Complex Products Manufacturers Coalition

August 30, 2024

Melanie Loyzim, Commissioner
Maine Department of Environmental Protection
17 State House Station
Augusta, Maine 04333-0017
PFASproducts@maine.gov

Re: Concept Draft; Chapter 90 Rule Regarding Products Containing PFAS

Dear Commissioner Loyzim:

The Complex Products Manufacturers Coalition (Coalition) appreciates this opportunity to provide input and continue the dialogue with the Maine Department of Environmental Protection (MDEP or Department) during the rulemaking process to implement Maine's statute regulating per- and polyfluoroalkyl substances (PFAS) in products. The Coalition hereby provides its comments on MDEP's Concept Draft language for the Chapter 90 rule to implement the recently amended statute regarding products containing PFAS.

The Coalition brings together numerous trade associations and individual businesses, many with in-state locations, and most of whom distribute their durable goods and equipment in commerce in Maine. 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 industrial, commercial and consumer products such as appliances, vehicles, vessels, motors, lighting, heating, ventilation, air conditioning, refrigeration, and water heating equipment (HVACR- WH), electronics, and their replacement parts.

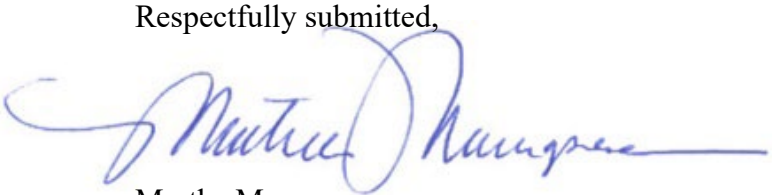
Coalition members serve and support nearly every major sector in the nation, providing critical products and services for government agencies, the military, law enforcement, first responders, and public safety, food and agriculture (including commercial fishing and sea farming), energy, transportation 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, or food preservation and processing and for critical health and life sciences. These products and services constitute a vital part of the economy, at all levels, including for public safety.

The Coalition is the only collective industry voice for companies that are committed to continued access for all Americans to products that meet critical societal needs, such as vehicles, vessels, appliances, electronics, and heating and cooling systems and their replacement parts. Our mission is to participate in all relevant legislative and regulatory initiatives regarding PFAS in products and ensure that the voice of these important industries is heard, and our goals are considered by legislators and regulators, as follows:

- Prioritization - Laws and regulations should prioritize PFAS using a risk-based approach that considers both hazard and exposure;
- Avoid Class-Wide Targets - The over 12,000 chemicals in the PFAS family have a wide variety of different properties and uses so each chemical should be regulated for its specific risk;
- Adequate Time and Notice - Laws and regulations should provide reasonable timelines and abundant notice to account for complex global supply chains;
- Sound Science - Risk evaluation and risk management should be based on the best available sound science;
- Focused Reporting - Reporting requirements should take a practical approach and focus on the source: chemical producers; and
- Product Bans as Last Resort - Product bans should be considered only after other management tools are used; reasonable and appropriate exemptions should be provided.

As such, the Coalition appreciates MDEP's openness for dialogue with stakeholders throughout the legislative and now regulatory process to develop this unprecedented framework for implementing requirements for PFAS in products. The Coalition agrees that the only way to develop a PFAS framework that is possible to implement and enforce the by MDEP is through cooperation and dialogue with stakeholders. The Coalition, therefore, respectfully submits its comments in the attachment to this letter and urges MDEP to take this feedback into consideration in the official draft that will be submitted to the Board of Environmental Protection.

Respectfully submitted,



Martha Marrapese

Enclosure

Comments on Maine's Concept Draft for the Chapter 90 Rule to Implement the Statute Regarding Products Containing PFAS

August 30, 2024

The Complex Products Manufacturers Coalition (Coalition) appreciates this opportunity to provide input and continue the dialogue with the Maine Department of Environmental Protection (MDEP or Department) during the rulemaking process to implement Maine's statute regulating per- and polyfluoroalkyl substances (PFAS) in products.

