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U.S. Environmental Protection Agency
EPA Docket Center, Mail Code 28221T
Office of Pollution Prevention and Toxics (OPPT) Docket
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Docket No. EPA-HQ-OPPT-2021-0202.

The National Association of Manufacturers appreciates this opportunity to comment on the regulations promulgated recently by the Environmental Protection Agency under Section 6(h) of the Toxic Substances Control Act.

As the nation's largest manufacturing association, the NAM represents nearly 14,000 small, medium and large manufacturers in every industrial sector and in all 50 states. Manufacturers in the US are committed to the communities in which they live and serve, and dedicated to protecting the health, safety and vibrancy of those communities. Through constant innovation, investment and dedication, manufacturers in the U.S. have become leaders in environmental stewardship and sustainability, while continuing to be the engine that drives our economic growth and prosperity. As a result of its relentless drive toward sustainability, the manufacturing sector in the U.S. today is a clean and efficient operation that is technology driven and dedicated to the planet and its people.

The NAM supports human health and environmental protection and is committed to ensuring that products are developed, manufactured, distributed and used safely. NAM members are committed to manufacturing safe, innovative and sustainable products that provide essential benefits to consumers while protecting human health and the environment. No goal is more important than safety to manufacturers. Product safety provides the foundation of consumer trust, and manufacturers devote significant resources to achieve this goal. Every member of the value chain has an important part to play in ensuring the products consumers use are safe for their intended use, that the end customer knows how to use them safely and that their products have a sustainable end of life.

Overview

These comments focus on the regulations pertaining to phenol, isopropylated phosphate (3:1) (CAS No. 68937-41-7), also referred to as PIP (3:1).[1] It is important to emphasize at the outset that we **support** the objective of these regulations to minimize exposure to PIP (3:1) to the extent practicable, including PIP (3:1) that may be contained in manufactured articles.[2] We also commend EPA for its recent outreach to industries potentially affected by the new TSCA regulations. However, we are concerned that, with respect to manufactured articles in particular, certain aspects of the PIP (3:1) rule are unworkable. If the rule is implemented as currently codified, it would result in severe economic disruption and diminished availability of products essential to safety, health and well-being, such as heating, ventilation and air conditioning systems, refrigeration equipment, life sciences and biomedical equipment and electrical generation and transmission equipment. To avoid this unintended outcome, we believe modifications to the rule are needed in four areas:

i. The timeline for removing PIP (3:1) from articles distributed in commerce should be extended to eight years;

ii. An exemption should be provided to allow continued distribution and processing of PIP (3:1) and products and articles containing PIP (3:1) for use in replacement parts for articles that are manufactured prior to the end of the phase-out period;

iii. An exemption should be provided for articles that contain *de minimis* levels of PIP (3:1); and

iv. The regulated community must be provided with specific, practicable options for demonstrating that manufactured articles are in compliance with the regulations.

In addition, EPA should retain the important exclusions currently contained in the PIP (3:1) regulations, such as the exclusion for new and replacement parts used in motor vehicles and aerospace applications.[3]

The bulk of our comments elaborate on the four modifications to the regulations highlighted above, and the reasons why these modifications are necessary. In addition, we discuss measures that could be implemented for future rulemakings under TSCA Section 6(a) to facilitate more robust and effective stakeholder engagement and to ensure that EPA has

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[1] *Phenol, Isopropylated Phosphate (3:1) (PIP 3:1); Regulation of Persistent, Bioaccumulative and Toxic Chemicals Under TSCA Section 6(h),* 86 Fed. Reg. 894 (Jan 6, 2021), codified at 40 CFR § 751.407, (hereinafter referred to as the “PIP (3:1) rule”).

2 TSCA section 3(7) defines the term "manufacture" to include import. References to “manufactured articles” in this document encompass imported as well as domestically manufactured articles.

3 See 40 C.F.R. § 751.407(b). Furthermore, we ask EPA to clarify that the current exclusion for motor vehicles applies to on- and off-road heavy, medium and light duty vehicles including those used in agriculture, construction and mining.

accurate information to guide regulatory actions that might result in restrictions being imposed on manufactured articles in the future.

