COALITION OF MANUFACTURERS OF COMPLEX PRODUCTS

May 19, 2023

Kerri Malinowski-Farris
Safer Chemicals Program Manager
Maine Department of Environmental Protection
Office of the Commissioner
17 State House Station
Augusta, Maine 04333-0181

Re: Proposed Regulation 06-096: Chapter 90: "Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances"

Dear Ms. Malinowski-Farris:

The Coalition of Manufacturers of Complex Products ("Coalition") respectfully submits the following comments to the proposed regulation 06-096: Chapter 90: "Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances" addressing requirements to report products that contain intentionally added substances defined as PFAS, set forth in 38 M.R.S. §1614(2)(A). These regulations establish a requirement for manufacturers to notify the Department of Environmental Protection ("Department") of any product for sale in Maine that contains intentionally added PFAS, as defined by Subsection 1614(1)(D), beginning January 1, 2023, unless an extension has been granted.

Coalition members manufacture equipment and products by assembling tens to hundreds or thousands of parts, components, and raw materials to provide, in many cases, critical services to society. These include commercial and consumer products such as appliances, vehicles, vessels, motors, heating, ventilation, air conditioning, refrigeration (HVAC-R) and water heating equipment, electronics, and their replacement parts. Coalition members serve and support nearly every major sector in the nation, providing critical products for government agencies, the US military, law enforcement, first responders, and public safety, food and agriculture (including commercial fishing and sea farming), energy, transportation and logistics (including for commuting and for island residents), public works and infrastructure support services, critical manufacturing, the defense industrial base, conservation, and life-saving climate control and ventilation in homes, hospitals, schools, and eldercare facilities. For purposes of this proposed rule, the Coalition supports:

- Coordinated supply chain reporting mechanisms;
- A single list of reportable PFAS identified by Chemical Abstracts Service (CAS) numbers; and

- Recognition given to the continued need, if any, for the availability of replacement parts and recognition that certain essential uses of PFAS chemicals, where they provide important safety and performance features in complex products in internal components and parts, such as resistance to high temperatures, present an extremely low likelihood of release to the environment.

The Coalition greatly appreciates the efforts of Department staff, especially the extensive stakeholder outreach, regarding this involved issue.

1. **The Second Concept Draft of Regulation Implementing Maine's Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution (Second Concept Draft) has maintained reporting requirements and procedures that may create challenges for regulated industries and a deluge of irrelevant information for Department staff to process and protect as confidential business information (CBI).**

The new proposed requirements ask manufacturers to report the sales volume into Maine in PFAS disclosure notifications. Complex goods are sold through several multi-step supply chain pathways including distribution and through retailers. The quantity and type of equipment sold into specific states is unknown. This complexity is likely to result in over or under-reporting or simply incorrect information with this requirement.

Complex supply chains make it difficult to know which party will be the "responsible" reporting entity as the company which markets the product and whose name appears on the product label may be different. For products sold directly to distributors and not directly to retailers or individuals, it will be virtually impossible for the original equipment manufacturer (OEM) to report on sales into Maine. International marketing companies further confound responsibilities as to whether the importer or others in the supply chain will have reporting obligations and could lead to over- or under-reporting.

The Coalition recommends an alternate construct and asks that manufacturers be allowed to notify their suppliers that their components are in products sold in Maine, and have the supplier notify the Department directly on that basis. Manufacturers could report a list of suppliers that have been notified and the response that they have received as to whether that suppliers' components contain PFAS or not and separately report the absence of a response along with contact information for all suppliers. The Coalition suggests that a six-month period would be reasonable to notify suppliers and that another 6 months to one year should be allowed to report the information that the rule requires to the Department.

