



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA-HQ-OPPT-2019-0080; FRL-10018-88]

RIN 2070-AK58

Phenol, Isopropylated Phosphate (3:1) (PIP 3:1); 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 phenol, isopropylated phosphate (3:1) (PIP (3:1)) (CASRN 68937-41-7), which EPA has determined meets the requirements for expedited action under TSCA. This final rule prohibits the processing and distribution of PIP (3:1) and PIP (3:1)-containing products, with specified exclusions, and prohibits the release of PIP (3:1) to water during manufacturing, processing, and distribution. This final rule also requires commercial users to follow existing regulations and best practices to prevent the release to water of PIP (3:1) and products containing PIP (3:1) during use. These requirements will result in lower amounts of PIP (3:1) being manufactured, processed, distributed in commerce, used and disposed, thereby reducing 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:* Ingrid Feustel, Existing Chemical Risk Management Division, Office of Pollution Prevention and Toxics (7404T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-3199; email address: feustel.ingrid@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 phenol, isopropylated phosphate (3:1) (PIP (3:1)) or products containing PIP (3:1), especially flame retardants in plastics or functional fluids in aircraft and industrial machinery. 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);
- Petroleum Lubricating Oil and Grease Manufacturing (324191);
- Paint and Coating Manufacturing (NAICS Code 32510)
- All Other Basic Organic Chemical Manufacturing (NAICS Code 325199);
- Plastics Material and Resin Manufacturing (NAICS Code 325211);
- Adhesive Manufacturing (NAICS Code 325520);
- Polish and Other Sanitation Good Manufacturing (NAICS Code 325612);
- All Other Miscellaneous Chemical Product and Preparation Manufacturing (NAICS Code 325998);
- Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing (NAICS Code 333415);
- Other Communications Equipment Manufacturing (NAICS Code 334290);
- Automobile Manufacturing (NAICS Code 336111);
- Other Motor Vehicle Parts Manufacturing (NAICS Code 336390);
- Automobile and Other Motor Vehicle Merchant Wholesalers (NAICS Code 423110);
- Other Chemical and Allied Products Merchant Wholesalers (NAICS Code 424690);
- New Car Dealers (NAICS Code 441110);
- Research and Development in the Physical, Engineering, and Life Sciences (NAICS Code 541710);

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). PIP (3:1) (CASRN 68937-41-7) is one such chemical substance. 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 processing and distribution in commerce of PIP (3:1) and products containing PIP (3:1) except for the following:

- Processing and distribution in commerce for use in hydraulic fluids either for the aviation industry or to meet military specifications for safety and performance where no alternative chemical is available that meets U.S. Department of Defense specification requirements;
- Processing and distribution in commerce for use in lubricants and greases;
- Processing and distribution in commerce for use in new and replacement parts for the automotive and aerospace industry, and the distribution in commerce of those parts to which PIP (3:1) has been added;
- Processing and distribution in commerce for use as an intermediate in a closed system to produce cyanoacrylate adhesives;
- Processing and distribution in commerce for use as an adhesive and sealant until

January 6, 2025, after which such activity is prohibited;

- Processing and distribution in commerce for use in specialized engine filters for locomotive and marine applications;
- Processing for recycling and distribution in commerce for the recycling of PIP (3:1) containing plastic provided no new PIP (3:1) is added during the recycling process;
- Processing and distribution in commerce of articles and products made from recycled PIP (3:1)-containing plastic provided no new PIP (3:1) is added during the recycling process or to the articles and products made from the recycled plastic; and
- Processing and distribution in commerce of PIP (3:1) for use in photographic printing articles and PIP (3:1)-containing photographic printing articles until January 1, 2022.

This final rule also prohibits releases to water for from manufacture, processing, distribution in commerce, and commercial uses that are permitted to occur, as outlined in the preceding bullets.

Persons manufacturing, processing, and distributing in commerce PIP (3:1) and products containing PIP (3:1) are required to notify their customers of these prohibitions on processing and distribution, and the prohibition on releases to water via Safety Data Sheet (SDS) or labeling.

Persons manufacturing, processing, and distributing in commerce PIP (3:1) are required to maintain, for three years from the date the record was generated, ordinary business records related to compliance with the restrictions, prohibitions, and other requirements set forth in this rule. These records must include a statement that the PIP (3:1), or the PIP (3:1)-containing products or articles, are in compliance with 40 CFR 751.407(a) and be made available to EPA within 30 calendar days upon request.

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 PIP (3:1), "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 exposure to PIP (3:1) 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 Phenol, Isopropylated Phosphate (3:1) (PIP (3:1)) 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 human and environmental exposures to PIP (3:1). As discussed in more detail in Unit II.A., EPA did not perform a risk evaluation for PIP (3:1), nor did EPA develop quantitative risk estimates. Therefore, the Economic Analysis (Ref. 3) qualitatively discusses the benefits of reducing exposure under the final rule for PIP (3:1), as summarized in Unit III.B.2.

- *Costs.* Total quantified annualized social costs for this final rule are approximately \$23.8 million at a 3% discount rates, and \$23.0 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 final rule will impact approximately four small businesses of which none are expected to incur cost impacts of 1% or greater of their revenue.

- *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 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. 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 exposures to PIP (3:1) 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. 4).

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 persistent, bioaccumulative, and toxic (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. While 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. The details of the proposal for PIP (3:1) 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, including occupational nonusers, consumers, 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 PIP (3:1) 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 PIP (3:1). As described in the proposed rule, EPA conducted a review of available literature with respect to PIP (3:1) 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 proposed to find that exposure to PIP (3:1) 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, processing and distribution in commerce activities that are for uses not specifically excluded are prohibited. The

specified activities with particular exclusions are those which EPA determined were not appropriate to regulate under the TSCA section 6(h)(4) standard. Consistently, based on the Exposure and Use Assessment, activities associated with PIP (3:1) 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 is in the Response to Comments document for this rulemaking (Ref. 5).

3. EPA did not conduct a risk evaluation or 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 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 PIP (3:1). 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 argued 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 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.”

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 these issues raised in the comments is in the Response to Comments document (Ref. 5).

4. Replacement parts and articles.

In the preamble to the proposed rule, EPA explained that it did not read provisions of TSCA section 6 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, including the difficulty of certifying newly designed replacement parts for automobiles and aircraft, and the difficulty importers face in knowing what chemicals are present in the articles they import. As noted 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 suggestion 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, taking the discussion in this **Federal Register** document and the additional discussion in the Response to Comment document on these issues into account, 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. The results of those reviews are in Unit III.A.

C. PIP (3:1) Overview, Health Effects, and Exposure

PIP (3:1) is used as a plasticizer, a flame retardant, an anti-wear additive, or an anti-compressibility additive in hydraulic fluid, lubricating oils, lubricants and greases, various industrial coatings, adhesives, sealants, and plastic articles. As a chemical that can perform several functions simultaneously, sometimes under extreme conditions, it has several distinctive applications. In lubricating oils, PIP (3:1) is a flame retardant, anti-wear additive, anti-compressibility additive, or some combination of the three. In adhesives and sealants, PIP (3:1) is a plasticizer and flame retardant (Ref. 4). PIP (3:1) can also be added to paints, coatings, and plastic components, where it is a plasticizer or flame-retardant additive. In the past, some plastic components to which PIP (3:1) may have been added included those intended for use by children. EPA received comments that PIP (3:1) acts as a flame-retardant gel in filters surrounding engines in some marine and locomotive applications (EPA-HQ-OPPT-2019-0080-0569).

