October 25, 2019

Before the United States Environmental Protection Agency
Persistent, Bioaccumulative, and Toxic Chemicals Under
Section 6(h) of the Toxic Substances Control Act
84 Fed. Reg. 36,728 (July 29, 2019); Docket EPA-HQ-OPPT-2019-0080-0001

Comments of the Chemical Users Coalition

The 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") proposed rule concerning certain persistent, bioaccumulative, and toxic chemicals ("PBTs") that were identified pursuant to Section 6(h) of the Toxic Substances Control Act ("TSCA").

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.[1] CUC encourages regulators to develop and implement requirements to protect health and the environment in a manner that enables the regulated community to pursue technological innovation simultaneously with sustainable 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.

CUC recognizes the considerable efforts required for EPA to meet the demanding schedule and deadlines imposed by the 2016 amendments to TSCA. In light of the number of challenges the Agency is facing and the limited resources with which it must work, CUC encourages EPA to identify and adopt practical regulatory measures that appropriately reduce potential risks of exposure to and inadvertent releases of chemical substances, especially PBTs.

In sum, the following comments support EPA's efforts to carefully consider stakeholder input and to propose pragmatic measures intended to limit exposures to the PBTs considered to the extent practicable. CUC is making several suggestions concerning ways in which the proposal can and should be clarified before a final PBT rule is promulgated. Importantly, CUC encourages EPA to perform a credible risk assessment of the risks to human health and the environment based on the basic use and exposure information EPA has obtained for the 5 PBT substances at issue. Among CUC's other suggestions, we encourage EPA to clarify the proposal to: (a) address how the Agency has taken into account certain requirements in the amended law that relate to the selection of risk mitigation measures, and those provisions requiring specific findings with respect to exposures to substances within manufactured articles, including replacement parts; (b) specifically state that the regulations proposed would permit the continued use and distribution in commerce of *existing* products (e.g., previously formulated products, replacement parts/components, and manufactured articles) that may contain the PBT substances; (c) remove ambiguity in the recordkeeping provisions; (d) provide guidance on how EPA intends to monitor and enforce compliance with the final rules and establish a mechanism for regulated

[1] The members of CUC are Airbus S.A.S., The Boeing Company, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, and United Technologies Corporation.

entities to request exemptions or extensions in the compliance dates; (e) limit the prohibition on releases to water of PIP 3:1 to those which are intentional; and (f) provide for the presence of small quantities of regulated PBTs that are unintentionally present in a product or article.

CUC Comments Concerning Legal and Policy Matters

CUC appreciates and encourages EPA's outreach efforts. It is clear from the record established for the proposed PBT rulemaking that Agency personnel engaged directly with stakeholders in the regulated community and in public interest groups to seek their input on matters of importance to them. CUC encourages the Agency to continue this approach on other regulations that are likely to be developed and proposed as the Agency fulfills its numerous obligations under the amendments made to Sections 4, 5, 6, 8 and 14 of TSCA.

CUC encourages EPA to perform a credible risk assessment to support this important rulemaking. Although Section 6(h) states that EPA "shall not be required" to conduct a risk evaluation on substances from the Work Plan list that EPA considers to have met the statutory standard for PBTs, CUC recommends that, at the minimum, a basic risk assessment be conducted by the Agency before the final rule is issued, and that the preamble to the proposal and supporting docket be updated to reflect the Agency's findings, and additional comments be solicited in this regard. The absence of even the most basic risk assessment makes it impossible for the regulated community and other interested parties to determine the merits of the proposed regulation and whether it is even necessary to mitigate risks. The absence of a risk assessment also makes it unlikely EPA can satisfy its statutory obligations under the amended law to consider various factors set forth in Section 6(c)(2) — including to ascertain the costs and benefits of the rulemaking and at least one or more alternative regulatory approaches. *See also* discussion below. Moreover, without some effort to assess the risks presented by *products* and *articles* that contain the PBTs under consideration, EPA cannot fulfill its regulatory review obligations under Executive Orders 12866 and 13563 which require the Agency to quantify the costs and benefits of a proposed regulation before it is promulgated. EPA has plainly acknowledged in the proposal's preamble its current inability to meet this obligation in the absence of a more in-depth analysis of the risks and benefits of the PBT substances, the potentially affected products, the technical and economic feasibility of alternative substances and products, and impacts of the proposed rule.[2] The applicable statute, sound public policy, a long line of Executive Orders, and established Agency policies make clear the need for EPA to more carefully consider the benefits and impacts of its regulatory actions. Performing a basic risk assessment would enable EPA to undertake a more credible analysis of the benefits of the PBT proposal.