IMPACTS OF THE PIP (3:1) RULE ON MANUFACTURERS OF ARTICLES

To provide EPA with detailed, reliable information regarding the use of PIP (3:1) in manufactured articles and the impact of the PIP (3:1) regulations on manufacturers of articles, the NAM undertook a comprehensive survey of its members examining, among other things: the types of articles in which PIP (3:1) is used; the function of PIP (3:1) in those articles; the steps needed to transition away from the use of PIP (3:1) in those articles; and the obstacles to phasing-out its use. To protect confidential business information and other competitively sensitive information, the results of this survey were aggregated and anonymized. Key insights are summarized below.

A Wide Range of Articles Incorporate Components Containing PIP (3:1)

Because of its effectiveness as both a plasticizer and a flame retardant, PIP (3:1) is found in a wide range of manufactured articles, in addition to the classes of articles excluded under the regulations (*i.e.*, automotive and aerospace parts and specialty filters).[4] Manufactured articles containing PIP (3:1) include, in no particular order, heavy equipment and machinery used in construction, forestry, mining and agriculture; scientific instruments and laboratory devices (including those being used to identify genetic variants of SARS-CoV-2 for the development of next generation vaccines and therapeutics); computers and peripherals; consumer electronics; heating, ventilation and air conditioning (HVAC) systems and refrigeration equipment; machinery used in the manufacture of semiconductors; equipment used in everyday life sciences research; electrical generation and transmission equipment; security and safety devices for buildings and public spaces, and electrical appliances, including home appliances.

For the vast majority of these products, PIP (3:1) is found, or expected to be found, in component parts that are assembled into the larger article. These include electrical components such as wire harnesses, coated wire, data and power cables, printed circuit connectors, capacitors, transformers, amplifiers, inverters, and electrical housings, as well as gear assemblies, hoses, gaskets, clamps, igniters, and sealing devices for shafts and bearings. In general, PIP (3:1) is utilized in these components because it provides critical safety and/or performance functions, including preventing equipment fires and providing structural integrity and flexibility. In many instances, the use of PIP (3:1) enables the components, and the articles into which they are assembled, to satisfy third-party safety and performance standards, such as UL 94, UL 758, UL 1446, NFPA 75, NFPA 701, and UL 60950-1. NAM member companies noted that certifying to some of these standards can require significant time investments, including long-term (*i.e.*, greater than 10 months duration) testing.

One important feature shared by many of the manufactured articles identified above is a long service life. For example, HVAC systems, manufacturing equipment, electrical generation and transmission equipment, appliances and construction and agricultural machinery all have expected service lives that can span multiple decades. To ensure the continued safe and efficient operation of these articles, users must have access to original replacement parts that are designed and tested for use in the equipment they are operating. For this reason, as

[4] *Id.*

discussed in more detail later in this document, it is important that EPA amend the PIP (3:1) regulation to allow for the continued processing and distribution of PIP (3:1) and articles containing PIP (3:1) for use in replacement parts for articles.

Complex Supply Chains Necessitate A Longer Phase-Out Period

Modern supply chains are complex, extensive and multi-national in scope. They can include small, medium and large suppliers all providing component parts that are used in a single product, and they often entail multiple tiers of suppliers -- from material suppliers, to component manufacturers, to suppliers of complex sub-assemblies that are ultimately assembled into the final manufactured article. Navigating these supply chains to, first, identify which components of a manufactured article contain PIP (3:1) and then identify, qualify and deploy suitable substitutes for those components is a highly complicated and time-consuming process. This process becomes exponentially more complicated for complex articles.

Moreover, the complexity of the manufactured article is not the only factor that determines the degree of difficulty in tracking and replacing the use of PIP (3:1) through a supply chain. Manufacturers with diverse and extensive product lines face comparable difficulties even if their individual products may appear less complex. For example, one company noted that their product offerings include several thousand manufactured articles that, collectively, have more than 50 million individual component parts. Other companies indicated that investigations of their supply chains involve outreach to between 2,000 and 20,000 individual suppliers. Similarly, one member related that their “software as a service” provider which obtains and tracks material compositions has indicated that they have approximately 90 million supplier declarations in their database, but only 10% include full material disclosures and only a small number address the presence of PIP (3:1) (which is not surprising, given its heretofore unrestricted status). Many small and medium-sized suppliers lack such systems and rely on manual collection of data, which is often dated and lacking general substances of concern. Thus, navigating supply chains to identify, qualify and substitute components containing PIP (3:1) is a very complicated task for manufacturers of complex articles as well as manufacturers with extensive product offerings.