Exposure information for PIP (3:1) is summarized here and is detailed in EPA's Exposure and Use Assessment (Ref. 4), and the proposal. There is potential for exposure to PIP (3:1) under the conditions of use at all stages of its lifecycle (*i.e.*, manufacturing, processing, use (industrial, commercial, and consumer), distribution, and disposal) (Ref. 4). PIP (3:1) is manufactured, processed, distributed, and used domestically. For the 2012 Chemical Data

Reporting (CDR) period, data indicate that four sites manufactured (including imported) PIP (3:1) in the United States. For the 2016 CDR period, data indicate nine sites manufactured (including imported) PIP (3:1) in the United States (Refs. 6 and 7). The total volume of PIP (3:1) manufactured (including imported) in the United States was 14,904,236 lbs in 2011; 3,191,017 lbs in 2012; 2,968,861 lbs in 2013; 5,632,272 lbs in 2014; and 5,951,318 in 2015 (Ref. 7).

PIP (3:1) is toxic to aquatic plants, aquatic invertebrates, sediment invertebrates, and fish. Data indicate the potential for reproductive and developmental effects, neurological effects and effects on systemic organs, specifically adrenals, liver, ovary, and heart in mammals. The studies presented in the document entitled “Environmental and Human Health Hazards of Five Persistent, Bioaccumulative and Toxic Chemicals (Hazard Summary) (Ref. 8) 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 (Ref. 8).

In the 2014 Update to the TSCA Work Plan for Chemical Assessments, PIP (3:1) scored high (3) for hazard (based on neurotoxicity in mammals and aquatic toxicity); high (3) for exposure (based on use as a flame retardant in industrial and consumer products); and high (3) for persistence and bioaccumulation (based on high environmental persistence and high bioaccumulation potential) (Ref. 1). The overall screening score for PIP (3:1) was high (9).

Taking all this into account, and the discussion in Response to Comments document and in this Unit and in Unit III., EPA determines in this final rule that PIP (3:1) meets the TSCA section 6(h)(1)(A) criteria. Comments received pertaining to this finding are discussed further in Unit III.A.1. 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 PIP (3:1) is likely under the conditions of use to the general population, to a potentially exposed or susceptible subpopulation, or the environment. EPA's determination is based on the opportunities for exposure throughout the lifecycle of PIP (3:1). EPA did not receive any comments with information to call the exposure finding into question.

D. EPA's Proposed Rule Under TSCA Section 6(h) for PIP (3:1)

In the proposed rule (84 FR 36728), EPA proposed to prohibit the processing and distribution in commerce of PIP (3:1), and products containing the chemical substance except for the following:

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

EPA proposed to prohibit releases to water from manufacture, processing, distribution in commerce, and commercial use activities that are permitted to occur.

EPA also proposed to require persons manufacturing, processing, and distributing PIP (3:1), and products containing PIP (3:1), in commerce to notify their customers of these prohibitions on processing and distribution, and the prohibition on releases to water.

In addition, EPA proposed to require that all persons who manufacture, process, or distribute in commerce PIP (3:1) and articles and products containing PIP (3:1) maintain ordinary business records, such as invoices and bills-of-lading, that demonstrate compliance with the prohibitions and restrictions. EPA proposed that 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 a 30-day extension provided (Ref. 5). 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.

In this preamble, EPA has responded to the major comments relevant to the PIP (3:1) final rule. Of these comment submissions, thirty addressed EPA's proposed regulation of PIP (3:1). Additional discussion related to this final action can be found in the Response to Comments document (Ref. 5).

F. Activities Not Directly Regulated by this Rule

EPA is not regulating all activities or exposures to PIP (3:1), even though the Exposure and Use Assessment (Ref. 4) 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, Resource Conservation and Recovery Act (RCRA) and its implementing regulations and state laws, as well as the Clean Air Act, the Clean Water Act (CWA), and the Safe Drinking Water Act (SDWA). As described in the proposed rule, regulations promulgated under the authority of the RCRA govern the disposal of hazardous and non-hazardous wastes. Although PIP (3:1) is not a listed or characteristic 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 types of waste are accepted. Disposal by underground injection is regulated under both RCRA and SDWA. In view of this comprehensive, stringent program for addressing disposal, EPA proposed that it is not practicable to impose additional requirements under TSCA on the disposal of the PBT chemicals, including PIP (3:1).

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 PIP (3:1)-containing wastes would be expensive and difficult to establish and administer. In addition, imposing 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 PIP (3:1)-containing wastes for disposal. More information on the comments received and EPA's responses can be found in the Response to Comments document (Ref. 5). One commenter, the Institute of Scrap Recycling Industries, Inc. (ISRI) (EPA-HQ-OPPT-2019-0080-0559), 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 has added an exclusion in the final regulatory text for processing and distribution in commerce for disposal.

EPA also proposed not to use its TSCA section 6(a) authorities to regulate commercial use of products and articles containing the PBT chemicals, such as televisions and computers, because such regulation would not be practicable. It would be extremely burdensome, necessitating the identification of products containing PIP (3:1), and the disposal of countless products and articles that would have to be replaced. If EPA prohibited the continued commercial use of these items, widespread economic impacts and disruption in the channels of trade would occur while the prohibited items were identified and replaced. Although some commenters agreed with EPA's proposed determination that it is not practicable to regulate commercial use, and others disagreed, for the reasons noted in the proposal and discussed further in the Response to Comments document (Ref. 5), EPA continues to believe that prohibiting or otherwise restricting the continued commercial use of products and articles containing PIP (3:1) would result in extreme burdens in exchange for what in most cases would be minimal exposure reductions. Thus, EPA concludes that it is impracticable to prohibit or otherwise restrict the continued commercial use of PIP (3:1)-containing products.

EPA also 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 OSHA has not established a permissible exposure limit (PEL) for PIP (3:1). 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 1920.134(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 1920.134(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. Such regulations would not be practicable. 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 regulations, (29 CFR 1910.1200, 29 CFR 1910.132 through 1910.140), in addition to the regulatory measures taken for each chemical, meaningfully reduce the potential for occupational exposures. While some commenters agreed with this approach,

others thought that 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 PIP (3:1) to suggest this is not the case. Further, EPA has not conducted a risk evaluation on PIP (3:1) or any of 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 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 resale of PIP (3:1)-containing products and articles, as well as products and articles containing 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 products or articles containing PIP (3:1) at a garage or yard sale (EPA-HQ-OPPT-2019-0080-0559). EPA did not intend to impose these final PIP (3:1) regulations on yard sales or used product or article sales and has added language in 40 CFR 751.401 to clarify this. The prohibition and recordkeeping requirements in this final rule exclude PIP (3:1)-containing products and articles that have previously been sold or supplied to an end user, *i.e.*, any person who purchased or acquired the finished good for the purposes of resale.

