Before the United States Environmental Protection Agency
Regulation of PBTs Under TSCA Section 6(h):
Phenol, Isopropylated Phosphate (3:1); Further Compliance Date Extension
86 Fed. Reg. 59684 (October 28, 2021); Docket EPA-HQ-OPPT-2021-0598
Comments of the Chemical Users Coalition

Introduction

Chemical Users Coalition ("CUC") appreciates the opportunity to provide these comments in response to the U.S. Environmental Protection Agency's ("EPA's" and "the Agency's") recent notice announcing the proposed compliance date extension for Phenol Isopropylated Phosphate (3:1) ("PIP (3:1)"). In that notice, EPA announced its intention to commence a new rulemaking effort to regulate PIP (3:1) and 4 other PBT chemicals that have been regulated under TSCA 6(h). Specifically, EPA noted its intention to thoroughly review the justifications underlying exclusions in both the PIP (3:1) and other PBT final rules, consistent with the statutory directive to reduce exposure to the extent practicable.

CUC is an association of companies from diverse industries that typically acquire and use, rather than manufacture or import, chemical substances.[1] Our Members depend on the availability of certain existing substances for which 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. Consequently, our Members encourage 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.

As an entity that submitted comments on the original PIP (3:1) rule when it was initially proposed, and as one of the first groups to bring to EPA's attention the problems the PIP (3:1) rules' deadlines presented to the importers and manufacturers of articles that contain complex component parts, CUC recognizes and appreciates EPA's efforts to date to address the serious supply chain issues that would have existed had EPA not adopted short term modifications to the compliance deadline for certain imported and manufactured articles. CUC also recognizes EPA's desire to carefully review the PBT rules in light of current marketplace and supply chain realities as well as the priorities being emphasized by the Agency's current leadership.

Actions Being Taken By CUC And Its Members

Since our May 2021 comments were submitted, we have again surveyed CUC Members concerning the Agency's further information needs and their progress towards meeting the Agency's PIP (3:1)-related deadlines. The following briefly summarizes what we have learned.

[1] CUC's Members include Airbus S.A.S., The Boeing Company, Carrier Corporation, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, Raytheon Technologies Corporation, Sony Electronics, Inc., and TDK U.S.A. Corporation.

First, some CUC Members have advised us that they continue to be actively working with suppliers to put them on notice of the need to eliminate the use of PIP (3:1) in products and parts that are not specifically exempted under the current rule and to find technically feasible alternatives. For many CUC Members, this also means they are needing to review and reassess their specific agreements with suppliers in this regard.

Second, CUC Members have again emphasized that this task remains, as CUC has advised in meetings with EPA managers, and in written comments previously submitted, a complicated process, involving sometimes thousands of different suppliers for any given CUC Member. The regulation as written presents tremendous problems for CUC Members for several reasons, including (but not limited to):

(a) many CUC Members act as the importers of manufactured articles and the rule focuses on the presence of a substance that has not previously been regulated outside of the US and might be present in component parts of products assembled abroad; and

(b) compliance is determined based on the date of processing and/or distribution in commerce of PIP (3:1) containing articles, rather than the date of "manufacture" of a PIP (3:1) containing article -- even with respect to the substance being potentially present at trace levels in an article.

Third, CUC Members also have reviewed and further assessed their need to have an inventory of replacement parts for the finished goods they manufacture and service (and those which they use, and which are serviced by others), as well as the length of time for which such replacement parts remain available.

Fourth, those CUC Members who rely on materials or assemble articles that are not subject to the specific exemptions have advised us they are also working diligently with suppliers to consider alternative chemicals to PIP (3:1) and their technical feasibility (some of which are identified in these comments).

Finally, CUC Members have reiterated the need and multiple bases for an indefinite R&D Exemption for PIP (3:1) when used in R&D activities, articles, and in equipment used for R&D.

Accordingly, we write once again to provide information to the Agency in light of CUC's Members' ongoing efforts to address issues surrounding the presence of PIP (3:1) in component parts and finished articles. We also write to advise that CUC Members generally support the proposed October 2024 deadline in so far as it would relate to, and have no adverse effect on, the other deadlines and exemptions and exclusions in the PIP (3:1) rule, and other PBT rules being potentially reconsidered. Thus, these comments will serve to reiterate the importance of ensuring that exemptions contained in the original rules are preserved, clarified, and that the exemptions are appropriately expanded upon (as discussed briefly here, and in greater detail in our prior comments).[2]

[2] Rather than repeating CUC's previously-submitted comprehensive comments which we submitted in May of 2021, we are enclosing and incorporating those comments by reference in this submission. See comments as posted to the

CUC Comments on Extension Date for Articles Containing PIP (3:1)

Summary of PIP 3:1-Related Comments

CUC Members request that EPA retain all of the very critical exemptions and exclusions to the final PIP (3:1) rule promulgated on January 6, 2021. CUC Members strongly believe that the issues raised below are integral to ensuring the goals of reducing exposure to PBTs while maintaining a consistent and predictable flow of goods that move in US commerce. In the absence of the existing exemptions being preserved and the expansions being implemented which CUC Members have previously requested, and continue to advocate for in this correspondence, the October 2024 deadline will not be achievable for all CUC Members.

2024 Compliance Date Extension May Be Adequate But Must Be Tied To Date Of Manufacture/Import And Provide A Sell-Through Provision And Spare Parts Exemptions

The extension of the effective date of the general prohibition on the processing and distribution of PIP (3:1)-containing products and articles to October 2024 will likely provide CUC Members that produce articles that are not subject to the existing exemptions and exclusions, with the needed time to respond to the new deadlines. As noted above, CUC Members who do not benefit from existing exemptions have already been advising their suppliers of the importance of ensuring that materials containing PIP (3:1) are no longer shipped to the United States after definitive deadlines pertaining to those materials have been established. Certain CUC Members are continuing to communicate to their suppliers the necessity to swiftly identify and test and qualify replacement chemistries in the components they supply that are within the scope of the articles that will be prohibited from entering US commerce after specific dates established by the rule. Further, depending on their respective market sectors, some CUC Members may be required to test entire finished products with any modified components incorporated to demonstrate conformance with applicable performance and compliance standards.

This is an enormous and complex undertaking requiring, in certain instances, changes being made in contract terms, and even qualifications and material specifications in some CUC Members' sectors. While these efforts are continuing, CUC Members are hopeful that the 2024 compliance date extension, if finalized, will provide enough time for these directives to be implemented throughout the supply chain. However, the full extension to the end of October 2024 that has been proposed will be absolutely essential for those CUC Members' suppliers to accommodate such requirements. Any compliance date which is sooner than the October 2024 proposed date will not be sufficient, given the complexity of the goods CUC Members import and manufacture, and the multifaceted, international nature of the supply chains within CUC Members' respective industries.[3]

docket at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2021-0202-0135; and https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0202-0135/attachment_1.pdf.

[3] It is important to note that these deadlines are made even more challenging when, due to the nature of the business sectors they are supplying, a CUC Member, or any downstream customer, must need to test and requalify a chemically-modified or alternative replacement material or component in their product(s). This is especially a challenge to the manufacturers of products used in the aerospace and defense sectors, in which testing and requalification processes can take years to complete.

Importantly, CUC Members recommend and reiterate our prior comments that the compliance date pertinent to manufactured (imported) articles should be based on the date of manufacture for goods produced domestically, and the date of import for articles arriving from abroad. Distributors do not necessarily ship finished goods based on when they receive it, and consequently it may be extremely difficult for an importer/manufacturer/distributor/retailer to differentiate with certainty between the same components or goods that might have differing chemical compositions (e.g., containing PIP (3:1) vs. containing a substitute).

The phrasing of the current compliance deadlines with prohibitions based on the date of "distribution in commerce" is unworkable for many reasons. First, distribution in commerce has been very broadly interpreted by EPA enforcement personnel and has included, in some context, any movement of a regulated product (even among facilities within the same business enterprise and its affiliates and subsidiaries). In the consumer products sector, for example, the "distribution in commerce" date makes every distribution among its various tiers (i.e., from producers to distributors to retailers and even to end-user customers) to be regulated (and prohibited after a date certain). However, the date of manufacture is generally something that is possible to identify and track for products produced or assembled in the US. Our Members recognize that the date of import for articles that are produced abroad might be appropriate for purposes of the PBT rules simply because the term "manufacture" includes "import" for TSCA purposes.

