Comments of the
National Electrical Manufacturers Association (NEMA)
to
U.S. Environmental Protection Agency

RE: Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h)

Docket No. EPA-HQ-OPPT-2021-0202; FRL-10021-08
May 17, 2021

The National Electrical Manufacturers Association (NEMA) represents nearly 325 electrical equipment and medical imaging manufacturers that make safe, reliable, and efficient products and systems in seven industrial sectors. NEMA Member companies represent over 370,000 American manufacturing jobs in more than 6,100 facilities. Worldwide annual sales of products in the NEMA scope exceed $140 billion.[1]

The U.S. Environmental Protection Agency (EPA) has requested comments on its recently-issued final rules on five persistent, bioaccumulative, and toxic (PBT) chemicals: Phenol, Isopropylated Phosphate (3:1) (PIP), Hexachlorobutadiene (HCBD), Pentachlorothiophenol (PCTP), 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP), and Decabromodiphenyl Ether (DecaBDE).

We urge EPA to exercise its statutory authority to grant appropriate exemptions from restrictions on *all five* PBTs. If unable to provide permanent regulatory relief, we then ask EPA to grant reasonable and sufficient time for finding and implementing a suitable alternative for *all five* PBTs. We ask for regulatory relief for *all five* PBTs because we believe this sets an appropriate precedent as EPA considers promulgating future rules for other chemicals. Although EPA has requested information on *all five* PBTs, *these comments focus mainly on PIP*.

Summary of NEMA Comments on PIP

1. EPA Must Grant Critical Use Exemptions
2. EPA Must Grant Additional Exemptions
3. Call for Eight-Year Phase-Out Periods
4. EPA Exceeded Its Authority
5. Partnership Needed for Effective Chemical Management

[1] For more information, please visit: https://www.nema.org/.

EPA Must Grant Critical Use Exemptions

Criteria for a Section 6(g) Critical Use Exemption

NEMA urges EPA to provide a Critical Use Exemption. NEMA understands that EPA has certain statutory obligations under amended TSCA, however, the Agency has discretionary authority as well. We therefore show how EPA can meet its legal obligations while still providing manufacturers with an ability to obtain compliance without undue burden. Under TSCA Section 6(g)(1), EPA has authority to grant an exemption from a risk management rule if the Agency finds that:

> (A) the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure;
>
> (B) compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or
>
> (C) the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

Use of PIP in electroindustry manufacturing substantially benefits health and public safety; a ban on PIP in electroindustry uses would significantly disrupt the national economy and essential functions across multiple lines of critical infrastructure; and use of PIP in electroindustry manufacturing is a critical or essential use for which no technically feasible safer alternative is currently available. Imposing this ban upon US manufacturers makes these manufacturers less competitive in the global marketplace and threatens US-based jobs. Therefore, NEMA requests that EPA use its authority under TSCA Section 6(g) to grant a critical use exemption for electroindustry uses of PIP.[2]

We also request EPA use its authority under TSCA Section 6(g) to grant critical use exemptions for electroindustry uses of *all five* PBTs to set an appropriate precedent as EPA considers promulgating future rules for other chemicals.

[2] EPA-HQ-OPPT-2019-0080-0037; See also OMB meeting documentation: EPA-HQ-OPPT-2019-0080-0036.

PIP Is Essential for Use in Electroindustry Manufacturing

Because PIP serves variable and sometimes overlapping service as a flame retardant, elastomer, and lubricant, the electroindustry incorporates the chemical into a variety of manufactured articles. PIP is also used in electroindustry manufacturing facilities in hydraulic fluids, sealants, adhesives, and others.

Products manufactured through the use of PIP provide substantial benefits to nearly every major manufacturing sector in the nation including transportation, energy, communications, defense, and healthcare. A representative sample of products made possible by the qualities unique to PIP include medical devices, capacitors, inverters, generators, transformers, semiconductor wafers, computers, electrical appliances, and electronics.

