



January 28, 2025

Maine Board of Environmental Protection Maine Department of Environmental Protection 17 State House Station Augusta, Maine 04333

RE: Ch. 90 rulemaking Comments

Members of the Maine Board of Environmental Protection:

The American Apparel and Footwear Association (AAFA) and National Council of Textile Organizations (NCTO) write regarding the Ch. 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances rulemaking. NCTO and AAFA are not-for-profit trade associations established to represent the entire spectrum of the United States textile sector, from base fibers to finished sewn products, as well as supplier sectors that have a stake in the prosperity and survival of the U.S. textile and apparel manufacturers. U.S. textile and apparel producers are extremely diverse, technically advanced, and highly capital-intensive manufacturers involved in a multistage production chain. Our industry is a key American economic driver, employing more than 500,000 workers nationwide. More information regarding our trade associations and the industry in general can be found on the <u>AAFA website</u> and the <u>NCTO website</u>.

Respectfully, we request that the definition of "textile article" exclude personal protective equipment (PPE), i.e. products used to minimize exposure to occupational hazards that can cause serious injury or illness from contact with or exposure to workplace or professional hazards. Examples of PPE include various items such as medical gowns, surgical drapes, hazardous material suits, firefighting turnout gear, electric arc protection gear, outdoor gear designed for enhanced visibility and weather protective gear for outdoor activities. Under the proposed rule, "textile articles" are defined to describe goods "customarily and ordinarily used in households and businesses" and are subject to a January 1, 2026, ban unless they receive a "Currently Unavoidable Use" designation. Of course, PPE is not customarily and ordinarily used in households and businesses.

Excluding it from the definition of "textile articles" would provide clarity that the prohibition against the sale of PPE with an intentionally added PFAS would go into effect on January 1, 2032, unless it received a "Currently Unavoidable Use" designation. This would also provide sufficient time for identification and commercialization of feasible alternatives, versus the





January 1, 2026 ban in place for non-technical textile articles. Last summer, the California legislature considered a bill to ban the sale of firefighting gear with an intentionally added PFAS effective July 1, 2026 – later than the "textile articles" deadline under the Maine law – and the California Department of Forestry and Fire Protection (CAL FIRE) noted for the Senate Appropriations Committee that "there is not currently a PFAS-free product that could replace its structural turnout gear."¹ The California legislature ultimately did not pass this bill.

If PPE is deemed a "textile article," AAFA and NCTO respectfully request that it be subject to the same treatment as r "outdoor apparel for severe wet conditions." These products are subject to January 1, 2029 disclosure requirements and a January 1, 2032 prohibition unless approved as a "Currently Unavoidable Use." While PPE is not exclusively designed for outdoor sports experts, there are categories of it that are designed to "provide protection against extended exposure to extreme rain conditions or against extended immersion in water or wet conditions to protect the health and safety of the user and are not marketed for general consumer use." Additionally, there are categories of PPE that cannot currently achieve necessary protective characteristics, like electric arc protection gear, without certain PFAS chemistries.

Finally, AAFA and NCTO stress that the June 1, 2025 deadline for filing a "Currently Unavoidable Use" proposal is not enough time for producers to collect necessary information, draft and file requests to potentially allow for continued access to these important products that help keep many Mainers, including first responders, safe. Sales and distribution channels will not be able to process through existing products in this timeline, even in the select instances where alternatives are starting to come online. Without a longer timeline, these products may be disposed of.

If you have any questions, please contact Chelsea Murtha (<u>cmurtha@aafaglobal.org</u>) or Auggie Tantillo (atantillo@ncto.org). We appreciate your consideration of our views.

Sincerely,

American Apparel and Footwear Association National Council of Textile Associations

¹ At 08/02/24 – Senate Appropriations Bill Analysis: <u>Bill Analysis - AB-2408 Firefighter personal protective</u> equipment: perfluoroalkyl and polyfluoroalkyl substances.



January 28, 2025

Submitted via email to rulecomments.dep@maine.gov

Kerri Malinowski Farris 17 State House Station Augusta, ME 04333 (207) 215-1894

RE: Comment on Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

Dear Ms. Malinowski Farris:

The Alliance for Automotive Innovation (Auto Innovators)¹ appreciates the opportunity to provide comments on the Maine Department of Environmental Protection's (DEP's) Draft Rule: Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances.² Auto Innovators represents the full auto industry, including the manufacturers producing most vehicles sold in the U.S., equipment suppliers, battery producers, semiconductor makers, technology companies, and autonomous vehicle developers. Our mission is to work with policymakers to realize a cleaner, safer, and smarter transportation future and to ensure a healthy and competitive auto industry that supports U.S. economic and national security.

Auto Innovators appreciated DEP's support in spring 2024 of amendments to 38 M.R.S. § 1614 that excluded vehicles and most of their components from the scope of the law, which enabled the continued use of PFAS in many performance-critical applications. Those amendments did not cover PFAS uses in refrigerants or "textile articles," and so Auto Innovators remains interested in DEP's currently unavoidable use (CUU) provisions, in case they must be utilized down the line.

Auto Innovators agrees with and supports the Maine Chamber of Commerce's comments on this issue. Businesses should be able to submit CUU proposals more than 36 months in advance of the product's sales prohibitions. In the auto industry, vehicle development and manufacturing are on long timelines, with development starting several years in advance of time of sale and final certification and confirmatory testing of products already taking place several months if not a few years before time of sale. The auto industry would need regulatory certainty on a timeline earlier than that being proposed by DEP. For similar reasons, Auto Innovators also supports CUU determinations being valid for a period longer than five years, if justified. For automotive uses, for example, a longer CUU determination would provide greater certainty given product development

² <u>https://www.maine.gov/dep/rules/index.html#13139124</u>

¹ Auto Innovators represents the full auto industry, including the manufacturers producing most vehicles sold in the U.S., equipment suppliers, battery producers, semiconductor makers, technology companies, and autonomous vehicle developers. Our mission is to work with policymakers to realize a cleaner, safer, and smarter transportation future and to ensure a healthy and competitive auto industry that supports U.S. economic and national security. Representing approximately 5 percent of the country's GDP, responsible for supporting nearly 10 million jobs, and driving \$1 trillion in annual economic activity, the automotive industry is the nation's largest manufacturing sector. www.autosinnovate.org.

needs. Auto Innovators also agrees with the Chamber's suggestion that a streamlined renewal process would also make obtaining a timely CUU more feasible for regulated entities.

Thank you for your consideration of our comments. We welcome any additional discussion or questions regarding this submission.

Sincerely,

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Catherine Palin Alliance for Automotive Innovation



January 28, 2025

Kerri Malinowski Safer Chemicals, Office of the Commissioner Maine Department of Environmental Protection 17 State House Station Augusta, ME 04333-0017

Re: Draft rule, *Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances*, implementing the *Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution*, 38 M.R.S. §1614, including amendments of April 2024.

Submitted via e-mail: rulecomments.dep@maine.gov

Dear Mrs. Malinowski:

The American Coatings Association ("ACA")¹ appreciates the opportunity to comment on MDEP's draft rule towards implementing the *Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution*, 38 M.R.S. §1614. We are committed to working with Maine DEP to help ensure an accurate understanding of PFAS in products and any associated risks to the public and the environment.

The Association's membership represents 90% of the paint and coatings industry, including downstream users of chemicals, as well as chemical manufacturers. Our membership includes companies that manufacture a variety of formulated products including paints, coatings, sealants and adhesives and their raw materials that may be affected by MDEP requirements, due to the broad set of covered chemicals, regardless of associated hazards.

ACA appreciates DEP's willingness to consider stakeholder perspectives. ACA appreciates that implementing a PFAS reporting requirement and ban presents many challenges. ACA also

¹ ACA is a voluntary, non-profit trade association working to advance the needs of the paint and coatings industry and the professionals who work in it. The organization represents paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals. ACA serves as an advocate and ally for members on legislative, regulatory and judicial issues, and provides forums for the advancement and promotion of the industry through educational and professional development services. ACA's membership represents over 90 percent of the total domestic production of paints and coatings in the country.

appreciates the legislature and MDEP's willingness to consider industry perspectives and modify requirements, while considering the public's interest in limiting use of PFAS in products.

Recognizing MDEP's goals, ACA is providing recommendations to enhance administrative implementation of rules while further refining the rule's focus on potentially harmful PFAS substances. ACA provides several suggestions related to the CUU (currently unavoidable use) application process and the agency's evaluation. ACA recommends including text in the rule previously found on MDEP's website during the prior CUU application period providing examples of products that would be considered CUU. The timing of CUU applications of 36-18 months prior to prohibition could also be extended so applicants could file earlier, and MDEP would make earlier decisions on applications. This would assist with planning for compliance. ACA recommends establishing case-by-case time limits for CUU determinations, instead of a standard five-year period for all CUU designations.

ACA appreciates DEP's expanded criteria relevant to evaluating PFAS alternatives as part of the CUU process, as included in the proposal. ACA supports the inclusion of criteria, including evaluation of health, safety and environmental impact of the alternative, commercial availability, cost differences and effect on manufacturing processes.

ACA suggests improvements to the proposal addressing fees, confidentiality, notification of products and prohibition of PFAS. ACA recommends establishing a fee cap and reduced fees. ACA also recommends establishing stronger procedures for protection of confidential information submitted in a CUU application, while also ensuring that confidential information is given the same weight as publicly disclosed information in the agency and Board's decision-making process. ACA further recommends establishing unlimited sell-through for products manufactured prior to the prohibition date, where such products are not associated with contamination. Regarding updates to product notifications, ACA recommends establishing an annual reporting period to update previously filed notifications, rather than requiring updates on an ad-hoc basis, which can prove difficult for manufacturers to track. ACA also recommends additional flexibility in measuring PFAS amounts, allowing reasonable estimates and measurements based on modifications of commercially available analytical methods. ACA also suggests public engagement when identifying products associated with PFAS contamination.

ACA suggests changes to definitions in Section 2 of the draft rule to enhance clarity. ACA recommends changes to definitions of the following terms:

- significant change
- commercially available analytical method and
- *intrinsic to the design or construction of a building.*

ACA and its members respectfully submit the following comment:

I. ACA recommends adopting into the rule, MDEP's prior online statement regarding products that are essential to the daily functioning of society.

In its Concept Draft, MDEP references the definition of "Essential for Health, Safety or the Functioning of Society" from the statute at 38 M.R.S. §1614(1), as amended in April 2024.² The definition incorporates consideration of products whose removal from the market would disrupt "daily functions on which society relies." To provide further clarification, ACA recommends adding text into the rule from MDEP's prior online guidance explaining, "Essential for the Functioning of Society includes but is not limited to climate mitigation, critical infrastructure, delivery of medicine, lifesaving equipment, public transport, and construction."

MDEP offered this guidance on its website in May 2023 in relation to applications for CUU (currently unavoidable use) designations, prior to the amendment of April 2024. The guidance is aligned with the new definition's reference to "daily functions on which society relies." It would provide CUU applicants with additional context and information when filing a CUU application. This additional context could enhance the quality of information provided to the agency by applicants.

II. ACA recommends expanding the time for submission of CUU applications with a clear time frame for MDEP determinations on applications.

At Section 9(A), MDEP requires that a manufacturer submit CUU applications between 36 to 18 months prior to prohibition of its products. The suggested timing can be logistically difficult in situations where MDEP does not grant the CUU application. In this case, inevitably, the manufacturer would have a very short time to remove a product or multiple products under one product grouping from market. With coatings, this can result in consumers not having access to desired home restoration products, commercial construction products, etc. Coatings manufacturers would have a very short time to identify all affected formulations and coordinate with distributors to remove products from Maine.

