proposed concentration limit, as will zinc PCTP at lower purities that contains PCTP at or below 1% concentration by weight, EPA believes that the proposed concentration limit is practicable and is finalizing a limit prohibiting manufacturing, processing, and distribution in commerce of PCTP or PCTP-containing products and articles, unless PCTP concentrations are at or below 1% by weight. Any manufacturing, including import, or processing of zinc PCTP containing PCTP above the 1% concentration by weight threshold would not be permitted, including for use in the manufacture of golf balls. In addition, any manufacturing, including import, or processing of PCTP above the 1% concentration by weight threshold to create zinc PCTP would not be permitted. Thus, the manufacture and processing of PCTP and the presence of PCTP in any products and articles is significantly impacted by the prohibitions codified in the final rule. EPA believes restricting the allowable concentration will result in limited use options for PCTP and will encourage the use of available PCTP alternatives, if other PCTP-related production occurs. EPA is finalizing a limit for PCTP concentrations above 1% by weight rather than prohibiting any manufacture or processing of PCTP for this reason.

### *3. Compliance date for the prohibitions.*

The proposed rule did not delay the compliance date beyond the rule’s effective date; the manufacturing and processing 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 reasonable available information, such as information submitted in comments on the Exposure and Use Assessment or in stakeholder dialogues. Such a presumption 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 impact an EPA determination on whether or how best to adjust the compliance deadline to ensure that the final compliance deadline chosen is both “as soon as practicable” and provides a “reasonable transition period.”

EPA received public comments regarding the 60-day compliance date for the prohibition in the proposed rule. Commenters stated that this date would be unrealistic and requested that EPA phase in the compliance deadlines for the bans on importation or distribution of products and articles containing PCTP over a longer period following promulgation of the final rule (EPA-HQ-OPPT-2019-0080-0549, EPA-HQ-OPPT-2019-0080-0557). In addition, one commenter requested EPA allow products or articles containing PCTP that are manufactured and imported prior to the compliance deadlines to be distributed thereafter without restriction (EPA-HQ-OPPT-2019-0080-0549). Commenters stated this would be needed to prevent an untold number of lawfully manufactured and imported articles from suddenly becoming unsaleable,

which would result in significant costs for retailers and importers. Other commenters supported the compliance date (EPA-HQ-OPPT-2019-0080-0566).

However, in response to commenters requesting additional time for products and articles to clear the channels of trade, e.g., given complex supply chains, including the request for a sell-through provision to clear products and articles containing PCTP prior to the compliance deadlines, EPA is extending the compliance date for the prohibition on distribution in commerce to one year. Extending the compliance date to one year will, as commenters note, allow additional time for products and articles containing PCTP that were produced prior to the compliance date for the prohibition on manufacture and processing to clear channels of trade.

EPA is not extending the compliance date for the prohibition on manufacture and therefore is not extending the compliance deadline for the prohibition on import which under TSCA section 3 is a subset of manufacture activities. Unless reasonably available information otherwise supports that it is not practicable to impose a 60-day compliance deadline for manufacture, which includes import, or for processing of PCTP and PCTP-containing products and articles, for purposes of meeting EPA's obligations under TSCA section 6(h), EPA presumes a compliance date of 60 days is "as soon as practicable." EPA received only general comments taking the position, without support, that the 60-day compliance period for the prohibition on manufacture or processing is not practicable, while also receiving more specific support from a manufacturer of PCTP-containing products for the proposed 60-day timeframe (EPA-HQ-OPPT-2019-0080-0566).

Therefore, this final rule includes a compliance date of 60 days after publication of the final rule for the restrictions on manufacturing and processing and, to address commenters' concerns, a compliance date of one year after the publication of this final rule for the restrictions on distribution in commerce of PCTP and PCTP-containing products and articles, unless PCTP concentrations are at or below 1% by weight.

#### *4. Recordkeeping.*

In addition, EPA is requiring that all persons who manufacture, process, or distribute in commerce PCTP and articles and products containing PCTP maintain ordinary business records related to compliance with the prohibitions and restrictions, such as invoices and bills-of-lading. EPA revised this language slightly from the proposal to improve clarity. These records will have to be maintained for a period of three years from the date the record is generated, beginning on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

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

*1. Health effects, exposure, and environmental effects.*

PCTP is toxic to protozoa, fish, terrestrial plants, and birds, with data for analogous chemicals indicating the potential for liver effects in mammals and systemic effects for PCTP in mammals. 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 PCTP's health effects, use, and exposure is in Unit II.C. and is further detailed in EPA's Hazard Summary (Ref. 11) and Exposure and Use Assessment (Ref. 5).

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

During the manufacture of rubber, PCTP has been used as a peptizer to reduce the viscosity of rubber during processing. PCTP has been used as a mastication agent in the rubber industry and, more specifically, a peptizing agent for natural rubber viscosity reduction in the early stages of rubber manufacturing (Ref. 13). Mastication and peptization are processing stages during which the viscosity of rubber is reduced to a level facilitating further processing (Ref. 14). It is possible to reduce the viscosity of natural and synthetic rubbers through solely mechanical efforts, but peptizers allow this process to be less sensitive to varying time and temperature, which improves the uniformity between batches (Ref. 13).

