

Before the United States Environmental Protection Agency
Decabromodiphenyl Ether and Phenol, Isopropylated Phosphate (3:1).
Proposed Revision to the Regulation of
Persistent, Bioaccumulative, and Toxic Chemicals Under Section 6(h) of TSCA
88 Fed. Reg. 82287 (November 24, 2023); Docket EPA-HQ-OPPT-2023-0376
Comments of the Chemical Users Coalition

Introduction and Background

Chemical Users Coalition (“CUC”) appreciates the opportunity to provide these comments regarding the U.S. Environmental Protection Agency’s (“EPA’s” and “the Agency’s”) recent proposal to amend its final regulations concerning certain persistent, bioaccumulative, and toxic chemicals (“PBTs”) that were identified pursuant to Section 6(h) of the Toxic Substances Control Act (“TSCA”).¹ CUC Members are grateful for the manner in which EPA has taken steps to solicit continuing participation by the stakeholder community when the Agency has considered amendments to ensure an orderly phasedown of certain uses of substances regulated as PBTs.

CUC is an association of companies from diverse industries that typically acquire and use, rather than manufacture or import, chemical substances.² CUC has been an active participant in the development of the 2016 amendments to TSCA and in providing comments in response to virtually every rulemaking the Agency has undertaken pursuant to the amended statute. This is because our members depend on the availability of certain existing substances for which often there are not technically feasible substitutes, as well as a reliable pipeline for innovative new chemistries to be able to thrive in a competitive global economy. CUC Members have consistently encouraged EPA to develop regulatory approaches that encourage innovation and permit sustainability. Thus, CUC supports measures that protect health and the environment in a manner that enables the regulated community to pursue technological innovation simultaneously with economic development in the United States. This is critical in the area of chemical regulatory policy, which necessarily addresses emerging information about health and environmental risk. Consistent with this approach, CUC has provided comments on each of the several phases of the PBT rules development.³

Consistent with our initial comments, CUC Members continue to encourage the Agency, when seeking to phase down or restrict the use of chemical substances of concern using its TSCA authorities, to collaboratively work with entities such as CUC that represent “downstream” users

¹ 40 CFR Part 751, Subpart E.

² The members of CUC are Airbus S.A.S., The Boeing Company, Carrier Corporation, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, National Electrical Manufacturers Association, RTX Corporation, Sony Electronics Inc., and TDK U.S.A. Corporation.

³ CUC provided timely comments to EPA on the initial proposed TSCA Section 6(h) rules concerning 5 PBTs and was among the few associations to have provided comments specifically raising concerns about the timelines proposed for the PIP (3:1) related restrictions.

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

CUC also had a leadership role in securing a March 1, 2021 meeting with the acting Assistant Administrator for Chemical Safety and Pollution Prevention concerning the urgent need for OCSPP to delay the March 8, 2021, effective date for the final PIP 3:1 rule’s general prohibition.

(who acquire and rely upon formulated products and manufactured articles) to identify practical phase-in periods. EPA's regulatory efforts with longer lead times will serve to encourage better communication within and across supply chains globally and further enable the Agency's objectives to promote responsible environmental practices with regard to manufactured articles that currently generally move with very few restrictions in international commerce.

For purposes of these comments, CUC will address the proposed PIP (3:1) amendments first, the proposed decaBDE amendment second, and other comments on the proposal more generally last.

CUC Comments on Proposed Amendments to PIP (3:1) Rule

CUC Supports a 10-Year Extension for PIP (3:1) in Equipment and Semiconductor Manufacturing

CUC Members appreciate and very much support EPA's proposed amendments to the PIP (3:1) provisions to enable an additional 10-year period for the continued processing and distribution in commerce of certain PIP (3:1)-containing articles and the PIP (3:1) used to process those articles for use in manufacturing equipment and in the semiconductor manufacturing industry. CUC Members agree with the Agency's findings that the electronics and electrical manufacturing, semiconductor manufacturing, and manufacturing equipment sectors require the extended compliance date to allow time to clear the existing articles through the supply chain, to find and certify alternative chemicals, and to produce or import new articles or complex goods that do not contain PIP (3:1).