The proposed rule fails to address findings required under TSCA Section 6(c), including findings required for regulated articles. CUC is concerned that the preamble to the Agency's proposal does not explain how the Agency addressed important requirements in the amended law that are pertinent to the proposed PBT rulemaking. Because Section 6(h) directs EPA to promulgate its PBT rule pursuant to Section 6(a) of TSCA, the Agency must do so in accordance with the

[2] "Due to the lack of risk information, EPA was not able to quantify the benefits of this proposal and the alternatives. A qualitative discussion of the potential benefits associated with the proposed option for each chemical is provided." Proposal at p. 36731.

requirements of Section 6(c)(2). Section 6(c) requires EPA Section 6(a) rulemakings to include a statement addressing numerous statutory factors and how the Agency took these factors into consideration "to the extent practicable." The proposal's failure to specifically address these obligations in the context of the Agency's proposal to regulate articles and manufactured products that contain the regulated PBTs represents an oversight of particular importance to the sector of the regulated community that purchases and uses products and articles manufactured by others, such as CUC's member companies.

The amended law requires EPA, when selecting regulatory controls that will be imposed under Section 6(a) on *articles* containing a chemical substance, to select "only" those restrictions "necessary to address the identified risks from exposure to the chemical substance or mixture from the article" such that the chemical substance or mixture will not "present an unreasonable risk of injury" to health or the environment identified in its "risk evaluation". *See* Section 6(c)(2)(E). The preamble to the Agency's PBT proposal does not satisfy this requirement as there is nothing in the record explaining whether EPA has attempted to ascertain the extent to which the PBT substances are reasonably anticipated to be released from manufactured products or articles at material levels.

Similarly, Section 6(c)(2) specifically exempts replacement parts for complex durable and consumer goods that are designed prior to the effective date of a risk management rule. Such replacement parts are exempted from a risk management rule's requirements 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." *See* Section 6(c)(2)(D). Again, the record in support of the proposal contains nothing to suggest whether or how EPA has attempted to ascertain the extent to which the various PBT substances are reasonably anticipated to be released from such critical replacement parts at material levels.

Without an assessment which finds that the pertinent PBT substance will be released from the articles or otherwise exempt replacement parts in which it is present, and evidence to support that the quantity released is material in the context of potential risk to human health or the environment, the Agency is unable to articulate a sufficient basis to support the Section 6(c) findings it is required to make when engaged in rulemakings affecting articles or otherwise exempt replacement parts under the amended statute. By electing not to perform even the most basic risk assessment of the chemicals and products being regulated, EPA has not met its obligation to state whether and how (in the absence of conducting a risk assessment) EPA has determined it has selected "only" those mitigation techniques that are "necessary" to reduce the "identified risks from exposure to the chemical substance" to levels below which such risks will be considered reasonable.

CUC requests EPA address whether the Agency may use its Section 6(h) authority in future rulemakings. The proposal does not make clear whether EPA considers the amendments to TSCA that include Section 6(h) to enable the Agency to use the same criteria at a later date to identify other PBTs and to expedite rulemakings affecting such substances in the future. CUC interprets the expedited process called for under Section 6(h) to pertain solely to the subset of

existing substances EPA identified as candidates for this action in 2016. Nevertheless, CUC requests that this be clarified in the final PBT rule.

CUC Comments on PBT Proposal's General Provisions

CUC requests EPA clarify and correct certain definitions.

The definitions section of the proposed rule contains a definition for the term "chemical substance" which appears to differ from the one in the statute. CUC expects this will create potential confusion. CUC recommends the final rule simply refer to the statutory definition.

The proposal also states the definitions in "subpart A of this part" will apply. However, we understand the proposed rule will be codified as "subpart E" of a new part 751 (for which no subpart A currently exists). CUC requests EPA clarify what subpart A definitions EPA is referencing.

The proposal uses the term "product" throughout, but it is not defined in the rule. In certain passages, it appears EPA uses the term interchangeably with "article," but in other contexts it also is used to describe formulations which are distributed in commerce for use (e.g., lubricants, hydraulic fluids). Formulations are distinct from articles (a term defined under numerous other TSCA regulations). It appears EPA intends that the term product means any commercial good which is sold or distributed in commerce for use by another party. However, the term also can apply to manufactured goods that might be distributed without sales or commercial transactions or exchange, for example when transferred to various facilities within the same commercial entity for use and consumption by the same entity (e.g., a formulation which is distributed for further processing). The use of the terms product and article should be addressed and clarified.