Accordingly, CUC asks that EPA clarify that finished articles that contain PIP (3:1) that have been *manufactured on or before October 31, 2024*, may continue to be processed and distributed in the US (i.e., "sold through"). To avoid the risk of confusion, the Agency should clarify in the rule language (or minimally in the Preamble) and any interpretive guidance, that EPA does not intend to prohibit the "sell through" of any articles (including components therein) that were manufactured or imported before such dates -- including those that might be situated in warehouses or in the channels of trade and transportation, and that such articles may be used and reused by the producers and their customers indefinitely.

The Need for Additional Exemptions

CUC Members reiterate the need for EPA to preserve the exemptions in the PIP (3:1) regulation, and to enhance the exemptions in a manner discussed in detail in our May 2021 comments and reiterated here.[4] Furthermore, CUC Members believe that EPA, when promulgating any rule regulating the use of a substance (including substances the Agency considers to be PBT substances, such as PIP (3:1)), must abide by the statutory requirements under TSCA. Moreover, EPA should not be reluctant to exercise its authority under Section 6(g) to provide for further exemptions to the general prohibition on processing and distribution of a substance (including, when appropriate, PIP (3:1)). Doing so would be in accordance with both the letter and the spirit of Section 6, would address many of the supply chain related issues presented by the approach taken in the January 2021 version of the PBT rules, and doing so at this time could potentially begin to ameliorate the absence of the mandated findings that should have

[4] The existing exemptions for aeronautics, automotive, and defense applications remain critical to CUC Members and CUC continues to support as well the exemptions for certain adhesives and for recycling and reuse of PIP (3:1) containing articles.

accompanied the rulemaking. Accordingly, CUC believes the following changes and exemptions to be necessary. Specifically, the Agency should:

- Establish a *de minimis* level for the presence of which PIP (3:1) (e.g., 0.1% by weight of the finished product or article) to enable the continued processing, use, and distribution of products in which PIP (3:1) is determined to be present only at or below such level;
- Exempt large-scale manufacturing equipment and other durable commercial and industrial use machinery deployed in essential commercial, military, and defense applications (and to which consumers and the general population are not exposed due to the nature and conditions of these uses) and the PIP (3:1)-containing products used to service and repair such equipment;[5]
- Broaden and extend indefinitely exemptions for new and replacement parts and materials used to service complex durable good and consumer products designed before the effective date of the final regulation (including complex goods and equipment beyond just the automotive and aerospace sectors of the economy and for more than just "vehicles" that are produced or used by those sectors).[6]
- Exempt "existing articles" that were *produced before* the compliance deadline -- whether "new" (i.e., manufactured before the deadline but remaining in storage or the channels of trade) or "previously used" (e.g., being moved in commerce among a company's facilities or being returned to, or serviced by, the supplier/manufacturer or a third party).
- Enhance and clarify the existing exemptions to include manufactured materials which are similar in nature and conditions of use (e.g., a PIP (3:1)-containing adhesive or sealant produced before January 2025 or a PIP (3:1)-containing grease) and clarify that these exemptions include the products and articles in which the exempt materials are incorporated.
- Enable, without time limits, research and development (R&D) activities that require the use of the regulated PBTs, including PIP (3:1) and PIP (3:1)-containing products and articles (and laboratory and experimental *equipment* that might include PIP (3:1)-containing components) *without* limitation.[7]

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[5] This should include the use of PIP (3:1)-containing products and articles (e.g., replacement parts and service supplies) when needed to restore these appliances and equipment to their original condition when necessary due to breakdowns and normal wear and tear.

[6] As noted in our prior comments, certain state requirements and service contracts with customers require some CUC Members to have replacement parts available for a period of time that would greatly exceed by many years the October 2024 date proposed. At least one Member maintains an inventory of greater than 50,000 replacement parts for maintenance of its products/articles it currently markets or products manufactured during the preceding 5 year period. Other CUC Members must maintain replacement parts for products/articles which are subjects of existing service agreements. Another Member advises that large scale, durable equipment within its facilities that is critical to its manufacturing operations can have thousands of component parts, each of which (when serviced or in need of repair) must be replace using essentially identical component parts to ensure no loss in continuity in the equipment being used and the integrity of the products that are manufactured using the equipment.

[7] CUC Members have advised that many R&D exercises require the use of chemicals and equipment that is obtained from unique suppliers with whom the Members do not routinely deal (in comparison to those who supply routine

Legal Concerns Related to Exemptions and Regulatory Considerations

CUC acknowledges that TSCA Section 6(h) gives EPA the authority to propose rules for certain substances under 6(a) absent a risk evaluation. However, the lack of a risk evaluation does not absolve EPA of other obligations under Section 6, such as: those set forth in Section 6(c)(2) which require the agency to ascertain the costs and benefits of the final rule in contrast to other regulatory approaches; those set forth in 6(c)(2)(D) concerning the exemption from regulation of replacement parts for complex durable and consumer goods; and those under 6(c)(2)(E) that establish the considerations that must be met when the Agency intends to place restrictions pertaining to the presence of a chemical in articles. The regulatory record to date contains none of the findings specifically required under the aforementioned sections.

CUC interprets Section 6(h)(4) to specifically require EPA when issuing its PBT regulations to select only those prohibitions and other restrictions that will reduce reasonably predictable exposures to the substance and that will reduce such exposures to the extent that is practicable. In the absence of having conducted a critical assessment concerning whether a specific product or article will release and expose humans or the environment to a PBT during the product's or article's conditions of use, EPA should allow for the maximum permissible flexibility for a Section 6 rule and thereby provide common sense and legally justifiable exemptions, such as those CUC is seeking.

When considering the hazard posed by the aforementioned uses and associated exposures to PIP (3:1) from such uses, providing for exclusions is consistent with the objectives to address risks posed and reduce exposure to the extent practicable. PIP (3:1)-containing articles have not been demonstrated to release PIP (3:1) in a manner that can lead to unreasonable risks to product users. Furthermore, direct exposure to PIP (3:1) does not frequently occur to the users of products and articles that contain PIP (3:1). Releases from such products and articles are not expected to occur during normal use, and the components of such products/articles are serviced only by skilled technicians. Moreover, when PIP (3:1)-containing component parts are embedded into larger components and then into finished articles, such internal component parts are not present on product surfaces that are readily accessible to the general public and end user consumers/users.[8]

The exemptions being requested by CUC will not materially increase exposure-derived risks, and such exposures will decline over time as substitutes are qualified and can be phased in. Without changes and the inclusion of additional exemptions, the rule will unintentionally lead to

components and equipment). Other R&D materials can include mixtures and articles specifically fashioned for customer-specific R&D exercises. Thus, the composition of the research materials may not be known, or the materials acquired may by necessity contain a substance or a component used as a "standard" against which alternative materials and chemicals might be measured for performance and qualification purposes. Thus, it is critical to have access to mixtures and products and research equipment that might contain PIP (3:1) indefinitely, especially if EPA wishes to encourage and enable the quest for technically feasible alternatives to PIP (3:1).

[8] It is possible, and CUC's prior comments have noted, the PIP (3:1) could be present in certain features of finished products that are on an exterior surface of otherwise accessible to end-user customers. Nevertheless, it is not anticipated, and we are aware of nothing in the rulemaking record that documents, that PIP (3:1) is readily released to the environment during the useful life of an article in which the substance is embedded within a solid resin or similar material.

unnecessary disposal of existing products and articles which could lead to environmental loading of PIP (3:1)-containing articles.

If EPA does intend to modify the PIP (3:1) regulation (and the other PBT rules) in a manner other than to extend the phase-in periods or expand the exemptions, CUC requests that EPA provide specific public notice of the changes that are under consideration and provide an opportunity for further public input and consultation concerning the specific terms being considered and the anticipated timing of such requirements.

Comments in Response to EPA Information Requests

In addition to comments on the proposed compliance date extension for PIP (3:1) and expressing its intention to commence a new rulemaking effort on PIP (3:1) and the other four chemical substances regulated under TSCA section 6(h), in the Federal Register notice, EPA also requested information on:

- The specific uses of PIP (3:1) in articles throughout their supply chains.
- Concrete steps taken to identify, test, and qualify substitutes for those uses, including details on the substitutes tested and the specific certifications that would require updates;
- Estimates of the time required to identify, test, and qualify substitutes with supporting documentation; and
- Documentation of the specific need for replacement parts, which may include the documented service life of the equipment and specific identification of any applicable regulatory requirements for the assurance of replacement parts.