This practical reality is reflected in the results of the NAM survey. Most companies are actively interrogating their supply chains to identify the specific components in their manufactured articles that contain PIP (3:1), and most of these companies anticipate that an additional **six months to one year** will be needed to complete those investigations. However, several manufacturers with particularly complex or extensive product offerings indicate that they expect their supply chain investigations to require an additional **two years** to be completed. As we discuss later in this document, the PIP (3:1) regulation should be amended to account for the time frames needed to interrogate supply chains to identify affected components containing PIP (3:1).

Identifying, Qualifying and Deploying Suitable Substitutes Will be Challenging and Time-consuming

Once manufacturers map the components of their products that contain PIP (3:1), they will need to work with their supply chains to identify potential substitutes, assess the suitability of those substitutes, implement manufacturing and, possibly, design changes needed to

accommodate the substitutes, and in many instances, test and certify their finished articles according to applicable safety and performance standards, such as those discussed previously.

In this regard, it is worth noting that EPA's Economic Analysis for the PIP (3:1) regulation identified only three "confirmed" substances and ten "potential" substances that could possibly substitute for PIP (3:1).[5] However, this analysis considered only a handful of applications in which PIP (3:1) was thought to be used at the time the rule was promulgated. As NAM investigations reveal, and as EPA itself has acknowledged, PIP (3:1) is found in a much broader and more extensive universe of manufactured articles than EPA originally believed when it promulgated the rule.[6] As a consequence, it is reasonable to expect that the potential substitutes for PIP (3:1) that were identified in EPA's Economic Analysis may not be suitable for all affected articles and/or applications and that additional time will be needed to seek out and/or develop new alternative chemistries to substitute for PIP (3:1) in some applications.

In addition, it can be expected that many component manufacturers may be slow to adopt alternatives to PIP (3:1), for at least two reasons. First, they are unfamiliar with, and unprepared for, the phase out contemplated by EPA's regulation. NAM member companies report that their supply chains were almost uniformly ***unaware*** of the PIP (3:1) rule until being alerted to the rule by the article manufacturer following the rule's promulgation. In addition, and perhaps less obvious, because component manufacturers supply a global manufacturing base and the United States is the ***only*** country to restrict the use of PIP (3:1) in articles, component manufacturers have less incentive to investigate and deploy alternatives to PIP (3:1). This is of particular concern as global supply chains continue to be disrupted by the COVID pandemic and suppliers already struggle to satisfy existing demands.

Clearly, there will be a high degree of variability, from one manufactured article to the next, in terms of the amount of time needed to identify, test, and deploy component parts that utilize substitutes for PIP (3:1). Overall, most companies expect that substitution (including identifying, qualifying and deploying suitable substitutes) can be completed within **three to six years** after supply chain investigations are completed and all affected component parts are identified. As might be expected, more complex articles, such as life sciences research equipment, appliances, HVAC and refrigeration systems, manufacturing machinery, and construction and agricultural equipment tend to be at the higher end of that range, while less complex articles such as films, architectural products and certain electrical equipment tend to be at the lower end of the range. However, we note that this pattern is not uniform. So, for example, some manufacturers of complex articles anticipate that substitution can be completed in three years. In addition, some manufacturers (including, for example, heavy equipment

[5] EPA, *Economic Analysis for Regulation of Phenol, isopropylated phosphate (3:1) (PIP (3:1)) Under TSCA Section 6(h)* (December 16, 2020), EPA-HQ-OPPT-2019-0080-0644 (hereafter "Economic Analysis") at p. 2-29.