Based on past and current experience, complex product manufacturers require additional time beyond that contemplated in the proposed rule to survey their complex supply chains for the presence of specific chemicals in the components, parts, and raw materials that they purchase. They often face an initial lack of responsiveness from suppliers, as well as claims that the chemical make-up of components is a trade secret. We ask the Department to consider if it is

possible to avoid the need for these often-protracted negotiations and still obtain the information the rule requires. We strongly encourage the Department to modify the proposed exemption from fees and reporting for component manufacturers (*e.g.*, with respect to the note in proposed Section 6.A), to allow direct reporting by component manufacturers for their components that are included in final products sold in Maine. In cases where a component manufacturer may not separately sell the component in Maine, the component that these companies manufacture is nonetheless in commerce in Maine when it is in a final product that is distributed in Maine. Companies that sell components to complex product manufacturers do so knowing that the parts are intended to be installed in final products that may be sold throughout the United States, if not the world.

Providing this option will reduce duplicative reporting or incomplete information due to claims of intellectual property concerns. It would allow for more streamlined reporting and facilitate the Department's determinations about quantities of PFAS in Maine. This allowance could be accomplished through the definition of "responsible party". Hopefully, the Department can determine a pathway responsive to these considerations in developing the reporting structure.

2. **The Coalition thanks the Department for clarifying that the broad definition of PFAS only applies to chemicals with a CAS number. The Coalition asks the Department to provide a single list of PFAS chemicals by CAS number for which reporting is required.**

The Department stated in its October 28, 2022, "Frequently Asked Questions" (FAQ) document that "[t]he statute requires manufacturers to report the amount of intentionally added PFAS in their products by CAS number." The FAQ confirms that the Department "interprets that PFAS subject to the reporting requirement of the law are limited to those that have a CAS number." In addition, the proposed rule includes a note which states that "M.R.S. § 1614 requires notification of intentionally added PFAS by CAS number." It would be consistent and helpful if this CAS number approach for reporting can be further incorporated into the final regulation.

Specifically, the Coalition asks the Department to establish a list of reportable PFAS chemicals under the definition in the legislation, with their specific CAS numbers included. This is how manufacturers downstream identify and search for ingredients in their products – by CAS number. Complex product manufacturers are not in the business of understanding or interpreting a complex chemistry definition or recognizing chemical structural diagrams. They make equipment, not chemicals. Because the Department only expects reporting for chemicals with CAS numbers, having a list will make reporting clear and efficient. The Department recognizes the need for CAS numbers and has confirmed that reporting entities must use them but is not providing the regulated community with the same necessary information.

The Department's FAQs recommend that companies subject to reporting utilize the U.S. EPA's webpage of chemicals considered to be PFAS. In addition, we thank the Department for including a note with the definition of PFAS (proposed section 2.P) that directs the regulated community to this website. Our review of the federal webpage indicates that it contains several links to lists of PFAS, in many cases identified by CAS numbers, that have been already compiled

by EPA, the Organization for Economic Cooperation and Development (OECD), KEMI the Swedish Chemicals Agency, and community efforts. However, some of the lists also identify PFAS using only chemical structure diagrams, so directing the reporting community to this website alone may still lead to significant confusion. While the Coalition appreciates that no reporting is required if a CAS number does not exist, this statutory directive seems to support to the development of a list by Maine.

Furthermore, the U.S. EPA's webpage currently lists over 12,000 PFAS chemicals. To survey supply chains for this entire of family of chemicals could take decades. Testing for those chemicals in hundreds, thousands, or even tens of thousands of parts and components is literally impossible. We recommend that the Department follow the EUs Global Declarative Substance List (GADSL) which recently identified a list of around 500 priority PFAS chemicals.

3. **The Coalition thanks the Department for clarifying that the definition of "intentionally added PFAS" excludes the presence of chemicals that do not provide functionality to components, parts, and raw materials (*e.g.*, contaminants). The Department may wish to further refine reporting requirements to exempt products which qualify as "articles" containing *de minimis* levels of PFAS. The Coalition suggests that a "*de minimis*" level could be further clarified as PFAS in quantities of less than 0.1% by weight of the final product.**

Maine is the first state requiring reporting of such a broad array of chemicals in components. Chemicals in plastic parts and electrical components are widely used across a broad range of manufactured articles globally. OEMs have limited visibility and control over complex, multi-tiered, global supply chains. The clarification the Department has provided clarifies that when components in HVAC-R equipment are manufactured at the same facilities producing other components for industries that intentionally contain reportable substances, the potential for unintentional, cross-contamination in *de minimis* quantities does not trigger reporting for the HVAC-R component or the final product in which it is installed.