CUC, in its prior comments, provided detailed information on the specific uses of PIP (3:1) in articles throughout the supply chain of member companies. Furthermore, the bases for an exemption for replacement parts has been addressed by CUC's previous submissions and in the foregoing passages in these comments. Our Members have provided certain additional information which follows.

Many CUC Members have chemical management standards that control the use of regulated substances. Such standards may include engineering control specifications and multiple CUC Members have described robust compliance validation processes to ensure parts/products/articles they receive and use are compliant with all applicable environmental laws and regulations globally. Other CUC Members note that suppliers are not necessarily asked to comply with specific environmental regulations, but instead are asked to meet performance specifications that state a company's criteria for compliance. Nevertheless, CUC Members have advised supply agreements and other environmental-related requirements are being updated to include compliance with certain environmental laws and related regulations, including PIP (3:1)-specific requirements.

As noted above, some CUC Members have supplier compliance validation processes. For example, suppliers may need to provide information which is used to document the environmental

data necessary to establish compliance of procured parts and products to internal company requirements and other applicable regulations. Certain CUC Members also refer suppliers to, and might request documentation of, a supplier's conformance with certain industry-wide specifications. Such documentation is validated and refreshed, and for certain CUC Members the validation process is subject to internal audits. Furthermore, to ensure suppliers are equipped to deliver compliant parts and assemblies, some CUC Members provide periodic training and education throughout the year to relevant suppliers. Collectively, these processes are intended to ensure a company's products/articles are compliant with all applicable environmental laws and regulations globally.

Accordingly, CUC Members have advised they have listed PIP (3:1) as a restricted chemical, and suppliers must comply with this standard. In this fashion, CUC Members are informing suppliers that parts/products/articles going forward must not contain PIP (3:1), and that manufacturers need to identify parts and components that do not meet that requirement. Yet, notwithstanding the quick response of CUC Members to EPA's actions to restrict PIP (3:1), complexities still exist, both in terms of addressing products/articles currently in the marketplace and ensuring that, going forward, suppliers can meet the required specification using a chemical other that PIP (3:1).

Prior to contemplating substitutions or alternatives for PIP (3:1), the process of identifying the components that contain PIP (3:1) is required. Manufacturers of electronic finished goods may have multiple suppliers for thousands or more components across all their product lines. Manufacturers have already begun surveying their vast number of suppliers to determine the presence of PIP (3:1). This process is a complex and significant undertaking which, we are advised by some Members, will take at least another year or more to complete with any degree of accuracy; and for some Members may take considerably more than a year.

After the components are identified, a technically feasible and available substitute for PIP (3:1) needs to be found. In the electronics manufacturing sector, for example, component suppliers generally make the decisions around what alternatives to use for chemicals that comprise a component. The criteria the supplier must use are the manufacturer's specifications for the finished goods, which dictates standards for functionality, performance, safety, quality, and avoidance of restricted chemicals. A significant concern for CUC Members is the potential for regrettable substitutions that could be worse for human health or the environment if ample time is not allowed to transition away from the use of PIP (3:1). As of the date of these comments, most CUC Members generally expect the compliance date extension to October 2024 would provide time to adequately assess and vet alternatives to reduce the risk of regrettable substitutions; although there are some industry sectors that likely will require more time (e.g., aerospace). This assumes, of course, that technically feasible alternative substances exist and are available for use (i.e., those which also perform in accordance with the same technical standards as PIP (3:1) in its numerous applications).[9] However, at this time, it is difficult to be certain whether potential substitutes for substances that have the performance characteristics of PIP (3:1) could be identified for prioritization by EPA for regulatory assessments under TSCA at a later date.

[9] One CUC Member has been advised by suppliers that aluminum hydroxide (CAS #21645-51-2) and magnesium hydrate (CAS # 1309-42-8) are candidate alternative chemicals in certain applications where PIP (3:1) has been used.

Even once reliable substitutes for PIP (3:1) can be identified, it is unclear whether there will be sufficient capacity for all of the suppliers in the affected supplier industries to transition to alternatives and manage these changes. At each step of the supply chain, there are greater demands as the diversity of suppliers increases; each must respond to different timelines across different component families and across different suppliers. There may be an increased demand leading to this phase in the timeline spanning longer than anticipated. At present, no CUC Member has specific and definitive insight into precisely how significant a challenge this will be.

Summary and Conclusion

CUC Members are actively engaged in the process of working with thousands of suppliers around the world to identify and phase down the manufacture/import, processing, and use of PIP (3:1)-containing products and articles they may acquire. While most CUC Members expect the proposed extension of certain compliance dates may enable this process to be successfully completed, other Members note that, due to the complexities of the Members' supply chains, the products/articles they produce, and the nature of the manufacturing equipment they possess and rely upon to support essential industries, it remains possible that CUC Members may learn from one or more suppliers at a later date, that the proposed extension until October 2024 may not be sufficient. Moreover, a number of CUC Members manufacture products that must meet government agencies' specifications (e.g., Department of Defense, the Federal Aeronautics Administration) and such requirements may explicitly (or implicitly) require the use of PIP (3:1).

For the foregoing reasons, it might not be known until much later whether all component suppliers will identify and be able to acquire for use, technically feasible chemical alternatives for PIP (3:1). Thus, CUC Members remind EPA that, notwithstanding their ongoing efforts at due diligence, it is not always possible for entities that rely on complex, multifaceted, international supply chains to "see around" every corner and to anticipate when they might acquire information which is currently unforeseen.

CUC Members urge EPA to retain all the very critical exemptions to the final PIP (3:1) rule (and the other PBT rules) promulgated on January 6, 2021, including, for example, those drafted to accommodate the need for undisrupted production of materials and products that are used in supporting certain aerospace industry and defense applications and for which no suitable substitutes to PIP (3:1) currently exist.

Further, CUC reiterates its support for further timely amendments to the PIP (3:1) rule (and other PBTs rules) that will:

- establish a *de minimis* level for the presence of PIP (3:1);
- Exempt large-scale manufacturing equipment and other durable commercial and industrial use machinery deployed in essential commercial, military, and defense applications and the PIP (3:1)-containing products used to service and repair such equipment:

- Exempt large-scale manufacturing equipment and similar durable commercial and industrial goods which are used in essential industries (e.g., semiconductor manufacturing):
- Broaden and extend indefinitely exemptions for new and replacement parts and materials used to service complex durable goods and consumer products designed before the effective date of the final regulation
- Exempt "existing articles" that were produced before the compliance deadline.
- Enhance and clarify the existing exemptions to include manufactured materials which are similar in nature and conditions of use, and clarify that these exemptions include the products and articles in which the exempt materials are incorporated; and,
- Enable, without time limits, research and development (R&D) activities that require the use of the regulated PBTs, including PIP (3:1) and PIP (3:1)-containing products and articles (and laboratory and experimental equipment that might contain PIP (3:1)-containing components) without limitation.

These exemption requests should be supported by EPA not only as a matter of responsible public policy, but because TSCA *requires* the Agency, when issuing Section 6 regulations and selecting effective phase-in dates, to contemplate what is technically and economically feasible, what is reasonable and practicable, and to accommodate the need for replacement parts on a going-forward basis for complex durable goods that were designed before EPA regulations took effect.

In closing, CUC Members again express our appreciation for the Agency's considerable efforts to address these concerns to date, and for soliciting further public input on the PIP (3:1) rule specifically and the PBT Section 6(h) rules in general. As noted above, 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 all the PBT rules.

Attachment:

Comments Submitted May 17, 2021

Before the United States Environmental Protection Agency
Persistent, Bioaccumulative, and Toxic Chemicals Under Section 6(h) of TSCA
86 Fed. Reg. 14,398 (March 16, 2021); Docket EPA-HQ-OPPT-2021-0202
Comments of the Chemical Users Coalition

Introduction

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 decision to request additional public comment on 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 is an association of companies from diverse industries that typically acquire and use, rather than manufacture or import, chemical substances.[2] Our members depend on the availability of certain existing substances for which 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. Consequently, our members encourage 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.

Background

In October 2019, CUC provided timely comments to EPA on the proposed TSCA Section 6(h) rules concerning 5 PBTs.[3] These comments addressed many subjects, including: various important legal and policy considerations concerning the rule and TSCA Section 6; the language in the rule on phenol, isopropylated phosphate (3:1) (PIP 3:1); the importance of clarifying the PBTs rules to ensure research and development uses of PBTs be allowed to continue in the US; recommending the final rule clearly address that continued use of existing articles produced prior to the final rule's effective date will be permitted; and noting CUC's support for continuation of recycling of such articles going forward.