[6] As noted in the March 8, 2021 "No Action Assurance" memo for the PIP (3:1) rule: "because numerous companies and trade associations only commented after the final rule publication that PIP (3:1) is present or may be present in a wide range of articles for industrial and consumer markets in the United States, ***the final rule potentially has a broad ranging impact that the agency did not intend when finalizing the rule*** and the March 8, 2021 compliance deadline." Memo from Lawrence E. Starfield to Michal Freedhoff, *No Action Assurance Regarding Prohibition of Processing and Distribution of Phenol Isopropylated Phosphate (3:1), PIP (3:1) for Use in Articles, and PIP (3:1)-containing Articles under 40 CFR 751.407(a)(1)* (March 18, 2021) (hereafter, "No Action Assurance Memo") (emphasis added).

manufacturers) anticipate that ***more than*** six years will be needed to complete the substitution phase.

Finally, it is important to understand that the estimated substitution periods are not merely speculative. Several manufactured product segments noted that their estimates of the time required to substitute PIP (3:1) are based on prior experiences with similar chemical phase-outs under the EU REACH regulation as well as other regulatory and stewardship programs.

THE TIMELINE FOR PHASING-OUT ARTICLES WITH PIP (3:1) SHOULD BE EXTENDED

As the previous discussion demonstrates, the deadline currently set forth in the regulations for ceasing distribution and processing of articles containing PIP (3:1) is unworkable. To comply with that deadline, large swaths of industry would be forced to cease operations and discontinue distribution of their products immediately. NAM members estimate that their individual losses in such a scenario could range from tens of millions of dollars per year to more than $1 billion per year, with concomitant job losses; and these consequences would linger for several years, until suitable alternatives to PIP (3:1) for all affected products are identified and deployed. In addition, a large number of manufactured articles of importance to industry and consumers would become unavailable in the US, with corresponding negative repercussions for the broader economy.

EPA has explained that for purposes of assessing whether a particular regulatory measure to reduce exposure is "practicable" under TSCA Section 6(h), it is necessary to consider such factors as the "achievability, feasibility, workability and reasonableness" of the measure, which includes an examination of "the economic burden and complexity" of the measure as well as "the utility of the chemical and whether there are technically and economically feasible alternatives available for the chemical."[7] By any of these measures, the deadline currently set forth in the regulations for ceasing distribution and processing of articles containing PIP (3:1) is not practicable. Indeed, a phase-out period for articles containing PIP (3:1) shorter than **eight** years would be impracticable.

As discussed earlier, because of the complex, multi-tiered and global nature of supply chains, most companies expect that a period of **6 months to two years** will be needed to fully investigate their supply chains to pinpoint any PIP (3:1)-containing components in their manufactured articles. Once those components are identified, manufacturers will need to work with their supply chains to identify potential substitutes for PIP (3:1), assess the suitability of those substitutes, implement necessary manufacturing changes and test their finished articles. At that point, manufacturers can begin distributing articles made without PIP (3:1) while, simultaneously, existing inventories of previously-manufactured products are drawn down and ultimately depleted. Based on real world experiences, the NAM member companies believe that

[7] USEPA, *Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h), RIN 2070-AK34, Response to Public Comments* (December 2020) (hereafter, "Response to Comments Document"), at 26.

the entire substitution process, including a sell-through period for inventories of previously manufactured product, can be expected to take as long as **six years** to complete.[8]

With respect to the substitution process, it bears repeating that at present, it is not known whether suitable substitutes for PIP (3:1) are available for all of the manufactured articles and applications in which the substance is currently used.[9] Notably, one reason articulated by EPA for ***not*** restricting the use of PIP (3:1) in automotive parts is that "substitutes for PIP (3:1) in these parts have not been identified and tested."[10] That same rationale is applicable to the majority of manufactured articles. Similarly, another reason EPA concluded that it would be impracticable to restrict the use of PIP (3:1) in automobile parts is because of the chemical's important role in assuring the safety of those products. More specifically, EPA determined that "any restriction on the processing and distribution in commerce of new parts for the automotive industry could increase costs and safety concerns without meaningful exposure reductions."[11] Those precise considerations are equally relevant to the articles manufactured by the NAM's members. For most of those articles, PIP (3:1) is embedded in the polymer matrix of a component that is itself embedded in a much larger manufactured article and is typically inaccessible to workers, consumers, and end-users. Consequently, exposure to PIP (3:1) from the manufactured article is likely to be negligible, as it is with automobile parts. PIP (3:1)'s low volatility also reduces the likelihood of inhalation or other exposure risks.[12] Similarly, with respect to most, if not all, of the articles manufactured by the companies that participated in the NAM survey, PIP (3:1) provides critical fire safety protection for users of the manufactured article. Thus, the same factors that led EPA to conclude that it would be impracticable to restrict the use of PIP (3:1) in automobile parts also support the conclusion that it would not be practicable to restrict the distribution and/or processing of manufactured articles containing PIP (3:1) without providing an extensive phase-out period.

