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National Electrical Manufacturers Association

July 28, 2021

By email: Danielle_Y_Jones@omb.eop.gov

U.S. Office of Management & Budget
Office of Information and Regulatory Affairs
The White House
1600 Pennsylvania Avenue
Washington DC 20500
Attn: Desk Officer for the EPA

Re: TSCA Section 8(a)(7) reporting and recordkeeping requirements for perfluoroalkyl and polyfluoroalkyl substances, 86 Federal Register 33926 (June 28, 2021)
Docket ID Number EPA-HQ-OPPT-2020-0549
EPA ICR number 2682.01

To Whom it May Concern:

The National Electrical Manufacturers Association (NEMA) is the primary trade association representing the interests of the US electrical products and medical imaging industry. Our 325 Member companies ensure the efficient, reliable supply of power to every aspect of human endeavor while promoting effective health care through screening, diagnosis, and treatment. Worldwide sales of NEMA products and systems exceed $140 billion annually.[1]

NEMA Members are commenting on proposed reporting and recordkeeping requirements for Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) announced by the US Environmental Protection Agency (EPA or the Agency) under the Toxic Substances Control Act (TSCA), as amended by the Fiscal Year 2020 National Defense Authorization Act (NDAA). As required by these amendments, EPA has proposed a mandatory, one-time reporting obligation applicable to "*certain persons that manufacture (including import) or have manufactured these chemical substances in any year since January 1, 2011.*" EPA stated rationale for this Information Collection Request (ICR) is to "*provide greater transparency on the uses and risks associated with PFAS.*"

NEMA is aware of the far-ranging authority and responsibility granted to EPA under TSCA to assess risks to human health and the environment potentially stemming from chemical substances, and to take action to minimize those risks.[2] Our Members also recognize that regulatory measures aimed at risk reduction must stem from comprehensive, reliable, and relevant scientific and technical information if they are to be effective and defensible. In that context, the proposed ICR for PFAS may have potential to add a difficult to quantify value to the Agency's effort to evaluate this broad family of chemicals.

[1] For more information, please visit: https://www.nema.org/.
[2] As stated on EPA's web site, the Agency's statutory mandate in this regard is very clear: "*The purpose of risk evaluation (under TSCA) is to determine whether a chemical substance presents an unreasonable risk to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulations*."

This EPA action, however, like all ICRs proposed by federal regulatory authorities, is subject to review by OMB under 44 U.S. Code § 3501. OMB review is a safeguard intended to 1) minimize the burden imposed by federal efforts to collect information from private parties, and 2) ensure the greatest possible public benefit from, and maximize the utility acquired through, the government's use of the information.[3]

Examined in this context, the PFAS ICR represents an enormous and likely insurmountable compliance challenge for NEMA Members and other producers across the industrial manufacturing spectrum. Not only does the obligation apply retroactively from 2011, but it also contains none of the reasonable allowances afforded to manufacturers in the TSCA Chemical Data Reporting rule. There are no exemptions for PFAS present as impurities or at *di minimis* levels, PFAS as by-products, for imported articles, for R&D activities or for small businesses.

Given this unrestricted scope and the ubiquitous nature of PFAS in today's high-tech economy, virtually any company that supplies complex products or "articles" is legally bound to respond to the ICR. Consequently, the "one time" PFAS reporting event envisioned by this proposal threatens to be the most onerous, far-reaching, and costly data collection mandate EPA has ever imposed on manufacturers.

PFAS is a large, diverse, and ever-expanding group of man-made chemicals. While the proposal states that "*EPA identified at least 1,364 chemical substances and mixtures that are PFAS*," other sources indicate the number is substantially higher.[4] In fact, the Agency's own "CompTox Chemicals Dashboard" website listed just over 6000 chemicals in 2019 and now in July 2021 lists over 9000.[5]

The small fraction of PFAS used in commercial applications differ widely in their physical and chemical properties, health, and environmental profiles, uses, and benefits. Although scientific studies suggest that some PFAS are persistent, bioavailable, and mobile, there are thousands of variations in PFAS chemicals. Despite extensive research into PFAS forms such as PFOA and PFAS, many questions remain unanswered as to whether PFAS present an "unreasonable risk" to humans or the environment under particular conditions of use.[6]

Yet the implication of such an unbounded, all-inclusive ICR is that the mere presence of ***any*** PFAS – at any measurable quantity[7] - in any product, component, or material, no matter how deeply embedded and inaccessible to workers, handlers, and consumers, must be discerned to inform the Agency's assessment of risk. This approach seemingly disregards the fundamental notion of risk as a function of both hazard and exposure, which is a central theme of the Lautenberg Chemical Safety Act.[8]

