

EPA's Authority to Regulate Chemicals in Finished Products: PFAS, PIP (3:1), and Beyond

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EPA is claiming expansive authority to use the Toxic Substances Control Act (TSCA) to regulate more than just chemical substances and mixtures. EPA's Assistant Administrator recently said, "Generally speaking, articles are manufactured goods or finished products – and the chemicals in them ARE subject to TSCA."^[1] Taken literally, this represents a significant expansion of EPA's regulatory authority under TSCA. EPA's proposed reporting and record-keeping rule for per- and polyfluoroalkyl substances (PFAS) and the final rules for PIP (3:1) already reflect that "importers" of finished "articles" will need to comply with new TSCA regulatory requirements. We look at EPA's statutory authority to use TSCA to generally regulate a finished "article" containing these chemicals, and more broadly.

EPA Regulation of Articles Containing Chemicals Under TSCA

Recently, Michal Freedhoff, Assistant Administrator for the Office of Chemical Safety and Pollution Prevention at EPA, spoke to the Product Stewardship Society. In her remarks, Freedhoff stated, "Generally speaking, articles are manufactured goods or finished products – and the chemicals in them ARE subject to TSCA."^[2] Freedhoff went on to say that "the law is very clear that when a chemical enters the United States, or is distributed or processed in the United States – whether in bulk form *or in an article* – it can be subject to regulation under TSCA."^[3] Freedhoff then walked through recent examples of where EPA is moving toward regulation of articles. These include the final rules for five Persistent Bioaccumulative, and Toxic chemicals (PBTs) and the proposed PFAS reporting and record-keeping rule. TSCA does expressly provide EPA with authority to regulate an "article" containing chemicals in certain provisions. Broad authority to regulate chemicals in articles across TSCA would, however, represent a significant change.

Defining the Word "Article"

The Frank R. Lautenberg Chemical Safety for the 21st Century Act went into effect on June 22, 2016. This amended and updated TSCA of 1976. Congress then directed EPA to adopt a PFAS reporting rule in TSCA by adding section 8(a)(7) in December 2020. This provision applies specifically to those who "manufactured a chemical substance" that is a PFAS.^[4]

Congress has included definitions of “chemical substance” and “mixture” in TSCA since 1976. The statute also consistently used the term “article” throughout. Congress did not, however, specifically define “article”—neither in 1976 nor in the TSCA amendments of 2016.⁸ Other provisions provide insight into the meaning that Congress attributed to “article.”

First, Congress defined “chemical substances” as “any organic or inorganic substance of a particular molecular identity.” Congress then specifically excluded from the term any “mixture” (as that term is separately defined in TSCA); any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act); tobacco or any tobacco product; any source material, special nuclear material, or byproduct material (as defined in the Atomic Energy Act of 1954); firearms and ammunition; and any food, drug, cosmetic, or device (as those terms are defined in the Federal Food, Drug, and Cosmetic Act).⁹ The more general term “article” is not, however, named among what is excluded. Because the statute does not “define articles as a category of substances exclusive of chemical substances,” EPA said in the proposed PFAS reporting rule that the “ability to regulate chemical substances [] encompass[es] authority to regulate articles containing such chemical substances.”^[7]

Nevertheless, other provisions of TSCA suggest that Congress viewed an “article” as distinct from either a chemical substance or a mixture. “Process” is defined as “the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce,” including “as part of an article containing the chemical substance or mixture.”¹⁰ Likewise, “distribution in commerce” is defined as follows:

when used to describe an action taken with respect to a chemical substance or mixture **or article containing a substance or mixture** mean[s] to sell, or the sale of, the substance, mixture, **or article in commerce**; to introduce or deliver for introduction into commerce, or the introduction or delivery for introduction into commerce of, the substance, mixture, or article; or to hold, or the holding of, the substance, mixture, or article after its introduction into commerce.¹¹

TSCA’s provisions contain other examples of where Congress added the word “article” in an apparent effort to broaden the reach of certain provisions.

Explicit Authority to Regulate “Articles” Found in Sections 5 and 6

There is express textual support for TSCA to permit regulation of articles in specific provisions, though not necessarily generally. Amendments to the statute signed into law in 2016 explicitly give EPA certain authority to regulate articles in particular circumstances. For instance, section 5(a)(5) states:

The Administrator may require notification under this section for the import or processing of a chemical substance **as part of an article or category of articles** . . . **if** the Administrator makes an **affirmative finding** . . . that the reasonable potential for exposure to the chemical substance through **the article or category of articles** subject to the rule justifies notification.^[10]

Thus, EPA may require manufacturers, processors, or importers of articles to notify EPA of a new chemical substance contained in an article or significant new use of an existing chemical substance within the article prior to beginning manufacture, processing, or importing. Nevertheless, this provision requires a predicate finding by EPA that the article is a reasonable exposure pathway for the chemical. In other words, the agency cannot simply decide to generally regulate all articles containing a chemical under this subsection.