Furthermore, CUC submitted correspondence to,[4] and on March 1, 2021 met with, the acting Assistant Administrator for Chemical Safety and Pollution Prevention concerning the urgent need for the incoming Assistant Administrator of OCSPP to provide for a delay in the March 8,

[1] https://www.federalregister.gov/documents/2021/03/16/2021-05138/regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under-tsca-section-6h-request-for.
[2] CUC's members include Airbus S.A.S., The Boeing Company, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, Raytheon Technologies Corporation, Sony Electronics, Inc., and TDK U.S.A. Corporation.
[3] http://chemicaluserscoalition.org/ckfinder/userfiles/files/PBT%20Rule%20Proposal%20Comments.pdf.
[4] http://www.chemicaluserscoalition.org/ckfinder/userfiles/files/CUC-TSCA%20PBT%20Rule%20PIP%20Extension%20Request%20020921.pdf.

2021 effective date for the final PIP 3:1 rule's general prohibitions on the distribution in US commerce of products and articles containing PIP 3:1.[5] CUC members are very grateful that prompt relief was provided by EPA (in the form of EPA's No Action Assurance) and would like to see it immediately amended to cover formulated products containing PIP 3:1[6] and to extend its duration so that it remains in effect until the effective date of any final amended rule.

Nevertheless, if certain clarifications are not provided by EPA, and certain targeted amendments to the terms and effective dates in the PIP 3:1 regulation itself are not included in an amended rule, many production processes and the delivery of products that are critical to the economy and our national defense will come to a halt (e.g., at the expiration of the No Action Assurance) because the untenable alternative will be to continue to acquire and use critical materials that may be PIP 3:1-containing products and articles in violation of the current deadlines in the final rule.[7]

More broadly, CUC continues 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 (who acquire and rely upon formulated products and manufactured articles) to identify practical phase-in periods. This is especially important in situations, such as the PIP 3:1 rule, where the targeted substance has (heretofore) not been identified previously for restrictions in non-US markets and multi-national regulatory bodies. CUC supports greater transparency in their supply chains about the chemical content of the products and components they acquire. EPA regulatory efforts with longer lead times will serve to encourage further 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.

CUC Comments on Rule for Phenol, Isopropylated Phosphate (3:1) (PIP 3:1)

Summary of PIP 3:1-Related Comments

CUC generally supports the Agency's objective to phase out and discontinue the use of PIP 3:1 for use in products and articles that may be manufactured or distributed in the US.

[5] http://www.chemicaluserscoalition.org/ckfinder/userfiles/files/CUC-TSCA%20PBT%20Rule%20PIP%20Extension%20Request%20020921.pdf.

[6] Unfortunately, the No Action Assurance (NAA) does not affect the requirements and deadlines in the final rule related to formulated products that contain PIP 3:1. Thus, the NAA provided little relief for CUC members that acquire and use formulated products (e.g., certain hydraulic fluids and machinery that contains such fluids) that might fall outside of the existing exclusions in Section 751.407(b) because the fluids (and equipment containing the fluids) might be used in essential industrial or commercial apparatus (e.g., robotics, heavy equipment including construction and agricultural apparatus) or in land- or marine-based applications (e.g., satellite and radar installations) not specifically involving aircraft and/or not subject to a particular Department of Defense specification. These appliances and pieces of apparatus are designed to have long service lives and require service of a highly specialized nature and components meeting original product specifications.

[7] In fact, because of the phrasing and limited scope of the No Action Assurance, certain companies have already stopped ongoing sourcing and processing of critical materials containing PIP 3:1 that are not excluded from the prohibition, so production of some articles is being impeded now or is likely to be impeded prior to expiration of the No Action Assurance.

However, during the course of EPA's ongoing review of the PIP 3:1 rule, CUC members strongly request that EPA retain all of the very critical exemptions and exclusions to the final PIP 3:1 rule promulgated on January 6, 2021 and make certain additional changes noted in these comments. Many of the exemptions were specifically and carefully considered by the Agency (for example, those drafted to accommodate the need for undisrupted production of materials and products that are used in supporting certain aviation and defense applications and for which no suitable substitutes to PIP 3:1 currently exist). Unfortunately, the immediacy of the March 8, 2021 effective date for the general prohibitions in Section 751.407(a)(1) on the processing and distribution of products and articles containing PIP 3:1, CUC members have learned that the limited phase-in periods and exemptions granted in the January 6, 2021 publication are inadequate and should be modified. Because the No Action Assurance does nothing to change the effective dates in the final rule itself, and does not include all formulated products that might contain PIP 3:1, it will remain an insufficient remedy if EPA does not in a timely way significantly modify the final PIP 3:1 rule to:

- Exempt large-scale manufacturing equipment and similar durable commercial and industrial goods which are used in essential industries, and the PIP 3:1-containing products used to service and repair such equipment;[8]
- Extend the effective date of the general prohibition on the processing and distribution of PIP 3:1-containing products and articles for 5 years from the effective date of a final amended rule;
- Clarify in a revised version of the Preamble or amended Final Rule that finished 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 US, 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 US and abroad);
- Broaden and extend indefinitely exemptions for new and replacement parts and materials used to service products designed before the effective date of the final regulation including complex goods and equipment beyond just the automotive and aerospace sectors of the economy and beyond just "vehicles" that are produced or used by those sectors;
- Enhance and clarify the existing exemptions to include manufactured materials which are similar in nature and conditions of use (e.g., a PIP 3:1-continaing adhesive or sealant produced before January 2025 or a PIP 3:1 containing grease);
- Establish a *de minimis* level for the presence of which PIP 3:1 (e.g., 0.1% by weight of the finished product or article)[9] to enable products in which PIP is determined to

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

[9] 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.

be present only at or below such level may continue to be processed and distributed for use in the US;

- Enable research and development (R&D) activities that require the use of PBTs including PIP 3:1 and PIP 3:1-containing products and articles (and laboratory and experimental *equipment* that might contain PIP 3:1-containing components) *without* limitation.

CUC members request that EPA delay the general prohibition in Section 751.407(a) for the full 5-year period from the effective date of a final amended rule that is permitted by Section 6(d) of TSCA because this is a more reasonable and practicable period of time for CUC members and their many suppliers to: (i) poll their supply chains or otherwise receive notice of these new regulations in the US;[10] (ii) identify the numerous component parts and products they supply which contain PIP 3:1; (iii) select alternative substances that may be potentially suitable for use as replacements in specific formulated products and/or article applications; (iv) enable suppliers of such products and articles and CUC members to test materials produced using alternative chemistries; and (v) determine that the replacements and articles will continue to meet or exceed the performance standards pertinent to existing PIP 3:1-containing products. The efforts that will be made throughout these complex supply chains during this 5-year phase-in period to identify and qualify replacement products and components that contain PIP 3:1 will effectively ensure that gradual reductions in potential exposures will be occurring immediately and continue throughout the process as uses of PIP 3:1 are identified and phased down. Importantly, this process will help avoid unfortunate substitutions and the use of technically unqualified products and articles that could disrupt public safety and the efficacy of highly specialized products and materials (e.g., products in the aerospace and defense industry that are dictated by military specifications).

As in our 2019 comments on the proposed rule, CUC again encourages EPA to include a provision in a final amended rule that acknowledges, and makes permissible, the importation, processing, and distribution in commerce of finished products and articles that might contain PIP 3:1 at levels EPA considers to be *de minimis* (e.g., at no greater than 0.1% by weight of the finished product or article in question).[11]

Finally, if EPA intends to modify the PIP 3:1 regulation (and the other PBT rules) in a manner other than to extend the phase-in periods or expand the exemptions, CUC requests that EPA provide specific public notice of the changes that are under consideration and provide an opportunity for further public input and consultation concerning the specific terms being considered and the anticipated timing of such requirements. CUC also requests that EPA broaden the No Action Assurance's applicability to include formulated products and extend its duration so that it remains in effect until the effective date of an amended final rule.

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[10] It is common that US-based industries rely on formulated products and components that are produced abroad, where the awareness of US regulatory requirements (especially those issued pursuant to TSCA) are not well-known.

