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Re: Phenol, Isopropylated Phosphate (3:1) (PIP (3:1)) Pursuant regulating persistent, bioaccumulative, and toxic (PBT) chemicals under Section 6(h) of the Toxic Substances and Control Act (TSCA)
Docket Identification Number EPA-HQ-OPPT-2019-0080 and EPA-HQ-OPPT-2021-0202
Request for Modified Compliance Deadline

The United States Chamber of Commerce ("Chamber") is pleased to write in response to the request for comment regarding recently finalized rules regulating persistent, bioaccumulative, and toxic (PBT) chemicals under Section 6(h) of the Toxic Substances and Control Act (TSCA). These comments pertain to the articles and products subject to the U.S. Environmental Protection Agency's ("EPA") Final PBT Rules, and, in particular, EPA's Final Rule, "Phenol, Isopropylated Phosphate (3:1) (PIP (3:1); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h)" ("Final PIP (3:1) Rule"), 86 Fed. Reg. 894 (Jan. 6, 2021).

We sincerely appreciate the EPA's March 8 "No Action Assurance" regarding enforcement discretion of certain compliance deadlines for PIP (3:1), and the agency's concurrent opening of a comment period to seek additional feedback on potential impacts that the Final PBT Rules. Industry stakeholders are undertaking robust, good faith efforts to comply with these rulemakings, but need additional time to appropriately identify these components as many of these components and articles that contain PIP (3:1) are fully enclosed within supply chains. To be clear, the Chamber does not dispute EPA's statutory mandate to reduce exposures to PBT chemicals to the extent practicable; our concern is ensuring adequate compliance timelines and appropriate scoping to focus restrictions on the conditions of use that lead to meaningful exposure reductions. We believe reconsideration of these factors are more than reasonable, particularly considering the fact that the agency did not undertake an effort to make specific risk findings or determinations associated with these chemicals.

Specific Recommendations

As detailed within the comments that follow, the Chamber's suggestions include: a 5-year compliance date across industry, with a 7-year transition period for the construction industry specifically; a military/national security exemption to provide time for contract adjustments for companies who serve as contractors for national defence, and a de minimis threshold for proven industry involvement with PIP (3:1). We also recommend that the effective date of any regulation consider the date of manufacture and should grandfather existing equipment and replacement parts, in order to limit rendering current equipment and products useless as a result of the rule. The Chamber also recommends establishment of a clear end date for the already manufactured goods to remain in commerce, so that companies do not need to pull inventory from shelves. We think that two years is a reasonable timeline for already manufactured goods to continue in commerce.

Need for Standardized Approach to Risk Management

While we believe there are many areas of concern relating to the implementation of the Final PBT Rules that must be addressed, these concerns also illuminate broader shortcomings pertaining to the current TSCA risk management process. As the Chamber stated in its March 4, 2021 letter[1], development of a TSCA Risk Management framework that encourages transparency and dialogue between the agency and stakeholders is essential to successful implementation of the law.

In fact, last year the Chamber joined several other trade associations in urging the agency to provide stakeholders better clarity and guidance on its approach to risk management so as to minimize such potential disruptions: "the continuous implementation of immediate bans on distribution for already finished goods as EPA manages 20 or more risk management outcomes in a given period of time over the coming years may cause numerous, unintended market disruptions, and require complex supply chain interventions that either do not currently exist or are unable to effectively, reliably function within the proposed timeframes EPA has put forward in certain proposals (e.g., 60 days)."[2] We were pleased that development of a risk management framework to limit the potential for such disruptions was included in the most recent Office of Management and Budget semiannual regulatory agenda, and hope that EPA makes this rulemaking a priority while working with stakeholders as the agency considers next steps on this proposal.

Supply Chain Challenges and Compliance Timelines

The complexity of modern international supply chains can create major significant challenges for businesses seeking to comply with the Final PBT Rules. Chamber members report hearing from numerous small- and medium-sized businesses within their supply chains that have limited awareness of the Final PBT Rules and, upon learning about it, have limited capacity to comply without significant disruptions.

Timing is a major factor behind these limitations, with respect to both the comment period itself and the actual compliance timeframes. As required by statute and noted in the agency's request for comment, TSCA requires a reasonable transition period for compliance deadlines to be set "as soon as practicable." Many business consumers do not know where PIP (3:1) exists in their supply chains, and it takes much longer than 60 or 180 days to determine the scope of this information and synthesize it to share with the EPA, and significantly longer to practicably identify, procure, and incorporate substitutes into supply chains. While the proposed compliance deadlines were public prior to finalization, the agency should not assume that companies start making business decisions prior to any final rule is issued. Because proposals are always subject to change, it would be unreasonable for EPA to expect companies to undertake costly efforts to disrupt their supply chains prematurely or to comprehensively investigate whether a chemical exists in their products prior to the agency taking final action to restrict a chemical.