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[3] https://www.law.cornell.edu/uscode/text/44/3501

[4] See https://pfas-1.itrcweb.org/fact_sheets_page/PFAS_Fact_Sheet_History_and_Use_April2020.pdf

[5] https://comptox.epa.gov/dashboard/chemical_lists/pfasmaster

[6] See https://www.niehs.nih.gov/health/topics/agents/pfc/index.cfm#footnote2, and https://www.atsdr.cdc.gov/pfas/health-effects/overview.html

[7] Parties obligated under this reporting requirement presumably will report PFAS quantities that are detectable using standardized analytic techniques. There is no mention in EPA's proposal, however, of PFAS that may be present in levels that fall below the threshold of detection.

[8] §2605 (b)(1)(A) "…the process to designate the priority of chemical substances shall include a consideration of the *hazard and exposure* potential of a chemical substance or a category of chemical substances…[emphasis added]"

Furthermore, computing these quantities is an immensely complicated task. Within a multi-tiered supply chain system, the origin of PFAS in a component or material may be multiple levels "above" the vendor that supplied it, and that distant supplier may not have access to content information without surveying its own supply base.

Simply stated, the EPA mandate under TSCA is to determine which chemicals in commerce could potentially harm persons or places, characterize that harm, then take measures to prevent it from occurring. A rational first step in the case of a broad, diverse group of chemicals would be to narrow the "list of suspects" within the group to those individual formulations that display structural and behavioral characteristics consistent with toxicity endpoints. This is the strategy EPA invoked in evaluating the 2014 Work Plan chemicals, whereby the Agency characterized certain substances as High Priority.

Any targeted PFAS should be identified by its unique Chemical Abstract Service Registry Numbers (CASRN). CASRN are unique numerical identifiers assigned by the Chemical Abstracts Service (CAS) to every chemical substance described in the open scientific literature from 1957 through the present. Without the CASRN to pinpoint the chemical in question, it would be difficult (if not impossible) to accurately assess the impact of any impending regulatory action.

Once the primary targets are identified, the next step is to determine where and how the target chemicals are used, as a precursor to revealing the potential for human exposure or release to the environment.

The PFAS ICR seems unconnected to this logical process. Much of the information that obligated parties will report will reveal no hazard or exposure potential. Yet "manufacturers"[9] must invest untold time and resources scrutinizing complicated, global supply chains for literally thousands of complex products, seeking data that often may not be attainable.

More detailed comments on aspects of this proposal follow below.

Breadth of Information Required

The Agency's proposal references TSCA section 8(a)(2) to define the scope of the recordkeeping and reporting obligation manufacturers would bear under this ICR. This means that reporting parties must determine, acquire, compute, or estimate – for each individual PFAS and for each of ten years – all of the following.

- Common or trade name, chemical identity, molecular structure
- Categories or proposed categories of use
- Total amount manufactured or processed, estimates of the total amount to be manufactured or processed, including for each category of use
- Description of byproducts resulting from manufacture, processing, use, or disposal
- All existing information concerning environmental and health effects
- Number of individuals exposed, and reasonable estimates of the number who will be exposed in their places of employment and the duration of such exposure
- In initial report, the manner or method of disposal; in any subsequent report, any change in such manner or method

[9] Defined in the proposal as "*Persons who have **manufactured** a chemical substance identified in § 705.5 at any period from January 1, 2011 to the effective date of this rule*," where "Manufacture" includes importing

While the above may constitute a valuable 'wish list' for EPA staff tasked with conducting risk assessments, from the standpoint of the reporting parties it is an insurmountable exercise that for some categories will be impossible to complete. This is especially true for small to medium enterprises that have limited staff resources and financial wherewithal. Several of these reporting categories are evaluated further below.

Common or trade name, chemical identity, molecular structure

On the surface, seeking the 'trade name' of a chemical present in a product is a reasonable request, not difficult under most instances to provide. Chemical identity and molecular structure, however, are not simple concepts. Determining chemical identity is a core competency in the practice of chemistry, involving the use of properties to classify as well as to differentiate among substances.[10]

Similarly, the molecular structure of many chemical substances may be known or easily determined,[11] but this will not be true for specific PFAS. While All PFAS contain a chain of carbon atoms bonded to fluorine atoms, some also have a functional group at the end of the chain. These structures are the basis for different chemical properties and different chemical names.[12]

The implicit assumption embodied within the PFAS ICR is that this information is readily accessible to parties obligated to report for any PFAS present (at any level) in the vast array of components and materials that comprise complex, highly manufactured products. NEMA expects this assumption will prove unrealistic for most companies affected by the ICR and render compliance difficult, if not impossible.