The presence of PIP in electroindustry components ensures that the parts perform appropriately and contribute to product safety. Without PIP (or an effective alternative, yet to be identified), many products and processes would not function as intended and would experience a decrease in performance and safety. Thus, simply eliminating PIP from these uses is not an option for these manufacturers.

Use of PIP in Electroindustry Manufacturing Substantially Benefits Health and Public Safety

Products manufactured through the use of PIP provide substantial benefits to health and public safety. For example, many medical devices, including ventilators, depend on the unique properties of PIP. Servo amplifiers are used in medical devices and also by the semiconductor industry to make wafer fabrication equipment for manufacturing chips. And servo amplifiers themselves use PIP as plastic jacketing for electrical wiring. If PIP were immediately banned, manufacturing of medical devices and semiconductors would be severely jeopardized as *there are currently no known alternatives to PIP*.

NEMA Members support the heating, ventilation, air conditioning and refrigeration (HVACR) industry by suppling variable frequency drives (VFDs) for HVACR equipment that provide climate control and ventilation in homes, eldercare facilities, hospitals, schools, military bases, data centers, shopping malls, sport complexes, and others. VFDs, which contain PIP, optimize energy consumption through efficient control of fans, pumps and compressors used in a building. Such equipment is also used to control pump systems in water and wastewater treatment plants across the nation. An immediate ban on PIP without suitable replacement will severely impact building and drinking water infrastructures all over the U.S.

A Ban on PIP Would Disrupt the National Economy

As described above, PIP is a critical component for a variety of essential electroindustry uses vital to health and public safety. Electrical products and systems constitute an essential part of

the economy at all levels, including healthcare, energy, communications, aerospace, and national defense sectors.

For example, NEMA Members provide servo amplifiers to the semiconductor industry used in wafer fabrication equipment to manufacture chips found in smart devices, automotive electronic systems, and aerospace control technologies. Electroindustry manufacturing in the U.S. and internationally would be substantially disrupted by a ban on use of PIP in manufacturing facilities, given the current lack of technically feasible alternatives.

No Technically and Economically Feasible Safer Alternative to PIP Is Available

No technically and economically feasible safer alternative to PIP for use in electroindustry manufacturing is currently available. A literature review shows that due to the unique characteristics of this chemical, no PIP substitute has been shown to meet the rigorous standards applicable to these applications. While some NEMA Members have begun the lengthy process for validating an alternative to PIP as a flame retardant in electroindustry manufacturing, an adequate transition period is needed to assure safety given the thousands of products and multiple supply chains that are impacted.[3]

EPA Must Grant Additional Exemptions

In addition to an exemption to a ban on PIP, the electroindustry asks that EPA provide additional relief through four additional exemptions. NEMA asks EPA to provide *de minimis* exemptions for articles containing less than 1.0% (by weight) of PIP, replacement parts exemptions, large-scale manufacturing equipment exemptions, and an inventory "sell through."

EPA Must Grant De Minimis Exemptions

Due to the complexities of the international, multi-tiered supply chain, determining a presence below the threshold of 1.0% by weight is nearly impossible.[4] Manufacturers must rely on the accuracy of reporting from every supplier throughout the entire supply chain on trace amounts of a chemical, even those that are present unintentionally. There is little, if any, evidence to suggest that the presence of trace amounts of a chemical in an article can contribute to *exposure*, which must be considered in any risk determination. Furthermore, there has been much scientific debate over whether it is actually possible to achieve 100% confidence in any formulation.

[3] Please see the "Call for Eight-Year Phase-Out Period" section of these comments for more information.
[4] Please see the "Determining the Presence of NMP in the Supply Chain and in the Manufacturing Processes" section of these comments for more information.

