

February 9, 2021

Via Email

Michal I. Freedhoff, Ph.D.
Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention

Yvette Collazo Reyes, Director
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20004-0001

**Re: Request to Extend Compliance Dates for PBT Rules and to Clarify
TSCA § 6 Rule for Phenol, Isopropylated Phosphate (3:1) (PIP 3:1)**

Dear Dr. Freedhoff and Ms. Collazo Reyes:

The Chemical Users Coalition (CUC)¹ is contacting you seeking your prompt intervention in the context of the ongoing review your office has been asked by the White House to undertake of the recently-published TSCA Section 6 regulations concerning certain substances EPA considers to be persistent bioaccumulative toxins (PBTs). Those rules include March 8, 2021 prohibitions on certain activities that will, without your intervention, effectively eliminate from manufacturing supply chains critically important products that may contain certain PBTs. We look forward to our constructive engagement and to conferring with you soon about the importance of this issue.

Information on Chemical Users Coalition

CUC is an association of companies from diverse industries interested in chemical regulatory policy from the perspective of entities that typically acquire and use, rather than manufacture or import, chemical substances. CUC has a history of very positive and collaborative engagement with OCSPP and OPPT on important topics. In particular, CUC has been active on regulatory matters that can affect the production and importation of manufactured articles. In October 2019, CUC submitted timely comments concerning

¹ The members of CUC are Airbus S.A.S., The Boeing Company, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, Raytheon Technologies Corporation, and Sony Electronics Inc.

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the proposed PBTs rules.² Many of the concerns we are raising now were addressed in our October 2019 comments. CUC supports the final regulations and its members are taking steps to ensure they come into conformance with the final regulations. CUC also recognizes the considerable efforts that have been required for EPA to meet the demanding deadlines imposed by the 2016 amendments to TSCA and we have consistently encouraged EPA to identify and adopt practical regulatory measures that appropriately reduce potential risks of exposure to and inadvertent releases of chemical substances, especially PBTs. However, CUC requests that during the ongoing review of the PBTs rules, the Agency immediately issue no less than a three-year extension of the compliance deadlines with respect to the production, processing, and distribution in commerce of articles used in electronic components and electrical equipment (plus an unlimited period for replacement parts for those articles) that may contain certain PBTs, and Phenol, Isopropylated Phosphate (3:1) (PIP 3:1) in particular. CUC also requests that the Agency clarify the restrictions on research and development (R&D) activities involving the PBTs (including when present in manufactured articles) when such R&D uses are important in investigating the performance capacities of substitute chemical substances and articles containing the PBTs.

Additional Background

Compliance with the PBTs rules in general, and especially the near-term provisions such as the March 8, 2021 prohibition on the distribution of certain articles that contain chemical constituents such as PIP 3:1, will present substantial difficulties for enterprises that are producers, importers, distributors, and users of manufactured components or electronics and electrical articles and the complex finished articles they comprise (e.g., manufacturing equipment, aircraft, mobile telephones, computers, printers, automotive components, durable household and commercial-use appliances). CUC's members operate on a global scale and for manufacturing operations in the US they may rely on affiliated companies and independent suppliers abroad. Consequently, the US-based entities are likely to be manufacturers and/or importers of numerous complex pieces of electrical equipment that may contain a multitude of individual components, each of which are finished articles themselves. Although CUC members intend to engage in good faith efforts to ensure materials they distribute in US commerce meet the requirements of the PBT rules, CUC's members and similar businesses are very unlikely to have sufficiently in advance of the March 2021 compliance deadline the critical information they would need from their various suppliers concerning the chemical composition of *each component* in a manufactured/imported piece of electronics or

²<http://www.chemicaluserscoalition.org/ckfinder/userfiles/files/PBT%20Rule%20Proposal%20Comments.pdf>.

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electrical equipment or finished product to be able to determine whether the goods manufactured/imported might contain PIP 3:1, or any other of the PBTs that are subject to the final Section 6 rules.³ Further, CUC members are manufacturers of products that must meet the technical specifications of their downstream customers (including military specifications) which require customer approval before changes may be made that can affect product safety and performance.