Similarly, section 6(c)(2)(E) states:

The Administrator shall apply such prohibitions or other restrictions to an **article or category of articles** containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article or category of articles so that the substance or mixture does not present an unreasonable risk of injury to health or the environment **identified in the risk evaluation** . . .¹²

Here again, Congress grants EPA the authority to apply one or more of the requirements or prohibitions listed in section 6(a)(1)(7) to an article. Yet this is authorized only where EPA has completed a risk evaluation concluding that

the article is an unreasonable exposure risk.

Overall, the text of TSCA confirms that EPA has some authority to regulate articles given the presence of chemical substances or mixtures contained within the article. The broader context, however, appears to imply that such authority must be exercised within a risk-based framework, with chemical-specific analyses.

Proposal to Regulate Products Containing PFASs

In June 2021, EPA proposed a reporting and record-keeping rule for PFAS in accordance with section 8(a)(7) of TSCA. PFAS are found in many consumer goods sold by retailers. According to EPA, examples of where PFAS can be found include cleaners, textiles, leather, paper and paints, firefighting foams, and wire insulation.^[12] This rule is one of the “Key Actions” in EPA’s “PFAS Strategic Roadmap: EPA’s Commitments to Action 2021–2024,” released on October 18, 2021.^[13]

If finalized as proposed, the PFAS section 8(a)(7) reporting rule would require persons who have manufactured or imported^[14] a PFAS at any time since January 1, 2011—including finished articles containing or using PFAS—to make reasonable efforts to report this to EPA. Regulated manufacturers and importers would have a six-month submission period to report requisite information, with the reporting period beginning six months after the effective date of the final rule.

Notably, TSCA section 8(a)(7) does not expressly require reporting of PFAS use in articles. Nevertheless, EPA’s preamble states: “TSCA does not define articles, nor does the statute define articles as a category of substance exclusive of chemical substances. EPA therefore considers its ability to regulate chemical substances to encompass authority to regulate articles containing such chemical substances.”^[15] EPA specifically requested comment on whether articles should be included within the scope of the rule. The comment period for the proposed rule closed in late September.

Environmental groups articulated support for EPA’s regulation of PFAS-containing articles under section 8(a). These groups said that they agree with EPA’s reasoning that the definition of “chemical substances” does not exclude articles. They also present a textual argument grounded in the definition of “process.” Specially, the groups contend that TSCA section 8(a)(1) authorizes EPA to require reporting by PFAS processors. Because the definition of “process” references chemical substances or mixtures that are “part of an article,” they argue that Congress authorized the proposed reporting.^[16]

Certain industry stakeholders nevertheless asserted that the TSCA does *not* provide a textual basis for imposing the proposed record-keeping requirements on PFAS-containing articles. Their bases for excluding PFAS-containing articles from regulation include that the term “article” has been defined in regulations implementing section 8. Thus, an article is distinct from a “chemical substance.” Other stakeholders contend that Congress’s failure to expressly exclude articles from the definition of “chemical substance” does not mean that articles are included in the definition of “chemical substance.”^[17] Rather, they contend that the text and structure of TSCA clearly establishes three different categories: a chemical substance, a mixture, or an article. Industry comments also highlight the historic exemption of articles from TSCA inventory requirements and Chemical Data Reporting, as well as the burden of reporting on regulated entities.^[18]

Implications of PBT Regulations

Prior to the proposed PFAS reporting rule, EPA promulgated final rules to regulate five PBT chemicals, including phenol, isopropylated phosphate (3:1) (PIP (3:1)). PIP (3:1) is used as a plasticizer, a flame retardant, an anti-wear additive, or an anti-compressibility additive. It is used in many commercial and consumer products sold by retailers, including hydraulic fluid, lubricating oils, lubricants and greases, various industrial coatings, adhesives, sealants, and plastic articles.^[19]

The final PIP (3:1) rule was finalized in January 2021. It applies to processing and distributing PIP (3:1) in articles and imposes certain record-keeping requirements. In this final rule, EPA also contended that it could regulate replacement parts and articles without a specific risk assessment of section 6(c)(2). EPA’s reasoning for this rule, however, was more nuanced. EPA asserted a “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 section 6(h).”^[20]

After the final rule was promulgated, regulated entities informed EPA that there would be significant challenges to comply with the PIP (3:1) regulations in the time frame provided. At the center of this concern was that many manufacturers and importers of articles do not know whether or where PIP (3:1) is in their supply chains.^[21] In response, EPA extended the deadline for compliance with the PIP (3:1) rule until March 8, 2022.^[22] In her remarks to the Product Stewardship Society, AA Freedhoff said that EPA is not sympathetic to industry complaints about rules “simply ask[ing] them to survey their supply chains and tell the Agency what they found.”^[23] On October 28, 2021, however, EPA proposed to extend the compliance dates of certain PIP (3:1)-containing articles until October 31, 2024.^[24] Comments on the proposal close on December 27, 2021.