CUC Members request that EPA clarify the proposed amendments to ensure the term "manufacturing equipment" is better understood. For example, CUC recommends EPA clarify the term manufacturing equipment referred to in the proposed extension for semiconductor manufacturing is applicable to equipment that is in use beyond just semiconductor fabrication facilities (or "fabs") and applies to ancillary facilities in the electronics sector related to semiconductor manufacturing, as well as the assembly of use- and product-specific packages and components, and to their installation within other products and finished articles in which they are used.⁴ CUC Members recommend the Agency provide a definition of the term "manufacturing equipment" with a non-exclusive list of examples. The definition could be used to illustrate that the terms of the extension apply more broadly to existing manufacturing equipment and newly-installed equipment, which may be in use in various manufacturing functions in the electronics industry, the semiconductor manufacturing industry, and other commercial sectors, such as those identified in the preamble to the proposed amendments (e.g., those in which certain PIP (3:1) uses are permitted to continue pursuant to various extensions or exemptions -- such as the aviation space and automotive sectors where robotics and similar equipment may be in use).

CUC notes that in the examples provided by EPA in the Preamble to the Proposed Amendments, a wide variety of industries even beyond semiconductor manufacturing are identified by the Agency where large pieces of complex equipment exist and are used (such as

⁴ This could be accomplished by changing the end of the proposed text in 751.407(a)(2)(ix) from "manufacturing, processing, and distribution of PIP (3:1)-containing products and articles for use in manufacturing equipment **and** in the semi-conductor industry" to "use in manufacturing equipment **or** in the semi-conductor industry."

medical appliances, diagnostic equipment, and laboratory appliances). It might be more straight forward for the 10-year extension to apply to all such pieces of heavy equipment in operation in the U.S. and to replacement parts produced to service and repair such existing pieces of such equipment.⁵

CUC Supports the Exclusion for PIP (3:1) Uses in Circuit Board Applications

CUC Members also support EPA's proposal to include an exclusion from the PIP (3:1) rules for wire harnesses, circuit boards, and circuit board coatings, and for the processing and distribution in commerce of PIP (3:1) and PIP (3:1)-containing products for use in wire harnesses and circuit boards. Our members in the electronics sector agree with EPA's finding that it would be impracticable to impose a timeline for this exclusion given the lack of availability of technically feasible substitutes across the multitude of functions severed by PIP (3:1) in these uses and components (i.e., as a plasticizer or flame retardant, etc.)

CUC Members request EPA clarify the scope of the items included within the exclusion. This could be achieved by providing a definition with a non-exclusive list of examples of various electronic components that would be covered. CUC Members recommend the list of examples to be provided be more expansive than "wire harnesses and circuit boards" and include any item that is attached to an electronic circuit board or that is necessary to secure, cover, or insulate an electronic component that gets attached to a circuit board.

We also ask that EPA make clear that this exclusion related to circuit boards and harnessing takes precedence in situations where other exemptions or phase-in periods are more limited in nature. For example, if a PIP (3:1)-containing circuit board is used in the production or repair of a piece of manufacturing equipment that is used in semiconductor manufacturing, or is installed or in need of repair in a piece of heavy equipment used in automotive manufacturing, after the extension period has expired for the semiconductor manufacturing equipment or heavy machinery in automotive manufacturing, the PIP (3:1) containing circuit board would still remain subject to the indefinite exclusion.