The concept draft does not address timing of DEP's determinations on CUU applications once submitted. Earlier decision-making would assist with planning for compliance, when a CUU application is rejected. ACA requests MDEP stipulate by rule, that it will reach a decision on all

3

² The amendment of April 2024 provides the following definition:

[&]quot;Essential for health, safety or the functioning of society" means a use of a PFAS in a product when the function provided by the PFAS is necessary for the product to perform as intended, such that the unavailability of the PFAS for use in the product would cause the product to be unavailable, which would result in: (1) A significant increase in negative health outcomes; (2) An inability to mitigate significant risks to human health or the environment; or (3) A significant disruption of the daily functions on which society relies.

CUU applications at least one year prior to the prohibition date, where applications are submitted in advance.

III. ACA recommends procedures for rolling CUU applications.

Section 9 of the Concept Draft does not include a clear procedure for new products that may qualify for a CUU designation after the January 1, 2032 product ban or for seeking a CUU designation for existing products after 18 months prior to prohibition. Such procedures are needed to encourage individual evaluation of products and to prevent premature bans of essential products. ACA can envision a scenario where a new product incorporating an environmentally benign fluorinated chemistry can replace a more toxic existing product.

Under the current proposed CUU procedure, the ban of January 1, 2032 prohibits introduction of any new products containing fluorinated chemistries. The proposed rule includes a provision that CUU applications after that date will be considered in a separate rulemaking. ACA requests clarification regarding the intended rulemaking cycle for CUU applications after January 1, 2032, preferably based on a rolling applications process. In the alternative, DEP may consider an biannual filing period for new applications.

ACA encourages DEP to recognize the broad variations of PFAS-types and to provide adequate avenues to introduce beneficial chemistries, when health and environmental risk are minimized. PFAS chemistries include over a thousand chemicals, many of which are not associated with environmental contamination and health effects. Many of these provide critical functionality to specialty products used in critical infrastructure, water delivery systems and other applications.

IV. ACA recommends options to issue a CUU designation with extended expiration dates or no expiration date.

ACA recommends that MDEP determine expiration of CUU designations on a case-by-case basis considering potential for alternatives, functionality of the fluorinated chemistry in a product and degree of potential risk to environment and human health. The proposed rule, in Section 9(B) establishes a uniform duration of five years for all CUU designations. Due to the broad range of PFAS chemistries, their varying functions and potential risks, a uniform five-year CUU duration is unnecessarily short for certain uses that cannot be phased out within that time.

Although MDEP proposes a CUU renewal process, this process introduces significant risk for long-term project planning, where critical products may include coatings with fluorinated chemistries. Project planners must consider the possibility that MDEP will not renew a CUU designation, potentially removing a critical coating from use for the project. To avoid this scenario, MDEP should designate duration of the CUU designation on a case-by-case basis, leaving open the possibility of designations that remain in effect longer than five years, including designations with no expiration date, when the chemistry is non-toxic and deemed essential. For example, ACA urges the agency to consider fluoropolymers that are typically nontoxic. These are required to meet certain product performance standards. Substitutes are not as effective, resulting in more frequent coating application and less effective protection, requiring greater resource use. ACA would welcome the opportunity to provide additional information about this topic as needed.

V. Reporting should be required on an annual basis or upon request from MDEP.

ACA recommends updates to initial product notifications on a schedule that could be easily incorporated into a regulatory calendar. Requiring updated reports or revised reports upon changes in a formula, supplier, or contact information is difficult to monitor and track. Changes in formulas could occur with each new shipment of raw materials to a coatings manufacturer. This could result in numerous reports being required over the course of a year. Tracking and monitoring these changes across all required reporting data points is a complex task. The agency may also face challenges evaluating multiple updates over the course of a year that could prove confusing and taxing on agency resources. An annual reporting schedule is more likely to serve MDEP's needs, while easing the administrative burden on manufacturers.

VI. ACA recommends flexibility to modify commercially available analytical methods to provide reasonable estimates of PFAS in products.

ACA commends the agency in providing flexibility in estimating the amount of PFAS in products. The redrafting of requirements related to notification of PFAS amounts from the first concept draft demonstrates a deep understanding of the challenges faced by end-use product manufacturers in identifying trace amounts of PFAS, not identified on an SDS (Safety Data Sheet). At Section 3(A)(1)(e) of the proposal, MDEP stipulates four methods of measuring PFAS amounts for notification:

- As an exact quantity using commercially available analytical methods, Section 3(A)(1)(e)(i).
- As a measurement of total organic fluorine using a commercially available analytical method, Section 3(A)(1)(e)(ii).
- Based on information provided by the supplier or as falling within a range approved by the Department, in Section 3(A)(1)(e)(iii).
- Total weight of the product, if specific quantities are not known, Section 3(A)(1)(e)(iv).

ACA is not aware of commercially available analytical methods for measuring PFAS in products and total fluorine is not an accurate measurement of PFAS in products. Further, total weight of a product provides no meaningful information regarding PFAS content in a product, although ACA supports inclusion of this option as a last option, when no other information about PFAS content is available.

Most downstream product manufacturers will develop estimates based on information provided by a supplier as allowed in Section 3(A)(1)(e)(iii). As currently drafted, MDEP indicates that amounts based on supplier information can be made based on calculations of inputs and outputs during a manufacturing process and/or reported as an approved range. ACA

recommends adding language explaining that manufacturers can provide reasonable estimates based on ranges provided by raw materials suppliers. MDEP should recognize that measuring PFAS quantities is not an exact process using any of the listed options. Even if commercially available analytical methods were available, these would have significant variance based on the type of product. They would also typically require modification based on the type of product. Similarly, using a total organic fluorine measurement has a high degree of variance rendering the test an unreliable substitute for measuring PFAS content.

Recognizing variability in measurement and methods of estimation, ACA recommends adding explanation that downstream product manufacturers can make "reasonable estimates" of PFAS amounts based on information provided by a supplier and/or publicly available information. This flexibility is needed as most companies will rely on their internal scientific staff to calculate PFAS amounts. Based on ACA's experience, company scientists are diligent about complying with all parameters written into a regulation, aiming for exact measurements specified in regulations. Without some flexibility written into the regulation to provide estimates, analytical chemists are unlikely to provide reasonable estimates. Instead, company scientists will provide total weight of the product, since that is the only measurement that can be made within desired level of accuracy.

A. Commercially available analytical methods are not available for products.

Currently, manufacturers are not aware of standardized analytical methods for PFAS identification in articles and chemically formulated products. EPA's test methods are not designed for products. MDEP's reporting requirement would inevitably require third-party testing and development of analytical techniques by a third-party. This could entail modification of an existing commercially available analytical method so it is suitable to measure PFAS in a product.

On its PFAS webpage, EPA identifies analytical methods identifying PFAS in water and air. EPA explains that it is currently developing test methods for PFAS to understand PFAS contamination across other environmental media. Notably, EPA has not developed analytical methods for PFAS in products, and it has not identified existing analytical methods for products. As explained on EPA's PFAS webpage:

EPA scientists are developing validated analytical methods for drinking water; groundwater; surface water; wastewater; and solids, including soils, sediments, biota, and biosolids, which may eventually become standard methods or research methods.³

To the extent possible, ACA requests MDEP to clearly identify analytical methods for reporting of PFAS in chemicals, formulated products, articles and other types of products, while providing

³ See additional information here: PFAS Analytical Methods Development and Sampling Research | US EPA

flexibility to provide reasonable estimates that could be based on supplier's information or a modified commercially available analytical method.

B. The definition of "commercially available analytical method" may need to be modified to allow for modifications.

In the definition of *commercially available analytical method* in Section 2 of the proposal, MDEP stipulates that third-party laboratories cannot modify the test method. As noted above, commercially available analytical methods measuring PFAS in products typically are not available. To provide a measurement, a laboratory would need to modify an existing method or develop a new test method. ACA further notes that this is a costly option, suggesting companies should explore other methods of measurement allowed by the regulation. Nonetheless, some companies will want to invest in providing test data and measurements. ACA suggests allowing modifications of existing commercially available analytical methods so they are suitable to measure PFAS in a particular product. Modifications would be product specific. That is, ACA is not aware of an analytical test method generally applicable to multiple products.

MDEP should also note that the proposed definition, in Section 2 of the proposal, unnecessarily creates a distinction between third-party and in-house laboratories while noting that in-house laboratories must *not* modify an analytical method, but makes no mention of whether third party laboratories must not modify an analytical method. Any restriction or allowance for modifications should apply to both in-house and third-party laboratories.

C. Total organic fluorine is not an accurate substitute for measuring PFAS content.

ACA cautions against adoption of a total organic fluorine test as an indicator of intentionally added PFAS. Total fluorine testing does not distinguish types of fluorinated chemistries from overall fluorine content, resulting in inaccurate and over-inclusive reporting. Noting limitations of total fluorine measurements, a study concludes, "Measurement of total fluorine (TF) is inexpensive, but it is not as reliable of a proxy for PFAS because it includes inorganic fluoride in addition to organic fluorine."⁴ Instead of testing for total organic fluorine, end-use product manufacturers can identify and report intentionally-added PFAS by relying on disclosed information from raw materials suppliers, above SDS thresholds with appropriate due diligence requirements and/or by providing reasonable estimates based on suppliers information.

VII. ACA recommends mitigating excessive fee payment with a fee cap and reduced fees.

ACA appreciates MDEP's revised proposal of an administrative fee of \$1,500 per notification, lowering the \$5000 notification fee suggested in the most recent Concept Draft. ACA notes that this fee could remain potentially excessive for ACA members, who manufacture a variety of

⁴ Young, Anna, et. al., Organic Fluorine as an Indicator of Per- and Polyfluoroalkyl Substances in Dust from Buildings with Healthier versus Conventional Materials, Environ. Sci. Technol. 2022, 56, 23, 17090–17099, available online at: https://pubs.acs.org/doi/10.1021/acs.est.2c05198#

formulated products, depending on how manufacturer's group their products. The fee rate of \$1,500 per notification encourages manufacturers to group coatings products that use the same type of PFAS together in one notification, although downstream uses might vary. Downstream uses might be more readily detailed where fees are lowered such that coatings manufacturers might differentiate products with individual applications.

ACA strongly recommends MDEP incorporate fee mitigation strategies into a rule. For example, MDEP should consider waiving the fee for notifications filed by a manufacturer after the first notification. MDEP may also require a lower fee amount after the first notification. Another alternative is a fee cap to prevent excessive fees. Additional information related to the agency's costs to evaluate each notification would assist with evaluating the relevance of the proposed fee amount.

VIII. ACA recommends providing adequate protections for confidential information with equal consideration of confidential information as publicly disclosed information.

ACA recommends that MDEP consider all information submitted as confidential in the same manner it would consider information disclosed to the public as part of the CUU rulemaking process. As such, ACA recommends altering the note included at page 20 in Section 9. Here, MDEP "strongly recommends that all proposals for currently unavoidable use determinations do not contain claims of confidentiality," and that if such claims are included, "the Department may determine that there is insufficient publicly available information to justify a rulemaking" allowing a CUU designation.