The Coalition recognizes and appreciates that the Concept Draft endeavors to address several concerns we have expressed in earlier comments on implementation of 38 M.R.S. § 1614.[1] We thank MDEP for making changes that acknowledge the challenges of companies with complex supply chains. The Coalition is aware that the rule under development must stay within the confines of the statute, but within these confines the Coalition urges the to build a rule with a *risk-based approach* as its foundation that considers both hazard *and* exposure. To best protect human health and the environment, a risk-based approach focuses limited agency resources on the highest priorities based on actual environmental, health, and safety risk of particular chemistries, not just the mere presence of a substance.[2]

The Coalition hereby provides its comments on MDEP's Concept Draft in the order that the sections appear in the publicly available draft for Chapter 90 to implement the recently amended statute regarding products containing PFAS.

A. Definitions

1. Non-consumer electronics

The Coalition strongly supports the statutory exemption for non-consumer products and understands the scope of this section to be fairly broad. It would be useful if MDEP would define

[1] 38 M.R.S. §1614, as amended by Public Law 2023, c. 630, An Act to Support Manufacturers Whose Products Contain Perfluoroalkyl and Polyfluoroalkyl Substances (LD 1537, 131st Legislature, effective August 9, 2024).

[2] The mandate to evaluate both hazard and exposure in prioritizing, evaluating, and regulating existing chemicals is well established at the federal level. As outlined in 15 U.S.C. Section 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" (emphasis added). Similarly, 15 U.S.C. Section 2605 (b)(4)(D) states a requirement to "Integrate and assess available information on hazards *and exposures* for the conditions of use of the chemical substance" (emphasis added). The requirement is also stated repeatedly throughout the Lautenberg Chemical Safety Act because it is a logical way to approach complex chemical management.

term “non-consumer electronics” by incorporating the proposed definition of “electronics” with the words “industrial and commercial” and providing examples. This approach is consistent with the proposed definition in the Concept Draft for “juvenile products”, which includes examples of products that fall under this definition. The Coalition requests the following examples for “non-consumer electronics” be included:

i. Outdoor, industrial, and commercial lighting and residential light fixtures (luminaires);

ii. Lithium batteries (for vehicles and mobility devices);

iii. Solar panels;

iv. Electric hydrogen technology.

2. Heating, ventilation, air conditioning, cooling, refrigeration (HVAC-R)

The Coalition is grateful for the inclusion of “Cooling, heating, ventilation, air conditioning or refrigeration equipment” in the Concept Draft. It is important for MDEP to define this term to clarify the inclusion of additional key products in the HVAC sector, specifically water heaters, heat pumps, and related equipment. We ask MDEP to specify the inclusion of these key products in Section 5(F)(1) of the Concept Draft.

3. Definitions for article, complex consumer good and complex durable good

MDEP should provide definitions for “article”, “complex consumer good” and “complex durable good” and use these terms instead of the term “complex product” in the pre-proposal. These terms are more descriptive and would improve clarity. MDEP could base these definitions on existing and well-established definitions from federal law.

i. The term “article” is a well-understood regulatory term defined by the U.S. Environmental Protection Agency (EPA) at 40 C.F.R. § 720.3(c)) and the Occupational Safety and Health Administration (OSHA) at 29 C.F.R. § 1910.1200(c).

ii. 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 the Toxic Substances Control Act (TSCA) that largely capture the complexity of the final products our Coalition members manufacture:

- 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
- The term “complex durable goods” means manufactured goods composed of 100 or more manufactured components, with an intended useful life of five or

more years, where the product is typically not consumed, destroyed, or discarded after a single use.

4. Degradation byproducts

The Coalition thanks the Department for clarifying that the definition of "intentionally added PFAS" excludes the presence of chemicals, including degradation byproducts, that do not provide functionality to components, parts, and raw materials (e.g., contaminants). The Coalition does not support the notation that a definition of "intentionally added PFAS" should include degradation by-products. Although we recognize that degradation byproducts are referenced in the statutory definition at 38 M.R.S. § 1614, degradation byproducts by nature are not intentionally added, but rather may develop over time. Nor are they intended for a functional purpose; that is instead served by their precursors. The Coalition sees this clarification as important, given that many downstream companies will not have the expertise or knowledge to identity degradation products. We think the Concept Draft provides the necessary clarity for companies to conclude that degradation byproducts are excluded from scope providing they do not serve a functional purpose or technical effect within the product or its components, which allows the vast majority of degradation byproducts to be eliminated from consideration.