Clarify that existing products and articles will not be affected by the proposed (and final) Section 6(h) rule. Each of the proposed rules would prohibit the manufacture (import) and processing for use of the 4 regulated PBTs in products and manufactured articles. CUC understands EPA does <u>not</u> intend that the rule, when finalized, will prohibit the continued use and processing of *existing* products and articles that contain one or more of the regulated PBTs. Thus, when final, the PBT rules should affect only newly-manufactured products and articles. This should be clarified in no uncertain terms in the final rule, if not sooner, so the public may provide comment on both the language in the proposal, and whether it serves the Agency's intent.

Address how compliance will be demonstrated and provide for longer lead times for demonstrating compliance, and provide a mechanism to request exceptions or extensions. EPA should consider providing a supplemental proposal which clarifies this issue and how the Agency would expect manufacturers (importers) and processors to demonstrate their compliance with a requirement which affects only newly-manufactured goods. Such a supplement should provide and clarify a "phase-in" date for each of the PBTs (and products) that will be affected.

EPA could use the opportunity to supplement its proposal to provide guidance on how compliance should be demonstrated.[3] For many products that contain a large number of complex components (many of which in certain industries may be subject to customer, technical, and regulatory specifications), a lengthy phase-in period will be necessary before "compliance" must be demonstrated. For example, EPA should take into consideration that many pieces of complex equipment must be tested and certified pursuant to legal as well as performance-based standards for which long lead times are required whenever components are updated or replaced. The pipeline for development of a product by a CUC member can be as much as a decade (and potentially longer for products placed on the global market). From global supply chains that can include thousands of suppliers of "OEM" equipment, manufacturers must select potential candidates and conduct lab-scale evaluations of the candidates, then perform pilot-scale tests to prove reliability and repeatability with respect to performance specifications. Following these steps, customers' acceptance of the qualifications must be obtained. This may first require, or be followed by, obtaining certifications from US federal agencies and/or their international counterparts. Additional time is required to move such modified products and instruments into commercial production for the market.

For this reason, a short and inflexible phase-in period, such as the three-year period for decaBDE, that does not account for products that may require years in development may not be appropriate. The Agency should establish in the regulation a mechanism whereby regulated entities may submit requests to EPA for exemptions or extensions to the compliance date based on product- or use-specific needs. CUC considers such a provision to be within the discretion granted to the Agency by the 2016 amendments, and Section 6(g) in particular.

For these reasons, CUC members would be pleased to meet and confer with EPA to provide further guidance on the time required for phasing in such requirements for complex materials such as those produced by our members and to discuss the need for a mechanism to request exemptions and extension requests.

Address R&D and laboratory uses of PBTs. The scope of the rule with respect to laboratory use substances should be made clear. CUC requests that EPA specifically exempt in the final rule all of the regulated PBTs when they are manufactured (imported) or processed solely for use in R&D and for use as a "laboratory standard" and related applications.

[3] CUC notes EPA's proposals in relation to decaBDE and PIP 3:1 to maintain ordinary business records, such as invoices and bills of lading, to demonstrate compliance with the proposed restrictions. CUC questions whether such prescriptive documentation requirements are truly necessary for demonstrating compliance. Instead, EPA should give regulated entities broad latitude to demonstrate compliance via means tailored to their industry and supply chain. For instance, manufacturers of complex goods routinely provide material and process specifications that their operations and their suppliers are required to follow to manufacture a given product or article. Compliance with a relevant PBT restriction, therefore, can be readily demonstrated by reference to those specifications and the absence (or presence) of a regulated PBT in those specifications. In those instances, a bill of lading or invoice stating the absence (or presence) of a PBT in compliance with a restriction would be wholly unnecessary and only adds burden and complexity to existing supply chain communications. EPA should consider that manufacturers and suppliers in various industry sectors have or are adopting supply chain communication protocols and requirements that are tailored to their particular circumstances. Any EPA proposal that does not account for those circumstances risks substantial disruption of those efforts.

Clarify TSCA Sections 12 and 13 implications of proposed PBT rule. CUC requests EPA supplement the proposed rule to address how "articles" that contain the identified PBT substances will be treated for purposes of the TSCA Section 12 export notification requirements and how imported articles would be treated for purposes of the TSCA Section 13 import certification requirements. The current Section 12 rule at 40 CFR Part 707 requires export notification for all substances subject to even *proposed* Section 5 and 6 rules, including articles *if* the specific rule in question so specifies. Section 13 import certifications are not required for articles unless EPA specifies by rule. However, Section 13 import certifications include within their scope a determination that the contents of an import shipment are in compliance with Sections 5, 6 and 7. Given that the proposed PBT rule specifically covers certain products (including mixtures) and articles, the absence of guidance on this point in the proposed rule creates considerable ambiguity and presents challenges for importers *and* exporters of products and articles that might contain one or more of the PBT substances.