Furthermore, CUC recommends EPA consider simplifying its exemptions for "heavy machinery" used in "automotive manufacturing" and "semiconductor manufacturing equipment." CUC suggests it would be appropriate and simpler to propose applying the same indefinite exclusion as applied to circuit boards and related wire harnessing to the heavy machinery and manufacturing equipment referred to above. CUC considers this to be reasonable, and a more practicable approach, because the technological complexity of heavy machinery used in automotive manufacturing and semiconductor manufacturing equipment often present the same set of challenges to identifying technically feasible alternative chemicals as are faced by the producers of circuit boards and related housing, harnesses, and enclosures. Moreover, the need for compatible replacement parts meeting the same performance standards as the original materials will persist for the rest of the service life of heavy equipment used in auto manufacturing or semiconductor manufacturing machinery.

⁵ This should include the use of PIP 3:1-containing products and articles when needed to repair or restore these appliances and equipment to their original condition when necessary due to breakdowns and normal wear and tear.

CUC Requests EPA Retain Exclusion for Lubricants and Greases and Products Containing Them

CUC Members oppose EPA's proposal to narrow the current broad exclusion for PIP (3:1)-containing lubricants and greases (and products containing them) to a 5-year phase in period for non-aerospace uses. The proposal is impractical because our members in certain high-tech sectors (such as semiconductor manufacturing as well as the production and distribution of electronic equipment) are uncertain whether the 5-year period will be sufficient. CUC Members continue to be actively engaged throughout their industries in finding alternatives (where technically feasible) for PIP (3:1) containing lubricants and greases. However, at present, it is not reasonable to assume that technically feasible alternatives will be identified in the near term, nor that they might be tested and qualified for uses in high-technology applications within a 5-year period. CUC Members recommend EPA more seriously consider making broadly applicable the 30-year time limit EPA is considering only for aerospace and turbine applications. EPA has acknowledged the degree to which PIP (3:1) is a crucial anti-wear component for lubricants and greases that are used in electronics and other applications beyond aerospace, and which nevertheless must perform dependably and safely within extreme ranges of temperatures and in stressful climate conditions. At present, alternative chemistries are still not available, and a period of time that is considerably longer than 5 years will be required to bring substitute materials and components through regulatory and customer qualification processes.

Other PIP (3:1) Related Comments

CUC Supports Exclusion for Recycling PIP (3:1)-Containing Products/Articles and Products Made from Recycled Plastics

CUC Members consider this approach to represent environmentally sound policy in furtherance of EPA's general pollution prevention priorities. This approach also avoids the unintentional consequence of a prohibition on PIP 3:1-containing articles which can lead to unnecessary disposal and environmental loading where reuse and recycling can occur instead.

CUC Supports Requiring Inhalation and Dermal PPE During Domestic Manufacturing and Processing of PIP (3:1), But Not When Processing PIP (3:1)-Containing Products and Articles

CUC Members support the use of PPE in workplaces where exposure to PIP (3:1) during manufacture and processing of the substance itself is reasonably likely to occur. However, CUC does not consider it appropriate for EPA to require use of PPE where (as here) the Agency has not made an affirmative finding that exposures to workers is reasonably likely to occur from PIP (3:1) that is present in manufactured products and articles. As such, EPA should not prescribe controls that may not be appropriate for the particular circumstances of an individual workplace, and should limit the PPE requirement to processing which involves disassembly and recycling activities of PIP (3:1) containing articles when such activities are likely to generate airborne dusts and/or broken materials creating physical debris in the workplace which is likely to contain PIP (3:1).

CUC Members Favor Deadlines Including “Manufactured By” Dates

CUC Members continue to advocate for amendments to the Final Rules to clarify that products that contain PIP (3:1) that have been *manufactured prior* to the final prohibition dates in the final rule may continue to be processed in the U.S., distributed (i.e., “sold through”), and used indefinitely (including those that might be situated in warehouses or in the channels of trade and transportation in the U.S. and abroad).