5. What is a "significant change"

The Coalition wishes to obtain confirmation and guidance from MDEP that the change in composition concept in this definition, which refers to the "product," applies to the entire product as reported by the manufacturer. A "product" is defined in Maine's statute as "an item manufactured, assembled, packaged or otherwise prepared for sale to consumers, including its product components, sold or distributed for personal, residential, commercial or industrial use, including for use in making other products."[3] The Coalition suggests that the term "significant change" pertaining to a 10% change in concentration is determined by whether the reporting company manufactures an entire piece of equipment or simply a component. For companies that manufacture the entire piece of equipment, the change would need to be a 10% change in composition of the entire piece of equipment. Without this clarification, this added layer of complexity will make compliance and verification more challenging. Perhaps the presence or removal of certain chemicals should be the focus instead.

B. Notification Requirement

1. Product Description

The Coalition members manufacture thousands of models of products (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 to group products under "brick" categories or other Department

[3] 38 M.R.S. §1614(1)(G).

allowed categories to simplify reporting, because there are many similar products that can be grouped together.

In prior comments, the Coalition asked MDEP for flexibility concerning the use of product classification codes. We support MDEP's decision to allow other internationally used product classification codes such as Harmonized Tariff System (HTS) code, as alternatives to Global Product Classification (GPC) brick codes. Often, companies do not use GPC brick codes. We urge MDEP to provide the possibility for using other internationally recognized codes as well, such as the European Union Substances of Concern or SCIP database, or the United Kingdom's Standard Occupational Classification (SOC), as alternatives to GPC brick codes.

As explained in our comments submitted last May, prior to the 2024 amendments to Maine's PFAS statute, the companies should be required to use a recognized product classification code but should not be required to use a single option which they may not use as a normal commercial practice. Not allowing for the range of currently used reporting systems would be very challenging for manufacturers of complex consumer and durable goods. In that regard, MDEP should improve the clarity of the draft language by adding an "or" between 3(A)(1)(a)(i) and 3(A)(1)(a)(ii). As currently written, it implies that both are required, and would thus be much less flexible.

Lastly, in Section 9(A) when discussing CUU proposals, the Concept Draft provides for flexibility in allowing requests for product categories, stating that "a separate proposal must be submitted for each individual combination of product category and industrial sector". MDEP should carry this flexible language consistently throughout the draft regulation.

2. Total units sold

The Concept Draft would require manufacturers with CUU exemptions to report the sales volume into Maine. 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. Therefore, the Concept Draft should clarify that only units directly sold by the holder of the CUU exemption need be provided, and there is no requirement to obtain sales information from indirect distribution chains.

3. Identity of PFAS

We strongly support the Chemical Abstracts Service Registry Number (CAS number) approach for reporting and suggest that CAS numbers should be the exclusive means of reporting for CUU exempt products.

i. MDEP 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 "38 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.

ii. 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. For this purpose, MDEP could use the list provided by EPA on its website for the TSCA Section 8(a)(7) Reporting.[4]

iii. The Coalition does not support or understand the purpose of providing an alternative "description approved by the Department." It will be difficult and cumbersome to get pre-approval and reporting should be limited to PFAS with CAS numbers.

4. Quantity

For notification of CUU exempt products, the Coalition supports reporting on the concentration of each PFAS in a product, and not the total amount of each chemical, or the total of all chemicals.

i. 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.

ii. 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 confidential business information (CBI). Manufacturers would only rely on this methodology for reporting PFAS if the notification system allows for Department-approved ranges of concentrations.

iii. 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 allow notification by knowledgeable suppliers.

iv. MDEP should provide ranges for reporting in the rule itself rather than propose to approve ranges on a case-by-case basis.

For complex consumer and durable goods, the Coalition suggests that MDEP align its notification requirements with the reporting options provided by EPA in its TSCA Section 8(a)(7) PFAS Reporting Rule.[5] An article importer may submit as the production volume the total weight

[4] EPA, Public List of TSCA PFAS for 8(a)(7) Rule (May 16, 2024).