For the reasons just discussed, a total phase-out period of eight years is necessary to ensure that manufacturers will have sufficient time to identify the PIP (3:1)-containing components in their manufactured articles, and to find, assess, qualify and deploy suitable substitutes for PIP (3:1) in those components**. Accordingly, we urge EPA to amend the PIP (3:1) regulation to delay the prohibition on distribution and processing of PIP (3:1) and products containing PIP (3:1) for use in articles, and articles containing PIP (3:1), for a period of eight years.** This timeframe is consistent with TSCA Sections 6(d)(1)(C), (D) and (E),

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[8] Appendix 1 to these comments contains a schematic of the steps involved in phasing-out a chemical of concern from a component found in a complex article. This schematic was adapted from a more detailed chart provided by one of the member companies that participated in the drafting of these comments.

[9] As mentioned earlier, while EPA's Economic Analysis refers to three "confirmed" and ten "potential" substitutes for PIP (3:1), the Agency, when it was preparing that analysis, was not aware of the full breadth of articles and applications in which PIP (3:1) is used. For this reason, the Economic Analysis is not a reliable indicator of whether suitable substitutes for PIP (3:1) are available for the wide variety of articles in which PIP (3:1) is currently used.

[10] *See* 84 Fed. Reg. 36,749 (July 29, 2019).

[11] *Id. See also Response to Comments Document* at 78 ("it would not be practicable to regulate processing and distribution of PIP (3:1) for use in new and replacement parts for automobiles as they are **important to the performance and safety of automobiles, have no currently available feasible alternatives, and there is low potential for consumer exposure**") (emphasis added).

[12] PIP (3:1) is estimated to have a low vapor pressure due to its structure, as reported in EPA, Design for the Environment. August 2015. "Flame Retardants Used in Flexible Polyurethane Foam: An Alternatives Assessment Update," pp. 7-273 to 274.

which together provide that the compliance date for a ban or phase-out requirement under a Section 6(a) rule must "start" within 5 years of promulgation of the rule, that "full implementation" of the ban or phase-out must be required "as soon as practicable," and that a reasonable transition period must be provided.[13] Under the PIP (3:1) rule, implementation of the phase-out of PIP (3:1) has already begun. We are requesting that, for manufactured articles other than those excluded or subject to separate phase-out deadlines under the current regulations, the deadline for completion of the phase-out should be eight years. And eight years is necessary because a shorter time period is neither practicable nor reasonable.[14]

We also urge EPA to allow continued distribution and processing of PIP (3:1) and products and articles containing PIP (3:1) for use in replacement parts for articles manufactured prior to the end of the eight-year phase-out period. As discussed, many of the manufactured articles identified as containing components with PIP (3:1) have long service lives that can span multiple decades. Examples of such articles include life sciences research equipment, HVAC systems, manufacturing equipment, electrical generation and transmission equipment, appliances, construction and agricultural machinery, and medical devices.[15] To ensure the continued safe and efficient operation of these articles, users must have access to original replacement parts that are designed and tested for use in the equipment they are operating. These same considerations contributed to EPA's decision not to restrict replacement parts for automobiles and aerospace vehicles.[16] Moreover, as EPA noted with respect to replacement parts for automobiles, it is not practicable to require manufacturers to reformulate or redesign replacement parts for articles that have been phased out.[17] Thus, to ensure that the PIP (3:1) regulation is practicable, EPA should amend the regulation to allow for the continued processing and distribution of PIP (3:1) and products and articles containing PIP (3:1) for use in replacement parts for articles manufactured prior to the end of the 8-year phase-out period recommended above.[18]

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[13] *See* 15 U.S.C. § 2605(d)(1).