Lastly, and possibly most importantly, EPA has precedent for providing *de minimis* exemptions.[5] The *de minimis* exemption allows covered facilities to disregard certain minimal concentrations (1.0% or below) of chemicals in certain situations. Although this exemption is limited, it shows that the Agency understands the difficulties associated with tracking and managing chemicals below this threshold. Therefore, we urge the EPA to extend that relief to this application as well. Not having a *de minimis* exemption puts an unreasonable burden on manufacturers so EPA should provide permanent regulatory relief.

EPA Must Grant Replacement Parts Exemptions

Another exemption EPA should provide relates to replacement parts. Many manufacturers are required to maintain replacement parts for years to ensure that consumers' products can continue to remain operational and meet warranty demands. It is not economically feasible for manufacturers to redesign and produce replacement parts years after they were originally made, because many of these parts are no longer being actively manufactured. So that companies can meet legal and consumer requirements, we urge EPA to provide a fifteen-year exemption for all replacement parts.

EPA Must Grant Large-Scale Manufacturing Equipment Exemptions

EPA should also exempt large-scale manufacturing equipment. This is equipment that exists at manufacturing facilities that does not enter into commerce, is often legacy equipment, and provides essential functions for which there is no known replacement. Existing equipment should not need to meet new compliance requirements. Accordingly, replacement parts for such equipment should also be exempted.

EPA Must Grant a Three-Year "Sell Through" Period

Finally, EPA must provide manufacturers with a reasonable "sell through" period. Manufacturers may have millions of dollars' worth of inventory through products that have already been manufactured that contain PIP, through machinery that has already incorporated the chemical, or in already purchased PIP meant to be used for production. Due to the economic burden associated with losing this inventory (small business being especially harmed), we ask EPA to provide a three-year "sell through" period to allow manufacturers to deplete current inventory.

We also request that EPA grant these additional exemptions for electroindustry uses of *all five* PBTs. We ask for regulatory relief for *all five* PBTs because we believe this sets an appropriate precedent as EPA considers promulgating future rules for other chemicals.

[5] 40 CFR §372.38(a).

Call for Eight-Year Phase-Out Period

If EPA chooses not to provide permanent relief in the form of the requested exemptions, we expect EPA to use its discretion under TSCA Section 6(d) to allow eight years for affected entities to comply with any final rules. Section 6(d) states that the Administrator shall, "specify mandatory compliance dates for the *start* [emphasis added] of ban or *phase-out* [emphasis added] requirements under a rule under Subsection (a), which shall be as soon as practicable, but not later *than 5 years* [emphasis added] after the date of promulgation of the rule…" and furthermore states the Administrator shall "specify mandatory compliance dates for full implementation of ban or phase-out requirements under a rule under Subsection (a), which shall be as soon as practicable; ***and*** *provide for a reasonable transition period* [emphasis added]." Therefore, EPA has the authority to provide five years for the start of any ban or required phase-out of any chemical, and further allow for a reasonable amount of time for manufacturers to transition to alternatives.[6] Therefore, we expect EPA to grant eight years to allow manufacturers a reasonable time period for addressing this complex issue.

Further, there is global precedent for allowing reasonable phase-out periods for complying with chemical bans. NEMA notes that the European Union's "RoHS Directive"[7] allows for several years for manufacturers to eliminate substances that are being restricted. For example, the most recent RoHS II Amendments under Directive 2015/863 provided for four to six years to implement restrictions. EU Directive 2015/863 was issued June 4, 2015 with an effective date of July 22, 2019 for most product sectors, and an effective date of July 22, 2021 for medical devices and monitoring and control equipment.

Moreover, European authorities routinely have granted "exemptions" to the RoHS thresholds for restricted substances in designated uses. The maximum time allowable under the RoHS Directive for such exemptions extends to seven years for certain categories of products. The European authorities recognize the complexities of the chemical management process and accordingly grant sufficient time for affected entities to implement change. EPA should follow precedent, as well as their own statutory authority to grant a reasonable phase-out period of eight years. This time will allow manufacturers to determine the presence of PIP throughout its supply chain and manufacturing processes, find a suitable alternative, and implement the alternative.