To justify a CUU rulemaking, MDEP is requesting manufacturers submit details about PFAS functionality in products, assessment of alternatives, etc. A detailed CUU application is likely to contain proprietary information, that could include information about chemical formulations, confidential specific chemical structure, amounts of PFAS in products and how, use function and volume compare to potential alternatives. Maintaining confidentiality in a manner that does not result in compromising consideration of the application is critical to non-discriminatory application of the rule.

DEP should take note that confidential information would be available to the agency and Board, just not for public review. The public would still have access to summaries and general information, just not proprietary uses, chemical structure, etc. For example, a manufacturer may provide a generic trade name for a product, while claiming confidentiality of the specific chemical name since it would disclose chemical identity. The generic name with accompanying descriptions would enable public participation.

Failure to consider confidential information in the same manner as disclosed information would undermine protections important legal requirements for protection of confidential business information. These protections are in place to encourage businesses to invest in developing new products that benefit society, often replacing products with greater potential for harm to the environment or human health. Companies often spend several years and millions of dollars in research and development to formulate effective coatings products, while minimizing potential harm. As such, this information deserves complete protection without undue prejudice in the CUU application process. MDEP should also be aware that if confidential business information is disclosed in the State of Maine, the effect is to waive confidentiality in other jurisdictions, including at the federal level and globally. The impact of not providing adequate confidentiality protections is not just localized to Maine.

IX. ACA recommends an unlimited sell-through period for certain products manufactured prior to January 1, 2032.

ACA recommends allowing a sell-through period for covered products manufactured prior to January 1, 2032 that are not listed as products associated with contamination described in Section 5(G) of the concept draft. ACA members typically do not track products through distribution. A distributor may warehouse certain products for distribution as needed, across several regions. As such, controlling distribution of multiple warehoused products into the Maine market is logistically difficult. To address this concern, ACA requests an unlimited sell-through period for products with a manufacture date prior to January 1, 2032, where the product has not been identified as being associated with contamination.

X. ACA recommends adequate public participation when listing products associated with contamination.

In Section 5(G) of the Concept Draft, MDEP is authorized to list products associated with contamination while establishing a phase-out date for these products. Since these will be listed by rulemaking, ACA emphasizes the importance of public participation in the rulemaking process. Product manufacturers typically have information about their products that can assist the agency in understanding product hazards, risks and current risk mitigation strategies. ACA encourages DEP to leverage industry expertise in making decisions about products. ACA also recognizes the importance of engaging NGO's and other stakeholders who provide important perspectives about risk and impacts on the public. ACA encourages MDEP to publish detailed reasoning for proposing a product listing under Section 5(G), in its fact sheets that are typically made available when proposing a rule or prior to a formal proposal.

XI. Comments regarding definitions in Section 2 of the Concept Draft.

ACA suggests the following changes to enhance clarity of definition in Section 2 of the Concept Draft:

Definition of *significant change*. ACA recommends modifying the definition of *significant change* to clarify that companies must report any intentional increases in PFAS amounts, but not inadvertent changes less than the 10% threshold. DEP must also consider the lack of "commercially available analytical methods" to measure changes in PFAS amounts. Any analytical methods for products will be developed by a laboratory and will be specific to the

product at issue. These will not be commercially available analytical methods. In any case, developing test methods, even if not commercially available, is generally cost prohibitive.

ACA suggests the following change to the definition of *significant change* regarding the intentional addition of PFAS, as noted in brackets:

Significant change means a change in the composition of a product which results in the [intentional] addition of a specific PFAS; a change in the amount of PFAS of more than a 10% increase, above the method variability allowed by the commercially available analytical method used [or excluding any inadvertent variances occurring during the product's usual manufacturing process] of the concentration that has been reported when compared to the existing notification; or a change in responsible official or contact information.

2. Definition of *commercially available analytical method*. As noted above, the definition unnecessarily creates a distinction between third-party and in-house laboratories while noting that in-house laboratories must *not* modify the test method, but makes no mention of whether third party laboratories must not modify a test method.

ACA recommends allowing modified test methods, since modifications are necessary to measure PFAS in products. MDEP must further consider that modifications are product specific. If the agency decides to proceed with not allowing modifications, the requirement should apply to both in-house and third-party laboratories. To address the discrepancy in the current proposal, ACA suggests modifying the definition as follows:

Commercially available analytical method means any test methodology used by a laboratory that performs analyses or tests for third parties to determine the concentration of PFAS in a product <u>and can be used by a third-party laboratory</u> <u>or other laboratory</u>. Commercially available analytical methods do not need to be performed at a third-party laboratory; however, the method must remain unmodified <u>when used to determine the concentration of PFAS in a product.</u> not performed by a third-party laboratory.

3. Definition of *intrinsic to the design or construction of a building*.

The definition places an unnecessary emphasis on structural elements as the critical element of enhancing building functionality. To recognize the potential for other elements as being critical to functionality, ACA recommends adding the phrase "other elements" as noted in italics to the definition below:

"Intrinsic to the design or construction of a building" means those elements of a building or structure which are necessary to perform its intended purpose. Intrinsic to the design or construction of a building may include structural elements and *other* elements meant to block light, wind, or precipitation. Intrinsic to the design or construction of a building does not include elements which are solely decorative or otherwise merely enhance the attractiveness of a structure or its function or those elements that are quickly or easily removed from the structure.

ACA further notes that the last sentence excluding decorative elements is vague. ACA anticipates that determination of decorative versus functional elements will be made on a case-by-case basis.

XII. Conclusion

ACA and its members suggest the following changes to the proposed rule:

- Add text to the rule explaining that, "Essential for the Functioning of Society includes but is not limited to climate mitigation, critical infrastructure, delivery of medicine, lifesaving equipment, public transport, and construction."
- Extend the time-period so manufactures can submit CUU application at an earlier date while requiring MDEP to make earlier CUU determinations, at least one year prior to prohibition, but preferably earlier.
- Clarify procedure and timeframe for CUU applications after prohibitions take effect and after the initial CUU application process.
- Establish CUU expiration dates on a case-by-case basis, instead of a standard five-year CUU duration.
- Establish an annual reporting requirement, instead of ad-hoc updates to notifications.
- Allow modifications to commercially available analytical methods to provide reasonable estimates of PFAS in products.
- Implement a fee cap and reduced fees for notification fees.
- Eliminate preference for disclosure of confidential information during the CUU application process.
- Establish an unlimited sell through for products manufactured prior to the prohibition date.
- Maintain adequate public participation when listing products associated with contamination while providing detailed reasoning for the proposed listing.
- Implement changes to the following definitions as described herein: *significant change, commercially available analytical method* and *intrinsic to the design or construction of a building*.

ACA appreciates that DEP expanded criteria to evaluate PFAS alternatives to include availability of an alternative. ACA supports the alternatives criteria included in the proposal.

ACA appreciates MDEP's willingness to consider stakeholder perspectives. Please feel free to contact me if I can provide any additional information.

Respectfully submitted,

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Re: PFAS in Products

To Whom it May Concern:

The Association of Equipment Manufacturers (AEM)¹ appreciates the opportunity to comment on the Maine Department of Environmental Protection (MDEP), *Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances*² hereafter referred to as the proposed rule. We look forward to sharing the expertise and technical knowledge of our industry sectors. We believe it is critically important when developing regulations, that the interest of all stakeholders be considered and understood.

The off-road equipment manufacturing industry understands the value and importance of using sound science to inform future policymaking decisions. AEM strives to be a key stakeholder in these policymaking discussions. To ensure that new rules meet their objectives with accurate and complete data, AEM wants to support MDEP's approach as well as make a request that MDEP take into consideration the following point:

1. MDEP harmonize their refrigerant requirements and restrictions under the PFAS in Products program to those of the EPA SNAP program.

Restrictions on the Use of PFAS in Maine:

On December 20, 2024, MDEP released their Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalky Substances proposed rule. Under Section 5F of this rule, MDEP states:

The prohibition of this subsection does not apply to any such products sold, offered for sale or distributed for sale in used condition or to parts and other servicing needs for cooling, heating, ventilation, air conditioning or refrigeration equipment, including refrigerants used in servicing such equipment as long as the refrigerant is listed as acceptable, acceptable subject to use conditions or acceptable subject to narrowed use limits by

¹ AEM is the North American-based international trade group representing heavy-duty nonroad equipment manufacturers and suppliers with more than 1,000 member companies and over 200 product lines in the construction, agriculture, mining, forestry and utility industries. The equipment manufacturing industry in the United States supports 2.8 million jobs and contributes roughly \$288 billion to the economy every year. Our industries remain a critical part of the U.S. economy and represent 12 percent of all manufacturing jobs in the United States. Our members develop and produce a multitude of technologies in a wide range of products, components, and systems that ensure heavy-duty nonroad equipment remains safe and efficient, while at the same time reducing carbon emissions and environmental hazards. Finished products have a life cycle measured in decades and are designed for professional recycling of the entire product at the end of life. Additionally, our industry sectors strive to develop climate friendly propulsion systems and support robust environmental stewardship programs around the world.

² https://www.maine.gov/dep/rules/index.html#13139124

the EPA pursuant to the Significant New Alternatives Program at 42 U.S.C. 82(G), as long as the refrigerant, foam, or aerosol propellant is sold, offered for sale or distributed for sale for the use for which it is listed pursuant to that program.

This paragraph permits manufacturers to service existing equipment in the field with refrigerants that may contain PFAS chemicals.

Under a recent Federal Rule, as of October 24, 2023, EPA promulgated their Final Rule³ to restrict the use of certain hydrofluorocarbons in specific sectors or subsectors. The Final Rule established a Global Warming Potential (GWP) limit of 150 for refrigerants manufactured, distributed, or exported for use in motor vehicle air conditioning systems in nonroad vehicles, with a compliance date of January 1st, 2028. This restriction would apply to all products, except for those products sold or distributed, or in existence in the nonroad sector prior to December 27, 2020.

The established restriction limit of 150 GWP would effectively forbid the use of certain refrigerants, such as HFC-134a, in the nonroad sector but does allow for manufacturers to use low GWP refrigerant alternatives, like HFO-1234yf, or blends of different refrigerants to meet the new requirement. However, in practice the only realistic refrigerant that allows Original Equipment Manufacturers (OEM) to meet the requirements of the rule is HFO-1234yf.

The Proposed Rule, on the other hand, bans the use of all PFAS substances used in new heating and air conditioning equipment, and the refrigerant chemicals themselves, by 2040. This creates a unique standard for manufacturers to meet when looking to sell or service new equipment in Maine. Off-road equipment requires an efficient and operational heating and air conditioning system, not only for the comfort of the operator, but also for meeting health and safety requirements promulgated by OSHA.

At this point in time, there are no known substances that can adequately replace HFO-1234yf for use in off-road equipment. This risks the longevity of the entire off-road equipment sector in Maine. The EPA's SNAP program is a robust and well-known standard for assessing the viability and availability of refrigerants used in different sectors. This ensures manufacturers can meet environmental goals, while at the same time mitigate risks to industry. The SNAP program also ensures a harmonization of requirements across the United States.

For these reasons, AEM requests that MDEP harmonize their own requirements under the PFAS in Products program to those of the EPA SNAP program.

AEM Appreciates your consideration of these comments.

³ <u>https://www.federalregister.gov/documents/2023/10/24/2023-22529/phasedown-of-hydrofluorocarbons-restrictions-on-the-use-of-certain-hydrofluorocarbons-under-the</u>

Please feel free to contact Jason Malcore, AEM's Senior Director, Safety & Product Leadership at <u>Jmalcore@aem.org</u> if you have any questions or require any further information.