Manufacturers, assemblers, and distributors of finished articles often lack control over and visibility into the dates when the products they generate are likely to be distributed in commerce by their down-stream customers, such as distributors and retailers. A prohibition on distribution in commerce of PIP (3:1) containing articles could potentially lead to disruptions and confusion within the supply chain. This scenario could unintentionally force distributors and retailers to either dispose of finished goods containing PIP (3:1) or return them to the manufacturers -- creating logistical challenges and potential unnecessary PIP (3:1)-containing waste. To prevent such unintended consequences, it is more practical and realistic to avoid setting compliance dates that are associated with the distribution in commerce timeline, and to rely instead on a “manufactured-by date” approach.

CUC Members Support Indefinite Exemptions for Replacement Parts to Service Products

As noted above, it would be more practical and appropriate for EPA to provide an indefinite exclusion for the production, processing, and distribution in commerce of replacement parts to be installed in existing PIP (3:1) containing products and equipment that has been manufactured or installed before the effective date of prohibitions in the final regulation, including complex goods and equipment used in manufacturing and processing operations in the U.S. CUC respectfully disagrees with the Agency’s interpretation that Section 6(c)(2)(D) of the Act does not apply in the context of Section 6(h) rulemakings. CUC interprets TSCA to require EPA to provide an exemption for replacement parts for complex durable and consumer goods that are designed prior to the effective date of a risk management rule.⁶

In addition, under California's Right to Repair law, as cited in California Civil Code § 1793.03, consumer technology companies are obligated to provide service and repair facilities with necessary service literature and functional parts for electronics valued at \$100 or more. This requirement extends for at least seven years from the date of manufacture of each product model or type. However, it is important to note that manufacturers often make bulk purchases of parts, and these inventories are frequently stored outside the United States. Consequently, even if the prohibition takes place on an import date basis, it would be challenging for manufacturers to comply with the rules fully. Consequently, an indefinite exemption for replacement parts would effectively address the unique compliance challenges that would otherwise be present.

⁶ Such replacement parts must be exempted from a risk management rule’s requirement by operation of law unless EPA finds that the replacement parts “contribute significantly to the risk” identified in a “risk evaluation” to the “general population or to an identified potentially exposed or susceptible subpopulation.” Since no risk evaluation was conducted for the PBTs rule, CUC interprets TSCA to require that such a 5-year exemption must be provided. See Section 6(c)(2)(D).

CUC Supports Establishing a De Minimis Exemption for PIP (3:1)

CUC recommends that as a practical matter, EPA establish in all 6(h) regulations for PBTs a *de minimis* standard of 0.1% by weight of the finished product or article⁷ to enable products in which PIP (3:1) is determined to be present only at or below such level may continue to be processed and distributed for use in the U.S.

CUC Recommends Changes to Make Respirator Requirement Consistent with OSHA Requirements

Proposed § 751.407(f)(2)(iii) states that “the owner or operator must supply a respirator” for persons within the regulated area. As CUC has commented previously (such as on the Proposed Risk Management Rule for Perchloroethylene), the imposition of this obligation on an owner or operator will create tensions between EPA rules and Occupational Safety and Health Administration (“OSHA”) rules and lead to confusion and potential compliance issues. Under the standards overseen by OSHA, the entity responsible for provision of respiratory protection is the employer - not the facility owner or operator. For a facility that may have many contractors present, this new compliance mandate could create enormous complexities. CUC therefore recommends that EPA adopt the approach of requiring “employers” to be the entities responsible for providing respiratory protection, while the owner or operator would be the entity responsible for ensuring compliance with the requirement. The revised provision could state: “the owner or operator must ensure a respirator is utilized by persons when working in the regulated area.” This language change would be consistent with current OSHA practice and ensure protections are in place while not being overly burdensome.