[5] EPA, Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, 88 Fed. Reg. 70516 (Oct. 11, 2023).

of the PFAS-containing imported articles (e.g., in tons or pounds). Alternatively, the article importer may report the production volume in terms of quantity of the article imported (e.g., number of vehicles). Documentation provided to article manufacturers does not always or reliably include the weight or concentration of a PFAS (or other chemicals) contained in the article, making it almost impossible to calculate for articles the specific information MDEP requests. Requiring the submission of the weight or concentration of PFAS for articles goes beyond the scope of EPA's reporting standard of "known or reasonably ascertainable." For this same reason, the required quantity should be limited to direct imports to Maine by the holder of the CUU exemption, and the need to investigate distribution indirectly through complex supply chains should not be required.

5. Testing

The Coalition asks for clarification that Section 3(A)(1)(e) relating to the amount of each of the PFAS in the product or any product component includes a number of options, and companies are not required to generate the testing for (i) or (ii).[6] Please note that EPA's PFAS reporting standard under TSCA Section 8(a)(7) is "known or reasonably ascertainable" and requires no testing or surveying of the supply chain. Additionally, we ask MDEP to keep in mind the following aspects regarding the reporting of the amount of PFAS:

i. Testing would be cost-prohibitive and difficult because test methods are still under development.
ii. We support the flexibility to have other options, such as the ability to rely on supplier information or provide the weight of the product.
iii. A commercially available analytical method for most products, together with the Department-approved ranges for PFAS reporting must be in place. "Commercially Available Analytical Methods" for determining the content of PFAS in articles are still under development.

6. Waivers

The Coalition supports waivers from CUU notification where the information is already available and suggest that MDEP consider identifying specific reporting programs that will satisfy the waiver. Subsection 3(A)(2) of the Concept Draft 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 take into consideration federal reporting requirements, including TSCA Section 8(a)(7) reporting for PFAS.

7. Reliance on supplier notifications

[6] Maine's Concept Draft at Section 3(A)(1)(e)(i) and (ii) provides: (i) Reported as an exact quantity as a concentration, determined using commercially available analytical methods; (ii) The total organic fluorine if the amount of each PFAS is not known or easily ascertainable, determined using commercially available analytical methods.

In prior comments, the Coalition asked MDEP to provide greater flexibility to coordinate any required reporting with suppliers of components that include intentionally added PFAS. We thank the Department for proposing, in the Concept Draft after Section 3(A)(1)(e) that "for product components for which the Department has previously received notifications, which are used in more complex products containing the reported components, the manufacturer of the more complex product shall either report PFAS in the product including its components or refer to the supplier's submitted notifications for product components and any PFAS in the remainder of the product." The Coalition suggests that this provision should be included as a formal and standalone subsection instead of an explanatory note.

Under Section 6(A) on Fees, the draft notes that "product components that are incorporated into complex products which are sold, offered for sale, or distributed for sale in Maine are not subject to the notification requirement, even when information regarding the product components is provided as part of that product's notification submission." This note appears to contradict the statement cited in the previous paragraph, underscoring how complicated the current draft notification requirements are, especially in the case of complex products. We believe this should be provisional in the following way: if the final product notification includes the component, the product component manufacturer's notification does not need to report that unit. Product component manufacturers who do not sell their components in Maine may still provide a notification that can be referenced by final product customers.

The Concept Draft language on this point appears to align with the Coalition recommendation 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. The Coalition encourages the Department to implement accountability and enforcement requirements that ensure that suppliers inform downstream manufacturers of components and parts that warrant CUU exemptions of those that contain PFAS substances. Suppliers should be made aware of the need to disclose the use of PFAS to downstream customers well in advance of the need to request a CUU exemption, so that companies are aware of the need to make such requests.

C. Notification Fees

1. <u>The Coalition supports Maine's approach for grouping</u>. The law does not require that a separate fee must be paid for each of the thousands of stockkeeping units (SKUs) that manufacturers manage.

