

Insights

NEW TOXIC CHEMICAL REGULATIONS: IS YOUR SUPPLY CHAIN IMPACTED?

Mar 15, 2021

SUMMARY

There are new chemical regulations on the block, and your company's supply chain might be implicated. These rules prohibit both the manufacturing of certain bioaccumulating chemicals as well as the distribution of products that contain these chemicals. Read on for a high-level summary of the rules and what you should expect next.

The U.S. Environmental Protection Agency ("EPA") issued five final rules regulating the manufacture and distribution of certain persistent, bioaccumulative and toxic ("PBT") chemicals pursuant to the Toxic Substance Control Act ("TSCA") in January 2021. These rules became effective on February 5, 2021, and impact chemical and end use product manufacturers, suppliers, wholesalers, and merchants.

EPA is now revisiting the final rules following supply chain pressure. EPA announced a 60-day public comment period beginning March 8, 2021. EPA is seeking additional public comment on the five final rules. Significantly, EPA is exercising enforcement discretion in the form of a 180-day "No Action Assurance" for certain new requirements associated with one of the chemicals, PIP (3:1)—a common flame retardant chemical. Revised regulations or further guidance following the comment period are anticipated.

Under these new rules (and potential forthcoming changes), your company may need to closely review whether one or more of the newly regulated chemicals is present within its supply chain.

What are the Five Regulated PBT Chemicals?

- **2,4,6-TTBP** is commonly found in fuel additives, fuel injector cleaners and oil and lubricants.
- **DecaBDE** is used as a flame retardant in plastic enclosures and is commonly found in wire and cable rubber casings, textiles, building and construction materials, and aerospace and automotive parts.

- **PIP (3:1)** is commonly found in flame-retardants in plastics (including adhesives and paints) or functional fluids in aircraft and industrial machinery.
- **PCTP** is commonly found in rubber products.
- **HCBD** is commonly used as a solvent in rubber manufacturing and in hydraulic, heat transfer or transformer fluid.

How Will Manufacturers, Suppliers, Wholesalers, and Merchants Be Affected?

In 2016, Congress enacted the Frank R. Lautenberg Chemical Safety for the 21st Century Act as an amendment to TSCA. Pursuant to this amendment, Congress authorized EPA, under TSCA § 6(h), to take expedited regulatory action as to PBT chemicals without undergoing a traditional risk evaluation. EPA exercised this authority in regulating these five PBT chemicals.

Each new PBT chemical regulation includes a manufacturing or distribution and recordkeeping requirements. The restrictions on distribution in commerce are significant and will impact parties throughout the supply chain.

The regulations require manufacturers, suppliers, wholesalers, and merchants of “products” and “articles” (each as defined in 40 CFR § 751.403) to consider each article or product manufactured or distributed to determine whether any of the five PBT chemicals were incorporated into the article or product. If so, the products or articles may be prohibited from distribution in commerce and subject to other requirements, such as disposal and/or recordkeeping.

PIP (3:1) is getting particular attention given its common use. The final rule generally prohibits the processing and/or distribution in commerce of PIP (3:1) and PIP (3:1) containing products or articles after March 8, 2021, subject to specified exemptions and, now, a 180-day enforcement moratorium. This moratorium is intended to give downstream article manufacturers and distributors time to comply with the rule.

Downstream notifications to customers are expressly required for those manufacturing, processing, and distributing PIP (3:1) and products containing PIP (3:1). Companies must include specific language on the PIP (3:1) Safety Data Sheet or accompanying label, notifying customers of the PIP (3:1) restrictions. In the preamble to the final rule, EPA clarified that the downstream notification requirement only applies to scenarios in which a product is required to have an accompanying Safety Data Sheet (“SDS”). 86 Fed. Reg. 906 (Jan. 6, 2021). This guidance therefore clarifies that the downstream notification requirement does not apply to those products containing PIP (3:1) that do not require an accompanying SDS.

The restrictions are not knowledge or intent qualified. The strict liability nature of the restrictions suggest that upstream supply chain due diligence may be required. Neither the final rules nor EPA guidance specifies the extent to which companies may be required to investigate upstream

suppliers. The current strict liability approach means companies may need to review chemical composition as a part of their supply chain due diligence. The current PIP (3:1) rule does not allow such downstream manufacturers or distributors to rely on the absence of such PIP (3:1) notification from the upstream chemical manufacturer – due diligence may be required by downstream users. Moreover, EPA has not expressly required downstream notifications for the other four PBT chemicals, which may, in practice, require the downstream product or article manufacturer or distributor engage in additional upstream due diligence.