We also request that EPA grant an eight-year phase-out period for electroindustry uses of *all five* PBTs. We ask for regulatory relief for all five PBTs because we believe this sets an appropriate precedent as EPA considers promulgating future rules for other chemicals.

[6] Please see the "Finding a Technically and Economically Feasible Safer Alternative" and "Implementing a Technically and Economically Feasible Safer Alternative" segments of these comments for detailed information about why the electroindustry requires the maximum time allowable under the law.

[7] DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Determining the Presence of PIP in the Supply Chain and in Manufacturing Processes

The modern network between a company and its suppliers to produce and distribute a specific product consists of a global, nonlinear, multi-tiered supply chain. The system is vastly broad and complicated and includes levels starting with the raw materials supplier, moving on to a material formulator, to an article producer, to a component assembler, to an end producer, and to, finally, an original equipment manufacturer. And the network is not linear as portrayed in this simple example and is instead a complicated web of dealers, contractors, and sellers at any one tier in the chain. Further, suppliers can be found in any country throughout the world—often a product crosses many national borders several times before ultimately reaching a US consumer.

To comply with a chemical regulation, NEMA Members must first navigate the complexities of the international supply chain to determine the presence of a chemical in their supplier network. Next, they must determine the presence of a chemical in their manufacturing processes. When EPA does not provide a *de minimis* exemption, this process must be conducted for even trace amounts of a chemical, even for those that are not added intentionally. To do so, there must be reliance on the accuracy of reporting from every supplier throughout the entire supply chain. It can take months to get responses from suppliers deep within the supply chain. Therefore, manufacturers must devote considerable manpower and divert resources from other immediate activities to comply with an unnecessarily and artificially short regulatory timeframe. It is almost impossible to get internal approval divert time and money towards this endeavor in advance of an actual ban. Businesses cannot proactively begin this process for hundreds or even thousands of chemicals that might someday be banned. Small businesses are especially disadvantaged.

Furthermore, this process must be developed to track and manage chemicals throughout the entire supply chain to ensure compliance beyond any regulations' effective date. Most domestic manufacturers have not begun to develop that level of sophistication in materials management.

A conservative estimate is that the process of determining a chemical's position in the supply chain and developing a tracing program to ensure continued compliance would take at least 6-24 months to achieve. Clearly, an immediate ban on PIP will not allow manufacturers to undertake proper review of their supply chains to adequately ensure compliance.

Finding a Technically and Economically Feasible Safer Alternative

Because no technically feasible safer alternative for PIP in electroindustry manufacturing is currently available, manufacturers would need to identify an immediate substitution of alternate formulations for companies to maintain production. But finding a suitable chemical requires significant investment of time and resources, with no guarantee of success within a planned timeline.

- Time Requirements

  To find a substitute chemical, a conservative estimate of time to complete a *preliminary* screen for possible alternatives to PIP is four to six months, and possibly much longer depending on the complexity of the product. A more in-depth alternatives analysis including stakeholder surveys to collect additional information on safety, performance, and economic feasibility could take at least 6 to 12 months.[8]

  Based on our experience, an additional one to two years to conduct adequate performance testing is needed before manufacturers can commit to using a particular alternative. This step brings the entire process of finding a suitable alternative to a total timeline of two to three years, if not longer.

- Cost Considerations

  In addition to time requirements, substantial costs would be incurred to conduct an adequate alternatives analysis. Such costs might include those for performance testing and additional information gathering to fill data gaps and ensure an informed decision. If no viable alternatives are readily identified, producers must invest in research and development of new chemistries, with subsequent process development and scaling up necessary to evaluate feasible options.