III. Provisions of this Final Rule

A. Scope and Applicability

EPA carefully considered all public comments related to the proposal. This rule finalizes with some modifications EPA’s proposal to prohibit the processing and distribution in commerce of PIP (3:1), and products containing the chemical substance. The following are excluded from the prohibition in this final rule:

- Processing and distribution in commerce for use in hydraulic fluids either for the aviation industry or to meet military specifications for safety and performance where no alternative chemical is available that meets U.S. Department of Defense specification requirements;
- Processing and distribution in commerce for use in lubricants and greases;
- Processing and distribution in commerce for use in new and replacement parts for

the automotive and aerospace industry, and the distribution in commerce of those parts to which PIP (3:1) has been added;

- Processing and distribution in commerce for use as an intermediate in a closed system to produce cyanoacrylate adhesives;

- Processing and distribution in commerce for use as an adhesive and sealant until January 6, 2025, after which such activity is prohibited;

- Processing and distribution in commerce for use in specialized engine filters for locomotive and marine applications;

- Processing for recycling and distribution in commerce for the recycling of PIP (3:1) containing plastic provided no new PIP (3:1) is added during the recycling process;

- Processing and distribution in commerce of articles and products made from recycled PIP (3:1) containing plastic provided no new PIP (3:1) is added during the recycling process or to the articles and products made from the recycled plastic; and

- Processing and distribution in commerce of PIP (3:1) for use in photographic printing articles and PIP (3:1)-containing photographic printing articles until January 1, 2022.

This final rule also prohibits releases to water from manufacture, processing, distribution in commerce, and commercial uses that are permitted to occur, as outlined in the preceding bullets.

Persons manufacturing, processing, and distributing in commerce PIP (3:1) and products containing PIP (3:1) are required to notify their customers of these prohibitions on processing and distribution, and the prohibition on releases to water via Safety Data Sheet (SDS) or labeling.

Persons manufacturing, processing, and distributing in commerce PIP (3:1) are required to maintain, for three years from the date the record is generated, ordinary business records related to compliance with the restrictions, prohibitions, and other requirements set forth in this rule. These records must include a statement of compliance with this final rule

and be made available to EPA within 30 calendar days upon request.

1. Inclusion in TSCA Section 6(h).

In the proposed rule, EPA identified the five chemical substances EPA proposed as meeting the TSCA section 6(h)(1)(A) criteria for expedited action. PIP (3:1) is one of those five substances, with a “high” bioaccumulation score. The information EPA collected and reviewed in developing the proposal provided no basis to call into question the scoring for persistence, bioaccumulation, and toxicity performed in 2014 for these five PBT chemicals. Four commenters addressed classification of PIP (3:1) as a PBT, and one specifically took issue with PIP (3:1)’s classification as a PBT under TSCA section 6(h)(1)(A), with a focus on its bioaccumulation properties. Their concerns are described in this final rule and addressed in the Response to Comments for this rulemaking (Ref. 5). While one commenter submitted additional data, these comments and data submitted do not call into question the PIP (3:1) bioaccumulation score identified in the 2014 Update to the TSCA Work Plan for Chemical Assessments for the reasons described in the Response to Comments Document (Ref. 5).

Four commenters indicated that PIP (3:1) is not considered a PBT by the European Chemicals Agency (ECHA), based on information in the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers; according to the commenters, therefore PIP (3:1) does not meet the TSCA section 6(h)(1)(A) criteria. However, information in the REACH dossiers reflect the results of studies submitted to ECHA, and not necessarily determinations by ECHA. A single study submitted by industry representing results from their particular commercial product is not sufficient justification to call into question whether PIP (3:1) meets the bioaccumulation criterion. Commercial products may contain varying amounts of different isomers which constitute PIP (3:1) thus, a study on a particular commercial product alone for a chemical that may differ between various commercial products, is not adequate to call into question the specified score identified in the 2014 Update to the TSCA Work Plan for Chemical Assessments.

Additionally, PIP (3:1) is a UVCB substance, or a substance of unknown or variable composition, complex reaction and biological materials. In the case of PIP (3:1), it is a substance of unknown or variable composition. The chemical substance PIP (3:1), which is the subject of this regulation, has a variable composition in that mixtures of or containing PIP (3:1) may contain different proportions of isomers of PIP (3:1) or of different chemical congeners. An isomer is defined as “one of several species (or molecular entities) that have the same atomic composition (molecular formula) but different line formulae or different stereochemical formulae and hence different physical and/or chemical properties” (Ref. 9). A congener is defined as “one of two or more substances related to each other by origin, structure, or function” (Ref. 9). When considering a UVCB substance, the Agency considers whether any isomers or congeners which might be present in a UVCB substance are bioaccumulative and, if so, EPA considers the UVCB substance to be bioaccumulative. In these cases, the Agency has a longstanding approach for chemical evaluation and regulation that considers whether particular isomers or congeners which might be present in an identified substance are, for example, bioaccumulative and, as in this case, if so, EPA considers that identified substance to meet the criterion (Ref. 10). Because PIP (3:1) is a UVCB, and because commercial products may contain varying amounts of different isomers which constitute PIP (3:1), and, as detailed in the 2014 Update to the TSCA Work Plan for Chemical Assessments and the proposed rule, some of those isomers are identified as bioaccumulative, EPA continues to consider PIP (3:1) to be bioaccumulative.

Additionally, EPA does not interpret TSCA section 6(h)(1)(A) to require, as the commenter suggests, a “fresh look” at the scores for or issues of toxicity, persistence, or bioaccumulation of the Work Plan chemicals. Requiring EPA to re-evaluate any of these issues would delay what Congress intended to be an expedited rulemaking process. It also suggests a level of analysis not contemplated by Congress or clearly required for this rulemaking given that Congress did not compel risk evaluations for any chemicals meeting the TSCA section

6(h)(1) criteria. The only required additional assessment is the “exposure and use assessment” used to make the TSCA section 6(h)(1)(B) finding that exposures are likely under the conditions of use.

To the extent that commenters suggest that EPA used a “successor scoring system” (via the use and exposure assessment and hazard summary) to identify the score for the PBT chemicals, that is not the case. The Agency reaffirms that the scores identified in the 2014 Update to the TSCA Work Plan for Chemical Assessments and referenced in the proposed rule are based on the 2012 Methods Document criteria, and EPA’s responses to comments are based on those criteria. Because of PIP (3:1)’s status as a UVCB, any study on a single congener or commercial product would need to be considered in the context of all available information that informs the persistence and bioaccumulation of PIP (3:1). To the extent that commenters are suggesting that the statute requires, or that EPA should do an analysis consistent with, a systematic review to re-evaluate the persistence and bioaccumulation score for PIP (3:1), the Agency notes that it views that effort to be a successor scoring system approach. Systematic review or an analysis consistent with systematic review is inconsistent with the criteria and tools referenced in the 2012 TSCA Work Plan Chemicals: Methods Document. If EPA had used a successor scoring system, it would need to rescore the chemicals identified on the 2014 Update to the TSCA Work Plan for Chemical Assessments and the Agency did not do that and has no plans to do that at this time.

One commenter indicated that EPA has not adequately identified the chemical substance. EPA emphasizes that PIP (3:1) has been properly identified as the subject of this rulemaking. To clarify, TSCA section 6(h) requires EPA to issue a proposed rule to address chemicals “identified” in the 2014 Update to the TSCA Work Plan for Chemical Assessments and that meet other specified criteria. Chemicals “identified” in the 2014 Update to the TSCA Work Plan for Chemical Assessments are specified by chemical name and CASRN. In this case, PIP (3:1) is identified as Phenol, isopropylated phosphate (3:1) (iPTPP) and with CASRN

68937-41-7.