Moreover, chamber members report that original equipment manufacturers (OEMs) are still gathering information on affected components and that some OEMs are now testing components because they have no supply chain confirmation. Businesses are also very concerned about the risk of enforcement action if a supplier has not disclosed potentially relevant information. Members have informed the Chamber that, as recently as early May, "we were still learning about completely new types of components containing PIP (3:1)." Other members operating in the construction sector report that, while they are undertaking good faith efforts to comply with the rulemaking, it will take approximately six months to clearly understand how pervasive PIP is in their products. For this reason, we request an industry-wide exemption from the PIP (3:1) restriction and a 7-year transition period for PIP (3:1) in the construction industry specifically. For these reasons, additional relief is necessary beyond the currently planned September 4, 2021 termination of EPA's No Action Assurance decision.

[1] March 4, 2021 letter from the U.S. Chamber of Commerce. Available at https://www.globalenergyinstitute.org/sites/default/files/2021-05/210304_USCC_Comments_PIPRule_EPA.pdf

[2] June 3, 2020 petition from the U.S. Chamber of Commerce, American Coatings Association, National Association of Homebuilders, National Association of Manufacturers, and the Toy Association. Available at https://www.globalenergyinstitute.org/sites/default/files/2020-09/TSCA%20Section%2021%20Risk%20Management%20Petition.pdf

In the heavy-duty, industrial equipment sector in particular, it remains unclear if there are any technically and economically feasible alternatives for PIP (3:1) that do not compromise safety, durability, or reliability. Our members produce equipment designed to voluntary consensus safety standards and subject to third party certifications, customer requirements and regulatory testing obligations. Changes to materials and formulations which may affect fit, function, performance, or safety must undergo extensive testing to ensure the new design meets internal quality benchmarks, design specifications, and regulatory requirements. The sheer variety of applications and functionality of PIP (3:1) makes it difficult to estimate the time needed to identify, test, and qualify alternative chemical substances for each end use.

Moreover, traditional design cycles for complex products are approximately seven years from initial design to market entry. This includes time needed to identify whether and to what extent the chemical exists in the supply chain, to confirm function of the regulated substance for end use application, to discover alternatives, to design-out the banned chemical, to build supply chain discipline, to test for safety, regulatory, and quality requirements, to sell through existing inventory, and to re-introduce the product into the market.

Testing requirements often take the longest time to complete during this transition phase. Heavy-duty, industrial equipment operates in some of the most demanding and severe operating conditions over a product life cycle measured in decades. Such equipment is subject to various fire safety and flammability regulatory requirements set by such regulators as the National Highway Traffic Safety Administration, the Occupational Safety and Health Administration, the Mine Safety and Health Administration, the Department of Transportation, the Federal Railroad Administration, and the Consumer Product Safety Commission.

Several documents cited during the NPRM notice and comment period mentioned potential alternatives to PIP (3:1) already introduced in commerce. Various suppliers currently lack sufficient evidence demonstrating that these substances can withstand the extreme conditions under which heavy-duty, industrial equipment operate. While some of these substances may prove effective at replacing PIP (3:1) in some end use applications, manufacturers and their suppliers are still required to perform the years of necessary testing to confirm their viability.

More broadly, the agency's originally finalized compliance period of 60 days is wholly inadequate, given the aforementioned challenges associated with determining where PIP (3:1) exists in supply chains, identifying and procuring a suitable alternative for its use, and ultimately removing all components and articles with the chemical from a supply chain. This compliance timeframe sets up businesses to fail and be in violation of the final rule. However, we commend the agency's acknowledgement of these challenges in the notice for comment and EPA's statement that "it was clearly not EPA's intent during the development of the rule to have such a broad disruptive impact."

Furthermore, the PIP (3:1) compliance deadline is inconsistent with President Biden's Executive Order 14017 of February 24, 2021 ("America's Supply Chains"), 86 Fed. Reg. 11849 (Mar, 1, 2021), which seeks to secure and strengthen supply chains for many industries, including ones that are frequent users of PIP (3:1). As the President noted in the executive order, "[m]more resilient supply chains are secure and diverse – facilitating greater domestic production, a range of supply, build-in redundancies, adequate stockpiles, safe and secure digital networks, and w work-class American manufacturing base and workforce." The COVID-19 pandemic and associated supply chain disruptions in numerous sectors over the past year have illustrated how important a resilient and well-functioning supply chain is to both the economic and national security of the nation. Accordingly, we urge the agency to carefully consider and proactively address the potential that these rules could exacerbate existing supply chain shortcomings.