  Estimates for conducting evaluations of alternative technologies range from the hundred thousand-dollar range (with minimal new data acquisition) to several million dollars (if the evaluation requires extensive testing and acquisition of data). The EPA is aware of the enormous expenses required to evaluate chemicals. The Agency's *initial* fee for a manufacturer-requested risk evaluation on a single chemical included requires a $1,250,000 up-front payment; full costs are undoubtedly much higher.[9]

  Furthermore, if no viable alternatives are readily identified, the next likely step may be to invest in exploring entirely new technologies.

Implementing a Technically and Economically Feasible Safer Alternative

- Time Requirements

  Once an alternative formulation has been identified, additional time is needed for implementation. A conservative estimate of the time needed for to implement an alternative

[8] For more information about the complexities of a chemical alternatives analysis, please see the California Department of Toxic Substances Control (DTSC) 302-page guide: https://dtsc.ca.gov/wp-content/uploads/sites/31/2016/01/AA-Guide-Version-1-0_June-2017.pdf.
[9] https://www.epa.gov/tsca-fees/tsca-fees-table.

to PIP is three to five years. The process requires redesigning and testing new parts that contain PIP alternatives for compliance with applicable standards – a resource-intensive and time-consuming process. Similar tests and evaluations likely would be needed to eliminate PIP use in industrial machinery. Sufficient volume of the alternative formulation would need to be made available in the market to meet demand. Given that PIP is used in multiple electroindustry applications, these activities would disrupt and delay production schedules.

Specific tasks required to phase out existing products and introduce alternatives typically include:

- Procurement of appropriate substitute components
- Compliance assessments
- Quality assessments and certifications
- Safety assessments and certifications
- Supplier coordination
- Manufacturing modifications
- Shipment, import, and distribution

- Cost Considerations

The expense imposed on companies – small and medium-sized enterprises as well as large, multinational corporations – affected by a ban on the use of PIP would be substantial enough to disrupt the market and impact the national economy.[10] Implementation costs include manufacturing infrastructure redesigns, inventory loss, new formulation acquisition costs, product redesign costs, and many other expenses—both foreseeable and unforeseeable.

Even simple chemical substitutions can be very expensive. A great example is the process of substituting other chemicals for methanol in windshield washer fluid in Finland. The ECHA Committee for Socioeconomic Analysis (SEAC) reported this cost as $4 million dollars.[11] More difficult substitutions can quickly run into the tens of millions of dollars.[12]

Manufacturing facility redesign costs tend to be incredibly costly. Introducing a new chemical into the manufacturing process would result in "retooling" the manufacturing infrastructure as an unavoidable by-product of implementing new technology. These major changes require sufficient capital investment. Employees would need training.

[10] Please see the "A Ban on NMP Would Disrupt the National Economy" section of these comments for more information.
[11] https://echa.europa.eu/documents/10162/cc415549-cac9-4784-97dc-2170d0bf8f25.
[12] For example, see costs for substituting another chemical for BPA in thermal paper as reported by the ECHA Committee for Socioeconomic Analysis (SEAC), https://echa.europa.eu/documents/10162/7f8d2988-fad4-4343-bef3-4518336db109.

Furthermore, disruptions in production schedules to engage in parts reformulation and conducting testing to meet safety standards would have adverse downstream impacts and possibly broader repercussions across related markets in the United States. This process could shut down a whole industry in the US making our nation completely reliant on imports, consequently causing sharp cost increases for domestic manufacturers and potentially vast negative impact on US jobs. That in turn could cause the decimation on important manufacturing sectors of the nation, including healthcare, communications, energy, transportation, and defense.[13]

Due to the complex nature of the production process, product reformulations or facility redesigns can be extremely costly and can easily run in the tens of millions of dollars.

EPA Exceeded Its Authority

When EPA published its Proposed Rules on PBTs, NEMA and other manufacturers expressed concern that EPA exceeded its authority granted under TSCA to restrict articles containing substances in TSCA Section 6a, Subsection (c)(2) without having performed a risk evaluation.[14] This concern remains unresolved.