[11] This level is consistent with the standards in the Hazard Communications Standard administered by the Occupational Safety and Health Administration and codified at 29 CFR 1900.1200 for substances, such as PIP 3:1, that are not classified as potential human carcinogens. EPA has accommodated such an approach when it established a level for the presences of 2,4,6-TTBP in the pertinent final PBT rule for that substance. See: https://www.federalregister.gov/documents/2021/01/06/2020-28690/246-tristert-butylphenol-246-ttbp-regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under.

Reiteration of Certain Previously Stated Legal Concerns

In its 2019 comments, CUC urged EPA to perform a credible risk assessment to support the PBT rulemaking. While CUC acknowledges that TSCA 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 recommended that, at the minimum, a basic risk assessment be conducted by the Agency before the final rule was 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.

CUC expressed at that time the organization's view, which we continue to hold, that the absence of even the most basic risk assessment makes it impossible to identify, much less appreciate, the environmental benefits to be derived by implementing at great expense (and with considerable disruption to their businesses, and the US economy more generally) the very sudden and near-term requirements of the final regulation—and whether the Agency's requirements will, as a practical matter, mitigate risks. As CUC noted in 2019, the absence of a risk assessment also makes it unlikely EPA can demonstrate the final rule satisfies the Agency's statutory obligations under TSCA to consider various factors set forth in Section 6(c)(2)—including to ascertain the *costs and benefits* of the final rule and to compare these with less draconian regulatory approaches (such as permitting a 5-year phase-in period for the general prohibitions such as those accorded for other uses and end products). CUC notes that the very terms of the amended law, a long line of Executive Orders, established Agency procedures, as well as sound public policy, make clear the need for EPA to consider the benefits and impacts of its regulatory actions more carefully.

The regulatory record which resulted in the final PIP 3:1 rule, and the other PBT rules, reflects that the Agency, due to the exigencies of time and limited resources, simply elected not to address the findings specifically required under TSCA Section 6(c), including findings required for regulating complex durable goods and replacement parts as well as regulated articles.[12]

The Agency's decision to reopen this comment period for an abbreviated period provides an opportunity for EPA to pause, reexamine, and more carefully exercise its Section 6 authority to:

- Exempt pursuant to Section 6(g) large-scale manufacturing equipment and other durable commercial and industrial use machinery deployed in essential

[12] For example, 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). Section 6(c) also requires 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 final rules' failure to specifically address these obligations in the context of the final regulations' restrictions on articles and manufactured products that contain PIP 3:1 (and the other 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.

commercial, military, and defense applications (and to which consumers and the general population are not exposed due to the nature and conditions of these uses);[13]

- Meet its obligations under Section 6(c)(2)(D), including to provide for an exemption for replacement parts for complex durable and consumer goods that are designed prior to the effective date of a risk management rule.[14]
- Exercise its discretion under Section 6(d) of the law more appropriately to reasonably extend by 5 years from the effective date of a final amended rule the general effective date for the prohibition on distribution of PIP 3:1-containing products and articles, and to expand, enhance, and clarify the existing exemptions as discussed in these comments.

Comments in Response to EPA Information Requests

CUC is providing the following comments in response to specific areas of inquiry set forth in the Agency's March 16, 2021 Federal Register notice requesting this additional information.

Basis and Need for Modification to the March 8, 2021 Compliance Date Concerning Processing and Distribution of Products and Articles Containing PIP 3:1.

- CUC members assemble, manufacture, and distribute exceptionally complex products that are used in the aerospace and defense industries, commercial equipment, transportation products, and consumer appliances and electronics. These require and contain thousands of components and parts acquired and assembled by countless global suppliers, each of whom may never have a direct business relationship or contact with the manufacturer of the finished product.
- CUC members are communicating in good faith with their suppliers to attempt to determine whether the components and products they supply contain PIP 3:1. However, this is an ongoing process and will require a multi-year effort given the thousands of suppliers who might be involved in producing the multitude of components in any single article in the value chain, much less an assembled finished end-use product.
- The complexity of CUC members' international supply chains makes locating the presence of, and finding alternatives to, PIP 3:1 in components challenging. A PIP 3:1-containing part supplier may not be a direct supplier to a CUC member of a component or semi-assembled part. Each supply chain tier will need to identify the applicable components; identify, evaluate, and qualify substitutes; and phase out their inventories of existing parts.

[13] Such exemptions may be granted in accordance with Section 6(g) of the 2016 amendments to TSCA Section 6 when a condition for use is a "critical or essential use for which no technically and economically feasible safer alternative is available" or a restriction on a particular use of a regulated substance or article "would significantly disrupt the national economy, national security, or critical infrastructure." President Biden has made clear the Administration considers the semiconductor industry to qualify under the standards Congress enacted in Section 6(g). *See, e.g.*, https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/12/remarks-by-president-biden-at-a-virtual-ceo-summit-on-semiconductor-and-supply-chain-resilience/.

[14] Such replacement parts must be 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." Since no risk evaluation was conducted for the PBTs rule, such a 5-year exemption must be provided. *See* Section 6(c)(2)(D).

- This process has been and is ongoing, but it will not be successfully concluded before the current comment period expires. This means that, notwithstanding good faith efforts to make such inquiries and to urge their suppliers to provide only material and articles that do not contain PIP 3:1, there remains a significant risk that a manufacturer/importer/ distributor of complex pieces of equipment, such as products/articles that contain specialized electronic components, could find itself in violation of the final PIP 3:1 rule long after an article that may have been manufactured months ago arrives in the US and moves in commerce for potential use here.
- Many CUC members produce components and finished products/goods that must meet certification and performance standards such as customers' technical requirements, UL and CE marking requirements, military specifications, and specifications from government agencies that are not affiliated with the Defense Department (e.g., the Federal Aviation Administration, the Department of Transportation, NASA). Even as replacements and substitutes might be identified, meeting such certification requirements is a multi-year process.
- PIP 3:1 has not been regulated by other major regulatory bodies/treaties/commercial markets in the manner in which EPA has chosen to regulate. Heretofore, there has not been an economic or regulatory necessity to identify or make known the presence of PIP 3:1 in products and components. Thus, the presence of PIP 3:1 in chemical formulations, products, and articles may be largely unknown to the numerous users and manufacturers who acquire these formulations, products, and articles.
- Even if the terms of the No Action Assurance were extended significantly, this would not be sufficient because the NAA affects only articles and merely eliminates the risk of enforcement to the regulated community. It does not change the fact that non-exempt and non-excluded products and articles that have been processed or distributed after March 8, 2021 are non-compliant with the rule. To remedy this situation, CUC members request that EPA promptly modify the terms in Section 751.407(a)(1) to postpone the effective date for this prohibition for the full 5 years permitted by Section 6(d)(1)(B) of TSCA. This will more practicably ensure that phase-out and replacement of PIP 3:1 in both formulated products and manufactured articles can occur.
- Certain durable goods that were designed prior to the promulgation date of the final PBTs rules (such as large and complex manufacturing equipment as well as electronic products) have long service lives and are the subjects of binding contract terms, warranties, and service agreements (many of which include parties such as agencies of the federal government, state governments, hospitals, research and educational institutions, and other essential operations) that call for life-time service and repairs—which may only be possible if replacement parts meeting the initial product specifications can be provided. Thus, there is a critical need for EPA to exercise its authority under Section 6(c)(2)(D) to indefinitely exempt replacement parts and equipment used to service these complex durable goods.
- There is no recognized risk-related need for *existing* articles and products that contain PIP 3:1 to be immediately eliminated, as opposed to gradually phased down and out over time (such as the 5-year phase-in period CUC is requesting). The rulemaking record does not reflect that EPA has assessed, nor reached a conclusion, that the presence of PIP 3:1 in previously manufactured products/articles and components (whether already currently residing in warehouses abroad, on order, in route to the US on container vessels, residing in factories and processing facilities in the US, or present in the US now as existing stocks

residing in warehouses and distribution centers in US) represent a risk to users or consumers of such previously manufactured products/articles. Direct physical contact by processors and users of such previously manufactured products/articles has not been estimated to represent a risk, and releases of PIP 3:1 from such products and articles also have not been determined to be likely to occur under conditions involving processing and use of products and articles. Throughout the legislative development of the 2016 amendments to TSCA, CUC members encouraged Congress to enact the provisions Congress eventually did enact to require EPA to determine whether risks are being presented due to the presence of a chemical substance in articles before choosing to limit or restrict such articles. In the case of products and articles that contain PIP 3:1, a 5-year phase-in period will permit existing products/articles to be further processed and distributed to end users, and permit US industries to work with their suppliers to phase down the use of PIP 3:1 and replace it with technically feasible alternatives in formulations and finished products and articles in which PIP 3:1 heretofore has been processed, distributed, and used.