Best Regards,

Ju Mal

Jason Malcore Senior Director, Safety & Product Leadership Association of Equipment Manufacturers (AEM



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January 28, 2025

Commissioner Melanie Loyzim Maine Department of Environmental Protection State of Maine 17 State House Station Augusta, Maine 04333

Submitted via email: rulecomments.dep@maine.gov

Re: Posting Draft Proposed Rule, Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances (December 20, 2024)

Dear Commissioner Loyzim:

AGC Chemicals Americas Inc. ("AGCCA") and its parent company, AGC America, Inc., (together, "AGC") appreciates this opportunity to provide comments on the Maine Department of Environmental Protection (DEP) "Posting Draft Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances" (December 20, 2024) (hereafter "Proposed Regulations"). AGCCA manufactures and supplies a range of specialized industrial chemicals and materials, including resins, coatings, films and membranes, that are incorporated into a wide range of products essential to the daily lives of Maine residents and businesses.

We greatly appreciate the efforts that have been undertaken to date by the Department of Environmental Protection ("DEP") to implement LD 1537, PL 630 (adopted April 2024) which amended Maine's precedent-setting PFAS in products law. As outlined below, we believe further refinements are needed to ensure that Maine businesses and residents continue to have access to a range of products that are essential to their daily lives and continued success.

In addition to these written comments, we have also attached a red-lined version of the Proposed Regulations, incorporating many of our suggested changes (Attachment 1).

The Regulations Should Include An Exemption Or Categorical "Currently Unavoidable Use" ("CUU") Determination For Fluoropolymers

As discussed in greater detail in our March 1, 2024, submission to DEP (Attachment 2), although fluoropolymers fall within the extremely broad definition of "PFAS" used in 38 M.R.S. § 1614(1) they are far different from the problematic PFAS chemicals, such as PFOA and PFOS, that have been found in drinking water, groundwater and biosolids. Unlike other PFAS chemicals, fluoropolymers are not soluble in water, nor do they degrade into smaller, water-soluble molecules - so they cannot enter drinking water or groundwater or migrate easily in the environment. Also, fluoropolymers are not bioavailable (i.e., they do not cross cell membranes) nor do they degrade to smaller, bioavailable molecules, so they do not present toxicity concerns associated with PFAS chemicals of concern. Indeed, peer-reviewed studies demonstrate that, because of these and other characteristics, fluoropolymers satisfy internationally-recognized criteria for being "Polymers of Low Concern" (PLC) – that is, polymers deemed to have insignificant environmental and human health impacts.¹

In addition to being of low concern with respect to potential health and environmental impacts, fluoropolymers possess a unique combination of properties such as resistance to extreme temperatures and harsh chemicals, mechanical resilience and resistance to degradation, low dielectric constant, and resistance to extreme weather, among many other properties. This unique combination of properties underlies the irreplaceability of fluoropolymers in a wide range of applications, including hundreds of products and technologies that are critical to daily life, such as semiconductors, fuel cells, wind turbines, printed circuit boards, coated wires, batteries, solar photovoltaics, avionics and other aircraft components, motor vehicle engines, manufacturing equipment, scientific instruments, and laboratory and diagnostic equipment, among others.

Alternative materials may be able to achieve comparable performance to fluoropolymers for one or a few specific parameters or properties, but overall, due to deficiencies in other properties, they have lower performance and other disadvantages as compared to fluoropolymers. The unmatched performance of fluoropolymers across multiple areas of performance means that, for most applications in which fluoropolymers are used, attempting to substitute other materials for fluoropolymers will result in a loss of reliability and durability that in many instances will have negative effects on health, safety and the environment.

Because thousands of products of critical importance to Maine businesses and residents rely on fluoropolymers due to their unique combination of properties, and because fluoropolymers are

¹ See "A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers," Korzeniowski, Stephen H., et al., <u>Integrated Environmental Assessment and</u> <u>Management 19, 2 (2023): 326–354. DOI: 10.1002/ieam</u>; "A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers," <u>Integrated Environmental Assessment and Management, Henry,</u> <u>Barbara.J., et al., 14, 3 (2018): 316-334. DOI: 10.1002/ieam.4035</u>.

of low concern with respect to potential health and environmental impacts, products made with or containing fluoropolymers should be excluded from the regulations or, in the alternative, should receive a categorical CUU determination written into the regulations. Specifically, Section 9(B) of the proposed regulations should be amended to add the following:

(1) Fluoropolymers (defined as polymeric substances for which the backbone of the polymer is either a per- or polyfluorinated carbon-only backbone or a perfluorinated polyether backbone), and products consisting of fluoropolymers.

Additional information supporting such a categorical CUU determination is provided in Attachment 2.

The CUU Process Requires Greater Certainty and Predictability

Section 9(A) of the Proposed Regulations provides that a manufacturer seeking a CUU determination for a product must submit an application for CUU determination at least 18 months prior to the date on which sales of the product would be prohibited under the law. However, the regulations do not specify a timeline for DEP and the Board of Environmental Protection to act on such an application. This creates the possibility that a product essential to health or safety of Maine residents, or necessary for the normal functioning of society in Maine, may be banned from commerce for an indeterminate length of time because DEP and/or the Board of Environmental Protection failed to act on a CUU application that was submitted timely (i.e., submitted more than 18 months from the effective date of the ban). Similarly, if DEP and/or the Board of Environmental Protection fail to promptly act on a CUU application, manufacturers that have submitted CUU proposals may feel compelled to withdraw essential products from the market in Maine, in anticipation of impending prohibitions on sale.

To avoid these perverse outcomes and assure that Maine residents do not suddenly and/or inadvertently lose access to products that should appropriately be designated as CUU (i.e., products that are critical to the health, safety, or daily life of Maine residents), the regulations should specify that, with respect to products for which a timely CUU application has been filed, the prohibition on sales will become effective either: (i) the date specified in the statute; or (ii) twelve months after the date on which DEP and the Board of Environmental Protection render a final determination on the product's CUU application, whichever date is **later**. This provision anticipates that CUU determinations should take no longer than six months to complete. Without this type of provision, Maine residents might suddenly and unexpectedly lose access to products essential to their health and safety.

Specifically, we propose amending the second paragraph of Section 9(A) of the proposed regulations to read as follows (new language is underlined):

For initial currently unavoidable use proposals, the requester shall submit the information in this section no later than 18 months prior to the applicable sales prohibition. The Department will not consider any proposals for an initial currently unavoidable use determination prior to 36 months in advance of the applicable sales prohibition; any proposals received prior to this date will need to be updated and resubmitted between 36 and 18 months before the effective date of the applicable sales prohibition (with the exception of CUU proposals for sales prohibitions taking effect 2026, which must be submitted no later than June 1, 2025). For products included in a currently unavoidable use proposal submitted within the timeframes referenced above, the prohibition on sales will become effective either: (i) the date specified in the statute; or (ii) twelve months after the date on which DEP and the Board of Environmental Protection render a final determination on the product's CUU application, whichever date is **later**.

Submitters of CUU Proposals Should Be Required to Submit Information To The Extent Known Or Reasonably Ascertainable By The Submitter

The proposed regulations currently require submission of information on health and environmental impacts to the extent that such information is "known or reasonably ascertainable by the manufacturer" (*see* Section 9(A)(9)). This same standard should be applied to all information required to support a CUU proposal. Accordingly, we propose to amend the last sentence in Section 9(A) preceding the enumerated list of information requirements to read as follows (new language is underlined):

A proposal must at a minimum contain the following information to the degree it is known or reasonably ascertainable

The Regulations Should Provide For Automatic Renewal Of CUU Determinations Unless New Information Indicates A Prior CUU Determination Is No Longer Valid

The Proposed Regulations include nearly three pages of detailed information that must be submitted by an applicant seeking a CUU determination. And if a CUU determination is granted, it is approved for only five years -- at which time a renewal application would need to be submitted. The five-year duration of CUU determinations is insufficient, given the critical nature (by definition) of CUU products and their (by definition) essentiality to protecting the health and safety of Maine workers and residents and/or the daily functioning of society. Moreover, the five-year CUU duration bears no relation to the length of time needed to (i) identify, (ii) evaluate, (iii) qualify, and (iv) deploy replacement materials. Abundant evidence demonstrates that in most critical applications of the sort that would be subject to a CUU determination, at least a decade or more would be needed to deploy suitable replacements – *if*

*such replacements can be found.*² For this reason, the five-year duration for CUU determinations is wholly inadequate.

An equally important concern is the unduly burdensome and potentially disruptive process required to renew a CUU determination. Specifically, renewal of a CUU designation under the Proposed Regulations would require a new submission that addresses all of the same information elements addressed in the initial CUU application plus additional information regarding "any changes" since the time of the initial CUU determination as well as a summary of "efforts made during that time to develop or discover alternatives." Requiring a completely new application package addressing the same items of information as contained in the original CUU submission is unnecessarily burdensome for both the submitter and DEP. So is requiring the submitter to provide a detailed accounting of efforts undertaken to "develop" or "discover" a new alternative. Instead, the regulations should: (i) require the submitter to identify any changes to the originally-submitted information (including detailed information on potential replacements); and (ii) provide for automatic renewal of the CUU designation unless any new information not contained in the original submission indicates that automatic renewal is not warranted and a completely new submission is necessary. This approach is more efficient for both the applicant and the Department and would help to assure that Maine residents, businesses and workers have uninterrupted access to critical products that, by definition, are essential to health, safety or the functioning of society.

Specifically, we propose replacing the last two paragraphs of Section 9(A) with the following:

Upon the expiration date listed in Section 9(B), a currently unavoidable use determination shall be automatically renewed for an additional five years upon the submission of a renewal request unless information submitted with the renewal request leads the Department to conclude that a new CUU proposal must be submitted to renew the CUU determination. A renewal request under this paragraph must identify any changes to the information included in the most recent CUU proposal or renewal request submitted to the Department and must be submitted no later than 24 months prior to the expiration date of the CUU determination in effect. Within three months of receiving a renewal request the Department shall notify the submitter if the new information included in the renewal request requires the submission of a new CUU proposal. If the Department notifies a submitter that a new the CUU proposal is required, the proposal must be submitted to the Department within three months of that notification and the Department will have

² See, e.g., Letter from ThermoFisher to Minnesota Pollution Control Agency, March 1, 2024 (indicating at least 12 years needed to transition to alternatives); letter from <u>Truck & Engine Manufacturers Association to Minnesota</u> <u>Pollution Control Agency</u>, February 28, 2024 (indicating that decades may be needed to transition to alternatives); letter from Truck & Engine Manufacturers Association to Minnesota Pollution Control Agency, February 28, 2024 (indicating that decades may be needed to transition to alternatives); letter from Truck & Engine Manufacturers Association to Minnesota Pollution Control Agency, February 28, 2024 (indicating that decades may be needed to transition to alternatives). This correspondence may be accessed at the following url: (<u>https://minnesotaoah.granicusideas.com/discussions/39667-minnesota-pollution-control-agency-reguest-for-comments-on-pfas-in-products-currently-unavoidable-use-rule/topics/submit-a-comment-290</u>

three months to review the proposal. If a renewal request is not received within the time frame specified above, a new CUU proposal will be required, unless the Department in its discretion waives the deadline for submission of a renewal request.

Identical Products Should Be Regulated In The Same Manner

Due to the peculiar manner in which products are exempted under the statute and Section 4 of the Proposed Regulations, certain products may be simultaneously exempt from a prohibition on sales while identical products are banned from commerce. This is arbitrary and irrational, as well as detrimental to Maine residents and businesses.