[14] We also note that Section 6(c)(2)(E) of TSCA provides that, in a Section 6(a) regulation EPA shall impose restrictions on articles "only to the extent necessary to address identified risks from exposure to the chemical substance or mixture from the article . . . so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A)." EPA has not (and cannot) make the risk determinations that are a prerequisite to imposing restrictions on articles under this section of the statute.

[15] While medical devices are excluded from the scope of TSCA, the parts used in manufacturing those devices – when used "generically" and not dedicated solely to medical device applications -- ***are*** within the scope of TSCA.

[16] *See, e.g., Response to Comments Document* at 80. According to EPA, another factor that led the Agency to conclude that it would be impractical to prohibit the use of PIP (3:1) in replacement parts for automobiles and aerospace vehicles is the "multi-tiered international supply chain" for those products. *Id.* As already discussed, those exact same factors are present with respect to the articles manufactured by the NAM members.

[17] 84 Fed. Reg. 36,749.

[18] We also note that TSCA Section 6(c)(2)(D) states, in mandatory terms, that EPA "shall exempt" replacement parts designed prior to publication of a final Section 6(a) rule, unless the Agency determines that such parts "contribute significantly" to a risk identified under Section 6(b)(4)(A). EPA has not made such a determination with respect to PIP (3:1).

ARTICLES CONTAINING *DE MINIMIS* LEVELS OF PIP (3:1) SHOULD BE EXEMPT

As a practical matter, following the phase-out of PIP (3:1) from manufactured articles, despite manufacturers' vigilant policing of their supply chains, it is very likely that PIP (3:1) will continue to be inadvertently present in many articles. This is due to several factors that are beyond the manufacturers' control, including:

i. The prevalence of PIP (3:1) in plastic parts and electrical components that are widely used across a broad range of manufactured articles;

ii. The fact that the US is currently alone in restricting the use of PIP (3:1) in articles – which means that global demand for, and use of, these components will very likely continue unabated despite EPA's regulation; and

iii. The reality that manufacturers of articles typically have limited visibility into, and limited ability to exercise control over, the specific chemicals used in their complex, multi-tiered, global supply chains.

Given this constellation of facts it is not practicable to require manufacturers of articles to ensure, under threat of liability for civil penalties under TSCA, that their articles contain zero PIP (3:1). Indeed, in light of the widespread use of PIP (3:1) and the limitations of analytical chemistry, it is not clear that achieving a level of "zero" is technically possible. Therefore, to assure that the PIP (3:1) rule is practicable, we urge EPA to exempt from regulation articles that contain only a de minimis level of PIP (3:1). Specifically, we suggest that, for purposes of this exemption, EPA establish a *de minimis* level of **0.1% (by weight), or less**. This level is consistent with the threshold established in EPA's export notification regulations for substances subject to regulation under TSCA Section 6 that are known or suspected carcinogens.[19] We note that: (i) EPA is *not* requiring export notification for articles under the PIP (3:1) rule and (ii) EPA has *not* identified PIP (3:1) as a known or suspected carcinogen. Nevertheless, we think the export notification regulations provide a useful benchmark for substances subject to regulation under Section 6, and we expect that potential exposure to PIP (3:1) at this de minimis level will be negligible, since, as discussed earlier, for most manufactured articles PIP (3:1) is embedded in the polymer matrix of a component that is in turn embedded in a much larger manufactured article.

EPA SHOULD SPECIFY METHODS OF DEMONSTRATING COMPLIANCE

Unlike formulators of chemical products, who, in general, can easily identify the chemical components that comprise their formulations, manufacturers of articles have much more limited visibility into the specific chemicals that are utilized in manufacturing the various component parts that are assembled into a finished article. As discussed already, this lack of visibility is inherent in the complex, multi-tiered, global supply chains that characterize modern manufacturing. These same characteristics sharply limit the ability of manufacturers to exercise full control over all chemical inputs that go into the component parts that comprise a finished manufactured article. Moreover, it is unrealistic to expect that manufacturers will be able to conduct (or require their suppliers to conduct) chemical analyses of all of the component parts that comprise their finished articles. The impracticability of such an endeavor is highlighted in

[19] *See* 40 CFR § 707.60(c)(2).

