

Regulatory Alert

EPA Issued Final Rules Regarding Five PBT Chemicals

Country: USA

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INTENDED AUDIENCE

This Regulatory Alert is intended for IAEG members who are involved in the manufacture, import, processing, and distribution of certain persistent, bioaccumulative, and toxic (PBT) chemicals in the United States.

EXECUTIVE SUMMARY

On 6 January 2021, the Environmental Protection Agency (EPA) published the final rules (effective: 5 February 2021) under Section 6(h) of the Toxic Substances Control Act (TSCA), for five PBT chemicals listed below:

- Decabromodiphenyl ether (DecaBDE; CAS Number: 1163-19-5)
- Phenol, isopropylated phosphate (3:1) (PIP (3:1); CAS Number: 68937-41-7)
- 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP; CAS Number: 732-26-3)
- Hexachlorobutadiene (HCBd; CAS Number: 87-68-3)
- Pentachlorothiophenol (PCTP; CAS Number: 133-49-3)

The final rules detail requirements for prohibitions, restrictions and record keeping for the five PBT chemicals.

On March 8, 2021, EPA announced a 60-day public comment period to collect additional input on these final rules, and accepted comments until 17 May 2021. Also, EPA issued a 180-day “No Action Assurance (NAA)” regarding PIP (3:1) in articles. The NAA allows the EPA to exercise enforcement discretion related to prohibitions on processing and distribution of PIP (3:1) for use in articles and the articles to which PIP 3:1 has been added.

BACKGROUND ON REGULATION

TSCA regulates new and existing chemical substances, with the aim of protecting human health and the environment. It was enacted on 11 October 1976 by the EPA. TSCA regulates most chemical substances although there are some exemptions.

The TSCA regulation was revised in 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. These revisions impacted how chemicals are managed, tracked, evaluated, and disclosed. They include:

- Mandatory requirements for EPA to evaluate existing chemicals with clear and enforceable deadlines
- Risk-based chemicals assessments
- Increased public transparency for chemical information; and
- Consistent source of funding for EPA to carry out the responsibilities under this new act

Part 751 of the United States Code of Federal Regulations (CFR) establishes requirements pursuant to section 6(a) of TSCA regulating the manufacture/import, processing, distribution in commerce, use, or disposal of certain chemical substances and mixtures. The purpose is to address unreasonable risks associated with chemical substances or mixtures. 40 CFR 751.401 prohibited and restricted the manufacturing, processing, and distribution in commerce of five persistent, bioaccumulative, and toxic chemicals in accordance with section 6(h) of TSCA.

“PBT chemicals are of particular concern not only because they are toxic but also because they remain in the environment for long periods of time and can build up or accumulate in the body.”

APPLICABILITY

The EPA-issued final rules apply to the manufacture, import, processing, and distribution in commerce of the five chemical substances listed above and products or articles containing them. Certain activities for which the regulations do not apply are addressed in 40 CFR 751.401 (b). In addition, certain exclusions apply as described below.

RELEVANT DATES

- ❖ **TSCA effective:** 11 October 1976
- ❖ **EPA-issued final rules regarding five PBT chemicals published:** 6 January 2021
- ❖ **Final rules regarding five PBT chemicals effective:** 5 February 2021
- ❖ **180-Day NAA for PIP (3:1) effective:** 9 March 2021
- ❖ **180-Day NAA for PIP (3:1) expiry:** 4 September 2021 (11:59 PM ET)

Other relevant dates (for specific scope, requirements, and exemptions) are included in the sections below for each of the five PBT chemicals. However, the EPA may change these dates following the 60-day public comment period, which is scheduled to end on 17 May 2021.