Another complicating factor is that - due to their proprietary nature – the chemical composition of PFAS may be considered confidential or trade secret. Even if known, therefore, suppliers may be unwilling or unable to disclose content beyond what is required under regulations and product content restrictions already in force.

Description of byproducts resulting from manufacture, processing, use, or disposal

The concept of byproducts takes us again into the realm of chemistry. Simply stated, the term 'byproduct' refers to a product that is not desired but inevitably results from molecular fragments of starting materials and/or reagents that are not incorporated into the desired product, as a consequence of conservation of mass. Another view of byproducts is as impurities that appear during a chemical reaction as a result of side reactions.

How then does EPA anticipate manufacturers of complex products will identify and provide a "description" of all by-products stemming from PFAS that may have been integrated into components or materials far "upstream" in the supply chain? How also – on the other end – are they to understand and characterize byproducts stemming from disposal practices they don't control and may know little about?

This category of information, like the one before it, assumes a depth of knowledge regarding complicated engineering processes that most manufacturers simply will not possess and cannot readily obtain through their supply chains, or from parties downstream.

[10] https://pubs.acs.org/doi/pdf/10.1021/acs.jchemed.6b00387

[11] *E.g.,* the molecular structure of water is one oxygen atom covalently bonded to two hydrogen atoms – H_2O

[12] https://www.atsdr.cdc.gov/pfas/docs/PFAS_FamilyTree_EnvHealthPro-508.pdf

All existing information concerning environmental and health effects

The obvious question associated with this reporting category is *"What does the Agency mean by 'all'?*" Manufacturers are bound by law and self-interest to provide products that operate safely and effectively and pose no hazard or threat of harm under intended conditions of use. They meet this obligation in part by complying with restrictions, limitations, and prohibitions imposed by regulatory authorities that bear public responsibility for determining where risks exist and what safeguards are needed. It is obviously to the benefit of manufacturers to inform this regulatory process by providing relevant data and sharing their expertise.

Manufacturers typically are not toxicology centers, however, nor public health facilities conducting broad research into the potential hazards of chemical additives or formulations. Certainly, companies undertake testing regimes to evaluate new product compositions and ensure safety and performance standards are upheld. But few, if any, companies have compiled databases containing '*all existing information"* pertaining to potential effects of chemicals they ***know are present*** in their products, much less substances they've never before considered.[13]

NEMA considers it reasonable for EPA to ask for whatever studies or relevant information companies may have generated for their own purposes or that are readily accessible from public sources. But a request for "*All existing information"* suggests that what constitutes "all" in this context can even be determined. How will EPA be able to ascertain if the information submitted by an obligated party has met this standard?

Absent further clarification or modification, this element of the ICR will require companies – at significant cost – to fulfill an essential function of the regulatory authority. Manufacturers can aid and contribute to EPA's understanding of how PFAS might impact health or the environment by sharing whatever information they have. But they should not be required to act as the Agency's clearinghouse for the known scientific literature on this diverse chemical family.

Number of individuals exposed, and reasonable estimates of the number who will be exposed in their places of employment and the duration of such exposure

The level of detail EPA requires manufacturers to report under this category of the ICR is extraordinary, especially since the obligation is 'retrospective' and includes data from as long as a decade ago.

Consider one element of this category: "*For each PFAS, the maximum duration of exposure for any worker at the manufacturing site, in hours per day and days per year*." A complete and accurate response to this request requires not only comprehensive, highly specific workforce records over the ten-year period, but a virtual re-creation of the work site environments at every facility operated by the reporting party.

How else to compute the 'maximum duration of exposure for any worker' other than to determine the number and type of products (or 'articles') and manufacturing processes each worker encountered as part of his/her normal duties over the decade-long period, then somehow characterize which PFAS he/she ***might*** have encountered through all possible routes of exposure. This presupposes, of course, that companies can somehow even identify the products and processes over that period in which PFAS were present (even at trace levels), the potential for release, and the extent to which workers were protected from exposure.

[13] The term "all" evidently is not subject to time constraints, as the proposal notes that: "The scope of this information shall not be limited to studies conducted or published since 2011."

The notion that companies have the data and capabilities sufficient to reproduce these scenarios to any useful degree of accuracy is far-fetched, at best. Even a monumental investment of time and effort by companies would produce no more than a somewhat educated guess, far short of what is needed to inform a credible risk assessment.

Ten Year "Lookback" Requirement

As noted above, NEMA is concerned about the retrospective application of the PFAS ICR. Manufactured or imported articles frequently are finished products with multiform structures and few companies will be able to produce 10 years' worth of bill of material and sourcing history. Many articles and components imported over this time period are now obsolete or had multiple supplier changes, while some suppliers are no longer in existence.