EPA's Economic Analysis, which conservatively estimates that the cost of testing just one category of consumer products for the presence of PIP (3:1) would likely exceed ***$500 million***.[20]

For these reasons, we urge EPA to provide specific examples of documentation that article manufacturers can maintain to conclusively establish, for enforcement purposes, compliance with the restrictions on processing and distributing articles containing PIP (3:1). This non-exclusive list should include the following:

- Certifications of compliance from all immediate suppliers of components and sub-assemblies that are used in assembling the finished article;
- Documentation sufficient to demonstrate that the finished article does not contain more than a de minimis level (*e.g.,* 0.1% by weight) of PIP (3:1);
- Manufacturing specifications (or commercial contracts) for component parts and sub-assemblies that prohibit the use of PIP (3:1); and
- Declarations that conform with IEC 62474 or comparable standards.

We believe that providing article manufacturers with specific guidance on methods of demonstrating compliance that are feasible and reasonable is essential to ensuring that the restrictions set forth in rule are practicable.

ENHANCING STAKEHOLDER ENGAGEMENT

The NAM commends EPA for its recent efforts to obtain stakeholder input, and we note that the Agency's stakeholder engagement efforts included a public webinar as well as several meetings with individual stakeholders.[21] Nevertheless, as EPA acknowledges, a large segment of industry was not engaged in the rulemaking process, presumably because stakeholders in those industries were unaware of the full ramifications of the proposed regulation – particularly with respect to manufactured articles.[22] One consequence of this failure to engage is that in the PIP (3:1) rule "EPA established a compliance deadline that cannot be feasibly complied with as intended."[23]

As EPA moves forward with completing risk evaluations and promulgating risk management regulations under TSCA Section 6, it becomes more important than ever to ensure robust stakeholder engagement, particularly among stakeholders, such as manufacturers of articles, that have not traditionally been the direct focus of restrictions imposed under TSCA. Taking steps now to enhance participation in this manner should help EPA and the regulated

[20] *See* Economic Analysis at 4-18.

[21] The rulemaking docket includes notes from meetings with several stakeholders. *See, e.g.* EPA, Stakeholder Meeting with ICL, August 30, 2018, EPA Docket ID EPA–HQ–OPPT–2019–0080.

[22] *See* No Action Assurance Memo at 3 ("Moreover, because numerous companies and trade associations only commented after the final rule publication that PIP (3:1) is present or may be present in a wide range of articles for industrial and consumer markets in the United States, the final rule potentially has a broad ranging impact that the agency did not intend when finalizing the rule and the March 8, 2021 compliance deadline.")

[23] *Id.*

community avoid unintended outcomes, such as occurred with the PIP (3:1) rule. To that end, we encourage EPA to open a dialogue to explore options for enhancing engagement. We also urge EPA to consider, and grant, the June 3, 2020 petition filed by the NAM and others, requesting that EPA issue a framework risk management rule under TSCA Section 6.[24]

CONCLUSIONS

PIP (3:1) is found in a large number of components that are widely used in manufactured articles spanning across all sectors of the economy. In general, PIP (3:1) is utilized in these components because it provides critical safety and/or performance functions, including preventing equipment fires and providing structural integrity and flexibility. Because of the complex, multi-tiered and global nature of the supply chains for these manufactured articles, pinpointing the presence of PIP (3-1) containing components, and identifying, qualifying, and deploying suitable substitutes for those components in manufactured articles is a complicated and resource intensive multi-year process. And once those substitutes are deployed, and articles with these "new" components are manufactured, additional time will be needed to clear channels of trade of existing inventories of articles previously manufactured with PIP (3:1)-containing components. Based upon the NAM member companies' expertise and experience, including information derived from prior phase-outs of chemicals of concern, the timeline for removing PIP (3:1) from articles distributed in commerce should be extended to eight years to be practicable. Therefore, we respectfully urge EPA to amend the PIP (3:1) regulation to delay the prohibition on distribution and processing of PIP (3:1) and products containing PIP (3:1) for use in articles, and articles containing PIP (3:1), for a period of eight years.