2. <u>The Coalition opposes the concept of imposing a fee as a condition for keeping CUU exempt products on the market.</u> The Concept Draft carries forward that MDEP may grant CUU exemptions for PFAS-containing products and categories of products that are determined to be essential for health, safety, or the functioning of society. The purpose of these CUU exemptions is to ensure that certain PFAS-containing products are approved to remain on the market because without them, a significant disruption of the daily functions on which society relies would occur. Requesting a fee for being able to use an exemption

already granted appears contradictory to the statutory purpose of CUU exemptions and gives the inappropriate appearance of being "the cost of buying an exemption." These exemptions must be granted on factual grounds in recognition of their purpose, which is to avoid depriving Maine citizens of essential goods. A fee (especially one of the proposed magnitude - as discussed below) may have the opposite effect than intended by the statute's CUU exemption provisions and may prevent or deter companies from keeping these essential products on Maine's market.

3. The Coalition opposes the proposed fee amount of $5,000. The statute makes this fee discretionary. Should MDEP determine to go forward with a fee, the amount should be nominal to recover a reasonable portion of the expected costs associated with reviewing CUU exemption requests. According to Subsection 6 of the statute, "the department may establish by rule and assess a fee payable by a manufacturer that is required to comply with the notification requirement of subsection 2 to cover the department's reasonable costs in administering the requirements of this section."[7] The statute authorizes MDEP to establish a fee to cover the Department's *reasonable* costs in administering and implementing Maine's PFAS in Products program. This language supports the assessment of a nominal filing fee for the notifications. MDEP has not provided an estimate of the number of requests the state expects to receive, or an indication of how many of these requests will be duplicative in nature. However, it is likely that both the number of requests and the level of redundancy will be high. Requesting $5,000 for each CUU exemption holder goes well beyond recovery of *reasonable* costs in administering and implementing the statute and goes beyond the state's mandate. The proposed level appears designed to be a revenue-generating program which is inconsistent with the law's intent.

D. CUU Exemption Requests

The Coalition thanks Maine for recognizing and providing for essential uses of PFAS chemicals that deliver important safety and performance features in complex consumer and durable goods and their internal components, such as resistance to high temperatures and other extreme conditions. 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.

1. MDEP should use information received in March 2024 to propose CUU exemption categories under Section 9(B).

During the opportunity to comment on Maine's bill to amend the statute on PFAS in products (LD 1537, 131st Legislature), stakeholders were given the opportunity to request CUU exemption determinations for products and product categories. Numerous stakeholders including

[7] 38 M.R.S. §1614(6) as amended by Public Law 2023, c. 630, An Act to Support Manufacturers Whose Products Contain Perfluoroalkyl and Polyfluoroalkyl Substances (LD 1537, 131st Legislature, effective August 9, 2024).

the Coalition devoted considerable time, effort, and resources to draft and submit CUU exemption requests. We are not opposed to MDEP's decision to shift its focus to redrafting the previously proposed rule for Chapter 90 of the Code of Maine Rules (CMR). However, the Coalition does not agree with MDEP's decision to move forward without evaluating and considering all the CUU exemption requests received, and to require the resubmission of all of these requests in order to qualify for exemption. The Coalition respectfully requests that MDEP recognize the substantial effort that went into these prior submissions and evaluate them, and specifically propose CUU exemptions for specific product categories in the initial proposed rule in Section 9(B) of the regulation.

2. Maine should develop a standardized form for the CUU exemption request process.

The Coalition suggests that MDEP develop a standardized form for companies to submit CUU exemption requests. Such a form would provide additional clarity regarding the information MDEP seeks and would reduce the submissions of materials and information that is beyond or inconsistent with the scope intended by MDEP for such requests. Additionally, a CUU exemption request form would streamline and ease the review process for MDEP, thereby reducing the burden and resources needed to review these requests.

3. No staggered schedule for CUU exemption determinations.

The Coalition does not support the staggered schedule for submitting CUU requests of 18 to 36 months before the applicable ban would become effective. The proposed timeframes are too rigid. The Coalition understands that MDEP has limited resources to evaluate CUU exemption requests, however, evaluating CUU exemption requests only 18 – 36 months before the 2032 ban creates significant economic and commercial uncertainty. In commercial terms, it is detrimental for companies to wait until the ban is almost in effect to find out whether they can continue selling their products or not. The negative consequences of this uncertainty will be passed down to and felt by consumers as well. Creating significant market uncertainty can be best avoided by allowing CUU exemption requests to be submitted at an earlier point in time.