CUC Comments on Proposed Amendments to DecaBDE Rule

CUC considers EPA’s efforts to encourage the continued use and recycling of articles that contain decaBDE to be an appropriate exercise of Agency discretion and in recognition of EPA’s stated preference to encourage the reuse and recycling of substances and articles generally. This approach also avoids the unintentional consequence of a prohibition on decaBDE-containing articles which can lead to unnecessary disposal and environmental loading where reuse and recycling can occur instead. Furthermore, given the difficulties EPA has acknowledged with identifying which materials in a recycling stream may or may not contain decaBDE, CUC supports the current provisions of the decaBDE rule which permit the processing and distribution in commerce of recycled materials that contain decaBDE and products manufactured using such recycled content when no new decaBDE is added during the remanufacturing process.

⁷ This standard would align with the EU restrictions on chemicals designated pursuant to REACH as substances of very high concern when such substances are present in articles. *See e.g.*, ECHA Guidance on requirements for substances in articles, “Article 7(2) of the REACH Regulation must be interpreted as meaning that, for the purposes of application of that provision, it is for the producer to determine whether a Candidate List substance of very high concern, is present in a concentration above 0.1% weight by weight of any article it produces and, for the importer of a product made up of more than one article, to determine for each article whether such a substance is present in a concentration above 0.1% weight by weight of that article.” https://echa.europa.eu/documents/10162/23036412/articles_en.pdf.

As with CUC's recommendations on PIP (3:1), CUC recommends that as a practical matter EPA establish a *de minimis* exemption for finished products or articles containing decaBDE at 0.1% by weight or less such that such products may continue to be processed and distributed for use in the U.S.

Other CUC Comments on Proposed Amendments

- CUC Members request that EPA confirm its previously-expressed interpretive statements (i.e., those concerning Section 751.401(b)(1)) that the final rule does not prohibit movements in commerce of previously manufactured products (to include both consumer products *and* commercial, military, and industrial equipment), including shipments between facilities in the U.S. as well as customer returns for exchanges or servicing of commercial and consumer products. Thus, CUC asks EPA to reiterate that the provision at 40 CFR 751.401(b)(1) permits an article or product that has been purchased or acquired other than for resale to be re-distributed, leased, or re-sold.
- Because many international enterprises acquire and install and even relocate large and complex manufacturing equipment between facilities both within and beyond the U.S., CUC Members also request that EPA make clear that the language in Section 751.401(b)(1) permits the importation and movement within the U.S. of complex manufacturing equipment and durable goods that might contain PIP (3:1)-containing components when such equipment or durable goods were manufactured *prior* to the date of any final prohibition in the PIP (3:1) regulation.
- CUC also requests that EPA re-state its previously articulated position that the downstream notification requirements of the PBT rules do not extend to manufactured PBT containing articles when such articles are not normally accompanied by a Safety Data Sheet.
- CUC also asks that in any final amendments to the existing PBT rules, EPA clarify that the amendments do not have any bearing, or impose new restrictions, on existing products/articles manufactured before the effective various dates (no matter their location). CUC requests that EPA make clear that all existing products and articles that were manufactured prior to the various final effective dates in the PBT regulations are exempt. CUC understands EPA *does not* intend that the amended rule, if modifications are finalized, will prohibit the continued use and processing of existing products and articles that contain one or more of the regulated PBTs. This clarification is particularly important for replacement parts to service products, as explained above for PIP (3:1).
- CUC requests that EPA's prior interpretations on imports/exports of articles should not be changed. CUC requests the Agency not revisit or modify the positions EPA expressed in the final PBT rules specifically providing that "articles" that contain the identified PBT substances will not be subject to the TSCA Section 12 export notification requirements and will not be subject to TSCA Section 13 import certification requirements. This position was clearly stated already, and it aligns with the current Section 12 rules at 40 CFR Part 707 and long-established Section 13 interpretations. Any changes in this regard would be difficult, if not impossible, to enforce and impracticable for the regulated community to implement.
- CUC Members reiterate the comments we provided during the 2019 proposal phase that EPA should establish a mechanism whereby regulated entities may contact the Agency