To reiterate, this is an issue of critical importance to the US economy which CUC members raised in our October 2019 public comments, and in other contexts during the preceding year.⁴

Basis for Extension

A material extension of no fewer than three years to the deadlines limiting production, importation, processing, and distribution in commerce of manufactured articles that may contain PIP 3:1 in particular is a reasonable and prudent approach which should be granted immediately for several reasons. As noted above, assuring a manufacturer's complex supply chain is completely in compliance with such an obligation would be a difficult, if not an impossible, undertaking prior to March 8 of this year. CUC members assemble, manufacture, and distribute exceptionally complex products that are used in the defense industry, commercial equipment, transportation products, and consumer appliances and electronics. Many articles and components acquired for use by CUC members or distributed for use in operations throughout industries engaged in such enterprises are likely to contain, even if in very small quantities, certain of the regulated PBTs, including PIP 3:1. If such component parts (which may include critical wires, insulation, and housings used in protecting the safety of electronic equipment) are prohibited from being distributed in US commerce commencing March 8, many supply chain failures in CUC member industries will become apparent immediately, at a time when additional strains on the US economy could be catastrophic.

As reported in January 28, 2021 correspondence submitted to the Agency by the Consumer Technology Association and the Information Technology Industry Council, the Agency erred in its assessment that PIP 3:1 is not currently used in manufactured

³ This is especially true for PIP 3:1 because it is not a substance that is subject to similar use limitations in other international economic communities and national markets.

⁴ <http://www.chemicaluserscoalition.org/ckfinder/userfiles/files/CUC%20Comments%20to%20EPA%20061220.pdf>.

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commercial and consumer use articles.⁵ This means that, notwithstanding good faith efforts to come into compliance, there is a significant risk that a manufacturer/importer/distributor of complex pieces of equipment, such as products that contain highly specialized electronic components, could find itself in violation of the final PBTs rule long after an article that may have been manufactured months ago subsequently arrives in the US and moves in commerce for potential use here. Even inadvertent violations of TSCA are punishable through civil penalties, with potential assessments as high as \$41,000 per day/per violation. It is highly unlikely the Agency has, or can effectively deploy, the resources and the mechanisms required to accurately monitor and enforce the requirements of the PBTs rules, especially as they apply to the movement (“distribution”) of manufactured products that contain certain PBT substances, and PIP 3:1-containing articles in particular.⁶ Thus, just as is the case for importers and users of complex equipment and manufactured articles such as CUC members, EPA itself is not likely to have reliable information on the composition of complex imported finished articles and their many component parts.

If procedural limitations prevent a three-year delay in the effective date of the pertinent (e.g., PIP 3:1) regulations from being timely published, we request that EPA issue a memorandum prior to March 8 which grants enforcement discretion for a similar (3-year) period of time. A similar approach was successfully and timely implemented by the Agency in the context of the implementing the TSCA Fees Rule when a “No Action Assurance” statement was issued.⁷

Replacement Parts for Electronics/Manufacturing Equipment to Remain Available

EPA also should give additional consideration when extending compliance deadlines for PIP 3:1-containing articles to ensure the continued availability of replacement parts for components required to maintain existing electronical equipment and electronics products (including for commercial, home and office use electronics) and

⁵ See statements made in EPA’s [Response to Public Comments: Regulation of Persistent, Bioaccumulative, and Toxic Chemicals under Section 6\(h\) of the Toxic Substances Control Act](#).

⁶This is due in part to the fact that the Agency interprets the TSCA Section 13 Import Certification requirements not to apply to chemicals that are a part of articles (unless such a Certification is specifically required by an existing regulation under TSCA). See the implementing regulations developed by US Customs and Border Protection, in consultation with EPA, at 19 CFR 12.118 through 12.127 http://www.ecfr.gov/cgi-bin/text-idx?node=pt19.1.12#se19.1.12_1118 and EPA’s interpretive guidance at <https://www.epa.gov/tsc-import-export-requirements/tsc-requirements-importing-chemicals>.

⁷ https://www.epa.gov/sites/production/files/2020-03/documents/no_action_assurance_regarding_self-identification_requirement_for_certain_manufacturers_subject_to_the_tsc-fee_rule_march_24_2020.pdf.