- CUC interprets Section 6(h)(4) to specifically require EPA when issuing its PBT regulations to select only those prohibitions and other restrictions that will reduce reasonably predictable exposures to the substance and that will reduce such exposures to the extent that is practicable. In the absence of having conducted a critical assessment concerning whether a specific product or article will release and expose humans or the environment to a PBT during the product's or article's conditions of use, EPA should provide for the maximum permissible phase-in periods for a Section 6 rule and exempt replacement parts for phased-out products and articles indefinitely.

Identification of the Specific Products and Articles that Need the Alternative Deadline.

As noted above, CUC members are in the process of gathering information from their suppliers concerning the specific articles and products that might contain PIP 3:1. This is an ongoing process that eventually will involve efforts to identify technically feasible alternatives or substitute parts and products. Consequently, the examples provided here should not be considered to be an exhaustive list, but to reflect the most complete information CUC members could reasonably gather to date:

- Types of articles (including components) that CUC members understand may contain PIP 3:1.
    - Insulation covers/sleeves used in conjunction with internal and external cables and wirings.
        - These may include terminal covers, fuse housings, cable sleeves, tubes, casings, harnesses, clamps, and other holders for cables.
        - Examples of cables that incorporate insulating components include PVC cables, ground cables, and switch cables.
        - Internal and external cables include power supplies (and power supply cords), USB cables, HDMI cables, and connection cables.
    - Specialty clamps and connections that have insulating and anti-vibration properties (including those used in aerospace, as well as land- and marine-based, applications and apparatus).

- Condenser covers, internal tapes, gaskets, and sheets that are used to shield/protect from electromagnetic waves and for other safety measures in conjunction with circuit boards and other internal components for electronics products.
- Circuit board materials and circuit card assemblies, including in housings and components in storage devices.
- Tapes and the products to which such adhesives and tapes have been applied.
- Manufactured articles to which PIP 3:1-containing adhesives and sealants have been applied during testing or assembly.
- Finished manufactured articles (e.g., electronic equipment, manufacturing equipment, commercial and industrial apparatus, office and business use appliances, automotive and transportation products and equipment, and household consumer products) containing or including any of the above-listed items.

- Types of formulated products that CUC members understand may contain PIP 3:1 (non-articles)
  - Certain resins, coatings, epoxies, thermosets, sealants, potting compounds, pastes and other pliable materials, and formable insulation systems (i.e., those which might not fall within the terms of the current prohibition phase-in for adhesives and sealants).
  - Hydraulic fluids and other liquids which are used in apparatus and equipment which are not used in aviation or military equipment (including land- and marine-based uses in commercial shipping; rail transport; manufacturing, assembly, and warehouse equipment; agricultural and construction-use heavy equipment; and satellite and other data-gathering equipment, for uses including research efforts and which may not involve defense-related purposes or military specifications).

- Types of finished products that might contain such formulated products/components/articles:
  - Finished manufactured articles (e.g., electronic equipment, manufacturing equipment, commercial and industrial apparatus, office and business use appliances, automotive and transportation products and equipment, aerospace and defense-related products and equipment, and household consumer products) containing or including any of the above-listed items
  - Professional and consumer audio and video equipment
  - Audio devices in industrial, commercial, and consumer use components and assemblies
  - Equipment used in medical diagnostics and treatment (e.g., radiography)
  - Laboratory and research equipment (e.g., electron microscopy, chemical analytics)
  - Duplication, printing, and publication technologies and equipment
  - Robotic manufacturing equipment (e.g., automobile assembly, semiconductor manufacturing)
  - Heavy equipment (e.g., used in construction, agriculture)
  - Apparatus used in navigation and safety equipment in shipping and land based devices and appliances

CUC members note that the foregoing lists of articles/products reflect information that could be gathered to date working in cooperation with direct suppliers and others that are known to CUC members.

Support for the 5-Year Alternative Deadline CUC Members Propose.

- CUC's request for a 5-year compliance date delay from the effective date of a final amended rule is based on these assumptions:

    - Because of the multi-faceted and highly stratified layers in CUC members' supply chains and the geographic reach of their operations, and the complexity of the goods manufactured by CUC members, it will likely require well beyond the end of 2021 to reliably identify components containing PIP 3:1 and to effectively advise all sources of supply to discontinue use of PIP 3:1.
    - CUC members currently estimate it may require until the end of 2022 and perhaps later for suppliers to identify and then begin to test and deploy substitute chemistries in manufacturing replacement components/parts.
    - Internal quality/performance evaluations by users could require until end of 2023 or beyond.
    - An additional 6 or more months will be required for redesign and/or recertification of any newly reformulated manufactured products and components and finished articles in accordance with safety, performance, customer, military, and government specifications (including, UL testing and CE marking where applicable).
        - These processes can vary widely, and can differ from certifications needed for consumer products versus industrial, aerospace, or defense applications.
    - One year thereafter will be required to ensure new components, articles, and end-use products can reach all affected markets throughout the supply chains (including retail distribution as applicable), and sufficient time will be required thereafter to permit sell-through and movement in commerce of existing stocks of PIP 3:1-containing products and articles.

Support for Extended Timeline for Providing Replacement Parts for Existing Products, Articles, and Equipment

- An indefinite exemption period is needed for providing replacement parts for existing products, articles, and equipment and to service such equipment. Contractual and regulatory requirements may compel CUC members to provide replacement parts and to make repairs throughout the service life of certain machinery and durable goods. Such contracts may specify that machinery and equipment be serviced at certain intervals and when damaged, be repaired with parts to restore the equipment completely. Thus, such agreements and regulations will require that the replacement parts and servicing ensure the existing machinery continues to meet all of the original specifications. CUC members themselves also may have laboratory, research, and manufacturing equipment in their possession which may require such routine maintenance or repairs for the indefinite future

and for which only parts produced identically to the original components may be suitable for use with the existing equipment.

- For example, in California, replacement parts are required to be made available to consumers for seven years after the end of product/finished good sales.[15] For such products/articles that have been discontinued, manufacturers have already procured and stocked sufficient repair/replacement parts, and substitutes for these replacement and repair parts are therefore no longer available.
- For durable goods such as industrial, professional, and commercial use products and equipment, existing service and maintenance contracts may require the manufacturer to continue supplying applicable repair parts for the life of the appliance.
- Government and military contracts contain similar provisions for servicing and replacement parts meeting the original technical specifications for products having an extended life such as heavy equipment and other durable goods. Sometimes the equipment might be located temporarily or permanently abroad, and a PIP 3:1-containing component might need to be assembled in the US or shipped from abroad to the US. Thus, an indefinite exemption for replacement products and parts is critical, and it must allow for the free movement of such parts globally. Such an exemption is not only contemplated by the statute, it can and should be permitted pursuant to Section 6(c)(2)(D) without any special finding on the part of the Agency.

The Extensions and Exemptions CUC Members Seek Will Not Present New Unreasonable Risks

- PIP 3:1-containing articles have not been demonstrated to release PIP 3:1 in a manner that can lead to unreasonable risks to product users.
- Direct exposure to PIP 3:1 does not frequently occur to the users of products and articles that contain PIP 3:1, and releases from such products and articles is not expected to during normal use, and the components of such products are serviced only by skilled technicians. Moreover, environmental exposures are minimized when PIP 3:1-containing products are properly disposed at the end of their useful life in accordance with pertinent state and local waste regulations. Extending the phase-in time to the full 5-year period authorized by Section 6(d), and providing an indefinite exemption for servicing of products, equipment, and appliances using PIP 3:1-containing replacement parts under Section 6(c)(2) of TSCA, will further ensure the continued use, repair, and proper care of existing products and articles, and that appropriate disposal can be delayed until the end of a product or article's useful life.
- PIP 3:1-containing articles that are embedded in larger components and finished articles are not generally present on surfaces accessible to the general public and consumers/users and thus do not present a risk.
- The limited period for a 5-year phase-down being requested by CUC members will not materially increase exposure-derived risks, and such exposures will decline over time as substitutes are qualified and can be phased in.

[15] *See* https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=CIV&sectionNum=1793.03.