The Coalition would appreciate guidance regarding the situation of CUU exemption requests submitted before 2032, , but for which MDEP does not complete an evaluation and make a CUU exemption determination before a ban becomes effective. Will companies be allowed to continue distribution until MDEP makes a CUU exemption determination in that case? Allowing companies to apply for CUU exemptions as early as possible will help to avoid this situation from occurring.

4. A set timeframe for MDEP to make CUU exemption determinations once requests are submitted with opportunity for reconsideration.

The Coalition recommends the inclusion of a time period in the regulation, after receipt of a CUU exemption request, in which MDEP would respond to the request. MDEP should also

provide for a due process mechanism for a company to request reconsideration of a decision from MDEP to not grant a CUU exemption request.

5. Groupings

The Coalition supports the submission of CUU exemption requests collectively, as industry organizations, for product categories/industry sectors, avoiding the disclosure of individual companies and proprietary product information.

6. Time limited CUU exemptions

The Coalition does not support the Concept Draft proposal that CUU exemptions be time limited in all cases. MDEP should retain flexibility to make CUU exemption determinations that are not time limited for critical sectors in which there is little or no potential to expose consumers or the environment to PFAS during the product life cycle and after proper end of life disposal.

Extended implementation periods are also required for complex supply chains. In prior comments, this Coalition has provided information documenting that the time needed to make a single chemical substitution could take up to 20 years. This is because manufacturers must complete three lengthy, resource-intensive stages: 1) determine the presence of PFAS throughout its supply chain and manufacturing processes; 2) find a suitable alternative (if one is available); and 3) testing to implement the alternative. These efforts may affect hundreds or thousands of products, both directly and indirectly through the products in which they are used.[8]

7. Streamlining CUU exemption information requirements

The Coalition is concerned with the amount of information required in the Concept Draft for making CUU exemption request. The information required should be limited to that necessary to make the finding of essential for health, safety, and environment and for which alternatives are not reasonably available. We think that certain information proposals in the Concept Draft go beyond that which is necessary and ask MDEP to significantly reduce the requirements in this section.

Specifically, we ask MDEP to reconsider requiring the information listed in Section 9(A)(5) through (9) and (11).[9] For example, MDEP as a state authority is in a better position than

[8] See for example an extensive study prepared under an agreement with and funded by the U.S. Department of Energy, discussing the availability of alternatives for fluoropolymers and the feasibility of replacement: Stephanie Jacobs, David S. Kosson, *Assessment of Fluoropolymer Production and Use with Analysis of Alternative Replacement Materials* (January 2024).

[9] Section 9(A)(5)-(9) and (11) provide:
(5) A list of federal regulations, other State of Maine regulations, and regulations of other states which the product described in Subsection 1 is subject to by reason of containing PFAS, including;
(a) Details of any sales prohibition the product is subject to because of containing intentionally added PFAS including;
(i) Whether that sales prohibition is absolute or if there is a process similar to the State of Maine's currently unavoidable use determination.
(ii) If there is a similar process available, whether the requester has filed a proposal under the relevant state or federal program, and its status.

an individual company to assess how products are comprehensively regulated by federal and other state authorities. Even if this information were provided, it is not directly relevant to Maine's decision and MDEP would need to verify any information that was offered in an application in this area. Requiring this type of information in a CUU exemption request creates the impression that if a requester is unable to provide this information, or if MDEP considers the information insufficient, it can refuse to grant the request, even though the requester has otherwise provided sufficient technical information that the PFAS is essential and there are no feasible and safe alternatives. The outcome of a CUU exemption request should not depend on the ability of requesters to provide information that regulators and legislators in Maine are in a similar or better suited position to obtain.

The standard for alternatives is reasonably available. Therefore, the existence of potential alternatives should not disqualify a product from this exemption if the alternative is not reasonably available or mature for commercial scale use. Economic and technical feasibility must be part of this determination. It is not possible to set time limits on an exemption without a thorough understanding of the R&D process that would be required to change the product. As noted above, manufacturers must complete three lengthy, resource-intensive stages for finding and implementing alternatives. The time needed at each stage may be highly variable depending on the product and the downstream applications in which it is used.