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manufacturing equipment which is currently in use in US businesses. The preamble to the final rules suggests EPA considers the statute to be ambiguous about the applicability in the PBT rules context of the requirement under Section 6(c)(2) of TSCA that specifically exempts replacement parts for complex durable and consumer goods that are designed prior to the effective date of a final Section 6(a) risk management rule. However, the same preamble makes clear the Agency considers the “practicability” standard to permit EPA to extend compliance deadlines for PBT rules that could affect the availability of replacement parts for existing products.⁸ Accordingly, CUC members encourage EPA to not only extend by at least three years the March 8, 2021 prohibition on distribution of PIP 3:1-containing products, but to permit an indefinite period thereafter for the distribution in the US of PIP 3:1-containing replacement parts for existing products and equipment.⁹

Research and Development Efforts are Critical and Should be Encouraged

To make matters more complicated, the final PBTs rules appear to unintentionally prohibit the manufacture/importation/distribution in commerce of articles that contain PIP 3:1 (or the other PBTs) for research and development activities that would include investigations into alternative material as substitutes for use in articles to be manufactured or imported for use in the US. Specifically, the preamble to the final PIP 3:1 PBT rule states that R&D will not be permitted after March 2021 for “the development of a new product, or refinement of an existing product that contains the chemical substance.”¹⁰ Such investigations are a critical step when seeking to compare (and ultimately seeking to qualify) chemical substitutes (including those incorporated into newly-manufactured articles) with existing products that contain the PBT substance for which substitutes are being investigated. Without this capacity to conduct R&D on such products and articles in the US, it will be fundamentally impossible for CUC members to find timely replacements that must meet highly technical performance specifications for products they manufacture (including those that must meet specifications issued by the Defense Department and other federal agencies). Responsible chemical management programs should be permitted, and encouraged by EPA, to identify alternatives, investigate formulations and articles using existing and new components, and to conduct quality and safety assessments that are instrumental in seeking alternatives and incorporating them in manufacturing processes and supply chains. These processes

⁸ 86 Fed. Reg. at 898.

⁹ This is necessary for suppliers of components and parts to comply with state requirements, such as California’s, which requires entities that sell electronics and electrical equipment to make replacement parts available for at least 7 years following the date of manufacture. California Code 1793.03.

¹⁰ See 86 Fed. Reg. 894, at 901 (Jan. 6, 2021).

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cannot be undertaken and completed within a 60-day timeframe such as contemplated in the final PBT rules. The current pandemic in the US and abroad continues to impose limits on certain supply chains, increasing the difficulties associated with finding alternatives and suppliers who have capabilities in certain high-technology sectors.

The R&D provisions in TSCA regulations generally require that R&D be conducted in accordance with prudent laboratory practices, such as those prescribed in standards issued by the Occupational Safety and Health Administration. R&D conducted in accordance with such practices is not reasonably anticipated to result in human exposures or environmental releases of PBTs. Thus, there is no risk based reason to support having a different definition of R&D activities under the PBT regulations than other TSCA regulations (e.g., the TSCA Section 5 and 8 rules). Forbidding R&D investigations that will enable careful and appropriate chemical substitutions does not reflect prudent public policy and can inadvertently defeat the underlying purpose of the PBT rules if regrettable substitutions are made.

Conclusion

For the foregoing reasons, CUC respectfully requests that no less than a three-year extension be issued for the March 8, 2021 compliance date in the final PBT regulations which generally restricts the distribution of articles and equipment that contain PIP 3:1, with an additional indefinite period thereafter for the distribution in commerce of replacement parts for such articles. CUC also requests that consideration be given to potential changes to the PBT rules to assure that companies are able to undertake R&D activities to develop substitute chemicals and products. As noted above, if the Agency is unable to timely publish in the Federal Register a formal modification to the regulation to extend the March 8, 2021 deadline in the PIP 3:1 regulation, it is imperative that near term measures be taken to grant enforcement discretion for a similar period of time.

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CUC members would be pleased to meet with you, or designated members of your staff, to discuss this request at your earliest opportunity. Please contact me at 202-942-5477 or via email at lawrence.culleen@arnoldporter.com.

Sincerely,



Lawrence E. Culleen
Counsel for the Chemical Users Coalition

cc: Mark Hartman, Deputy Office Director, OPPT
Joel Wolf, Branch Chief, Existing Chemicals Risk Management