For example, Section 4(A)(9) includes an exemption for "motor vehicles" and "motor vehicle equipment" that encompasses cars, trucks, motorcycles, all-terrain vehicles and farm equipment. These types of vehicles are typically manufactured with certain PFAS-containing components, including fluoropolymer-coated electrical wires and cables as well as fuel lines, seals and gaskets, because these fluoropolymer-containing components are proven to maintain their integrity when exposed to the high temperatures, harsh chemicals, and mechanical stresses inherent in both internal combustion engines as well as electric vehicles. These same components (i.e., fluoropolymer-coated electrical wires and cables, fuel lines, seals and gaskets, among others) provide the same critical safety and reliability functions in vehicles and equipment that are apparently not included in Section 4(A)(9), such as locomotives and rail cars, recreational vehicles such as snowmobiles, construction equipment and factory and warehouse equipment. Thus, it appears that the same components, performing the same safety and reliability functions in motorized vehicles and equipment, are both exempt and banned from commerce under the Proposed Regulations depending on the specific vehicle or equipment in which they are incorporated – with no apparent rhyme or reason.

Similarly, Section 4(A)(13) exempts "manufacturing equipment" used to manufacture certain categories of durable and non-durable goods, such as motor vehicles, aircraft, watercraft, and non-consumer electronics. Manufacturing equipment for these types of goods often include PFAS-containing components that are essential for worker safety as well as equipment reliability, such as fluoropolymer-coated electrical wires and cables as well as hoses, tubes, gaskets, seals, O-rings, expansion joints, valves and pumps that, due to their fluoropolymer content, are able to maintain their integrity when exposed to the high temperatures, harsh chemicals, and mechanical stresses that are typical with heavy manufacturing equipment. These same components are used in manufacturing equipment employed to produce goods for other sectors, such as the energy, natural resources and construction sectors, and they provide the same critical reliability and worker safety functions; however, they appear to be excluded from the exemption in Section 4(A)(13). In other words, the same products, performing the same safety and reliability functions in heavy manufacturing equipment are both exempt and banned from commerce, based solely on the specific products made by that manufacturing equipment. This defies logic. Presumably workers utilizing a piece of heavy manufacturing equipment should be afforded the same degree of protection against catastrophic equipment

failure regardless of the specific goods being manufactured. Yet the Proposed Regulations would have the opposite effect – condemning some workers to utilize heavy manufacturing equipment with less durable and less reliable components simply because the goods they are manufacturing are utilized in industrial sectors other than those specified in Section 4(a)(13).

The same arbitrariness is evident elsewhere in Section 4. To avoid these harmful outcomes the statute must be implemented in a manner such that exempt products and product components are **uniformly** exempt and are not arbitrarily banned from commerce when used in some industry sectors but not others. This could accomplished by including in the regulations a categorical CUU determination for components of products enumerated in Section 4(A)(5) through (13) when used to perform the same or similar function in other products. Specifically, Section 9(B) of the proposed regulations could be amended to add the following:

(2) Components of the products enumerated in Section 4(A)(5)-(13) when used to perform the same or similar functions in other products.

DEP Should Expansively Interpret The Exemption In Section 4(A)(7) Of The Proposed Regulations

Section 4(A)(7) of the Proposed Regulations echoes Section 4(G) of the statute (38 M.R.S. § 1614(4)(G)) by providing for the exemption of products "developed or manufactured for purposes of public health, environmental or water quality testing." The precise scope of this exemption is unclear; however we urge DEP to interpret this provision broadly, to encompass PFAS-containing products manufactured for the purpose of providing a public health or environmental benefit. Under this interpretation, Maine residents would continue to have access to the public health and environmental benefits provided by fluoropolymer-based ion exchange membranes used for water purification and wastewater treatment, as an example.

The Regulations Should Explicitly Exempt Replacement Parts For Products Exempt Under Section 4(A)

The regulations should clarify that replacement parts for complex products and other equipment under section 4(A) are also exempt. The proposed regulations reflect the statutory exemption of several classes of complex products, such as watercraft, non-consumer electronics and certain manufacturing equipment. Failure to clarify that replacement parts for these products are also exempt could prevent their repair and lead to premature disposal of a large volume of otherwise serviceable equipment and products and could result in a substantial economic burden for Maine businesses, residents and government institutions. To address this concern we propose amending Section 4(A) by adding the following provision after item 13:

(14) Replacement parts for products described in Subsections 5 through 13, above.

The Notification Provisions Should Be Modified To Facilitate Reporting Of PFAS Identity Information

The Department has modified Section 3(A)(1)(d) to provide for reporting of PFAS substances by chemical name, following the nomenclature of the international union of pure and applied chemistry (IUPAC), in lieu of reporting by CAS registry number. However, suppliers are often unwilling to provide downstream product manufacturers (i.e., companies that will be submitting notifications under the proposed regulations) with either CAS numbers or IUPAC names because this information is frequently considered to be confidential business information and may be protected against disclosure under federal law. To address this concern and facilitate the reporting of PFAS identity information the Department should allow reporting of U.S. EPA-assigned Accession numbers, PMN numbers or LVE numbers as an alternative to reporting CAS numbers, since virtually all chemicals in commerce with confidential chemical identifiers, unlike CAS numbers and IUPAC names, are not themselves confidential, they are more readily obtained from suppliers. They can also be cross-referenced to EPA health and safety databases. Accordingly, we propose adding a new Section 3(A)(1)(d)(iii) as follows:

(ii) One of the following identifiers: EPA Accession Number, PMN number or Low Volume Exemption (LVE) number.

Thank you again for the opportunity to submit these comments. Should you have any questions or concerns about the information provided herein, please reach out to Ahmed El Kassmi at 610-423-4312 or by email at ahmed.elkassmi@agc.com.

Sincerely,

Christopher F. Correnti President and CEO AGC America, Inc.

A. SL Km

Ahmed El Kassmi, Ph.D Director, Product Stewardship & Regulatory Affairs AGC Chemicals Americas, Inc.

Attachment 1

Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

1.	Applicability	2
2.	Definitions	2
3.	Notification	
4.	Exemptions	11
5.	Prohibition on Sale of Products Containing Intentionally Added PFAS	
6.	Fees	16
7.	Failure to Provide Notice	16
8.	Certificate of Compliance	17
9.	Currently Unavoidable Use	17
A	. Proposal for Currently Unavoidable Use Determinations	
В.	. Department Designations of Currently Unavoidable Uses	
10.	Proprietary Information	

Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

SUMMARY: This Chapter details the sales prohibitions for new and unused products containing intentionally added Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) as well as the notification requirements for products containing intentionally added PFAS determined to be a currently unavoidable use pursuant to 38 M.R.S. § 1614.

- 1. Applicability. Unless exempted in section 4, this Chapter applies to all new and unused products sold, offered for sale, or distributed for sale in the State of Maine which contain intentionally added perfluoroalkyl and polyfluoroalkyl substances.
- 2. Definitions.

Adult Mattress. "Adult mattress" is defined at 38 M.R.S. § 1614(1)(A-1).

Aerosol propellant. "Aerosol propellant" is defined at 38 M.R.S. § 1614(1)(A-2).

Air care product. "Air care product" is defined at 38 M.R.S. § 1614(1)(A-3).

Aircraft. "Aircraft" is defined at 38 M.R.S. § 1614(1)(A-4).

Alternative. "Alternative" is defined at 38 M.R.S. § 1614(1)(A-5).

Architectural fabric structure. "Architectural fabric structure" is defined at 38 M.R.S. § 1614(1)(A-6).

Artificial Turf. "Artificial turf" is defined at 38 M.R.S. § 1614(1)(A-7).

Automotive maintenance product. "Automotive maintenance product" is defined at 38 M.R.S. § 1614(1)(A-8).

NOTE: Automotive maintenance products may be used on or marketed for use on any style of motor vehicle. Automative maintenance products do not include items which are used in the mechanical maintenance of an automobile, such as oil, coolant, filters, and other consumable and replacement and repair parts.

Brand name. "Brand name" means a name, symbol, word, or mark that identifies a product, and attributes the product to the owner of the brand.

NOTE: While the FAA considers unmanned aerial vehicles, commonly referred to as drones, to be aircraft, for the purposes of this rule, due to their unmanned nature, they do not meet the definition of aircraft.

Carpet or rug. "Carpet or rug" is defined at 38 M.R.S. § 1614(1)(A).

- **Chemically-formulated.** "Chemically-formulated" means a synthetic substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term does not apply to substances created by naturally occurring biological processes.
- Cleaning Product. "Cleaning product" is defined at 38 M.R.S. § 1614(1)(A-9).
- **Clothing item.** "Clothing item" means an article of wearing apparel designed to be worn on or about the human body. The term does not include accessories or special clothing, such as jewelry, watches, watchbands, handbags, handkerchiefs, umbrellas, scarves, ties, headbands, belts, and belt buckles, footwear, or articles of wearing apparel designed to be worn by animals.
- **Commercially available analytical method.** "Commercially available analytical method" means any test methodology used by a laboratory that performs analyses or tests for third parties to determine the concentration of PFAS in a product. Commercially available analytical methods do not need to be performed at a third-party laboratory; however, the method must remain unmodified when not performed by a third-party laboratory.
- **Consumer products.** "Consumer products" means goods which are marketed for and intended to be used primarily for personal, family or household purposes.
- **Container.** "Container" means any package as defined in 32 M.R.S. § 1732(4), which is meant to encase a liquid, powder, or gas by means of direct contact.
- **Cookware product.** "Cookware product" as defined at 38 M.R.S. § 1614(1)(A-10) is limited to houseware intended to be in direct contact with food or beverage. Cookware does not encompass items intended for use in and market exclusively for use in commercial, industrial, or institutional settings.
- **Cosmetic Product.** "Cosmetic Product" as defined at 38 M.R.S. § 1614(1)(A-11) to include inks, such as tattoos, implants, jewelry, and body modifications that are introduced into the human body unless otherwise exempted under section 4. Soap has the same meaning as 21 C.F.R. § 710.20, as amended up to April 1, 2024.
- **Cosolvent.** "Cosolvent" means substances added to a primary solvent in small amounts to increase the solubility of a poorly soluble compound.
- **Currently unavoidable use.** "Currently unavoidable use" is defined at 38 M.R.S. § 1614(1)(B).
- **Dental floss.** "Dental floss" means a product designed to clean between teeth in places that are not accessible with a toothbrush or an interdental brush. The product can be packaged

with pre-cut or continuous length of strong thread or fine tape and is specifically designed to be drawn between the teeth to remove food particles and prevent dental plaque, such as dental floss and dental tape. Dental floss includes products commonly referred to as flossers where a section of dental floss is mounted to a handle or device meant to facilitate the act of flossing. Dental floss does not include products such as water flossers or other similar devices.

Department. "Department" defined at 38 M.R.S. § 341-A(2).

- **Distribute for sale.** "Distribute for sale" means to ship or otherwise transport a product with the intent or understanding that it will be sold or offered for sale in Maine by a receiving party subsequent to its delivery.
- **Electronics.** "Electronics" means technology having electrical, digital, magnetic, wireless, optical, electromagnetic, or similar capabilities.
- **Environmental control technology.** "Environmental control technology" means any system, item of equipment or component having as its primary function the reduction or prevention of an environmental impact.
- **Essential for health, safety, or the functioning of society.** "Essential for health, safety or the functioning of society" is defined at 38 M.R.S. § 1614(1)(B-1).
- **Fabric.** "Fabric" means a textile made by weaving, knitting, or felting natural or synthetic fibers. For the purposes of this rule, fabric includes leather and synthetic leather.