We would like to point out that it would be consistent with federal and international reporting requirements for the Department to also consider establishing a *de minimis* exemption for intentionally added PFAS, below which reporting would be exempt for "articles". The EPA-administered Toxic Substances Control Act (TSCA) and Emergency Planning and Right to Know Act, and the Occupational Safety and Health Administration (OSHA) Hazard Communication Program (HazCom) are examples of federal laws that exempt businesses from reporting ingredients in *de minimis* quantities.[1] As a result, many downstream companies in complex

[1] Specifically, export notification is not required under TSCA for regulated chemicals present in products at less than 0.1% per 40 C.F.R. § 707.60(c)(2). Quantities of < 2,500 pounds are exempt from reporting in the case of the TSCA Chemical Data Reporting (CDR) program per 40 C.F.R. § 711.15. In addition, OSHA provides a 0.1% cutoff for inclusion of certain hazardous chemicals on safety data sheets (SDSs). It is difficult for companies to identify a *de minimis* amount of a substance in a product below the OSHA call-out. The difficulties associated with reporting would be lessened if companies were not required to exceed their current responsibilities to self-identify small quantity ingredients.

supply chains do not currently have robust tracking systems for ingredients under federally established thresholds, including certain PFAS chemicals. We are suggesting that the Department may want to exempt articles that contain only *de minimis* quantities of 0.1% by weight or less to allow for a practicable regulation that is reasonably implementable.

Coalition OEMs have limited visibility and control over complex, multi-tiered, global supply chains and have spent considerable time in attempting to assess the potential presence or absence of chemicals in their supply chains. The intimate knowledge of the chemicals comprising components is with either component manufacturers or their suppliers. This lack of transparency hampers the ability of manufacturers to be fully knowledgeable and in control of the chemistry of components. It is unrealistic for OEMs to mandate that their suppliers analyze each of the thousands of components to determine the presence or absence of chemicals in every component.[2] A *de minimis* threshold makes ingredient tracking more manageable. In many cases, de minimis quantities serve as a reasonable proxy for low potential exposure.

Similar to the U.S. thresholds, levels of chemical below a threshold of 0.1% do not tend to appear in global chemical management systems, like the International Material Data System (IMDS) used by the automotive industry.[3] In the European Registration, Evaluation, and Authorization of Chemicals (REACH) regulation, EU and European Economic Area (EEA) producers and importers of articles may be subject to notification if their article contains a substance on the EU Candidate List *only* if the listed substance is present above a concentration of 0.1%. Inclusion of a 0.1% *de minimis* threshold has proven to be effective in allowing the EU to focus on chemical manufacturing and use scenarios where the volume of the chemical is significant enough to pose a concern for exposure.

The term "article" is a well-understood regulatory term defined by EPA (40 C.F.R. § 720.3(c)) and OSHA (29 C.F.R. § 1910.1200(c)). In addition, there are definitions for the terms "complex consumer goods" and "complex durable goods" in section 6(c)(2)(D)(ii)(I) and (II) of TSCA that largely capture the complexity of the final products our companies manufacture:

> (I) the term "complex consumer goods" means electronic or mechanical devices composed of multiple manufactured components, with an intended useful life of 3 or more years, where the product is typically not consumed, destroyed, or discarded after a single use, and the components of which would be impracticable to redesign or replace; and

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[2] For example, EPA's Economic Analysis conservatively estimates that the cost of testing just children's products for the presence of PIP (3:1) would likely exceed $0.5 billion.

[3] The IMDS is viewed as the global standard for reporting material content throughout the automotive supply chain and for identifying which chemicals of concern are present in finished materials and components. The automotive industry has made significant investments in this data system to track compliance with global regulations impacting their products. The threshold for reporting for this system is 0.1% by weight. The IMDS now has over 15 years of data compiled relying on a *de minimis* level of 0.1%. The presence of any chemical below this threshold is not required to be reported in IMDS.