Even without these complications, large companies would need to evaluate many thousands of import transactions ***per year*** to meet their obligation. Whatever records can be retrieved will not provide the level of detail specified in the ICR and companies will be engaged in perennial investigations to achieve full compliance.

Inclusion of "Articles"

Including 'articles' in the scope of this reporting obligation is a break with most of EPA's actions to assess and regulate chemicals under TSCA. The Agency has exempted articles from all of the following.

- Testing under Section 4 (unless exception)
- PMN requirements under Section 5
- Significant new use rules (SNURs) (unless exception) under Section 5
- Reporting rules under Section 8(a)
- Export notification (unless exception) under Section 12(b)
- Import notification (unless exception) under Section 13
- Formaldehyde in composite wood products

This policy stems from a long-standing recognition by EPA that "*people and the environment will generally not be exposed to substances in articles."*[14] This presumption is reasonable for complex products from which chemical constituents are not intended/expected to be released. That being true, analyzing most products to determine their chemical contents is a costly endeavor that often produces little benefit in terms of assessing risk.

EPA does not lack authority to regulate articles when it perceives a compelling need, but rarely did so prior to 2020. Within the past year, however, the Agency has opted not to exclude articles from Significant New Use Rules issued for PFAS, the proposed fees to be imposed on manufacturers of high priority substances to fund risk assessments, and the Final Regulation of Persistent, Bioaccumulative, and Toxic Chemicals under TSCA Section 6(h).

By including articles in the PFAS ICR without exemption - with no exception for *di minimis* quantities and no limitation on which PFAS reporting parties must cite and quantify – EPA has issued a reporting obligation of virtually limitless scope. NEMA Member companies, like those in other industry sectors, manufacture (or import) tens of thousands of products, assemblies, components, and spare parts that qualify as articles under 40 C.F.R. § 704.3.

[14] 49 Fed. Reg. 35011, 35014 (Sept. 5, 1984)

Devising an internal system for conducting these assessments and producing the required data will be a major undertaking for obligated companies, straining their resource capabilities in what likely will be a futile effort to achieve full compliance. The burden will be especially heavy on small and medium size enterprises that lack the staff and financial flexibility that will be required.

Recommended Limitations on the PFAS ICR

OMB can reduce the burden of this reporting obligation and enhance its value to the Agency by recommending the following changes to the ICR.

1. Limit the scope to specific PFAS (listed by Chemical Abstract Service Registry Number) that either are manufactured in high volumes or have been implicated through scientific research as possibly associated with human health or environmental effects. This step would focus the effort where it is likely to generate the most value in terms of assessing potential risk.

2. Incorporate a *de minimis* threshold into the reporting obligation. Regulatory regimes across the world aimed at reducing chemical exposures from products – such as the REACH Regulation and RoHS Directive in the EU – specify a threshold level that must be exceeded before sales restrictions or reporting obligations apply. Some PFAS may be present in articles below the level that is measurable by standard detection methods. In those cases, companies that dutifully test but fail to report those undetectable quantities would technically be in violation of the rule.

3. Relax – or at minimum, clarify - the requirement that companies submit "*All existing information concerning environmental and health effects"* of PFAS. It is unreasonable to expect companies to undertake the extensive literature searches needed to meet this request for such a vast and varied family of chemicals. Limit this requirement instead to relevant studies and data that companies already possess or can readily acquire without undue expense.

4. Eliminate or shorten the ten year "lookback" period of the ICR. Manufacturing is a dynamic, rapidly evolving enterprise and much of the retrospective information EPA is seeking either will be unavailable, extremely costly to obtain, or offer little value to the Agency's risk assessment.

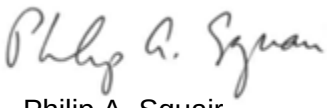
5. Incorporate a "small business" threshold that excludes companies below a certain size metric from this reporting obligation.

Conclusion

The EPA goal of compiling an information base to inform the risk assessment of PFAS is appropriate and consistent with the Agency's mission under TSCA. The proposed PFAS ICR, however, extends far beyond the capabilities of most affected businesses. There must be reasonable limits on the size and nature of this data request to ensure obligated parties are able to comply and the information EPA obtains through the action is truly pertinent to the determination of risk. NEMA therefore urges OIRA to exercise its authority under 44 U.S. Code § 3501 and direct EPA to modify its proposal.

If you have questions about these comments or would like additional information about NEMA and its Member companies, please contact Mark Kohorst at 202-412-3326 or mar_kohorst@nema.org. Thank you for your consideration.

Sincerely,



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