Fabric treatment. "Fabric treatment" is defined at 38 M.R.S. § 1614(1)(C).

NOTE: Fabric treatments do not include fabric dyes.

- **Finished product.** "Finished product" means a product that has been manufactured, packaged, and is in the form, packaging, and condition in which it will be sold, offered for sale, or distributed for sale.
- Foam. "Foam" is defined at 38 M.R.S. § 1614(1)(C-1).
- **Fully fluorinated carbon atom.** "Fully fluorinated carbon atom" means a carbon atom on which all the hydrogen substituents have been replaced by fluorine.
- **Functionally equivalent.** "Functionally Equivalent" means a product or product component that functions in the same basic manner as the product it is being compared against to perform the same purpose to the same standard as the original PFAS containing product or product component it is being compared against.
- **Fluorinated container.** "Fluorinated container" means any container which has been treated with fluorine atoms to create a permanent barrier.

Intentionally added PFAS. "Intentionally added PFAS" is defined at 38 M.R.S. § 1614(1)(D).

- NOTE: Intentionally added PFAS includes degradation by-products serving a functional purpose or technical effect within the product or its components. Products containing intentionally added PFAS include products that consist solely of PFAS. Intentionally added PFAS does not include PFAS that is present in the final product as a contaminant or PFAS used in the manufacturing process or comes into contact with the product during the manufacturing process but is not present in the final product.
- **Intrinsic to the design or construction of a building.** "Intrinsic to the design or construction of a building" means those elements of a building or structure which are necessary to perform its intended purpose. Intrinsic to the design or construction of a building may include structural elements and elements meant to block light, wind, or precipitation. Intrinsic to the design or construction of a building does not include elements which are solely decorative or otherwise merely enhance the attractiveness of a structure or its function or those elements that are quickly or easily removed from the structure.

Juvenile product. "Juvenile product" is defined at 38 M.R.S. § 1614(1)(D-1).

- **Known to or reasonably ascertainable by.** "Known or reasonably ascertainable by" is defined at 38 M.R.S. § 1614(1)(D-2).
- Laboratory equipment. "Laboratory equipment" means any analytical instrument or support equipment that is required to generate the results of an analysis. Laboratory equipment includes, but is not limited to, any tool, gear, or appliance that is intended to be used in the creation of a substance, such as reaction vessels, gas generators, or preparatory or purifying equipment.

Manufacturer. "Manufacturer" is defined at 38 M.R.S. § 1614(1)(E).

Mattress. "Mattress" means a resilient material or combination of materials enclosed by ticking, intended for sleeping upon, and may include adult, youth, crib, bunk bed, futon, flip chairs, sleeper, water, or air mattresses.

Medical device. "Medical device" is defined at 38 M.R.S. § 1614(1)(E-1).

Menstruation products. "Menstruation products" means products used to catch menstrual flow, such as disposable and reusable pads, tampons, period underwear, and menstrual cups.

Off-highway vehicle. "Off-highway vehicle" is defined at 38 M.R.S. § 1614(1)(E-2).

- NOTE: A vehicle manufactured by the brand Stellantis and badged with the Jeep brand does not qualify solely based on its brand name.
- **Offer for sale.** "Offer for sale" means to make a product available for purchase, including through online sales platforms that deliver into the State of Maine.
- **Outdoor apparel for severe wet conditions.** "Outdoor apparel for severe wet conditions" is defined at 38 M.R.S. § 1614(1)(E-3).
- **Perfluoroalkyl and polyfluoroalkyl substances (PFAS).** "Perfluoroalkyl and polyfluoroalkyl substances" or "PFAS" is defined at 38 M.R.S. § 1614(1)(F).
- **Person.** "Person" means any individual; partnership; corporation; firm; or public or private organization of any character.
- **Product.** "Product" is defined at 38 M.R.S. § 1614(1)(H).
- NOTE: Product includes packages, packaging components, and food packaging as defined in 32 M.R.S. § 1732, when sold individually or in bulk and not used in marketing, handling, or protecting a product.

Product component. "Product component" is defined at 38 M.R.S. § 1614(1)(H).

- Proprietary information. "Proprietary information" is defined at 38 M.R.S. § 1614(1)(H-1).
- **Publicly available.** "Publicly available" means information that is lawfully made available to the general public from federal, state, or local government records, widely distributed media, or disclosures made to the general public that are required by federal, state, or local law.
- **Reasonably available.** "Reasonably available" means a PFAS alternative which is readily available in sufficient quantity and at a comparable cost to the PFAS, to include changes to the manufacturing process, it is intended to replace and performs as well as or better than PFAS in a specific application of PFAS in a product or product component.
- **Refrigerant.** "Refrigerant" is defined at 38 M.R.S. § 1614(1)(J).
- **Resilient floor covering.** "Resilient floor covering" means a non-textile floor that provides underfoot comfort and characteristically bounces back from repeated traffic or compression.
- Semiconductor. "Semiconductor" means material having conductivity characteristics intermediate between conductors and insulators, as well as a discrete functional object having two or more layers of metallic, insulating, or semiconductor material, deposited or otherwise placed on, or etched away or otherwise removed from, a piece of

NOTE: A product must meet the definition of a semiconductor product will not be considered a semiconductor solely because other products that serve the same or similar purpose are semiconductors.

Significant change. "Significant change" means a change in the composition of a product which results in the addition of a specific PFAS; a change in the amount of PFAS of more than a 10% increase, above the method variability allowed by the commercially available analytical method used, of the concentration that has been reported when compared to the existing notification; or a change in responsible official or contact information.

Single Use. "Single use" is defined at 38 M.R.S. § 1614(1)(K).

- **Soap.** "Soap" means a product composed mainly of the alkali salts of fatty acids, that is, the material you get when you combine fats or oils with an alkali, such as lye.
- **Substantially equivalent information.** "Substantially equivalent information" means information that the Department can reasonably identify as conveying the same information required in section 3(A). Substantially equivalent information must all be in a single document or location. Substantially equivalent information may include an existing notification by a person who manufactures a product or product component when the same product or product component is offered for sale under multiple brands.

Ski wax. "Ski wax" is defined at 38 M.R.S. § 1614(1)(L).

Textile. "Textile" is defined at 38 M.R.S. § 1614(1)(M).

Textile article. "Textile article" is defined at 38 M.R.S. § 1614(1)(N).

Upholstered furniture. "Upholstered furniture" is defined at 38 M.R.S. § 1614(1)(O).

Used. "Used" means the condition of a product having been installed, operated, or utilized for its intended purpose by at least one owner or operator. Used does not apply to a product that has been returned to a retailer or that is otherwise offered for resale without the product having been installed, operated, or utilized.

Vehicle. "Vehicle" is defined at 38 M.R.S. § 1614(1)(P).

3. Notification.

A. Upon the applicable effective date listed in section 5, a product containing intentionally added PFAS is prohibited from being sold, offered for sale, or distributed for sale in the State of Maine. This prohibition is effective immediately for all covered products, including those already in the stream of commerce. Only those products for which there is a currently unavoidable use determination and the Department has received a completed notification meeting the requirements under this section, including the accompanying fee, are permitted for sale after the effective date of the sales prohibition.

Upon the applicable effective date found in section 5, for any product which is covered by a currently unavoidable use determination listed in section 9(B) any manufacturer, with greater than 100 employees, of a product subject to this Chapter which is for sale in the State and that contains intentionally added PFAS shall submit to the Department a notification consisting of the following to the extent known to or reasonably ascertainable by the manufacture:

- NOTE: To prevent sales disruptions, the Department encourages manufacturers to submit notifications in advance of any applicable effective date as detailed in section 5 of this rule.
- (1) A notification under this section must include:
 - (a) A brief description of the product, including but not limited to;
 - (i) Global Product Classification (GPC) brick category and code, if available;
 - (I) If GPC is not applicable to the product the United States International Trade Commission's Harmonized Tariff System (HTS).
 - (ii) The North American Industry Classification System code for the sector or sectors in which the products containing intentionally added PFAS will be utilized.
 - (iii) The general type of the product; and
 - (iv) Its intended use.
 - (b) An estimate of the total number of units sold annually in the State of Maine or nationally;
 - (c) The purpose for which PFAS are used in the product, including PFAS in any product component;
 - (d) The identity of each PFAS by:
- (i) Its name and its chemical abstracts service (CAS) registry number; or
- (ii) In the absence of this number tThe chemical name following the nomenclature of the international union of pure and applied chemistry (IUPAC); or-
- (ii)(iii)One of the following identifiers: EPA Accession Number, PMN number or Low Volume Exemption (LVE) number.
- (e) The amount of each of the PFAS in the product or any product component:
 - (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 reasonably ascertainable, determined using commercially available analytical methods;
 - (iii)Based on information provided by a supplier or as falling within a range approved by the Department.

If reporting PFAS as falling within a Department-approved range, implemented in the Department's online notification system, the manufacturer may rely on calculations specific to the inputs and outputs of their manufacturing process or that of a product component's manufacturer to determine the amount of PFAS present; or

(iv) If neither quantities of specific PFAS compounds or total organic fluorine are known or reasonably ascertainable, a manufacturer must provide the total weight of the product.

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.

(f) The name and address of the reporting manufacturer, and the name, address, email address, and phone number of a responsible official for the manufacturer. The responsible official provided must have the authority to execute or direct others to execute the steps in section 8 below.

For notifications submitted to the Department under the statutory requirement and prior to the availability of the digital reporting system, the notification must be submitted into the digital database within 90 days of its availability.

- (g) Identification, by citation to a specific section of this Chapter, of the applicable determination by the Department that the use of PFAS in the product subject to the notification if a currently unavoidable use.
- NOTE: To be considered a valid notification, where applicable, the information provided by the manufacturer must be consistent with the information listed in the applicable currently unavoidable use determination.
- (2) Waiver of notification. The Department may waive all or part of the notification requirement under section 3(A)(1) if the Department determines that substantially equivalent information is publicly available, except that the Department will not issue a waiver for the information required in subsections 1(f) and (g) above.
 - (a) The Department will evaluate issuing a waiver to the notification requirement if the manufacturer submits a request containing the following:
 - (i) A description of the product(s) for which a waiver is requested;
 - (ii) A list of which requirements of section 3(A)(1) the manufacturer seeks a waiver for;
 - (iii) A description of any publicly available records which contain information substantially equivalent to the information required in section 3(A)1, above;
 - (iv) A statement that information in subsection 2(a)(iii) above is updated in a similar manner as required by subsection D below and;
 - (v) A link to or copy of all publicly available substantially equivalent information described by the manufacturer.
 - (b) The manufacturer shall still complete the notification for any requirements that were not waived and include directions to where the publicly available substantially equivalent information can be found, and pay the fee established in section 6.
- **B.** The information required in subsection A above must be submitted in a form approved by the Department. Electronic submission of complete information to the Department's online notification system satisfies this requirement.
- **C.** A manufacturer may submit a single notification to the Department for multiple products if all of the products are covered by the same currently unavoidable use determination found in section 9(B).
- **D.** A manufacturer shall update the information in the notification whenever there is a significant change in the reported information or when requested to do so by the Department.