(II) the term "complex durable goods" means manufactured goods composed of 100 or more manufactured components, with an intended useful life of 5 or more years, where the product is typically not consumed, destroyed, or discarded after a single use.

Potential exposure to chemicals contained in components and final products that meet these definitions is low, given that they are often embedded in a polymer matrix in a component that is enclosed in a final equipment product and the chemicals are not intended for release into the environment.

The Department should articulate that at least the following options, and potentially others, are acceptable mechanisms to document compliance in the recordkeeping requirement of the regulation. Requirements for record-retention should be no greater than five years. Specific guidance regarding record-keeping will ensure that OEMs and the entire supply chain are well-prepared for compliance with the regulation, such as:

- Documentation sufficient to demonstrate that the finished article does not include more than *de minimis* levels such as a certificate of compliance from suppliers;

- Manufacturing specifications such as specification drawings noting that components cannot include more than *de minimis* levels of controlled substances; or

- Commercial contracts for components or sub-assemblies limiting the presence of PFAS chemicals to less than 0.1% by weight.

4. The Coalition asks the Department to consider an exemption for replacement parts for complex products with long life spans in proposed Section 5 of the regulations.

The current law permits a ban on products containing PFAS as of January 2030. We ask the Department to consider an exemption for replacement parts for complex final products that are designed prior to the date of the ban, for products that have a lifespan of many years such as refrigeration and heating equipment. These products are found in manufacturing facilities, commercial outlets, retail stores, and residential homes. Again, the risk of release of PFAS to the environment for these products is extremely low. We think an exemption for replacement parts would make the administration of this rule more reasonable without compromising the safety and well-being of the citizens of Maine.

5. The Coalition thanks the Department for proposing to share reporting services with other states and EPA to reduce the burden for both the Department and manufacturers.

Subsection 3 of LD 1503 allows the Department to waive notification requirements if substantially equivalent information is already publicly available. The Coalition asks the Department to explore agreements with other states to reduce duplicative reporting and consider federal reporting requirements. TSCA Section 8 reporting for PFAS is expected to be

underway in the same timeframe, which will require those that manufacture and import any identified PFAS to report information regarding uses, disposal, exposures, hazards, and production volumes to EPA.

The Northeast Waste Management Officials' Association, Inc. (NEWMOA), which consists of members from state environmental agencies from Maine, Connecticut, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont, released draft model PFAS legislation on May 2, 2023. The legislation covers PFAS intentionally added to products and defines PFAS as all members of the class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom. The draft legislation specifically advances the concept of an interstate clearinghouse that would be operated along the lines of NEWMOA's existing mercury and toxics in packaging clearinghouses to coordinate collection and review of manufacturer notifications. This may be an interesting option for structuring reporting for Maine to consider.

6. **The Coalition thanks the Department for allowing other internationally used product classification codes.**

The Coalition members manufacture thousands of models (and hundreds of thousands of components and parts) with safety and reliability at the forefront of their designs to protect consumers from unreasonable risk. We appreciate that the Department recognizes that manufacturers should be able group products under "brick" categories or other Department-allowed categories to simplify reporting, as there are many similar products that can be grouped together.

We also ask that the Department allow other internationally used product classification codes such as Harmonized Tariff System (HTS) code or the European Union Substances of Concern or SCIP database, as an alternative to Global Product Classification (GPC) brick code. Many companies do not use GPC brick code. To ease this new reporting burden, companies should be required to use an international product classification code but should not be required to use a single option. Without allowing for the range of currently used reporting systems, reporting will be even more challenging.

7. **The Coalition appreciates the Department's clarification that it is seeking reporting on the concentration of each PFAS in a product, and not the total amount of each chemical, or the total of all chemicals (Section 3.A.(1)(c)).**

This clarification will help reporting companies better understand any testing requirements to determine compliance, which is likely to evolve over time. The Department should allow for improved testing methodologies to develop, as well as determine these requirements before formalizing guidelines, particularly with respect to the use of a theoretical calculation based on the inputs and outputs of the manufacturing process. The Coalition supports being able to propose a concentration range, as this information will be more readily available. The use of range reporting is accepted practice in many government reporting programs and reduces the need to identify and protect formulations as CBI. Manufacturers would only rely on this

methodology for reporting PFAS if the notification system allows for Department-approved ranges of concentrations.