*3. The reasonably ascertainable economic consequences of the rule.*

*a. Overview of cost methodology.* EPA has evaluated the potential costs of the final action

for PCTP. Costs of the final rule were estimated based on the assumption that under regulatory limitations on PCTP, processors that use PCTP in their products would switch to available alternative chemicals to manufacture the product, or to products and articles that do not contain PCTP. Costs were assessed based on the assumption that manufacturers will use an alternative chemical, rather than an evaluation of the pricing of pre-existing PCTP-free products. For PCTP, the costs were assessed based on chemical substitutes only. Substitution costs were estimated on the industry level using the price differential between the cost of the chemical (or chemical product) and identified substitutes. Costs for rule familiarization and recordkeeping were estimated based on burdens estimated for other similar rulemakings. Costs were annualized over a 25-year period. Other potential costs include, but are not limited to, those associated with testing, reformulation, release prevention, imported articles, and some portion of potential revenue loss. However, these costs are discussed only qualitatively, due to lack of data availability to estimate quantified costs. More details of this analysis are presented in the Economic Analysis (Ref. 3).

*b. Estimated costs of this final rule.* Total quantified annualized industry costs for the final rule are approximately \$30,000 (at both 3% and 7% discount rates 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).

Total quantified annualized social costs for the final rule are approximately \$108,000 (at both 3% and 7% discount rates). As described earlier in Unit III.B.3, potential costs such as testing, reformulation, release prevention, and imported articles, could not be quantified due to lack of data availability to estimate quantified costs. These costs are discussed qualitatively in the Economic Analysis (Ref. 3).

*c. 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 final action for PCTP is provided. PCTP is persistent, bioaccumulative, and an aquatic toxicant. There are limited data on the potential effects of PCTP in mammals and no data were identified on the potential effects of PCTP in humans. Under the final regulatory action, manufacture and processing of PCTP and PCTP-containing products and articles will be limited to PCTP concentrations of 1% by weight or lower. With the final rule, there will be lower concentrations of PCTP in products and articles. These impacts will decrease the potential for dermal and inhalation PCTP exposures in workers involved in the manufacturing and processing of PCTP-containing products and articles, e.g., rubber products and golf balls, and decrease the potential for releases of PCTP to the environment, including through disposal activities. With decreased potential for releases to the environment and reduced presence of PCTP in products and articles, there will also be a decrease of the potential for exposures in the general population and potentially exposed or susceptible subpopulations, including through consumption of food from the persistence and bioaccumulation of food in animals or through persistence and uptake in agricultural food products. Thus, by reducing the concentration threshold for manufacturing and processing of PCTP for use in products and articles overall, the final regulatory action will have benefits for the environment, general population, and potentially exposed or susceptible subpopulations, such as workers.

*d. 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, although the rule may create some incentives for chemical manufacturers to develop new chemical alternatives to PCTP.

#### *4. Consideration of alternatives.*

As the result of a screening level analysis of likely alternatives based on the TSCA Work Plan Chemicals: Methods Document (Ref. 2), EPA believes that there are viable substitutes for PCTP in rubber manufacturing. Although this final rule is not prohibiting the manufacture or processing of PCTP and PCTP-containing products and articles for any use when PCTP concentrations are at or below 1% by weight, it is possible that some manufacturers and processors may choose to use alternatives instead of using PCTP at the concentration limit. At this time, EPA does not know whether products, including golf balls, are currently being made with halogenated organosulfur compound substitutes instead of PCTP. Based on information from patents, EPA believes that use of these substitutes may be occurring in golf ball manufacturing (Ref. 8, 9, and 15). Further, only one golf ball manufacturer has confirmed that it incorporates PCTP into its golf balls. EPA believes this limited use of PCTP is sufficient

evidence of the availability of substitutes.

The potential alternatives were evaluated and scored on three characteristics: hazard, exposure and the potential for persistence and/or bioaccumulation. Two chemicals, diphenyldisulfide and 2,2'-dibenzamidodiphenyl disulfide, scored lower for at least one characteristic (Ref. 3). With respect to pentafluorothiophenol, there was not enough information available to score each characteristic (Ref. 16).