- Without changes to the original March 2021 deadline in the final rule, the regulation will unintentionally lead to unnecessary disposal of existing products and articles which could lead to environmental loading of PIP 3:1-containing articles.
- The absence of a recognized *de minimis* level for the presence of PIP 3:1 in products and articles (e.g., 0.1% by weight of the finished product or article—such as is applied to the presence of substances of very high concern in manufactured articles in the EU pursuant to the requirements of REACH) will likewise contribute to the need for US enterprises to dispose of existing stocks of previously manufactured products and articles and imported products acquired during a period in which suppliers have not had adequate time to identify replacements for PIP 3:1 which will continue to meet the exacting standards which must be met for materials produced by CUC member companies.

Other CUC Comments on PIP 3:1 Rule

- *Heavy Equipment/Durable Goods.* As noted above, CUC members recommend EPA exempt large-scale manufacturing equipment and similar durable commercial and industrial goods which are used in "essential industries," and the PIP 3:1-containing products/articles used to service and repair such equipment;
    - CUC specifically requests EPA include an exemption to exclude from the prohibitions in the final PIP 3:1 rule industrial manufacturing equipment (including equipment used in semiconductor manufacture), and equipment that enables other US-based essential industries, including equipment necessary for construction and infrastructure improvements (e.g., bulldozers, forklifts, paving equipment, cranes) and machinery used in agricultural applications (e.g., combines, tractors), aerospace and defense equipment and applications (not limited to "motor and aerospace vehicles"), and rail and bus transportation vehicles (e.g., train engines, subway ad rail cars, buses, and related equipment).
    - The statute permits exemptions under Section 6(g) for specific "conditions of use" which are a "critical or essential use," or for which "no technically and economically feasible safer alternative is available," or where a prohibition would "disrupt the national economy, national security, or critical infrastructure." CUC members consider the foregoing examples to readily meet the statutory requirements Congress established in Section 6(g).
- *Other Areas in PIP 3:1 Rule Where Important Clarifications Are Needed.*
    - CUC members request that EPA issue a clarification that confirms and codifies the positions EPA has previously expressed in its 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 US as well as customer returns for exchanges or servicing of commercial and consumer products.
        - This might require that EPA amend the language in the preamble to an amended rule or in the provisions of 40 CFR 751.401(b)(1) to explicitly permit 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 US, CUC members also request that EPA make clear that the language in Section 751.401(b)(1) permits the importation and movement within the US of complex manufacturing equipment and durable goods that might contain PIP 3:1-containing components when such equipment or durable good was manufactured *prior* to the date of any final prohibition in the PIP 3:1 regulation. (Please refer to the section below on how "Existing Products/Articles Manufactured Before the Effective Dates Should Be Exempt No Matter Their Location.")
    - CUC members request that the exclusion for the processing and use of PIP 3:1-containing hydraulic fluids in Section 751.401(b)(1)(i) either for the aviation industry or to meet Department of Defense (DOD) specifications be enhanced to include similar equipment and component parts that also are incorporated in civilian and non-aviation sector uses including: surface- and marine-based applications such as sonar and radar arrays that support navigation and transportation; heavy machinery (such as is used in national and metropolitan rail, subway, and bus transportation systems); and agricultural and construction equipment and vehicles. For PIP 3:1 used in hydraulic fluids and PIP 3:1-containing hydraulic fluids that are necessary to meet military specifications, EPA should consider removing the requirement in each case that no alternative be available that meets DOD specifications. The fact that an alternative exists does not enable ready substitution if, for example, the substitution of PIP 3:1 triggers a redesign, recertification requirement, or customer contract amendment.
- *Downstream Notification Requirements*. CUC suggests EPA align the customer notification dates and record keeping terms in 40 CFR 751.407(e) with the end of an expanded and extended No Action Assurance and/or final changes to the rule (or, alternatively, that EPA clarify the final rule to explicitly provide that any product or article manufactured prior to the final effective dates may be processed, used, and commercially distributed (i.e., sold through) indefinitely).
    - As currently codified, the final rule requires that downstream notifications for distribution of PIP 3:1-containing products must commence not later than July 6, 2021. However, it is possible that an entity in the US could learn from an upstream supplier about the presence of PIP 3:1 in a product after that date and will be unable to then provide similar notice by the same July 2021 deadline concerning any product in which the PIP 3:1-containing component might have been incorporated previously (and which might remain in the CUC member's warehouses, distribution centers, or even retail centers).
    - When downstream notifications such as these are received by CUC members' customers (including retailers), they may effectively be receiving notice that a previously manufactured product they are obtaining also may be a product they cannot further distribute (e.g., to an end-user retail customer) if the No Action Assurance expires without modification to its scope or duration and/or without further changes to the final rules.
    - CUC also requests that EPA clarify that the final rule excludes from the downstream notification PIP 3:1-containing articles.

- *Recycling.* CUC supports the exclusions in 751.407(b)(1)(vi) and (vii) for plastic for recycling from PIP 3:1-containing products and articles and finished products and articles made from such recycled plastics.
    - This represents an environmentally sound policy which is 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 considers EPA's efforts to encourage the continued use and recycling of articles that contain PIP 3:1 (and 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.[16]

PBT Rules More Generally

- *EPA Must Support the Critical Importance of R&D in the US.* CUC supports clarification and enhancement of the R&D exemption—for all of the final PBT rules. The rule language is unnecessarily and unintentionally limiting in that it appears to forbid the use of PIP 3:1-containing materials (or any other of the 5 PBTs) in R&D for the development of a new product "or the refinement of an existing product that contains the chemical substance."
    - CUC reiterates the comments it submitted during the 2019 proposal phase that laboratory use of PBT substances should not be prohibited. CUC requests that EPA specifically exempt the use of the regulated PBTs when they are manufactured (imported) or processed in small quantities solely for use in R&D and without limitation on the nature of the R&D.
        - This should include use of the PBTs as a "laboratory standard" and related applications.
        - Small quantities need not be defined as the necessary quantities will differ by application and R&D exercise.
    - It is extremely important to be able to conduct R&D freely in the US and to include the prohibited PBTs and articles in such R&D exercises for purposes of finding substitutes and comparing performance with parts being phased down/out.
    - The wording in the current R&D definition at 40 CFR 751.403 is confusing and implies that PBT can never be used in R&D if the effort is in support of a new product—perhaps even a replacement part (see definition which concludes, "…but not for research or analysis for the development of a new product, or refinement of an existing product that contains the chemical substance.")
        - CUC requests the final rule be edited so the R&D definition in Section 751.403 be clarified in this regard and modified to be inclusive of equipment

[16] As a matter of sound environmental policy, CUC recommends EPA consider extending this approach to the other identified PBTs to the extent those substances also might be present in previously manufactured articles already in commerce that are recyclable (e.g., PCTP). Moreover, this would reflect OCSPP's efforts to implement the very "pollution prevention" ethos Congress established in the Pollution Prevention Act of 1990 (Chapter 133 of Title 42 of the USC) and EPA's stated goals of encouraging recycling. *See, e.g.,* https://www.epa.gov/recycle/recycling-basics.

that is used in laboratories and research settings where R&D occurs. The revised definition would read: "*Research and Development* means laboratory and research use for purposes of scientific experimentation or analysis, or chemical research on, or analysis of, the chemical substance, including methods for disposal, and products, articles (including prototypes), or equipment intended for investigational or laboratory use."

- In addition to editing the definition above, the preamble to the final rule could be revised. For example, the preamble to the revised rule should refer persons to the Agency's interpretive guidance on R&D issued in 1986 for the TSCA new chemicals R&D exemption for a better understanding of the kinds of activities that the Agency considers to be legitimate R&D.

  - Prototypical articles and parts also must continue to be permitted to be imported for R&D uses in the US as well as existing products/articles for uses in laboratories and in real-life comparative trials in R&D exercises. This activity is typically conducted in a controlled environment and in small quantities. These prototypical parts and products should not be prohibited as their use supports investigations EPA should encourage in the quest for substitutes and phase-out of existing products containing PIP 3:1.
  - Other manufactured articles and parts, such as prototypes, being manufactured/imported in small quantities for investigational purposes might also contain trace quantities of PIP 3:1 and should not be subject to this prohibition.
  - Policing such a prohibition is impossible given that the PIP 3:1 rule does not prohibit imported articles when such articles are considered among those which are exempt under the final regulation.
  - EPA should clarify that the R&D exemption for the PBTs rule does not establish volume limitations or time limitations and other requirements limiting the purpose for which the R&D may be undertaken.