REGULATORY OBLIGATIONS

In addition to being subject to export notification (TSCA section 12b) and import certification (TSCA section 13) provisions, the EPA-issued final rules for the five chemical substances are summarized in the table below:

Chemical	Scope, Requirements and Exemptions	Applications
<p>DecaBDE (CAS Number: 1163-19-5)</p>	<ol style="list-style-type: none"> 1. <i>Manufacturing, importing and processing of DecaBDE, and products or articles containing DecaBDE – prohibited^a</i> (Effective: After 8 March 2021) 2. <i>Distribution in commerce of DecaBDE, and products or articles containing DecaBDE – prohibited</i> (Effective: After 6 January 2022) 3. <i>Manufacturing, importing, processing and distribution in commerce for use in parts installed in and distributed as part of new aerospace vehicles, including replacement parts – prohibited^b</i> (Effective: After 8 January 2024) 4. <i>Recordkeeping: Manufacturers, importers, processors and distributors of DecaBDE, and products or articles containing DecaBDE – business records, such as invoices and bills-of-lading must be kept for three years after record has been generated (not required for first footnote – see below) to comply with prohibitions and other requirements in § 751.405</i> (Effective: After 8 March 2021) 	<p>Flame retardant in:</p> <ul style="list-style-type: none"> ● imported articles e.g. aerospace and automotive parts ● wire and cable rubber casings ● electronic equipment casings ● textiles ● building and construction materials

	<p>-----</p> <p>^a Exempts processing and distribution in commerce for the recycling of plastic containing decaBDE, and the products and articles made from such recycled plastics</p> <p>^b Importing, processing and distribution in commerce is prohibited for the following after the end of service lives of aerospace vehicles:</p> <ul style="list-style-type: none"> ● After 8 January 2024 - Manufacturing/importing, processing, and distribution in commerce of decaBDE for use in parts installed in and distributed as part of new aerospace vehicles and parts to which decaBDE was added ● All manufacturing, processing and distribution in commerce of decaBDE for use in replacement parts and the replacement parts for aerospace vehicles containing DecaBDE 	
<p>PIP (3:1) (CAS Number: 68937-41-7)</p>	<p>1. <i>Processing and distribution in commerce of PIP (3:1), and products or articles containing PIP (3:1) – prohibited</i> ^{a,b} (Effective: After 8 March 2021)</p> <p>2. <i>Releases to water from manufacturing, processing, and distribution in commerce of PIP (3:1), and products or articles containing PIP (3:1) – prohibited</i> (Effective: After 8 March 2021)</p> <p>3. <i>Processing and distribution 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 – prohibited</i> (Effective: After 6 January 2025)</p> <p>4. <i>Recordkeeping: Manufacturers, importers, processors and distributors of PIP (3:1), and products or articles containing PIP (3:1) – business records, such as invoices and bills-of-lading, must be kept for three years after record has been generated (not required for last two exclusions – see below) to comply with prohibitions and other requirements in § 751.407</i> (Effective: After 8 March 2021)</p> <p>-----</p> <p>^a Exclusions:</p> <ul style="list-style-type: none"> ● hydraulic fluids for aviation or to meet military specifications for safety and performance where no U.S. Department of Defense approved alternative chemical is available ● lubricants and greases ● new and replacement parts for motor and aerospace vehicles ● intermediate to produce cyanoacrylate adhesives in closed systems ● specialized engine air filters for locomotive and marine applications ● adhesive and sealant until 6 January 2025 ● recycling plastic from products or articles containing PIP (3:1) (no new PIP (3:1) added during recycling process) 	<p>Plasticizer, flame retardant, and additive in hydraulic fluids, lubricants and greases, various industrial coatings, adhesives, and sealants.</p>