2. Hydraulic fluids either for the aviation industry or to meet military specifications for safety and performance where no alternative chemical is available that meets U.S. Department of Defense specification requirements.

In this final rule EPA amends the language in the proposed rule on the exclusion from the processing and distribution in commerce restrictions of PIP (3:1) for use in for aviation hydraulic fluid and of PIP (3:1)-containing aviation hydraulic fluid, to include an exclusion from the prohibition on the processing and distribution in commerce of PIP (3:1) for use in hydraulic fluids either for the aviation industry or to meet military specifications for safety and performance where no alternative chemical is available that meets U.S. Department of Defense specification requirements. As noted in the proposed rule, these requirements remain necessary for the safe operation of commercial and military aircraft.

Five commenters confirmed or elaborated on the degree to which it would be impracticable to replace or reformulate hydraulic fluids containing PIP (3:1). Several of those comments supported the concerns outlined in the proposed rule, namely that aviation fluids are approved by major aircraft manufacturers who work closely with the Federal Aviation Administration (FAA), and any change in formula composition results in a full requalification process. As described in the proposed rule, this process is a joint effort between the fluid manufacturer and aircraft manufacturer, and resulting fluids are subject to extensive laboratory and field testing. At the end of this iterative evaluation process, there is no guarantee that a technically equivalent alternative will be developed (Refs. 3, 11 and 12).

While no comments opposed the exclusion for aviation hydraulic fluid specifically, several commenters opposed the exclusions from the prohibition on processing and distribution outlined in the proposal more broadly, particularly in that the exclusions are not time limited (EPA-HQ-OPPT-2019-0080-0546; -0567; -0570; -0572; -0575). Additional information is available in the Response to Comments document (Ref. 5).

EPA received one comment requesting that hydraulic fluid which may contain PIP (3:1) for other industries, including use specialized, industrial applications that include hydraulic control of valves for certain higher pressure, and more extreme environments, also be excluded from the rule. As explained in the proposal, for industrial hydraulic fluids (excluding aviation), various alternative products not containing PIP (3:1) are already available in commerce. However, to the commenter's point, synthetic hydraulic fluids which contain low levels of PIP (3:1) are certified to military specifications, such as MIL-DTL-32353A (Ref. 13) and represent an emerging technology in hydraulic fluids for various applications important to national security including hydraulic lubricating oils for valves in vessels. To that end, EPA is expanding the exclusion to ensure inclusion of those hydraulic fluids certified to military specifications which may be used in industries other than aviation. To be eligible for this exclusion, the hydraulic fluid must be required to meet military specifications for safety and performance and no alternative chemical is available that meets U.S. Department of Defense specification requirements. To the extent that PIP (3:1) containing hydraulic fluids are certified for turbine hydraulic fluid military specifications, those products would be encompassed by aviation hydraulic fluid.

For hydraulic fluids that are in use by the aviation industry or to meet military specifications for safety and performance where no alternative chemical is available to the end user to meet U.S. Department of Defense specification requirements, their processing and distribution in commerce must be excluded from the prohibition. For the reasons summarized in Unit III.A.2. and supported by the comments and Economic Analysis, the Agency is finalizing the proposed exclusion for processing and distribution in commerce for use in hydraulic fluids either for the aviation industry or to meet military specifications for safety and performance where no alternative chemical is available that meets U.S. Department of Defense specification requirements.

3. Lubricants and greases.

EPA is finalizing as proposed the exclusion from the processing and distribution in commerce restrictions of PIP (3:1) for use in lubricants and greases and of PIP (3:1)-containing lubricants and greases. Five commenters confirmed or elaborated on the degree to which it would be impracticable to replace or reformulate lubricants and greases containing PIP (3:1), which, as noted in the proposed rule, are necessary for the safe operation of commercial and military aircraft, as well as some non-aviation uses such as turbines for power generation (EPA-HQ-OPPT-2019-0080-0562; -0536; -0545; -0542; -0539). One commenter did not support the exclusion for PIP (3:1) in lubricants and greases, citing concerns over potential occupational and consumer exposure (EPA-HQ-OPPT-2019-0080-0572). EPA does not expect lubricants and greases containing PIP (3:1) to be available to consumers or workers in non-industrial settings, as lubricants and greases that contain PIP (3:1) are those that need to function in extreme environments, including extreme heat, cold, and high pressure. As mentioned in Unit III.A.2. several commenters oppose the exclusions from the prohibition on processing and distribution outlined in the proposal more broadly, particularly in that the exclusions are not time limited (EPA-HQ-OPPT-2019-0080-0546; -0567; -0570; -0572; -0575). Additional information is available in the Response to Comments document (Ref. 5).

In the proposal, EPA acknowledged the degree to which PIP (3:1) is crucial to the safe and effective performance of lubricants and greases, where it functions as a crucial anti-wear component. The Agency requested comment on the degree to which PIP (3:1) is crucial to the safe and effective performance of lubricants and greases in non-aviation industries. EPA received information from several commenters supporting the lack of alternatives to PIP (3:1) for aviation and non-aviation industries, the mandatory safety standards that are in place for non-aviation lubricants and greases, and the degree to which exposures are minimized. Additional details are in the docket and the Response to Comments document (Ref. 5). For lubricants and greases to be available to the end user, their processing and distribution in commerce must be excluded from the prohibition. For the reasons noted in Unit III.A.3., EPA is finalizing the

proposed exclusion for lubricants and greases.

Several commenters requested clarification on the scope of the exclusion for lubricants and greases. One commenter asked if metalworking fluids were within the scope of the exclusion. Two additional commenters requested clarification that brake fluids used in landing gear fall within the scope of lubricants and greases. Another noted that the scope should include lubricants used in marine and rail engine applications. EPA confirms that all the uses outlined in this paragraph, as well as use in aviation and non-aviation lubricants and greases more broadly, are within the scope of those lubricants and greases excluded from the proposed processing and distribution restrictions, as the regulatory definition of lubricants includes any chemical substance used to reduce friction, heat, or wear between moving or adjacent solid surfaces, or that enhance the lubricity of other substances (Ref. 14)

As requested by a commenter, EPA also confirms that, under the final rule, used oils, which fall within the scope of lubricants and greases, may continue to be recycled.

4. New and replacement parts for automobiles.

EPA is finalizing as proposed the exclusion from the proposed processing and distribution in commerce prohibitions of PIP (3:1) for use in new and replacement parts for automobiles and of PIP (3:1)-containing new and replacement parts for automobiles. Numerous commenters confirmed or elaborated on the degree to which it would be impracticable to replace or reformulate automobile components that contain PIP (3:1).

The rationale given by commenters from industry supported the information outlined in the proposal; namely, PIP (3:1) is used to meet safety standards in new and replacement parts for automobiles and there is currently no feasible alternative.