A commercially available analytical method for most products, together with the Department-approved ranges for PFAS reporting must be in place, for manufacturers and others to meet Maine reporting requirements. "Commercially Available Analytical Methods" for determining the content of PFAS in articles are still under development.

The Coalition reminds the Department that the best source of this information is the entity that added the chemical to the component, part or raw material, and notes that this requirement further highlights the need to have the option for reporting by knowledgeable suppliers rather than by manufacturers assembling supplied components, parts, and raw materials.

8. **The Coalition appreciates clarification of the process to protect CBI and trade secrets.**

There are remaining open questions regarding the overall process and protection of confidential information. The Department needs sufficient time to work through these and other important practical matters to ensure that the correct information is provided – and protected -- to support its analysis and understanding of the data it receives. It would be helpful to clarify which types of information can be claimed as confidential and to provide a simplified process for substantiating those claims, if necessary.

The Coalition appreciates the Department allowing companies to assert claims of CBI for any PFAS included in the TSCA Confidential Inventory or Uniform Trade Secrets Act and is concerned with use of the Interstate Chemicals Clearinghouse (ICC) Platform, which is a non-governmental organization without public accountability.

Again, the Coalition reminds the Department that the best source of this information is the entity that added the chemical to the component, part or raw material, and notes that this requirement further highlights the need to have the option for reporting by knowledgeable suppliers rather than by manufacturers assembling supplied components, parts, and raw materials.

9. **The Coalition appreciates the clarification as to whether every component, equipment model, packaging type, and replacement part would require that a fee be paid to the Department.**

Section 6 does not clarify whether a separate fee must be paid for each of the thousands of stockkeeping units (SKUs) that manufacturers manage. The fees and clarification of the ability to group product reporting for purposes of paying fees appears otherwise reasonable and sufficient to administer the program.

The Coalition appreciates that labeling requirements are not included as they are not an effective form of communication with consumers or end-users as these products are often in machine rooms or remote locations generally hidden from view.

10. **Manufacturers of articles containing PFAS should not be held responsible if their suppliers do not cooperate or comply with Maine's regulation.**

The Coalition encourages the Department to implement accountability and enforcement requirements that ensure suppliers inform downstream manufacturers of components and parts containing PFAS substances. Suppliers should be made aware of the need to disclose the use of PFAS in chemical formulations to downstream customers well in advance of the reporting deadline, so that companies subject to reporting have the information needed to report on articles containing chemicals of interest.

11. **The Coalition thanks the Department for the clarification of the term: "modification of significant change."**

The Coalition suggests that the term "significant change" pertaining to a 10% change in concentration may need to be reconsidered and clarified as to whether it pertains to an entire piece of equipment, component, or part. Without this clarification, this added layer of complexity will make compliance and verification more challenging. Perhaps the presence of certain chemicals should be the focus instead.

12. **The Coalition thanks the Department for the clarification of the concept regarding the "certificate of compliance."**

It would be helpful for the Department to provide additional information regarding the threshold that would result in the Department concluding that a violation of the reporting requirement has occurred, as well more information on the requirements needed for compliance certification, especially for *de minimis* levels.

13. **The Coalition supports additional time beyond the current allowance of a six-month extension to commence reporting for all PFAS in "articles."**

No manufacturers have reported to the Coalition that more than 30% of suppliers have responded to repeated requests for information regarding PFAS chemicals. Many companies have had lower levels of response. Manufacturers are still trying to assess their supply chains. A further extension of the reporting deadline for all PFAS in "articles" would provide more time for manufacturers to determine a compliance plan. We support the recommendation of the Maine Environment and Natural Resources Committee to unanimously to pass L.D. 217 through to the House and Senate for consideration. The bill would change the reporting deadline to January 2025. We understand, based on communications with the Department, that because the bill is now likely to pass, the Department no longer expects to need to process reporting extension requests, as the statutory extension would make them unnecessary. We note that the final legislation would require updating the deadline in Section 3.A of the proposed rule.