CUC Comments on PBT Proposal's Chemical-Specific Provisions

Recycling. 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 recognition of EPA's stated preference to encourage the reuse and recycling of substances and articles generally. *See* proposed § 751.405(a). Thus, CUC recommends EPA extend this approach to the other identified PBTs to the extent the proposed rule would affect newly-manufactured articles, especially given that there are manufactured articles already in commerce that contain those substances and for which recycling is already an ongoing, established practice (e.g., PIP 3:1, PCTP).

Clarification is needed on scope of PIP 3:1 exceptions for lubricants and greases and replacement/spare parts. The terms of the exceptions at proposed § 751.407(a)(1) would benefit from clarification. It is possible this could be accomplished through edits to the rule language, or through statements that could be included in the preamble to the final rule. Accordingly, CUC requests that the Agency specifically clarify that the exception provided for use of PIP 3:1 in "lubricants and greases" is broad in nature and is not limited to any particular industrial sector's uses in this regard. Thus, uses of PIP 3:1 in lubricants used in marine and rail engine applications should remain permitted, as should uses in hydraulic fluids common in the aeronautics industry. CUC also would like EPA to clarify the exception for PIP 3:1-containing replacement parts in proposed § 751.407(a)(1)(iii). CUC requests that the exception should be modified so it is not limited to replacement parts used in automobiles and other vehicles and instead should be clarified to include PIP 3:1-containing replacement parts used in other sectors that produce and must maintain high-performance, complex equipment such as the electronics, aerospace and defense industries.

Releases to water. To the extent EPA has proposed a prohibition on releases of PIP 3:1 to water, EPA should clarify how that prohibition will be interpreted and enforced. CUC recommends a final rule clarify that the prohibition is limited only to "purposeful" releases from manufacturing, processing and commercial uses of PIP 3:1-containing formulations. Although it might be anticipated or perhaps predictable that at some point accidental or unintentional releases of some

quantity of PIP 3:1-containing formulations might occur during such uses, such accidental and unintentional releases are not "purposeful" and should clearly be beyond the scope of this PBT regulation. EPA should consider clarifying the rule to specifically provide that inadvertent *de minimis* releases of PIP 3:1 are outside of the scope of the prohibition on releases to water.[4]

Downstream notifications. CUC recommends that EPA limit the requirement to modify and supply safety data sheets ("SDSs") for formulations that contain PIP 3:1 to the original manufacturer or importer of such formulations. Downstream users and distributors of these formulations simply are not required to generate their own SDSs for such products; that obligation rests solely with the upstream manufacturer or importer, and downstream users and distributors of such formulations are entitled to rely on the SDS provided by their upstream supplier. *See* 29 CFR § 1910.1200(g)(1) & (g)(5). If the SDS notice requirement is not limited to the formulation manufacturer or importer, downstream users and distributors will have an affirmative requirement to "author" SDS for these formulations in order to include EPA's mandated notices, which many downstream users and distributors simply do not have the capability to do and/or which would be unduly burdensome.

CUC further recommends that the preamble to any final PBT rule clarify that the downstream notification requirements for PIP 3:1-containing products do not apply to articles that contain PIP 3:1. The SDS requirements should not apply to such articles because it is not reasonable to anticipate that such articles will release material or measurable quantities of PIP 3:1 during ordinary use. Moreover, the Occupational Safety and Health Administration (OSHA) hazard communication standards concerning SDSs are focused on communication and control of physical and health hazards relative to use of *chemicals and mixtures*. They do not require creation or provision of an SDS for articles; nor do they contemplate how physical or health hazards associated with use of an article should be or would be communicated. Therefore, a requirement to provide an SDS for an article, with an EPA-mandated statement, would potentially require article manufacturers to develop SDSs from whole cloth for which there are no generally accepted or applicable standards or guidelines. *See* 29 CFR § 1910.1200. EPA also should provide in the downstream notification provisions a phase-in period (e.g., 90 to 180 days) sufficient to ensure all entities in the value chain receive notice of the PIP 3:1 content in material they provide or acquire.

Consultations concerning PBTs with other federal agencies should be documented. CUC understands EPA has made certain determinations that HCBD and other PBTs addressed in the regulation already are subject to regulations implemented by other federal agencies (e.g., OSHA). To the extent such determinations are made, and when such determinations affect decisions whether or not to exercise Agency authority under TSCA, CUC recommends those agencies be specifically consulted and that those consultations be documented in the rulemaking record. CUC considers this to be helpful for purposes of transparency in rulemakings, and consistent with the intent of Section 9 of the amended statute.