Three commenters from non-governmental organizations (NGOs) opposed the exclusion, noting that it should be time limited (EPA-HQ-OPPT-2019-0080-0541; -0572; -0575). Two of those NGOs are among commenters mentioned in Unit III.A.2. who oppose the exclusions from the prohibition on processing and distribution outlined in the proposal more broadly, particularly

in that the exclusions are not time limited (EPA-HQ-OPPT-2019-0080-0546; -0567; -0570; -0572; -0575). EPA determined that prohibiting the processing and distribution of PIP (3:1) for use in replacement parts is not practicable because PIP (3:1) is used to meet safety standards in new and replacement parts for automobiles and there is currently no feasible alternative. For those same reasons, EPA could not identify a time limit on the exclusion that would be practicable. Additional information is available in the Response to Comments document (Ref. 5).

Requiring the automotive industry to reformulate or redesign replacement parts for vehicle models currently on the market or vehicles no longer being manufactured is not practicable because of the safety concerns recognized in Unit III.A.4. Most importantly, any restriction on new and replacement parts for the automotive industries could increase costs and safety concerns.

5. New and replacement parts for aerospace vehicles.

In addition to the exclusion outlined in Unit III.A.4., in this final rule, EPA is broadening the scope of the exclusion from the proposed processing and distribution in commerce prohibitions to include processing and distribution in commerce of PIP (3:1) for use in new and replacement parts for aerospace vehicles and processing and distribution in commerce of PIP (3:1)-containing new and replacement parts for aerospace vehicles. Numerous commenters noted that many of the same challenges outlined for automobiles apply equally, if not more so, for aerospace vehicles. As noted by the commenters, the aerospace sector faces challenges similar to the automotive industry, including a multi-tiered international supply chain, strict safety standards, and the absence of feasible alternatives for these uses and costs. An airplane may be in use for 20 years and will need replacement parts to maintain airworthiness (EPA-HQ-OPPT-2019-0080-0545). As with the automotive sector, restrictions on new and replacement parts for the aerospace industries could increase costs and safety concerns. Therefore, EPA is finalizing an exclusion from the proposed processing and distribution in commerce prohibitions that includes processing and distribution in commerce of PIP (3:1) for use in new and replacement parts for

aerospace vehicles and processing and distribution in commerce of PIP (3:1)-containing new and replacement parts for aerospace vehicles.

6. Adhesives and sealants.

In the proposal, EPA did not exclude processing or distribution in commerce of PIP (3:1) for use in adhesives and sealants or processing or distribution in commerce of PIP (3:1)-containing adhesives and sealants from the prohibitions on processing and distribution, except under those circumstances where an adhesive is part of a new or replacement part for an automobile. EPA received numerous comments requesting clarification or modification of the proposed regulations relative to adhesives. Based on those comments, in the final rule, EPA has added an exclusion from the processing and distribution prohibitions for the processing and distribution of PIP (3:1) when used in a closed system as an intermediate in the production of cyanoacrylate adhesives, and additionally delayed the compliance date for the prohibitions on the processing and distribution in commerce of PIP (3:1) for use in any type of adhesives and sealants and the processing and distribution in commerce of PIP (3:1)-containing adhesives and sealants, from 60 days to four years.

Two commenters identified PIP (3:1)'s use as an intermediate in the production of cyanoacrylate adhesives (EPA-HQ-OPPT-2019-0538; -0558). At the time of proposal, EPA believed there were feasible alternatives to PIP (3:1) for this use. However, EPA received additional information in a public comment to indicate that while some cyanoacrylate adhesives are made without PIP (3:1), PIP (3:1)'s use as an intermediate can be central to achieving properties necessary to meet performance standards for cyanoacrylates used in important applications including medical, military, automotive, and aerospace sectors. PIP (3:1) is not expected to be present in the final product since it is used as an intermediate, and the manufacturing of cyanoacrylate adhesives occurs in a closed system. Therefore, EPA is finalizing an exclusion from the prohibitions for the processing and distribution in commerce of PIP (3:1) for this use because, without a feasible alternative for these applications, it would be

impracticable to prohibit.

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 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."

For the prohibition on the processing and distribution in commerce of PIP (3:1) for use in adhesives and sealants, and the processing and distribution in commerce of PIP (3:1)-containing adhesives and sealants more broadly, EPA is delaying the compliance date of the prohibition for four years. A commenter noted that the 60-day compliance period does not allow adequate time to transition to alternatives and would effectively ban an adhesive (EPA-HQ-OPPT-2019-0080-

0558). PIP (3:1) may act as a flame retardant within a formulation to meet industry flammability standards, and while alternatives are available, time is required to recertify new formulations to the required safety standards. The requested delay is within the bounds of time periods necessary to certify products to performance and safety standards in other sectors, including the automotive sector (EPA-HQ-OPPT-2019-0080-0036). Therefore, EPA agrees that more time is necessary to transition to available alternatives in the adhesives and sealants sector and will extend the compliance date of the restriction to four years from the publication of the final rule, which is “as soon as practicable” and provides a “reasonable transition period,” pursuant to TSCA section 6(d)(1), while reducing exposure “to the extent practicable” as required by TSCA section 6(h)(4).

EPA also clarifies that, regardless of the compliance date for the prohibition on the processing and distribution of PIP (3:1)-containing adhesives and sealants, processing and distribution of PIP (3:1) for use in adhesives and sealants in new or replacement parts for automobiles or aerospace and processing and distribution of such PIP (3:1)-containing adhesives and sealants are excluded from the general prohibition.

7. Specialized engine air filters for marine and locomotive applications.

In the proposal, EPA did not exclude processing or distribution in commerce of PIP (3:1) for use in specialized engine air filters for marine and locomotive applications from the prohibitions on processing and distribution. Based on a public comment (EPA-HQ-OPPT-2019-0080-0569), in this final rule, EPA has added an exclusion from the processing and distribution prohibitions for the processing and distribution of PIP (3:1) when used in specialized engine air filters for marine and locomotive applications and the processing and distribution of such PIP (3:1)-containing engine air filters.

The identified filters clean the combustion air intake for large, heavy duty industrial diesel engines, and prevent abrasive particles from entering the engines. The PIP (3:1) gel within the filters is the only identified substance able to self-extinguish in the event of sparks and to

maintain its functionality at freezing temperatures. Based on information received in the comment, EPA believes that it would not be practicable to prohibit processing or distribution of PIP (3:1) for this use, due to the critical role of PIP (3:1) for the functionality of heavy duty industrial diesel engines important to the transportation sector, and the lack of alternatives currently in use or under development.

8. Articles made from recycled plastics.

In the proposed rule, EPA requested comment on the extent to which plastic articles containing PIP (3:1) are recycled and whether the recycling of such plastic, and the manufacture, processing, and distribution in commerce of plastic items made from such recycled plastic, should be specifically excluded from this rule. EPA received numerous comments either supporting or opposing such exclusion, and EPA received no substantive information pertaining to PIP (3:1)'s presence in recycled plastics. Therefore, EPA is excluding articles made from recycled plastics containing PIP (3:1) and to which no PIP (3:1) has been added from the prohibitions in this final rule. This exclusion will allow processing, distribution, and use of PIP (3:1) in recycled products, when no new PIP (3:1) has been added. EPA is excluding from the processing and distribution prohibitions the processing and distribution in commerce of articles and products made from recycled PIP (3:1) containing plastic that has no new PIP (3:1) added during the recycling process or added to the articles and products made from the recycled plastic. A prohibition on these processing and distribution activities would result in potentially very high costs associated with testing and compliance assurance with respect to all articles and, based on reasonably available information at this time, without meaningful exposure reductions. Because PIP (3:1)'s addition to plastics will be prohibited, with a certain exclusion, over time PIP (3:1) will decrease in plastics overall, and, it follows, in recycled plastics. Additional details are in the docket and the Response to Comments document (Ref. 5).