voluntarily to seek some form of enforcement discretion or an informal extension to the compliance dates based on their situational or product- and use-specific needs. This might occur when a business has conducted reasonable “due diligence” such as advising its suppliers of the various prohibitions in the PBT rules, establishing contract terms and other agreements which are intended to specifically exclude the PBT substances in products and articles supplied, and the business nevertheless acquires information well after a prohibition takes effect that a supplier is (or has) previously provided the business with commodities that contain one or more of the prohibited PBTs. EPA should provide written guidance to entities on a going-forward basis concerning how to contact EPA and deal appropriately with such commodities in such situations. Penalties in such instances should be waived (or significantly reduced) to encourage such situations to be disclosed, addressed promptly, and timely mitigated.

- The proposed § 751.403 defines the term “regulated area” as an area where airborne concentrations or direct dermal contact of a specific chemical substance can reasonably be expected. While CUC agrees with the proposed requirement for dermal protection when contact is expected, we disagree with the EPA on dermal contact being a driver for a “regulated area.” The proposed rules for methylene chloride, perchloroethylene, carbon tetrachloride, and trichloroethylene all define a “regulated area” based on exposures to airborne concentrations of a specific chemical substance and protect against dermal contact as appropriate. One can rationalize airborne concentrations triggering a regulated area, as a person may enter an area unknowingly and be exposed by just breathing. However, when airborne concentrations are not expected, the risk of dermal contact would be low. CUC recommends that the EPA be consistent across all the TSCA rules when defining a “regulated area” and remove dermal contact from the proposed definition. The proposed 751.405(g) imposes a requirement to “follow any applicable regulations and best management practices for preventing the release of decaBDE.” CUC questions why a provision that mandates compliance with applicable regulations would be needed. Such compliance is required by simple operation of law. Furthermore, EPA has not provided any guidance or interpretation on what constitutes an applicable “best management practice.” Even if EPA did identify such practices, EPA would be making the compliance with an unknown and unspecified “best management practice” a regulatory requirement, which is problematic due to its lack of specificity and the opportunity it creates for arbitrary standards for interpretation and enforcement. CUC therefore recommends that this provision be eliminated, or at least that the clause concerning “best management practices” be removed.
- As mentioned above by PIP (3:1), CUC Members support the use of PPE in workplaces where exposure to decaBDE during manufacture and processing of the substance itself is reasonably likely to occur. However, CUC does not consider it appropriate for EPA to require use of PPE where (as here) the Agency has not made an affirmative finding that exposures to workers is reasonably likely to occur from decaBDE in processing of manufactured products and articles. As such, EPA should not prescribe the use of PPE in circumstances other than those that are likely to generate the opportunity for exposures to occur. CUC recommends EPA should limit the PPE requirement for decaBDE only to processing activities which involve the disassembly and recycling of decaBDE containing articles when such activities are likely to generate airborne dusts and/or broken materials creating physical debris in the workplace which is likely to contain decaBDE. CUC also

recommends that when dermal protection is required, and the material in question (such as decaBDE) would be in solid form (such as in a recycling facility), that EPA should make clear that the gloves selected for such use need not be chemically impermeable. Similarly, when respiratory protection is in the form of commonly worn N95 masks, only qualitative fit testing should be required.

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Summary and Conclusion

CUC reiterates that the compliance challenges posed by the presence of the PBTs in articles is substantial. Consequently, CUC recommends that: a de minimis limit be established; prohibitions should take effect based on a “manufactured-by” date; provisions that encourage recycling and reuse be maintained; and that the needed occupational exposure controls for those working with articles be determined by the industrial hygiene personnel at the facility.

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In closing, CUC Members again express our appreciation to the Agency for its efforts to address our concerns to date, and for soliciting public input on the proposed amendments currently under consideration. As always, CUC Members would be pleased to meet with EPA personnel to discuss these comments and related issues as the Agency continues its efforts to reconsider certain features of the PBT rules.