14. The Coalition thanks the Department for the refined definition of "alternative" to be limited to those that are technically feasible and commercially viable. We encourage the Department to further develop the procedure for making "currently unavoidable" determinations and help us better understand how the term "essential for health, safety, or the functioning of society" will be implemented. The Coalition supports including a process for requesting an exemption on this basis as part of this rulemaking.

The Coalition supports eliminating non-essential uses of PFAS and promoting safer alternatives. At the same time, the Coalition thanks the Department for understanding that there are currently essential uses of PFAS chemicals that provide important safety and performance features in complex products in internal components and parts, such as resistance to high temperatures. Ultimately, high performance solutions must be available commercially and in sufficient quantities to meet market demand, at a cost that is sustainable to consumers and end-users, especially for critical products to society.

The Coalition appreciates the additional details regarding how the Department would determine what is essential. Would the Department concur with the Coalition that HVAC-R and water heating equipment provide critical services to society, including life-saving climate control and ventilation in homes, hospitals, schools, and eldercare facilities? The cold chains for both food and vaccines depend on transportation and commercial refrigeration equipment. HVAC-R and water heating equipment were especially critical during the pandemic and, as we have recently been reminded, during severe climate events that are becoming all too frequent.

The Coalition is supportive of a process by which the Department determines by rulemaking that an application of PFAS is "currently unavoidable." It would be helpful to have more details on this process as soon as possible. For the Department's consideration, the Coalition would like to identify the criteria and process that EPA must utilize under section 6(g) of TSCA for considering exemptions for "critical or essential" uses of chemicals. The EPA Administrator may, as part of a rule promulgated under section 6(a), or in a separate rule, grant an exemption from a requirement of a section 6(a) rule for a specific condition of use of a chemical substance or mixture, if the Administrator 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.

In proposing an exemption, EPA must make its analysis of the need for the exemption available to the public. EPA can establish a time limit on any exemption as reasonable on a case-by-case basis, and, by rule, may extend, modify, or eliminate an exemption if the Administrator determines, based on reasonably available information and after adequate public justification, the exemption warrants extension or modification or is no longer necessary. EPA can condition the exemption on complying with reasonable recordkeeping, monitoring, and reporting requirements, to the extent necessary to protect health and the environment while achieving the purposes of the exemption. We think that aligning with the term "critical or essential use" for these cases, and consideration of the criteria above in establishing a procedural rule for granting these cases, would improve Maine's rule.

15. **The Coalition appreciates the Department's continuing open dialogue regarding all policy issues associated with this challenging regulation.**

The Coalition thanks the Department for its outreach to stakeholders associated with this challenging, unique policy.

Once again, the Coalition reminds the Department that the best source of this information is the entity that added the chemical to the component, part or raw material, and the need to have the option for reporting by knowledgeable suppliers rather than by manufacturers assembling supplied components, parts, and raw materials.

Coalition members support efforts to minimize exposure to hazardous chemicals. However, there are certain aspects of the regulation under consideration that may be unattainable which apply to components or articles with limited potential for exposure. Manufacturers that distribute complex products in Maine face tremendous difficulty identifying or reporting on the presence of PFAS in components because other parties add them to products. In addition, without a specific list of CAS numbers, or procedures in the rule for requesting exemptions for critical uses, the rule could create confusion for those who must comply.

It is also important to allow companies to continue to sell replacement parts and equipment for complex goods critical to society, such as life-saving climate control and ventilation and for cold chains for vaccines into Maine.

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The Coalition greatly appreciates the efforts of the Department and thanks the Department for consideration of these comments.

Respectfully Submitted,

COMPLEX PRODUCT MANUFACTURER COALITION
ASSOCIATION OF HOME APPLIANCE MANUFACTURERS