9. Photographic printing articles.

EPA received one comment requesting a TSCA section 6(g) critical use exemption for use of PIP (3:1) in photographic printing articles. PIP (3:1) is used as a solvent in photographic paper with commercial end uses in many sectors. Domestic manufacture and processing of PIP (3:1) for use in photographic printing articles was discontinued in October 2016 (Ref. 15). However, photographic printing articles containing PIP (3:1) are already in the channels of U.S. trade and are intended for import through October 2020, before the required promulgation of the TSCA section 6(h) final rule. As a result, the commenter requests additional time to allow for the continued processing and distribution in commerce of these articles. The commenter expects to cease import of articles containing PIP (3:1) and instead import the same product using an alternative to PIP (3:1) by October 1, 2020, and the shelf life and distribution period of existing stocks of articles is expected to be around 18 months (EPA-HQ-OPPT-2019-0080-0584). Exposure is unlikely during processing and distribution, and an immediate prohibition would require the commenter to dispose of the product all at once thereby increasing the incremental exposure from the disposal of film articles. EPA agrees an immediate prohibition is not practicable. It is costly to require disposal of articles already in the channels of U.S. trade by the time the rule is finalized and made effective, including costs for removal, disposal, and replacement. In addition, such action has potential to increase exposure by concentrating disposals in times and space, as opposed to allowing the articles to complete their natural lifecycle and be disposed of over time. Therefore, EPA adds a compliance date of January 1, 2022, for the prohibition on processing and distribution in commerce of photographic printing articles, in order to allow time to permit existing stocks of articles to clear the channels of trade, which is “as soon as practicable” and provides a “reasonable transition period,” pursuant to TSCA section 6(d)(1), while reducing exposure “to the extent practicable” as required by TSCA section 6(h)(4).

10. Releases to water.

EPA proposed to prohibit releases to water from the manufacturing, processing,

distribution in commerce, and commercial use activities that are permitted to occur (*e.g.*, use in hydraulic fluid, use in lubricants and greases, and use in new and replacement parts for the automotive industry). EPA is finalizing this proposal with some modification to accommodate the challenges of preventing releases to water during commercial use. Manufacturing, processing, and distribution of products containing PIP (3:1) takes place in contained environments, and sometimes even closed systems. These products also are used in the field. This is particularly true in the aviation sector. End uses of PIP (3:1) in hydraulic fluids and lubricants and greases are highly regulated, however, inadvertent releases of PIP (3:1) in the field are possible, for example, in wash-water from airplane parts, which may contain trace amounts of PIP (3:1) (EPA-HQ-OPPT-2019-0080-0542; -0562). Although it is not reasonable to expect all release to be completely prevented during the kind of commercial use activities involving PIP (3:1)-containing products and therefore not practicable to prohibit such release, it is practicable to require best practices and following existing statutes and regulations (*e.g.*, Oil Pollution Act, CWA) applicable to commercial uses (EPA-HQ-OPPT-2019-0080-0562). As a result, EPA maintains that prohibiting, as proposed, releases to water from manufacturing, processing, and distribution in commerce is practicable. However, for commercial use, EPA modifies the final regulation to accommodate the challenge of compliance when unintentional releases of small or de minimis amounts of PIP (3:1)-containing fluid are possible during commercial use. The final rule requires all persons to follow existing regulations and best practices to prevent the release to water of PIP (3:1) and PIP (3:1)-containing products during commercial use. Additionally, administrative and judicial procedures for addressing violations of restrictions under other programs consider good faith efforts to comply, including preventative and corrective actions, as well as root cause analyses to ascertain and rectify excess releases in the event of a violation.

While in some cases EPA has determined that it is not practicable to exercise its section 6(a) authorities to regulate certain exposures under TSCA section 6(h), outlined in Unit II.F., this is not the case for releases of PIP (3:1) to water for formulated products and end uses. The

formulated products and end uses of PIP (3:1) are highly regulated, though unintentional releases are possible. As discussed in this Unit, many regulatory restrictions on releases to water are administered by the EPA (e.g., Oil Pollution Act, CWA). As identified in the 2014 Update to the TSCA Work Plan for Chemical Assessment, PIP (3:1) was rated high (3) for aquatic toxicity, and high (3) for environmental persistence and bioaccumulation. Additionally, PIP (3:1) is used in emerging technologies where there are not yet available alternatives and has increasing production volume in some sectors. As a result, EPA has determined that a restriction on releases to water is appropriate in this case as it emphasizes and codifies the importance of best practices given these circumstances. Based on the above and comments on the proposed rule, EPA therefore maintains that it is practicable to require end users of products which contain PIP (3:1) to follow existing regulations and best practices to prevent the release to water of PIP (3:1) and PIP (3:1)-containing products during commercial use, and that codifying that requirement will highlight the importance of reducing environmental release of chemicals regulated by TSCA section 6(h), and reduce exposures that could occur.

11. Downstream notification.

Persons manufacturing, processing, and distributing PIP (3:1) and products containing PIP (3:1) will be required to notify their customers of these prohibitions on processing, distribution, and releases to water. EPA proposed the method of downstream notification was text inserted in sections 1 and 15 of the safety data sheet (SDS). Several commenters requested clarification on the downstream notification requirements or suggested changes to the proposed requirement. EPA clarifies in this final rule that the downstream notification requirement applies only to those scenarios where a product has an accompanying SDS.

EPA is also including in this final rule, an alternative method of compliance for downstream notification. If a manufacturer, processor, or distributor chooses, they may include specified text on their label, instead of on their SDS. This alternative allows manufacturers, processors, and distributors to choose the manner of notification most appropriate for their

customers and is not intended to broaden the scope of persons subject to the requirement.

Lastly, based on comments received, EPA has delayed the compliance date for downstream notification from 60 days to 180 days for processors and distributors from the date of publication, in order to allow adequate time for the notices to make their way through the supply chain. This length of time would allow downstream processors and distributors to gather information from suppliers and incorporate it in SDSs, and is consistent with the grace period offered under the Registration, Evaluation, Authorisation and Restriction of Chemicals regulation in Europe (EPA-HQ-OPPT-2019-0080-0542). Manufacturers (including importers) of PIP (3:1) are still required to implement downstream notification within 60 days from the date of the publication. Excluded from the downstream notification requirement are articles made from recycled plastics as described in Unit III.A.8., as long as no new PIP (3:1) is added during the processing of recycled materials.