### *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 to PCTP are likely in the Exposure and Use Assessment (Ref. 5) 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 subject to independent verification or peer review is adequate to justify their use, collectively, in the record for this rule. Additional information on the peer review and public comment process, such as the peer review plan, the peer review report, and the Agency's response to comments, are in the public docket for this action (EPA-HQ-OPPT-2018-0314). 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. February 2012.  
*[https://www.epa.gov/sites/production/files/2014-03/documents/work\\_plan\\_methods\\_document\\_web\\_final.pdf](https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf)*. Accessed March 1, 2019.
3. EPA. Economic Analysis for Regulation of Pentachlorothiophenol (PCTP) Under TSCA Section 6(h). December 2020.
4. EPA. Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h); *Response to Public Comments*. December 2020. (Docket EPA-HQ-OPPT-2019-0080).
5. EPA. Exposure and Use Assessment of Five Persistent, Bioaccumulative, and Toxic Chemicals. December 2020. (EPA-HQ-OPPT-2019-0080-0518).
6. EPA. Public Database 2016 Chemical Data Reporting. Washington, DC: US Environmental Protection Agency, Office of Pollution Prevention and Toxics.
7. Lucas, CR; Peach, ME. (1970). Reactions of Pentachlorothiophenol. *Canadian Journal of Chemistry*. 48:1869.
8. Watanabe, Hideo; Kasashima, Atuski, Multi-piece solid golf ball. US Patent Number US7367901B2, filed January 11, 2007, and published May 6, 2008.
9. Kennedy III, Thomas J., Binette, Mark L., Golf ball, US Patent Number 20060019771, filed July 20, 2004, and published January 26, 2006.
10. EPA. *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Pentachlorothiophenol*. August 2017. (EPA-HQ-OPPT-2016-0739-0003).

11. EPA. Environmental and Human Health Hazards of Five Persistent, Bioaccumulative and Toxic Chemicals. December 2020.

12. American Elements. Los Angeles, CA. Zinc Chlorothiophenolate.  
*<https://www.americanelements.com/zincchlorothiophenolate-117-97-5>*. Accessed March 3, 2019.

13. National Library of Medicine. ToxNet, Hazardous Substance Data Bank.  
Pentachlorothiophenol: CASRN: 133-49-3. *<https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/f?./temp/~ebPHHj:1>* Accessed March 4, 2019.

14. Struktol Company of America, LLC. Stow, OH. Rubber Handbook. 2004.  
*<http://www.struktol.com/pdfs/RubberHB.pdf>*. Accessed March 4, 2019.

15. Voorheis PR, Rajagopalan M. Golf ball core compositions comprising unsaturated long chain organic acids and their salts. US Patent Number: US6762247B2, filed September 9, 2002, published July 13, 2004.

16. EPA. Persistence, Bioaccumulation, Environmental Hazard and Human Health Hazard Ratings for Alternatives to PBT Chemicals Proposed for Regulation. April 2019.

17. 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.

18. 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 Pentachlorothiophenol (PCTP) Regulation of 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 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 4 processors and 1 distributor.

*Respondent's obligation to respond:* Mandatory (40 CFR 751.411).

*Estimated number of respondents:* 5

*Frequency of response:* On occasion.

*Total estimated burden:* 2.5 hours (per year). Burden is defined at 5 CFR 1320.3(b).

*Total estimated cost:* \$196.50 (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)*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* The small entities subject to the requirements of this action are small businesses that manufacture/import, process, or distribute PCTP. In total, only one small business is expected to be affected by the final action. This small business is not expected to experience negative impacts of more than 1% of revenue. Because there is only one small business directly impacted and negative impacts are less than 1%, EPA presumes no significant economic impact on a substantial number of small entities (no SISNOSE). No small entities are expected to experience impacts of more than 1% of revenues. 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 will 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 requirements of this action will primarily affect processors, and a distributor of PCTP. The total quantified annualized social costs for this final

rule under are approximately \$108,000 (at both 3% and 7% discount rate), which does not exceed the inflation-adjusted unfunded mandate threshold of \$160 million.

*F. Executive Order 13132: Federalism*

This action does not have federalism implications 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, 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 and Maine Tribes (Ref. 17 and 18).

*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 PCTP. More information can be found in the Exposure and Use Assessment (Ref. 5). This regulation will reduce the exposure to PCTP for the general population and for potentially exposed or 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 as a significant energy action by the Administrator of the Office of Information and Regulatory Affairs (OIRA).

*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. EPA believes that the restrictions on PCTP in this final rule will reduce exposure in the United States, thus benefitting all communities, including environmental justice communities.

*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 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. Amend § 751.403 by adding in alphabetical order the term “PCTP” to read as follows:

**Subpart E—Persistent, Bioaccumulative, and Toxic Chemicals**

**§ 751.403 Definitions.**

\* \* \* \* \*

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

\* \* \* \* \*

3. Add § 751.411 to read as follows:

**§ 751.411 PCTP.**

(a) *Prohibition.* After [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**], all persons are prohibited from all manufacturing and processing of PCTP or PCTP-containing products or articles, unless PCTP concentrations are at or below 1% by weight. After January 6, 2022, all persons are prohibited from all distribution in commerce of PCTP or PCTP-containing products or articles, unless PCTP concentrations are at or below 1% by weight.

(b) *Recordkeeping.* After [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**], manufacturers, processors and distributors of PCTP or PCTP-containing products or articles must maintain ordinary business records related to compliance with the prohibitions, restrictions and other provisions of this section, such as invoices and bills-of-lading. These records must be maintained for a period of three years from the date the record is generated.