We therefore ask the Biden Administration EPA to take these efforts into consideration and work with stakeholders to secure these supply chains rather than weaken them in such a critical time for the American

economy. Our membership strongly agrees that PIP (3:1) is prevalent in supplies that are critical to our ability to domestically manufacture key goods. A disruption in these supply chains would force us to go overseas to fill in the gap when we could be utilizing domestic companies instead.

A related issue faced by businesses is the lack of transparency in the production of articles globally. It is not apparent to many downstream users that they have any products with PIP (3:1) components. Accordingly, we believe there should be an affirmative defense for companies that made a good-faith effort to determine if and where PIP (3:1) exists in their supply chains. When there is no way of knowing where PIP (3:1) may exist in the complex components, and if the company went up the chain as best as they can, then they should not be penalized for being unaware of where the chemical may be.

Identification and Introduction of Substitutes

As indicated above, the process to replace PIP (3:1) in supply chains can take many years. The replacement process would include many steps, including but not limited to testing components for PIP (3:1); determining how much inventory is affected, going through the necessary identification, efficacy, and safety testing for a new alternative component, building up that inventory; introducing the new component into their supply chains, and resuming commerce. This multi-step process requires years for companies to do their diligence and ensure safety and continued operations.

More specifically, a member reports that "it generally takes 3-5 years to design and re-qualify equipment at a Nationally Recognized Testing Laboratory (NRTL)." To account for this reality, we recommend that the effective date of any regulation be based on the date of manufacture and should grandfather existing equipment and replacement parts, in order to avoid rendering current equipment and products useless in light of this rule. We also ask for a clear end date for the already manufactured goods to remain in commerce, so that companies do not need to pull inventory from shelves or jeopardize profits. We think that 2 years is a reasonable date in the future for already manufactured goods to continue in commerce.

Scoping Based on Risk and Consideration of Benefits

The Chamber has identified instances within its membership where PBT chemicals such as PIP (3:1) are not presenting any risks because the chemicals are not consumer-facing or potential exposures are de minimis in nature. Accordingly, it is important that EPA consider rescoping the application of PIP (3:1) restrictions to align with exposure reductions, particularly when end-use products deliver important societal benefits. For example, PIP (3:1) is often used in electrical equipment and related industrial settings where it is enclosed and inaccessible to workers. Eliminating use of PIP (3:1) in such instances can cause significant cost and disruption without a corresponding health benefit because exposure and risks are de minimis or non-existent to begin with. EPA should establish a de minimis threshold for the applicability of the Final PIP 3:1 Rule. At a minimum, the Final PIP (3:1) Rule should be evaluated on a case-by-case basis to allow for continued use of PIP (3:1) in instances where industry stakeholders can prove the essential use of the component and that their closed system provides no unnecessary risk to health or the environment.

It is also important to emphasize that articles manufactured with components that contain PIP (3:1) – which does not have a chemical in place to serve as a seamless alternative – are not superfluous. Rather, these components and the products they go into provide critical services to the United States economy and to ordinary Americans. We are not asking for reconsideration without cause; we are asking for it because we believe that this chemical, which in many cases does not have a substitute in place to serve as a seamless alternative, is important to commerce and industry. As one member stated, "all U.S. citizens rely every day on the safety and reliability of end products that contain semiconductors, including medical devices and equipment."

Conclusion

In summary, we are calling on EPA to establish a de minimis threshold for the applicability of the Final PIP (3:1) Rule. This approach will allow critical supply chains that pose no unreasonable risk to remain intact and will help facilitate supply chain communications and efforts to identify where the substance exists. We also ask that EPA issue a no action assurance on all PBT rules and enforcement for a minimum of two years to allow business to continue their diligent work toward finding replacement components in a safe and responsible way without interrupting the current commerce across our nation. We continue to urge EPA to implement its TSCA Risk Management framework rulemaking to allow for transparency, consistency, and enhanced stakeholder communication when addressing identified risks, while establishing a process for business stakeholders to work with EPA on compliance timeframes in the future so we do not face similar issues with each new rule that the agency issues.

The business community is committed to the success of EPA's chemical risk management efforts, and looks forward to strengthening its partnership with the agency to ensure enhanced protection and stewardship of public health and the environment, while also recognizing the practical realities of modern supply chains and business operations.

We appreciate this opportunity to provide this petition to you and look forward to working with you on how to better improve TSCA implementation in the future.

Sincerely,

Marty Durbin