Subsection 6(c)(2)(D) requires that replacement parts be exempt from rules adopted under Section 6(a) ***unless*** EPA finds that replacement parts "contribute significantly to the risk, identified in a risk evaluation conducted under Subsection (b)(4)(A), to the general population or to an identified potentially exposed or susceptible subpopulation."

Furthermore, Subsection 6(c)(2)(E) provides that EPA may apply "prohibitions or other restrictions to an article or category of articles" containing a chemical substance or mixture " . . . only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article;" and then only to the extent needed "so that the chemical substance or mixture does not present an unreasonable risk… identified in the risk evaluation conducted in accordance with Subsection (b)(4)(A)."

Because the action taken by the Agency was a rulemaking undertaken in accordance with Section 6(a), when the Agency elected to regulate replacement parts and articles, EPA was required to make these Subsection 6(c) findings -- and such findings must emanate from "a risk evaluation conducted in accordance with Subsection (b)(4)(A)."

[13] Please see the "Use of NMP in Electroindustry Manufacturing Substantially Benefits Health and Public Safety" section of these comments for more information.
[14] *See* NEMA Comments to EPA, "2019-10-28 NEMA Comments on EPA Proposed Regulation of PBTs Under TSCA."

In the final rules, with the exception of HCBD, the restrictions apply to "articles and products" that contain the substances. Yet the record indicates the agency ***did not*** conduct risk evaluations on these chemicals and thus could not have reasonably determined whether the presence of the PBT substances in such replacement parts or articles presented an unreasonable risk under TSCA Section 6(b)(4)(A).

NEMA is aware that Section 6(h)(2) of TSCA states that EPA is not required to conduct a risk evaluation when identifying PBT substances under Section 6(h) for expedited action. In exercising this discretion, however, the agency took the unprecedented position that the provisions in Subsection 6(c)(2)(D) and (E) did not apply. It is not clear this is the proper interpretation of the amended statute.

The result of this interpretation placed a significant, costly, and unnecessary burden on parties that manufacture, sell, or use articles containing the chemicals, which often are deeply embedded in product components and surfaces and present little opportunity for human exposures or environmental releases.

The article and replacement part provisions in TSCA protects suppliers and users of articles from unforeseen and unintentional violations due to the presence of restricted chemicals that do not lead to exposures nor contribute to health and environmental risks. By disregarding the importance of performing a risk assessment, EPA is setting a disturbing precedent for the agency's future risk management actions under Section 6 of TSCA.

Partnership Needed for Effective Chemical Management

EPA has undertaken efforts to reach out to and engage the regulated community. EPA has held numerous workshops and regularly disseminates information and updates. However, NEMA proposes that a formal government-industry council be established, similar to those found in other areas of government. This mechanism would provide a regular opportunity to meet as issues develop. EPA and manufacturers could work together to find reasonable, workable solutions that will enable us to tackle the tough challenge of balancing jobs and the economy with the goal of ensuring chemicals are managed appropriately for human health and the environment.

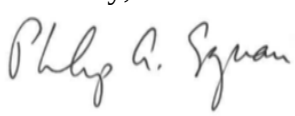
Conclusion

By opening the PBT rulemaking and issuing the "No Action Assurance," EPA has once again shown its commitment to broad outreach and engagement to ensure any final Risk Management rule will be both protective and practical. Therefore, we count on EPA to provide the regulatory relief we have requested:

1. Provide Critical Use Exemptions;
2. Grant 1.0% (by weight) *de minimis* exemptions, replacement parts exemptions, large-scale manufacturing equipment exemptions, and a three-year inventory "sell through" period;
3. In the absence of permanent regulatory relief, grant eight-year phase-out periods;
4. Increase stakeholder partnership; and
5. Set appropriate precedents for future rulemakings.

We would like to facilitate a meeting with you to discuss this matter further at your earliest possible convenience. Please contact Stacy Tatman (Stacy.Tatman@nema.org) to make arrangements.

Sincerely,



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