- (1) In the event of a significant change or request by the Department, a manufacturer shall update their notification:
 - (a) Within 60 days of a request by the Department;
 - (b) Within 30 days of any change in responsible official or contact information; or
 - (c) Prior to the start of sales of a product with a new formulation or when there is a significant change in the amount or type of PFAS present in the product.
- (2) A manufacturer may voluntarily update the notification whenever a PFAS is reduced or eliminated, or to inactive status whenever a product is modified such that it no longer contains any intentionally added PFAS.
- **E.** A notification is not effective until the Department has received payment of the fee required by section 6.
- **F.** A manufacturer shall provide, upon request by the Department, evidence sufficient to demonstrate the accuracy of the information reported in subsection A.
- **G.** Notifications to the Department expire on the same date the applicable currently unavoidable use determination, in section 9(B), lapses.

NOTE: See section 9(A) for procedures for requesting a new currently unavoidable use determination, including determinations for products covered by a determination that will expire.

4. Exemptions.

- A. The following are exempt from the requirements of this Chapter:
 - (1) A product for which federal law governs the presence of PFAS in the product in a manner that preempts state authority. For this purpose, the provisions of this Chapter are severable, and if any phrase, section, or subsection is preempted by federal law, the validity of the remainder of this Chapter shall not be affected;
 - (2) A package as defined at 32 M.R.S. § 1732(4), for a product, except when the package is the product of the manufacturer. The exemption under this subsection does not apply to the package of a product prohibited from sale, offer for sale, or distribution for sale pursuant to sections 5(B), (C), (E), or (F) if that package is a fluorinated container or container that otherwise contains intentionally added PFAS;
 - (3) A used product or product component;
 - (4) A firefighting or fire-suppressing foam or related product regulated under 38 M.R.S.

§ 424-C;

- (5) A prosthetic or orthotic device or any product that is a medical device, drug or biologic or that is otherwise used in a medical setting or in medical applications that are regulated by or under the jurisdiction of the United States Food and Drug Administration (FDA);
- (6) A veterinary product intended for use in or on animals, including diagnostic equipment or test kits and the components and any product that is a veterinary medical device, drug, biologic or parasiticide or that is otherwise used in a veterinary medical setting or in veterinary medical applications that are regulated by or under the jurisdiction of:
 - (a) The FDA;
 - (b) The United States Department of Agriculture (USDA) pursuant to the federal Virus-Serum-Toxin Act; or
 - (c) The Environmental Protection Agency pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, except that any such product approved by the EPA pursuant to that law for aerial or land application are not exempt from this Chapter.
- (7) A product developed or manufactured for the purposes of public health, environmental or water quality testing;
- (8) A product required to meet standards or requirements of the FAA, the National Aeronautics and Space Administration (NASA), the United States Department of Defense (DOD) or the United States Department of Homeland Security (DHS), except that the exemption under this subsection does not apply to any textile article or refrigerant that is included in or as a component part of such products;
- (9) A motor vehicle or motor vehicle equipment regulated under federal motor vehicle safety standards, as defined in 49 U.S.C. § 30102(a)(10), and any other motor vehicle, including an off-highway vehicle or specialty motor vehicle, such as an all-terrain vehicle, side-by-side vehicle, farm equipment or personal assistive mobility device, except that the exemption under this subsection does not apply to any textile article or refrigerant that is included in or as a component of such products;
- (10) A watercraft as defined in 32 M.R.S. § 13001(28), or a seaplane, expect that the exemption under this subsection does not apply to any textile article or refrigerant that is included in or as a component part of such products;
 - (11) A semiconductor, including semiconductors incorporated into electronic equipment, and equipment and materials used in the manufacture of semiconductors;

NOTE: While semiconductors incorporated into electronic equipment are exempted from

this Chapter, electronic equipment in their entirety is not. Manufacturers of

electronic equipment are still subject to sales prohibitions, currently unavoidable use determinations, and notification requirements on the balance of their product which is not comprised of semiconductors.

- (12) Non-consumer electronics and non-consumer laboratory equipment not ordinarily used for personal, family or household purposes; and
- (13) Equipment directly used in the manufacture or development of products described in subsections 5 through 12, above; and-
- (13)(14) Replacement parts for products described in Subsections 5 through 13, above.
- NOTE: The statutory basis for this rulemaking contains certain exemptions of products that are regulated by, or are under the jurisdiction of, certain federal agencies pursuant to federal law. The Department understands the legislative intent to be that any changes to federal law that affect these exemptions will apply to the exemptions as soon as the federal changes become effective. No amendment of this rule will be necessary for such changes to apply to the Department's operation of this program.

5. Prohibition on Sale of Products Containing Intentionally Added PFAS.

A. Except as provided pursuant to subsection H and section 9(B), effective January 1, 2023, a person may not sell, offer for sale, or distribute for sale in the State of Maine a carpet or rug that contains intentionally added PFAS.

This prohibition does not apply to the sale or resale of a used carpet or rug.

B. Except as provided pursuant to subsection H and section 9(B), effective January 1, 2023, a person may not sell, offer for sale, or distribute for sale in the State of Maine a fabric treatment that contains intentionally added PFAS.

The prohibition under this subsection applies to fabric treatment that does not contain intentionally added PFAS but that is sold, offered for sale or distributed for sale in a fluorinated container or in a container that otherwise contains intentionally added PFAS.

This prohibition does not apply to the sale or resale of a used fabric treatment or used product to which fabric treatment has been applied.

- **C.** Except as provided in subsection H and section 9(B), effective January 1, 2026, a person may not sell, offer for sale or distribute for sale in the State of Maine:
 - (1) A cleaning product containing intentionally added PFAS;

168

- (2) A cookware product containing intentionally added PFAS;
- (3) A cosmetic product containing intentionally added PFAS;
- (4) Dental floss containing intentionally added PFAS;
- (5) A juvenile product containing intentionally added PFAS;
- (6) A menstruation product containing intentionally added PFAS;
- (7) A textile article containing intentionally added PFAS. The prohibition under this subsection does not include:
 - (a) Outdoor apparel for severe wet conditions; or
 - (b) A textile article that is included in or a component part of a watercraft, aircraft or motor vehicle, including an off-highway vehicle;
- (8) Ski wax containing intentionally added PFAS; or
- (9) Upholstered furniture containing intentionally added PFAS.

The prohibitions under this subsection apply to any of the products listed in subsections 1 through 9 that do not contain intentionally added PFAS but that are sold, offered for sale or distributed for sale in a fluorinated container or container that otherwise contains intentionally added PFAS.

The prohibitions under this subsection do not apply to products that are sold, offered for sale or distributed in used condition.

- **D.** Except as provided in subsection H and section 9(B), effective January 1, 2029, a person may not sell, offer for sale or distribute for sale in the State of Maine;
 - (1) Artificial turf containing intentionally added PFAS; or
 - (2) Outdoor apparel for severe wet conditions containing intentionally added PFAS, unless the apparel is accompanied by a legible, easily discernable disclosure that includes the following statement: "Made with PFAS chemicals." The disclosure requirement under this subsection applies to all sales, offers for sale or distributions for sale in the State of Maine for outdoor apparel for severe wet conditions containing intentionally added PFAS.

The prohibitions under this subsection do not apply to any listed products that are sold, offered for sale or distributed for sale in used condition.

E. Except as provided in subsection H and section 9(B), effective January 1, 2032, a person may not sell, offer for sale, or distribute for sale in the State of Maine any product that is

not already prohibited for sale under subsections A, B, C, D, or G that contains intentionally added PFAS. This prohibition does not apply to the sale or resale of a used product.

The prohibition under this subsection applies to any such products that do not contain intentionally added PFAS but that are sold, offered for sale or distributed for sale in a fluorinated container or in a container that otherwise contains intentionally added PFAS.

The prohibitions under this subsection do not apply to:

- (1) Any such product sold, offered for sale or distributed for sale in used condition; and
- (2) Products subject to subsection F, below.
- **F.** Except as provided in subsection H and section 9(B), effective January 1, 2040, a person may not sell, offer for sale or distribute for sale in the State of Maine:
 - (1) Cooling, heating, ventilation, air conditioning or refrigeration equipment that contains intentionally added PFAS; or
 - (2) Refrigerants, foams, or aerosol propellants that contain intentionally added PFAS.

The prohibitions under this subsection apply to any of the listed products that do not contain PFAS but are sold, offered for sale or distributed for sale in a fluorinated container or in a container that otherwise contains intentionally added PFAS.

The prohibition of this subsection does not apply to any such products sold, offered for sale or distributed for sale in used condition or to parts and other servicing needs for cooling, heating, ventilation, air conditioning or refrigeration equipment, including refrigerants used in servicing such equipment as long as the refrigerant is listed as acceptable, acceptable subject to use conditions or acceptable subject to narrowed use limits by the EPA pursuant to the Significant New Alternatives Program at 42 U.S.C. 82(G), as long as the refrigerant, foam, or aerosol propellant is sold, offered for sale or distributed for sale for the use for which it is listed pursuant to that program.

- **G.** The Department has identified the following products by category or use that contain intentionally added PFAS. Beginning on the date listed below a person may not sell, offer for sale, or distribute for sale the listed items in the State of Maine:
 - (1) [Reserved]. Example: Beginning January 1, XXXX a person may not sell, offer for sale, or distribute for sale in the State of Maine PRODUCT CATEGORY that contains intentionally added PFAS.
- **H.** The prohibitions in section 5 do not apply to a retailer in the State of Maine unless the retailer sells offers for sale or distributes for sale in the State of Maine a product containing intentionally added PFAS for which the retailer has received a notification

pursuant section 8(2) that the sale of the product is prohibited.

6. Fees.

A. Fee amount. To cover the administrative costs incurred by the Department to administer the program, a manufacturer of products required by section 3 to provide notice shall, as part of the submission of notification, pay a fee of \$1,500 for each notification submitted.

For the purposes of calculating fees, each submission of all the information required in section 3(A)(1), which has not been waived, for either an individual product or a group of products reported under a single currently unavoidable use determination will be considered a separate notification.

NOTE: Notifications are required only for products which are subject to a currently unavoidable use determination and are sold, offered for sale, or distributed for sale in the State of Maine. 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.

A fee is required for notifications of products, including those submitted under a subsequent currently unavoidable use determination. No fee is required for information updates to an existing notification or changes to inactive status.

B. Fees will be considered paid either when funds are transferred to the Treasurer of the State of Maine or when a confirmation of electronic payment is transmitted. If paying electronically via the Department's reporting database, a receipt confirming digital payment will be issued.

7. Failure to Provide Notice.

A. Beginning January 1, 2032, unless granted a waiver in accordance with section 3(A)(2) above, a person may not sell, offer for sale, or distribute for sale in the State of Maine a product containing intentionally added PFAS regardless of whether the Department has determined a current unavoidable use exists if the manufacturer has failed to provide the information required under section 3.

The prohibition in this section does not apply to a retailer in the State of Maine unless the retailer sells, offers for sale, or distributes for sale in the State of Maine a product for which the retailer has received a notification pursuant to section 8(A)(2) that the sale of the product is prohibited.

NOTE: Violations of this Chapter are subject to the Department's enforcement authority under 38 M.R.S. §§ 347-A - 349. The Department's initial focus will be on encouraging voluntary compliance. If a person resists efforts to achieve voluntary compliance the Department may take progressive steps to achieve compliance.