As discussed at the beginning of this comment document, the Coalition suggests a risk-based component to this determination, in considering whether there will be no exposure during the lifetime of the product. If MDEP's concern about the potential hazard from and exposure to PFAS stems from the disposal of the products, then the Coalition suggests that the state should

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(6) If, in another jurisdiction, subject to an absolute prohibition or no currently unavoidable use determination or similar has been made, a list of comparable products that the proposer is aware of remaining available for sale, offered for sale, or distributed for sale within that jurisdiction;
(7) If a similar program's sales prohibition is identified as applicable in Subsection 5 and similar products are available for sale, offered for sale, or distributed for sale;
(8) A justification explaining how products available in compliance with other similar sales prohibitions are not reasonably available alternatives in the State of Maine. This may include demonstrating that additional sales in the State of Maine would result in such an increased demand for the PFAS alternative that it would no longer be available in sufficient quantities, such a demonstration must include an assessment that an increase in production of the PFAS alternative is not possible.
(9) Documentation demonstrating that products containing PFAS alternatives in other jurisdictions would not perform as intended in the State of Maine due to differing physical or climate conditions in the State of Maine;
(11) Any information known or reasonably ascertainable by the manufacturer regarding the impacts on human health or the environment of the product. At a minimum this should include the following items, if available;
(a) Any information documenting impacts on human health as a result of the specific use of PFAS in the product;
(b) A description of the likely pathways of human exposure for the specific use of PFAS in the product;
(c) Any information documenting environmental impacts as a result of the specific use of PFAS in the product;
(d) A description of any likely pathways for environmental release of PFAS as a result of the specific use of PFAS in the product; and
(e) A description of the product's fate at the end of its lifecycle. This should include;
(i) Documentation of any product stewardship programs or other government-imposed processes at the end of a product's lifecycle,
(ii) How the product is intended to be disposed of such as landfilling or via sewage or septage system, and
(iii) The recycling rate of the product.

address those concerns by updating its disposal laws. We believe that the fact that a product may end up on a landfill alone is insufficient to make an environmental exposure finding, as it is within the state's power to prevent that from occurring short of banning the use entirely.

8. Criteria for making the determination

Maine should consider proposing (or clarifying) the specific criteria it must use to grant the exemption for certainty, for consistency and to avoid appearing arbitrary in these determinations. For example, the EPA Administrator may, as part of a rule promulgated under TSCA 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. MDEP should consider including EPA's criteria that are established and tested in practice. We believe the criteria would improve Maine's rule to implement the PFAS in Products statute.

Additionally, the Coalition suggests that MDEP's criteria should include an evaluation of whether any available PFAS-alternative is a "regrettable substitution". The chemical characteristics among the thousands of PFAS captured by Maine's definition vary greatly, while non-PFAS chemicals may be linked to health and environmental concerns. MDEP should take this into consideration. Absent this comparative analysis, MDEP could risk banning a substance that is less harmful than its non-PFAS alternative, defeating the very purpose of this law.

E. Confidential business information.

Companies must be able to claim certain information submitted as part of these notifications and CUU exemption requests as CBI. For that purpose, MDEP should provide for a CBI and generic use description.

The Concept Draft purports to encourage companies not to submit CBI information. Specifically, the Concept Draft explains that although the statute provides a mechanism for protecting proprietary information. It goes on to describe how CUU exemption determinations are

subject to MDEP's rulemaking process, including approval by the Board of Environmental Protection in a public meeting and in response to public comments. Should a proposal for a CUU exemption determination contain claims of confidentiality, the Department threatens to make a determination that there is insufficient publicly available information to justify a rulemaking. On this basis, the Concept Draft "strongly recommends" that all proposals for currently unavoidable use determinations do not contain claims of confidentiality. We think MDEP's guidance in this area is inappropriate. We understand that CBI protection is more work for the agency, but the importance of CBI protection needs to be recognized. The Coalition asks MDEP to reconsider and remove this language in the Concept Draft and accommodate existing CBI protections in Maine law to protect commercial interests while establishing clear guidelines on the minimum public information required for these rulemakings.