- *Existing Products/Articles Manufactured Before the Effective Dates Should Be Exempt 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. Each of the final rules prohibit the manufacture (import) and processing for use of the regulated PBTs in certain products and manufactured articles. CUC understands EPA does not 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.
  - Notwithstanding CUC members' and similarly-situated businesses' best efforts to comply with the various effective dates and prohibitions, many products/articles may reside in various warehouses (both in the US and abroad), may have been previously ordered and/or paid for, and may enter the channel of trade and transit in the future due to the complex nature of certain supply chains. Such materials should be permitted to move to their final destinations where they can be processed, used, and provided to the final customers as originally intended when the material was manufactured.
  - Retail products/articles may reside in storerooms and (especially in light of the economic slowdown of the pandemic) on store shelves; the final regulation should be clarified to enable "sell through" of such products without concern for EPA

enforcement. EPA should make clear that any manufactured products and articles that were produced prior to the effective dates established in the final rule may be distributed in commerce indefinitely (whether previously delivered to an end user or not). In most cases, since retailers do not have the necessary procedures to sell-through old inventories before selling newer inventories, and they might not have an awareness of the presence of certain substances in a previously-manufactured article, there are difficult hurdles to clear through the channels of trade articles that might inadvertently contain newly-restricted PBT substances. This should be clarified soon, and in no uncertain terms. Otherwise, the final PBT rules could continue to create an unintentional enforcement nightmare for manufacturers and retailers who may have large quantities of products on site or in the channels of trade which are, or could become, non-compliant notwithstanding a business's good faith efforts to conform to the final rules.

- *All Existing Exemptions Should Be Preserved.* CUC reiterates its support for and the importance of preserving all of the exemptions and exclusions in all of the January 6 PBT rules.
- *EPA's Prior Interpretations on Imports/Exports of Articles Should Not Be Changed.* The Agency should not revisit or modify the positions EPA expressed in the final PBT rules specifically providing that "articles" that contain the identified PBT substances will <u>not</u> 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.
- *The Need for Enforcement Discretion Going Forward Should Be Recognized by EPA.*
    - CUC members reiterate the comments we provided during the 2019 proposal phase that short and inflexible phase-in periods, such as the periods provided in the final PBTs rules generally, make it critical that EPA 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 previously advised its suppliers of the various prohibitions in the PBT rules, and perhaps established contract terms and other agreements which are intended to specifically exclude the PBT substances in products and articles 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 to encourage such situations to be disclosed, addressed promptly, and timely mitigated.

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Summary and Conclusion

CUC members are actively engaged in the process of working with their multitude of suppliers to identify and phase down the manufacture/import, processing, and use of PIP 3:1-containing products and articles they may acquire. Unfortunately, due to the complexities of the members' supply chains, the products they produce, and the nature of the manufacturing equipment they possess and rely upon to support essential industries, CUC members will require a 5-year delay in the general prohibitions on the processing and distribution of PIP 3:1-containing products and articles. In many cases this time is required because there may not be technically feasible available alternatives for use of PIP 3:1 in products and articles that may be manufactured or distributed in the US.

CUC members urge EPA to retain all of the very critical exemptions to the final PIP 3:1 rule (and the other PBT rules) promulgated on January 6, 2021, including, for example, those drafted to accommodate the need for undisrupted production of materials and products that are used in supporting certain aerospace industry and defense applications and for which no suitable substitutes to PIP 3:1 currently exist.

Because the No Action Assurance does nothing to change the effective dates in the final rule itself, and does not cover formulated products that might contain PIP 3:1 in and of themselves (broadly speaking), CUC members request that the No Action Assurance be immediately amended to expand it to include formulated products and to extend its duration until the effective dates in a final amended rule that incorporates the changes discussed in CUC's comments.

Further, CUC reiterates its support for further timely amendments to the PIP 3:1 rule (and other PBTs rules) that will:

- Exempt large-scale manufacturing equipment and similar durable commercial and industrial goods which are used in the essential industries identified in our comments on page 12 above, and the PIP 3:1-containing products/articles used to service and repair such equipment (i.e., to restore these appliances and equipment to their original condition when necessary due to breakdowns and normal wear and tear);
- Extend the effective date of the general prohibition on processing and use of PIP 3:1-containing products and articles for 5 years from the effective date of a final amended rule;
- Enable the processing, use, and distribution of existing PIP 3:1-contining products and articles that were *manufactured* prior to the final prohibition dates in the final rule (including those that might be situated in warehouses or in the channels of trade and transportation in the US and abroad). This would allow PIP 3:1-containing products/articles that were *manufactured* prior to the various final effective dates to continue to be processed in the US, distributed (i.e., "sold through"), and used in US commerce indefinitely;
- Broaden and extend indefinitely exemptions for replacement parts and materials used to service consumer products/articles; complex commercial, industrial, and

military goods and equipment; and large-scale durable manufacturing equipment manufactured prior to the final prohibition dates (beyond just the automotive and aerospace sectors of the economy and beyond just "vehicles");

- Enhance and clarify the existing exemptions to include materials identified on pages 8–10 above which are similar in nature and conditions of use (including products and articles that include PIP 3:1-containing adhesives, sealants, and greases);
- Enable research and development (R&D) activities that require the use of PBTs (and research equipment with PIP 3:1-containing components) without limitation; and
- Include a provision in the final rule that acknowledges, and makes permissible, the importation, processing, and distribution in commerce of finished products and articles that might contain PIP 3:1 at levels EPA considers to be *de minimis* (e.g., at no greater than 0.1% by weight of the finished product or article in question).[17]

Our members have restated above some of the critical legal deficiencies in the final PBT rules that CUC raised in our 2019 comments; these can be mitigated (even if they all cannot be belatedly corrected as a legal matter), if EPA timely extends the general prohibition in Section 751.407(a) for the full 5-year period that is permitted by Section 6(d) of TSCA.

Taking into consideration the information that CUC members have provided above in response to EPA's published request, as well as the information we provided in our 2019 comments on the proposed rule, our February letter to Dr. Freedhoff, and during our meeting with Dr. Freedhoff on March 1, 2021, CUC believes its members have demonstrated that the 5-year extension period requested is not simply something CUC wishes to achieve. The period is a necessity if EPA expects CUC members (and similarly situated companies) to reasonably engage in an organized and practicable process to identify in collaboration with their numerous suppliers the component parts and products that may contain PIP 3:1, and to identify and select alternative substances that may be suitable for use, and determine that the replacements and articles will meet highly technical performance and safety standards pertinent to existing PIP 3:1-containing products.

The process described in CUC's comments, which is necessary to achieve these outcomes, should be supported by EPA not only as a matter of responsible public policy, but because TSCA requires EPA, when issuing Section 6 regulations and selecting effective phase-in dates, to contemplate what is technically and economically feasible, what is reasonable and practicable, and to accommodate the need for replacement parts on a going-forward basis for complex durable goods that were designed before EPA regulations took effect. Further, the lengthier and more appropriate phase-in period we have proposed here will better enable product manufacturers and processors, and the Agency as well, to become confident that the materials acquired for use and distribution in the US are compliant, and the products they produce will be consistent with the Agency's policy objectives.

[17] This level is consistent with the standards in the Hazard Communications Standard administered by the Occupational Safety and Health Administration (OSHA) and codified at 29 CFR 1900.1200 for substances, such as PIP 3:1, that are not classified as potential human carcinogens.

CUC members continue to support, as we did in our 2019 comments, EPA efforts in TSCA rulemakings, such as the PIP 3:1 rule and the decaBDE provisions, that permit existing products containing such substances to remain in use indefinitely; that encourage recycling of material contained in such products, rather than disposed unnecessarily; and that allow such materials to be reused to manufacture new articles.

Finally, CUC members seek to emphasize that if EPA intends to materially modify the PIP 3:1 regulation (and the other PBT rules) in a manner other than to extend the phase-in periods or to expand the exemptions, that the Agency should, in good faith, provide public notice of the specific contemplated changes that are under consideration, and provide an opportunity for further public input and technical consultations concerning the terms and timing of such changes to the PBT rule requirements.

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In closing, CUC members again express our appreciation to the Agency for its efforts to address these concerns to date, and for soliciting further public input on the PIP 3:1 rule specifically and the PBT Section 6(h) rules in general. As noted above, CUC members would be pleased to meet with EPA personnel to discuss these comments and related issues as the Agency continues is efforts to reconsider certain features of the PBT rules.