12. Recordkeeping.

EPA is requiring that all persons who manufacture, process, or distribute in commerce PIP (3:1) and articles and products containing PIP (3:1) maintain ordinary business records, such as invoices and bills-of-lading, that are related to compliance with the prohibitions and restrictions. 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**]. Exempted from the recordkeeping requirement are articles made from recycled plastics, as described in Unit III.A.8., as long as no new PIP (3:1) is added during the processing of recycled materials. EPA requested comment on alternative recordkeeping requirements that could help ensure compliance with the regulatory prohibitions, particularly for importers and others who do not produce articles. After reviewing the comments received, EPA has decided to include two additional requirements to help ensure compliance (EPA-HQ-OPPT-2019-0080-0539; -0542; -0546; -0549). First, the records that are

kept must include a statement that the PIP (3:1), or the PIP (3:1)-containing products or articles, are in compliance with 40 CFR 751.407(a). The statement need not be included on every business record, such as every invoice or bill of lading, although regulated entities may certainly choose to reformat their documents to include the statement. For example, importers of replacement automobile parts that contain PIP (3:1) who import from the same suppliers over and over need only have a single statement for each part or each supplier. Finally, EPA is adding a requirement that the records kept pursuant to this final rule be made available to EPA within 30 calendar days upon request to ensure that EPA can review records in a timely manner.

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

1. Health effects, exposure, and environmental effects.

PIP (3:1) is toxic to aquatic plants, aquatic invertebrates, sediment invertebrates and fish. Data indicate the potential for reproductive and developmental effects, neurological effects and effects on systemic organs, specifically adrenals, liver, ovary, and heart in mammals. 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 PIP (3:1) health effects, use, and exposure is in Unit II.C. and is further detailed in EPA's Hazard Summary (Ref. 8) and Exposure and Use Assessment (Ref. 4).

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

PIP (3:1) has multiple functional uses, including as a plasticizer, flame retardant, anti-wear additive, or as an anti-compressibility additive (Ref. 4). When PIP (3:1) is included in a formula, it is often for a combination of these functional uses; for example, as a flame retardant and an anti-wear additive. Additionally, PIP (3:1) is an isomer mixture, and through manufacturing, the proportion of various isomers can be manipulated to achieve specific properties which can affect the performance of a formula (Ref. 16). As an additional benefit, when used as an intermediate in the processing of cyanoacrylate glues, PIP (3:1) aids in the

ability of these glues to meet the requisite performance standards for specialized markets (EPA-HQ-OPPT-2019-0080-0538).

3. The reasonably ascertainable economic consequences of the rule.

i. Overview of cost methodology. EPA has evaluated the potential costs of the final action for PIP (3:1). Costs of the final rule were estimated based on the assumption that under regulatory limitations on PIP (3:1), processors that use PIP (3:1) in their products would switch to available alternative chemicals to manufacture the product, or to products that do not contain PIP (3:1). Substitution costs were estimated on the industry level using the price differential between the cost of the 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).

ii. Estimated costs of this final rule. Total quantified annualized industry costs for the final rule is \$23.6 million at a 3% discount rate and \$22.8 million at a 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 1 FTE at \$155,152 per year (Ref. 3).

Total quantified annualized social costs for the final rule are \$23.8 million at a 3% discount rates, and \$23.0 million at a 7% discount rate. 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).

iii. Benefits. As discussed in Unit II.A. and the Response to Comments Document, 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 PIP (3:1) is provided. PIP (3:1) is a neurotoxicant and aquatic toxicant with high persistence and high potential for bioaccumulation. Under this final rule, PIP (3:1) is prohibited for processing and distribution in all uses except for those specifically excluded from the prohibition, as detailed in Unit I.C. Additionally, releases to water are prohibited during manufacturing, processing, and distribution, and are restricted during commercial use. EPA anticipates that these requirements will result in decreased potential for occupational exposures, decreased potential for PIP (3:1) releases, and reduce potential for exposures to the general population, potentially exposed or susceptible subpopulations, and the environment.

iv. 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 PIP (3:1).

4. Consideration of alternatives.

EPA believes there are viable substitutes for PIP (3:1), except for the specified processing and distribution in commerce activities excluded from the final rule. In addition, EPA conducted an analysis of three identified potential substitutes for PIP (3:1) based on the process described in the TSCA Work Plan Chemicals: Methods Document (Ref. 2). Those potential substitutes all scored lower than PIP (3:1) in at least one criterion, indicating lower concern for hazard, exposure, or bioaccumulation/persistence. The economic feasibility of alternatives for all activities other than those excluded from the final rule is discussed in the Economic Analysis (Ref. 3).

C. TSCA Section 26 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 PIP (3:1) on 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 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 document, are in the public docket for the peer review (Docket ID Number 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. 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. Accessed March 1, 2019.
3. EPA. Economic Analysis for Regulation of Phenol, isopropylated phosphate (3:1) (PIP (3:1)) 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. July 2020.
6. EPA. Public Database 2012 Chemical Data Reporting.

7. EPA. Public Database 2016 Chemical Data Reporting.
8. EPA. Environmental and Human Health Hazards of Five Persistent, Bioaccumulative and Toxic Chemicals. December 2020.
9. International Union of Pure and Applied Chemistry. Compendium of Chemical Terminology, 2nd ed. (the "Gold Book"). Compiled by A. D. McNaught and A. Wilkinson. Blackwell Scientific Publications, Oxford (1997). Online version (2019-) created by S. J. Chalk. ISBN 0-9678550-9-8. <https://doi.org/10.1351/goldbook>. Search terms: "Isomer" and "congener."
10. EPA. (2015). TSCA New Chemicals Review Program Standard Review Assessment on Medium-Chain Chlorinated Parafins (PMN P-12-0282, P-12-0283) and Long-Chain Chlorinated Parafins (PMN P-12-0284). December 22, 2015.
https://www.epa.gov/sites/production/files/2015-12/documents/dover_-_standard_review_risk_assessment_p-12-0282-0284_docket_0.pdf. Accessed March 1, 2019.
11. EPA. Stakeholder Meeting with Akin Gump. September 27, 2018. EPA Docket ID EPA-HQ-OPPT-2019-0080.
12. EPA. Stakeholder Meeting with Boeing. May 2, 2018. EPA Docket ID EPA-HQ-OPPT-2019-0080.
13. U.S. Department of Defense. Detail Specification Hydraulic & Lubricating Oil, Synthetic Hydrocarbon Base. MIL-DTL-32353A (August 24, 2012). Downloaded from <https://quicksearch.dla.mil/qsSearch.aspx>. December 8, 2020.
14. EPA. Instructions for Reporting 2016 TSCA Chemical Data Reporting. June 2016.
15. EPA. Stakeholder Meeting with Fujifilm. February 12, 2017. EPA Docket ID EPA-HQ-OPPT-2019-0080.
16. EPA. Stakeholder Meeting with ICL. August 30, 2018. EPA Docket ID EPA-HQ-OPPT-2019-0080.
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 Executive Order 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, entitled *Economic Analysis for Regulation of Phenol, isopropylated phosphate (3:1) (PIP (3:1)) 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 five manufacturers/importers, 14 processors, and 13 distributors.

Respondent's obligation to respond: Mandatory (40 CFR 751.407).

Estimated number of respondents: 32

Frequency of response: On occasion

Total estimated burden: 36 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$2,831 (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 PIP (3:1). In total, four small businesses are expected to be affected by the final action. Of the four small entities assessed, none (0%) are expected to experience impacts of more than 1% of revenues. Because only four 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 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 total quantified annualized social costs for this final rule are approximately \$23.8 million at a 3% discount rates, and \$23.0 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, 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 (Refs. 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 PIP (3:1), however available data indicate the potential for reproductive and developmental effects from PIP (3:1). 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. 8). This regulation will reduce exposure to PIP (3:1) 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 by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action.