[4] For example, EPA should clarify that the proposed rule would not restrict activities that might result in *de minimis* releases, such as small spills or leaks that could occur during transfers between vessels or equipment of PIP 3:1-containing materials, or routine equipment cleaning operations during which wash water could contact a surface on which trace levels of PIP 3:1 might be present. Such unanticipated releases or spills are more appropriately addressed in accordance with federal and local regulations concerning wastes, rather than a TSCA Section 6(h) rule.

Enforcement. EPA should provide information concerning how it intends to enforce the various requirements of the regulation, especially those requirements related to technical standards (such as those providing a maximum concentration limit for products containing PCTP and the container size restrictions for TTBP when distributed in commerce. Such guidance will encourage better recordkeeping and provide insight to entities subject to the rules to prepare them for potential inspections or other compliance assurance activities involving EPA personnel. To assist in compliance, EPA should consider establishing a clear phase-in period for each of the PBT rules during which enforcement efforts would generally be relaxed. Such a period would enable product manufacturers and distributors to reduce their existing stocks and allow for previously-manufactured components and inventory to move through ongoing production processes involving complex equipment that might be assembled at multiple facilities.

Unintentionally Present Small Quantities of PBT Content in Products and Articles. CUC members are concerned that the PBT regulation, as proposed, fails to take into account that certain commercial products and manufactured articles might contain small quantities of the PBT substances that are unintentionally present as manufacturing impurities or byproducts which serve no functional or commercial purpose in such products and articles. For such substances, CUC recommends the Agency establish an exemption applicable to each of the regulated PBTs which is consistent with the Agency's regulations at 40 CFR § 720.30(h). Such an exemption would exclude from the final rule's prohibitions on the presence of the regulated PBTs in manufactured products and articles the PBT substances when they are not manufactured for distribution in commerce as chemical substances *per se* and have no commercial purpose separate from the substance, mixture or article of which they are a part. Thus, pursuant to such an exemption, a PBT which is present in small quantities in a manufactured product or article would not be considered to violate the rule when its presence occurs solely as a manufacturing impurity or byproduct that has no functional or commercial purpose in the finished product or article. Such an exemption would be applicable only to newly-manufactured products and articles produced after a reasonable phase-in period (similar to the standard proposed for PCTP in § 751.411(a)).

In the alternative, the Agency could consider establishing a concentration level for each of the PBTs below which the presence of a PBT would be considered permissible when it appears as an unintentionally present contaminant having no commercial benefit in a finished product or manufactured article. However, when doing so, the establishment of such a level should take into consideration consultations with the regulated and manufacturing communities to determine appropriate threshold standards that are based on the feasibility to meet such standards as well as existing methods of detection that have been verified, remain affordable, and are commonly accessible.

This concern further supports CUC's request that a lengthier and more appropriate phase-in period would better enable product manufacturers and processors to become confident that the materials they acquire are compliant, and the products they produce will be compliant.

Conclusion

As EPA continues to consider pragmatic measures to limit exposures to the PBTs at issue, CUC encourages the Agency to clarify elements of its proposal before a final PBT rule is promulgated. To do so more effectively, and to satisfy the legislative requirements of the amended statute, the Agency should undertake and make publicly available for comment a credible assessment of the risks presented to human health and the environment attributable to the PBTs — including due to the substances' presence in manufactured products and articles the Agency intends to regulate, as well as replacement parts. CUC recommends a supplement be published to the proposal in which the Agency solicits comments on the risk assessment and advises the public how this assessment informed EPA's selection of risk mitigation measures. Such a supplement also should state that the regulations proposed would permit the continued use and distribution in commerce of *existing* products that may contain the PBT substances; remove ambiguity in the recordkeeping provisions; limit the prohibition on releases to water of PIP 3:1 to those which are intentional; and provide for the presence of small quantities of regulated PBTs that are unintentionally present in a product or article while providing guidance on how EPA intends to monitor and enforce compliance with the final rules. Given the challenges that will be faced by entities who manufacture complex durable and consumer goods as they acquire and incorporate raw materials and component supplies for use following the effective date of the rule, CUC recommends EPA lengthen the phase-in period for the final PBT rule and incorporate a mechanism for regulated entities to request exemptions or extensions in the compliance dates.

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CUC appreciates the Agency's interest in soliciting public input on the proposed PBT Section 6(h) rulemaking. As noted above, CUC members would be pleased to meet with EPA personnel to discuss these comments and related issues as the Agency continues to develop its approach under the proposed PBT rule.