In addition, many of the manufactured articles identified as containing components with PIP (3:1) have long service lives that can span multiple decades. To ensure the continued safe and efficient operation of these articles, users must have access to original replacement parts that are designed and tested for use in the equipment they are operating. The NAM respectfully urges EPA to amend the regulation to allow for the continued processing and distribution of PIP (3:1) and products and articles containing PIP (3:1) for use as replacement parts for articles manufactured prior to the end of the 8-year phase-out period recommended above.

Also, it is not practicable to require manufacturers of articles to ensure that their articles contain zero PIP (3:1). Therefore, to assure that the PIP (3:1) rule is practicable, we urge EPA to exempt from regulation articles that contain only a *de minimis* level of PIP (3:1). Specifically, we suggest that, for purposes of this exemption, EPA establish a *de minimis* level of 0.1% (by weight), or less, consistent with the threshold established in EPA's export notification regulations for substances subject to regulation under TSCA Section 6.

Finally, to ensure that the PIP (3:1) rule can be practicably enforced with respect to manufactured articles, we urge EPA to provide specific, non-exhaustive examples of documentation that, for enforcement purposes, will conclusively demonstrate compliance with the restrictions on processing and distributing articles containing PIP (3:1). This should include: (i) certifications of compliance from all immediate suppliers of components; (ii) documentation demonstrating that the finished article does not contain more than a de minimis level (e.g., 0.1% by weight) of PIP (3:1); (iii) manufacturing specifications (or commercial contracts) for

[24] http://documents.nam.org/ERP/FINAL_TSCA_Petition_6-3-2020.pdf

component parts and sub-assemblies that prohibit the use of PIP (3:1); and (iii) supplier declarations that conform with IEC 62474 or comparable standards.

The NAM appreciates this opportunity to provide comments on the critically important PIP (3:1) rule, and we welcome the opportunity to work collaboratively with EPA and other stakeholders to ensure that the rule can be successfully implemented in a manner that is practicable and protective of human health and the environment. We advocated on behalf of our members for TSCA reform and applauded the passage of the Lautenberg Act in 2016. Five years later, we remain vested in ensuring its success.

Sincerely,

Rachel Jones
Vice President
Energy & Resources Policy

Appendix 1

Example Schematic of Steps in Component Substitution Process

	Process	Comment
1	Identify Current Use	Identify all places where chemical is used
2	Identify Alternatives	Identify potential alternative chemicals, formulate, formula testing, etc..
3	Source	Source appropriate supplier(s)
4	Formulation	Formulation of chemical
5	Chemical Testing	Testing of chemical (flammability, flexibility, corrosion resistance, etc.)
6	Results analysis	Chemical company, parts supplier and OEM review and adjust as needed
7	Formula Adjustment	Reformulate / adjust chemicals
8	Retesting	Testing of chemical (flammability, flexibility, corrosion resistance, etc.) as needed
9	Results analysis	Chemical company, parts supplier and OEM review and adjust as needed
10	Test Parts Development	Manufacture initial sample parts for testing – confirmation that compound will work
11	Testing	Testing of initial samples
12	Analysis	Review results and feedback for adjustment
13	Chemical manufacturing	Chemical company needs to manufacture enough chemical and depending on company, may be doing so for many customers
14	Modify manufacturing process	As needed, manufacturing processes, tools, etc. may need to be changed or new tooling made to allow use of new alternate chemical
15	Tooling Trial	Initial trial for use of new tool/process; analyze results

	Process	Comment
16	Modify/improve tooling or process as needed	If changes are needed, retesting may be required
17	Retrial/test	Retest and analyze results
18	Sample Parts	Receive sample parts
19	Parts safety approval	Perform applicable safety approval for parts
20	Parts testing	Testing of parts
21	Product Testing	Install and test in product
22	Drawing Updates	OEM needs to update applicable drawings, possible new model numbers, part numbers, etc. to control inventory
23	Product safety approval	Perform applicable safety approval for products
24	Order parts for mass production	Order after approvals
25	Produce products	OEM manufacturing
26	Ship to distribution	OEM's ship from factories to warehouses
27	Distribution ship to customers	Ship from OEM warehouse to distributor warehouse
28	Customers sell to end users	Distributor sells to contractor or customer for install