For example, the Concept Draft states that information submitted in a CUU exemption request is presumptively public record under Maine's Freedom of Access Act (FOAA), 1 M.R.S. §401 *et seq.*, which permits CBI claims. Any information submitted to the Department that the submitting party believes are not subject to disclosure under FOAA must be clearly marked as "claimed confidential." Any request to MDEP seeking records submitted under this chapter that are marked as "claimed confidential" must be processed in accordance with 38 M.R.S. §1310-B, Subsection 2.

Several of the detailed requirements in the Concept Draft regarding the information that submitter must include in a CUU exemption request submission relate to sensitive, proprietary information. As one example, Maine is asking companies for a "description of how the specific use of PFAS in the product is essential to the function of the product."

The comments in the Concept Draft on limiting CBI protection are a significant deterrent to submitting a CUU exemption request. Absent the possibility to claim certain information as CBI, companies may choose to refrain from making CUU exemption requests. If those products are essential for the health, safety and functioning of society, then harm to Maine's consumers may result.

The Coalition would appreciate the Department allowing companies to assert claims of CBI, including for PFAS on the TSCA Confidential Inventory, and consistent with Maine law and the Uniform Trade Secrets Act. The Coalition has concerns with Maine's use of the Interstate Chemicals Clearinghouse (ICC) Platform, which is a non-governmental organization without public accountability.

F. <u>Further Exemptions</u>

The Coalition lists below categories for MDEP to consider for proposing additional CUU exemptions, consistent with federal and international law, to ease the regulatory burden of having to evaluate countless requests for exemption for products that contain barely measurable amounts of PFAS, and to avoid a situation where replacement parts for essential products are unavailable in the state.

1. Articles. The Department may wish to further refine CUU 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. Due to the complexities of the international, multi-tiered supply chain, determining a presence below the threshold of 0.1 % by weight is nearly impossible. 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. Lastly, and possibly most importantly, international, and federal law has precedent for providing *de minimis* exemptions. The *de minimis* exemption allows covered facilities to disregard certain minimal concentrations (0.1% or below) of chemicals in certain situations. Therefore, we urge MDEP to extend that relief to this application as well.

2. Degradation Byproducts. As noted in the discussion of the definitions section, degradation byproducts are not intentionally added and therefore are not intended to serve a functional purpose. Most downstream companies will not have the expertise or knowledge to identity degradation products. The Coalition requests that MDEP provide a CUU exemption for degradation byproducts that could be said to contribute to a functional effect, so as to eliminate the need for individual companies to assess this category altogether in making their own CUU exemption requests.

3. Replacement Parts. The current law provides a ban on products containing PFAS as of January 2032. 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, heating, and lighting 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.

   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.

   Alternatively, the Coalition requests that MDEP clarify under Section 9(A) of the Concept Draft or include in the regulation language for CUU exemption determinations, at Section 9(B) that products sold under a CUU exemption determination are exempt from prohibition

for the lifetime of the product, including replacement parts. This would avoid disruptions in cases of complex products that have a product lifetime that significantly exceeds the duration of the CUU exemption determination. For example, in the energy industry, durable industrial products such as electrolyzers and fuel cells function for more than 20 years, while many HVAC products are designed to function for 30-40 years.

4. Large-Scale Manufacturing Equipment. To the extent not already exempt under the statutory exemption for non-consumer electronics, MDEP should also exempt other large-scale manufacturing equipment. This is equipment that exists at manufacturing facilities that does not enter commerce, has a long and useful lifespan, is often legacy equipment, and provides essential functions for which there is no known replacement. While products in this category may fall under the existing statutory exemption of "non-consumer electronics," the status of many types of equipment is unclear absent further guidance from MDEP, and it is conceivable that many types of equipment are not covered by that exemption. The Coalition requests that MDEP provide an exemption for this product category specifically.

Thank you for your consideration. We look forward to continuing the dialogue with MDEP throughout this rulemaking process. The contact for the Coalition is: Martha Marrapese, Partner, Wiley Rein LLP, 2050 M Street, N.W. Washington, D.C. 20036, (202) 719-7156, mmarrapese@wiley.law.