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 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 terms “Lubricants and grease” and “PIP (3:1)” to read as follows:

§ 751.403 Definitions.

* * * * *

Lubricants and grease mean any product used to reduce friction, heat, or wear between moving or adjacent solid surfaces, or that enhance the lubricity of other substances

PIP (3:1) means the chemical substance phenol, isopropylated phosphate (3:1) (CASRN 68937-41-7).

* * * * *

Add § 751.407 to read as follows:

§ 751.407 PIP (3:1).

(a) *Prohibitions.* (1) *General.* Except as provided in paragraphs (a)(2) and (b) of this section, all persons are prohibited from all processing and distributing in commerce of PIP (3:1), including in PIP (3:1)-containing products or articles after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

(2) *Phase-in Prohibitions for Specific uses of PIP (3:1) and PIP (3:1)-containing products and articles.* (i) After January 6, 2025, all persons are prohibited from all processing and distributing in commerce of PIP (3:1) for use in adhesives and sealants, PIP (3:1)-containing products for use in adhesives and sealants, and PIP (3:1)-containing adhesives and sealants.

(ii) After January 1, 2022, all persons are prohibited from all processing and distributing in commerce of PIP (3:1) for use in photographic printing articles and PIP (3:1)-containing

photographic printing articles.

(b) *Exclusions*. The following activities are not subject to the prohibitions in paragraph (a) of this section.

(1) Processing and distribution in commerce of:

(i) PIP (3:1) for use in hydraulic fluids either for the aviation industry or to meet military specifications for safety and performance where no alternative chemical is available that meets U.S. Department of Defense specification requirements, PIP (3:1)-containing products for use in such hydraulic fluids, and PIP (3:1)-containing hydraulic fluids either for the aviation industry or to meet military specifications for safety and performance where no alternative chemical is available that meets U.S. Department of Defense specification requirements.

(ii) PIP (3:1) for use in lubricants and greases, PIP (3:1) containing products for use in lubricants and greases, and PIP (3:1)-containing lubricants and greases.

(iii) PIP (3:1) and PIP (3:1)-containing products for use in new and replacement parts for motor and aerospace vehicles, the new and replacement parts to which PIP (3:1) has been added for such vehicles, and the motor and aerospace vehicles that contain new and replacement parts to which PIP (3:1) has been added;

(iv) PIP (3:1) and PIP (3:1)-containing products for use as an intermediate in a closed system to produce cyanoacrylate adhesives;

(v) PIP (3:1) for use in specialized engine air filters for locomotive and marine applications, PIP (3:1) containing products for use in specialized engine air filters for locomotive and marine applications, and PIP (3:1)-containing specialized engine air filters for locomotive and marine applications;

(vi) Plastic for recycling from products or articles containing PIP (3:1), where no new PIP (3:1) is added during the recycling process; and

(vii) Finished products or articles made of plastic recycled from products or articles containing PIP (3:1), where no new PIP (3:1) was added during the production of the products or

articles made of recycled plastic.

(2) Reserved.

(c) *Prohibition on releases to water.* After [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION OF THE **FEDERAL REGISTER**], all persons are prohibited from releasing PIP (3:1) to water during manufacturing, processing and distribution in commerce of PIP (3:1) and PIP (3:1) containing products, and all persons are required to follow all applicable regulations and best management practices for preventing the release of PIP (3:1) and PIP (3:1)-containing products to water during commercial use.

(d) *Recordkeeping.* (1) After [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE **FEDERAL REGISTER**], persons who manufacture, process, or distribute in commerce PIP (3:1) or PIP (3:1)-containing products or articles 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.

(2) These records must include a statement that the PIP (3:1), or the PIP (3:1)-containing products or articles, are in compliance with 40 CFR 751.407(a).

(3) These records must be made available to EPA within 30 calendar days upon request.

(4) The recordkeeping requirements in this paragraph (d)(1) do not apply to the activities described in paragraphs (b)(1)(vi) and (vii) of this section.

(e) *Downstream notification.* (1) Each person who manufactures PIP (3:1) for any use after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**] must, prior to or concurrent with the shipment, notify persons to whom PIP (3:1) is shipped, in writing, of the restrictions described in this subpart.

(2) Each person who processes or distributes in commerce PIP (3:1) or PIP (3:1)-containing products for any use after [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**] must, prior to or concurrent with the

shipment, notify persons to whom PIP (3:1) is shipped, in writing, of the restrictions described in this subpart.

(3) Notification must occur by inserting the text in paragraphs (e)(3)(i) and (e)(3)(ii) in the Safety Data Sheet (SDS) or by including on the label of any PIP (3:1) or PIP (3:1)-containing product the label language in paragraph (e)(3)(iii):

(i) SDS Section 1.(c): “The Environmental Protection Agency prohibits processing and distribution of this chemical/product for any use other than: (1) in hydraulic fluids either for the aviation industry or to meet military specifications for safety and performance where no alternative chemical is available that meets U.S. Department of Defense specification requirements, (2) lubricants and greases, (3) new or replacement parts for motor and aerospace vehicles, (4) as an intermediate in the manufacture of cyanoacrylate glue, (5) in specialized engine air filters for locomotive and marine applications, and (6) in adhesives and sealants before January 6, 2025, after which use in adhesives and sealants is prohibited. In addition, all persons are prohibited from releasing PIP (3:1) to water during manufacturing, processing and distribution in commerce, and must follow all existing regulations and best practices to prevent the release of PIP (3:1) to water during the commercial use of PIP (3:1).”; and

(ii) SDS Section 15: “The Environmental Protection Agency prohibits processing and distribution of this chemical/product for any use other than: (1) in hydraulic fluids either for the aviation industry or to meet military specifications for safety and performance where no alternative chemical is available that meets U.S. Department of Defense specification requirements, (2) lubricants and greases, (3) new or replacement parts for motor and aerospace vehicles, (4) as an intermediate in the manufacture of cyanoacrylate glue, (5) in specialized engine air filters for locomotive and marine applications, and (6) in adhesives and sealants before January 6, 2025, after which use in adhesives and sealants is prohibited. In addition, all persons are prohibited from releasing PIP (3:1) to water during manufacturing, processing and distribution in commerce, and must follow all existing regulations and best practices to prevent

the release of PIP (3:1) to water during the commercial use of PIP (3:1).”; or

(iii) Labeling: “The Environmental Protection Agency prohibits processing and distribution of this chemical/product for any use other than: (1) in hydraulic fluids either for the aviation industry or to meet military specifications for safety and performance where no alternative chemical is available that meets U.S. Department of Defense specification requirements, (2) lubricants and greases, (3) new or replacement parts for motor and aerospace vehicles, (4) as an intermediate in the manufacture of cyanoacrylate glue, (5) in specialized engine air filters for locomotive and marine applications, and (6) in adhesives and sealants before January 6, 2025, after which use in adhesives and sealants is prohibited. In addition, all persons are prohibited from releasing PIP (3:1) to water during manufacturing, processing and distribution in commerce, and must follow all existing regulations and best practices to prevent the release of PIP (3:1) to water during the commercial use of PIP (3:1).”

(4) The downstream notification requirements in this paragraph (e) do not apply to the activities described in paragraphs (b)(1)(vi) and (vii) of this section.

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