Key Takeaways

- EPA is signaling a significantly broader interpretation of its regulatory authority over finished products and imported articles after the new TSCA amendments of 2016.
- TSCA does grant EPA certain authority to regulate chemicals and mixtures in finished products and articles. Broader context nevertheless implies that EPA should make a risk-based finding on a pathway of exposure before regulation under certain provisions.
- Importers of finished goods and articles should closely monitor EPA’s TSCA regulatory actions going forward.
- Regulated entities should consider how increased scrutiny by EPA of finished products containing chemical substances may affect supply chains, reporting, and record-keeping obligations.

For further information or questions about regulation of articles under TSCA and potential impacts on your business, please contact [Jonathan D. Brightbill](#)* (Partner, White Collar, Regulatory Defense, and Investigations/Environmental Litigation), [Madalyn Brown](#) (Associate, Environmental), or your Winston relationship attorney.

* [Jonathan D. Brightbill](#) served in leadership of the Department of Justice’s Environment & Natural Resources Division from 2017 to 2021, ultimately as Acting Assistant Attorney General. Jon enforced TSCA and defended EPA rulemakings implementing TSCA.

Please note that government orders on the federal, state, and local level are changing every day, and the information contained herein is accurate only as of the date above.

^[1] Assistant Administrator Michal Freedhoff, Remarks at the Product Stewardship Society PSX 2021 (Sept. 28, 2021) (transcript available at https://insideepa.com/sites/insideepa.com/files/documents/2021/sep/epa2021_1858.pdf) (“Freedhoff Remarks”), at 3.

^[2] *Id.*

^[3] *Id.* (emphasis added).

^[4] 15 U.S.C. § 2607(a)(7).

^[5] EPA defined the term “article” in regulations. *see* 40 C.F.R. 704.3.

^[6] 15 U.S.C. § 2602(2).

^[7] 86 Fed. Reg. 33,930/1.

¹⁸ 15 U.S.C. § 2602(13).

¹⁹ *Id.* § 2602(5) (emphasis added).

¹⁰⁰ *Id.* § 2602(5)(a)(5) (emphasis added).

¹⁰¹ *Id.* § 2605(6)(c)(2)(E) (emphasis added).

¹⁰² EPA, *Risk Management for Per- and Polyfluoroalkyl Substances (PFAS) under TSCA*, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfas>.

¹⁰³ EPA, *PFAS Strategic Roadmap: EPA's Commitments to Action 2021–2024*, https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.

¹⁰⁴ The rule does not contain a definition of “importer” but instead uses “manufacturer” and “importer” interchangeably. (“In addition, please note that any use of the term ‘manufacture’ in this document will encompass ‘import’ and the term ‘manufacturer’ will encompass ‘importer.’” 86 Fed. Reg. 33,927/2.)

¹⁰⁵ 86 Fed. Reg. 33,930/1.

¹⁰⁶ See Earthjustice et al., *Comments on Proposed Amendments to 40 C.F.R. Part 705 to Add Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances Under TSCA Section 8(a)(7)*, Docket No. EPA-HQ-OPPT-0549-0092 (Sept. 27, 2021).

¹⁰⁷ See, e.g., Am. Chemistry Council, *Comments on TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances*, Docket No. EPA-HQ-OPPT-2020-0549-0022, at 4 (July 28, 2021).

¹⁰⁸ See U.S. Chamber of Com., *Comments on TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances*, Docket No. EPA-OPPT-0549-0021 (July 28, 2021); see also 3M, *Comments on Proposed Amendments to 40 C.F.R. Part 705 to Add Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances Under TSCA Section 8(a)(7)*, Docket No. EPA-HQ-OPPT-0549-0016, at 1 (July 28, 2021).

¹⁰⁹ EPA, *Persistent, Bioaccumulative, and Toxic (PBT) Chemicals under TSCA Section 6(h)*, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/persistent-bioaccumulative-and-toxic-pbt-chemicals>.

¹²⁰ 86 Fed. Reg. 898/3.

¹²¹ Freedhoff Remarks at 6.

¹²² 86 Fed. Reg. 51,823 (Sept. 17, 2021).

¹²³ Freedhoff Remarks at 8.

¹²⁴ 86 Fed. Reg. 59,684.

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Authors

[Jonathan D. Brightbill](#)

[Madalyn Brown Feiger](#)

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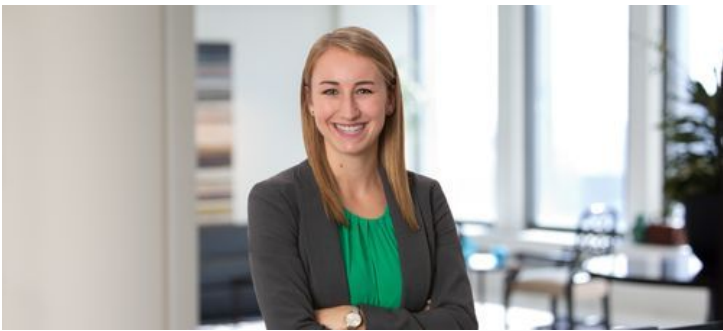
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[Jonathan D. Brightbill](#)



[Madalyn Brown Feiger](#)

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