Why is EPA Requesting Additional Public Comment?

In EPA's [March 8, 2021 pre-publication notice](#), it announced a post promulgation, additional 60-day comment period for the five PBT rules. EPA took this action to ensure the five rules are consistent with the new Biden Administration's policies. EPA also noted it would review any new information provided by stakeholders, and it "plans to consider revisions in response to implementation issues that have been raised by a range of stakeholders." EPA Prepublication Notice, at 5 (March 8, 2021). EPA is specifically seeking comment regarding implementation issues of the PIP (3:1) regulation, but it also invites comments on the rules associated with the other four PBT chemicals.

How does the 180-day Enforcement Moratorium for PIP (3:1) Work?

Due to a large number of stakeholders raising concerns over the March 8, 2021 compliance date for PIP (3:1), the EPA issued a ["No Action Assurance,"](#) declaring it will not pursue enforcement actions for certain violations of PIP (3:1) processing and distribution requirements. This moratorium is for 180 days (until September 4, 2021) or until EPA issues a new compliance date, whichever occurs earlier. During this time, EPA will reconsider the compliance date for the PIP (3:1) prohibitions and may issue a new, extended compliance date.

It is important to note that the enforcement moratorium does not extend to the entire PIP (3:1) regulation. EPA will still enforce the prohibition on releasing PIP (3:1) to water, the recordkeeping requirement that businesses maintain ordinary business records related to PIP (3:1), and the downstream notification requirement. The moratorium also does not extend to the other four PBT chemicals.

What Should My Company Be Doing?

Each business should determine whether it manufactures, processes, or sells any of the five PBT chemicals and if any of the products or articles it sells contains PBT chemicals. Your company's products or articles may be subject to the PBT chemical regulations if the product or article distributed in commerce contains a regulated PBT chemical—even if the PBT chemical was added to the product earlier in the supply chain.

If your business determines it manufactures, processes or sells products and/or articles containing a PBT chemical, it will need to determine 1) which chemical is involved, 2) when its compliance

date begins and 3) if it falls within an exempted category. If your company's compliance date has commenced, and the product or article does not fall within an exempted category, your operations need to adhere to all manufacturing, processing and distribution restrictions and prohibitions, and implement any required recordkeeping, certification and notification requirements.

Businesses that process and distribute products and articles containing PIP (3:1) will not be immediately subject to EPA enforcement of the processing and distribution prohibition in light of the moratorium. That said, because PIP (3:1) is pervasive, businesses should not wait to investigate and locate PIP (3:1) in their processes and supply chains.

Why Else Is This Important?

EPA's focus on PBT chemicals signals its further interest in regulating bioaccumulating chemicals throughout the supply chain. Additional efforts to regulate and better understand the toxicity and bioaccumulation of other chemicals, such as certain per- and polyfluoroalkyl substances ("PFAS") are also increasing. For more information on PFAS, please click [here](#).

PBT chemicals are also an area of increasing concern within the on-going sustainability and environmental, social, and governance ("ESG") narratives. The use and distribution of PBT chemicals is an increasing component of companies' sustainability objectives.

Lastly, it is important to note that these U.S. regulations may not track other jurisdictions. For example, PIP (3:1) is not currently regulated as a PBT by the European Chemicals Agency ("ECHA") under the Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH") regulations (although it is currently under assessment). Jurisdictional discrepancies may warrant further review within the supply chain, particularly to the extent supplies are imported from outside of the U.S.

Contact

For questions regarding the contents of this alert or how the new regulations affect your business, please contact Erin Brooks (+1 314 259 2393), Elyse Voyen (+1 312 602 5019), or your BCLP relationship attorney.

Links

U.S. EPA News Release, EPA Seeks Public Comment on Protecting Human Health and the Environment from PBT Chemicals ([link](#))

2,4,6-TTBP [86 Fed. Reg. 866 \(Jan. 6, 2021\)](#); [40 CFR § 751.409](#)

DecaBDE [86 Fed. Reg. 880 \(Jan. 6, 2021\)](#); [40 CFR § 751.405](#)

PIP (3:1) [86 Fed. Reg. 894 \(Jan. 6 2021\)](#); [40 CFR § 751.407](#)

PCTP 86 Fed. Reg. 911 (Jan. 6 2021);40 CFR § 751.411

HCBD 86 Fed. Reg. 922, 928-29 (Jan. 6, 2021); 40 CFR § 751.413

MEET THE TEAM



Erin L. Brooks

Chicago / St. Louis

erin.brooks@bclplaw.com

+1 312 602 5093

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