	<ul style="list-style-type: none"> finished products or articles made from recycled PIP (3:1) containing plastic <p>^b Manufacturers, importers, processors and distributors of PIP (3:1) and products containing PIP (3:1) must notify their customers of the restrictions in 40 CFR 751.407, via Safety Data Sheets or labeling: Manufacturers/Importer - After 3/8/21 and Processors/Distributors – After July 6, 2021</p>	
<p>2,4,6-TTBP (CAS Number: 732-26-3)</p>	<ol style="list-style-type: none"> <i>Distribution in commerce of containers (containing 2,4,6-TTBP) with a volume of less than 35 gallons – prohibited with concentrations above 0.3% by weight (Effective: After 6 January 2026)</i> <i>Processing and distribution in commerce of 2,4,6-TTBP oil and lubricant additives with concentrations above 0.3% by weight. (Effective: After 6 January 2026)</i> <i>Recordkeeping: Distributors of 2,4,6-TTBP – business records, such as invoices and bills-of-lading, must be kept for three years after a record has been generated to comply with prohibitions and other requirements in § 751.409 (Effective: After 6 January 2026)</i> 	<p>Antioxidant in fuel additives and fuel injector cleaners, and additives in oil and lubricants</p>
<p>HCBD (CAS Number: 87-68-3)</p>	<ol style="list-style-type: none"> <i>Manufacturing, importing, processing and distribution in commerce of HCBD, and products or articles containing HCBD – prohibited ^a (Effective: After 8 March 2021)</i> <i>Recordkeeping: Manufacturers, importers, processors and distributors of HCBD, and products or articles containing HCBD – business records, such as invoices and bills-of-lading, must be kept for three years after record has been generated to comply with prohibitions and other requirements in § 751.413 (Effective: After 8 March 2021)</i> <p>----- ^a Exemptions:</p> <ul style="list-style-type: none"> unintentional production of HCBD as a byproduct whilst producing chlorinated solvents processing and distribution in commerce of HCBD for burning as a waste fuel 	<p>Solvent in rubber manufacturing, and in hydraulic, heat transfer or transformer fluid</p>
<p>PCTP (CAS Number: 133-49-3)</p>	<ol style="list-style-type: none"> <i>Manufacturing, importing and processing of PCTP, and products or articles containing PCTP – prohibited with concentrations greater than 1% by weight (Effective: After 8 March 2021)</i> <i>Distribution in commerce of PCTP, and products or articles containing PCTP – prohibited for concentrations greater than 1 % by weight (Effective: After 6 January 2022)</i> 	<p>Rubber industry applications</p>

	<p>3. <i>Recordkeeping: Manufacturers, importers, processors and distributors of PCTP, and products or articles containing PCTP</i> – business records, such as invoices and bills-of-lading, must be kept for three years after record has been generated to comply with prohibitions and other requirements in § 751.411 (Effective: After 8 March 2021)</p>	
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On 8 March 2021, the United States EPA issued a temporary 180-day NAA (effective: 9 March 2021), which states that the EPA will exercise its enforcement discretion to not pursue enforcement actions for violations relating (only) to:

- prohibitions on processing and distribution in commerce of PIP (3:1) for use in articles, and PIP (3:1)-containing articles
- business records requiring a statement that PIP (3:1) and PIP (3:1)-containing articles are in compliance with the above bullet point

RISKS TO AEROSPACE AND DEFENSE

Violation of this regulation may result in civil and criminal penalties such as fines and imprisonment as well as damage to the company's reputation.

USEFUL LINKS

Summary of TSCA:

<https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act>

PBT Chemicals under TSCA Section 6(h):

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/persistent-bioaccumulative-and-toxic-pbt-chemicals-under#risk>

Final Rule for DecaBDE:

<https://www.federalregister.gov/documents/2021/01/06/2020-28686/decabromodiphenyl-ether-decabde-regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under>

Final Rule for PIP (3:1): <https://www.federalregister.gov/documents/2021/01/06/2020-28692/phenol-isopropylated-phosphate-31-pip-31-regulation-of-persistent-bioaccumulative-and-toxic>

Final Rule for 2,4,6-TTBP: <https://www.federalregister.gov/documents/2021/01/06/2020-28690/246-tristert-butylphenol-246-ttbp-regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under>

Final Rule for HCBd:

<https://www.federalregister.gov/documents/2021/01/06/2020-28693/hexachlorobutadiene-hcbd-regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under-tsca>

Final Rule for PCTP:

<https://www.federalregister.gov/documents/2021/01/06/2020-28689/pentachlorothiophenol-pctp-regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under-tsca>

No Action Assurance for PIP (3:1):

https://www.epa.gov/sites/production/files/2021-03/documents/oeca_naa_tsca_pip_3-1_rule_3_8_21.pdf

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