> DRAFT DATE December 20, 2024 Page 16 of 22

8. Certificate of Compliance.

- A. If the Department has reason to believe that a product contains intentionally added PFAS and is being sold, offered for sale, or distributed for sale in violation of sections 5 and 7, the Department may direct the manufacturer of the product to, within 30 days:
 - (1) Provide the Department with certification, on forms provided by the Department, attesting that the product does not contain intentionally added PFAS; or
 - (2) Notify any persons who sell, offer for sale, or distribute for sale that product in Maine that the sale of that product is prohibited in Maine, and provide the Department with a list of the names and addresses of those notified.

9. Currently Unavoidable Use.

A. Proposal for Currently Unavoidable Use Determinations.

Proposals for currently unavoidable use ("CUU") determinations may be submitted by manufacturers individually or collectively. A separate proposal must be submitted for each individual combination of product category and the associated industrial sector. The Department requests that manufacturers submit their proposals to <u>PFASProducts@maine.gov</u> with a subject line of "CUU Proposal for [GPC/HTC] in [NAICS] sector by [Proposal Submitter's Name or Organization]".

For initial currently unavoidable use proposals, the requester shall submit the information in this section no later than 18 months prior to the applicable sales prohibition. The Department will not consider any proposals for an initial currently unavoidable use determination prior to 36 months in advance of the applicable sales prohibition; any proposals received prior to this date will need to be updated and resubmitted between 36 and 18 months before the effective date of the applicable sales prohibition (with the exception of CUU proposals for sales prohibitions taking effect 2026, which must be submitted no later than June 1, 2025). For products included in a currently unavoidable use proposal submitted within the timeframes referenced above, the prohibition on sales will become effective either: (i) the date specified in the statute; or (ii) twelve months after the date on which DEP and the Board of Environmental Protection render a final determination on the products' CUU application, whichever date is later.

Proposals received after the 18 months prior to the sales prohibition effective date may be evaluated for inclusion in a subsequent rulemaking. Proposals received after the sales prohibition is in effect will be evaluated for inclusion in a subsequent Department CUU rulemaking.

A proposal must, at a minimum, contain <u>the following information to the degree it is known</u> or reasonably ascertainable:

(1) A brief description of the type of product to which PFAS is intentionally added

including:

- (a) A brief narrative of the product; its physical structure and appearance; how it functions; and if applicable its place in larger items, systems, or processes;
- (b) If applicable, the Global Product Classification (GPC) brick category and code, or if GPC is not applicable then the Harmonized Tariff System (HTS) code; and
- (c) The North American Industry Classification System (NAICS) code for the sector or sectors in which the products containing intentionally added PFAS will be utilized.
- (2) An explanation of why the availability of PFAS in the specific product identified in subsection 1 is essential for health, safety or the functioning of society. This may include or take the form of a description of the negative impact that would be caused by the unavailability of PFAS for use in the product and the subsequent unavailability or unsatisfactory performance of the product;
- (3) A description of how the specific use of PFAS in the product is essential to the function of the product. Including:
 - (a) If this use of PFAS is required by federal or state law or regulation, provide citations to that requirement. For the purposes of this subsection, "required" means the applicable statute or regulation specifically states that PFAS or a specific PFAS is required to be present in the product, not that the proposer's understanding or experience of PFAS is necessary to meet a performance standard; such performance standards may be addressed in subsection b, below; and
- NOTE: Products required to meet certain federal standards or regulated under certain federal programs are exempt from this Chapter. See section 4 for more information.
 - (b) The required specific characteristic or combination of characteristics that necessitate the use of PFAS chemicals.
- (4) A description of whether there are alternatives for this specific use of PFAS which are reasonably available including:
 - (a) Identification of specific compounds, classes of materials, or combinations of materials identified as potential alternatives including the removal of PFAS without substitution;
 - (b) An assessment of how the materials in subsection a, above, meet or fail to meet the criteria identified in 3(b);

- (c) An assessment if materials identified in subsection a, above, are anticipated to be available in sufficient quantities to meet production needs without regard to cost;
- (d) An assessment of the anticipated cost difference between obtaining PFAS for use in a product and obtaining the material identified in (a), for the same purpose;
- (e) A comparison of the known risks to human health and the environment between PFAS and the materials identified in (a); and
- (f) An assessment of whether there are feasible changes to the manufacturing process of the product that would eliminate the need for PFAS.
- (5) A list of federal regulations, other State of Maine rules, and regulations of other states which the product described in subsection 1 is subject to by reason of containing intentionally added 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.
- (6) If, in another jurisdiction the product is 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;
 - (a) A justification explaining how products available in compliance with other similar sales prohibitions are not reasonably available alternatives for the product subject to the proposed CUU 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; or
 - (b) 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;
- (8) Contact information for the submitter of the proposal. The contact person or persons should be familiar with the contents of the proposal and, if necessary, be able to

answer Department questions or provide additional requested information; and

- (9) Any information known or reasonably ascertainable by the manufacturer regarding the impacts on human health or the environment of PFAS in 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 governmentimposed processes at the end of a product's lifecycle,
 - (ii) How the product is intended to be disposed of, such as landfilling or via a sewage or septage system, and
 - (iii) The recycling rate of the product.

Information submitted to the Department must contain sufficient detail or supporting documentation to satisfy the requirements of the currently unavoidable use as essential for health, safety or the functioning of society for which alternatives are not reasonably available.

If any of the information above is omitted from the proposal, the requestor must explain why this information is omitted.

NOTE: While 38 M.R.S. § 1614(12) and section 10 provide a mechanism for the protection of proprietary information, currently unavoidable use determinations are subject to the Department's rulemaking process including approval by the Board of Environmental Protection in a public meeting and response to public comments. Should a proposal for a currently unavoidable use determination contain claims of confidentiality, the Department may determine that there is insufficient publicly available information to justify a rulemaking. The Department strongly recommends that all proposals for currently unavoidable use determinations do not contain claims of confidentiality.

Upon the expiration date listed in Section 9(B), a currently unavoidable use determination shall be automatically renewed for an additional five years upon the submission of a renewal request unless information submitted with the renewal request leads the Department to conclude that a new CUU proposal must be submitted to renew the CUU determination. A renewal request under this paragraph must identify any changes to the information included in the most recent CUU proposal or renewal request submitted to the Department and must be submitted no later than 24 months prior to the expiration date of the CUU determination in effect. Within three months of receiving a renewal request the Department shall notify the submitter if the new information included in the renewal request requires the submission of a new CUU proposal. If the Department notifies a submitter that a new the CUU proposal is required, the proposal must be submitted to the Department within three months of that notification and the Department will have three months to review the proposal. If a renewal request is not received within the time frame specified above, a new CUU proposal will be required, unless the Department in its discretion waives the deadline for submission of a renewal request.

Upon the expiration date listed in s 9(B), a currently unavoidable use determination is nolonger applicable, and all sales, offers for sale, or distributions for sale are immediatelyprohibited.

If a person believes the currently unavoidable use remains, they may submit a proposal to the Department for a new currently unavoidable use determination. That proposal, in addition to the information required above, must include a description of any changes since the time of the first currently unavoidable use determination and a summary of efforts made during that time to develop or discover alternatives or to make existing alternatives reasonably available. The Department will consider all subsequent proposals no sooner than 24 months prior to and no later than 12 months prior to the expiration date of the determination in effect. Proposals received after the expiration of the applicable-CUU designation will be evaluated and considered for inclusion in a subsequent-Department CUU rulemaking.

B. Department Designations of Currently Unavoidable Use.

The Department has determined that the following uses of PFAS are currently unavoidable uses. Each determination will remain in effect until the date listed below.

- (1) Fluoropolymers (defined as polymeric substances for which the backbone of the polymer is either a per- or polyfluorinated carbon-only backbone or a perfluorinated polyether backbone), and products consisting of fluoropolymers.
- (2) Components of the products enumerated in Section 4(A)(5)-(13) when used to perform the same or similar functions in other products.

NOTE: Example: The use of PFAS in products within the HTC/GPC classification #### in the industrial sector with the NAICS code #### is a currently unavoidable use until month day, year (either 5 years from applicable prohibition OR held blank to be filled in by SOS as 5 years from effective date).

10. Proprietary Information.

Information provided to the Department pursuant to this Chapter is a public record as provided by 38 M.R.S. § 1310-B(1). A party may designate proprietary information that it submits to the Department pursuant to this Chapter confidential in the manner prescribed by 38 M.R.S. § 1310-B(2). Such designations will be handled by the Department in accordance with 38 M.R.S. § 1310-B(2).

This subsection does not authorize a manufacturer to refuse to disclose to the Department information required under this Chapter.

AUTHORITY: 38 M.R.S. § 1614

Attachment 2



March 1, 2024

Commissioner Melanie Loyzim Maine Department of Environmental Protection State of Maine 17 State House Station Augusta, Maine 04333

Submitted via: pfasproducts@maine.gov

Re: Products to be Designated as "Currently Unavoidable Use" Under 38 M.R.S. § 1614

Dear Commissioner Loyzim:

AGC Chemicals Americas ("AGCCA") and its parent company, AGC America, Inc., appreciate this opportunity to identify products and product categories that should be designated as "currently unavoidable uses" ("CUU") under 38 M.R.S. § 1614 (for purposes of this submission, we will refer to this statute as the "PFAS in Products Law" or simply the "Law").

AGCCA manufactures and supplies a range of specialized industrial chemicals and materials, including resins, coatings, films and membranes, that are incorporated into a wide range of products essential to the daily lives of Maine residents and businesses. Many of these materials are comprised of fluoropolymers. Although fluoropolymers fall within the extremely broad definition of "PFAS" used in the Law, they are very much *unlike* the PFAS chemicals that have been found in drinking water, groundwater and biosolids, such as PFOA and PFOS. For example, unlike those PFAS chemicals of concern, fluoropolymers are not soluble in water, so they cannot enter drinking water or groundwater. Furthermore, fluoropolymers do not degrade into smaller, water-soluble molecules. Also, fluoropolymers are not bioavailable nor do they degrade to smaller, bioavailable molecules, so they do not present toxicity concerns associated with PFAS chemicals of concern. Indeed, peer-reviewed studies demonstrate that, because of these and other characteristics, fluoropolymers satisfy internationally-recognized

criteria for being "Polymers of Low Concern" (PLC) -- i.e., polymers deemed to have insignificant environmental and human health impacts.¹

Fluoropolymers also possess a unique combination of properties that make them critical to the performance of a wide range of products and technologies, such as semiconductors, fuel cells, wind turbines, printed circuit boards, coated wires, batteries, solar photovoltaics, avionics, aircraft components, motor vehicle engines, manufacturing equipment, scientific instruments, and laboratory and diagnostic equipment, among others. This unique, and irreplaceable, combination of properties includes the following:

- **Heat resistance**: fluoropolymers are able to maintain their physical properties at very high temperatures. This makes them particularly suitable for use in aerospace and electronic components.
- **Chemical resistance**: fluoropolymers are highly resistant to chemicals, acids, fuels, and solvents. This makes them a material of choice for use in chemical processing equipment, aerospace, automotive and pharmaceuticals.
- **Mechanical resilience**: mechanical properties include high tensile strength, flexibility, and impact resistance. This is particularly important in applications such as seals and gaskets as well as architectural films and coatings.
- **Electrical properties**: fluoropolymers have low dielectric constant, high insulation durability, and are used as sheathing materials for wire and cable due to their excellent electrical properties.
- **Inertness**: fluoropolymers are inert, non-reactive and stable (they do not degrade or decompose over time). These properties make them critical to a wide range of industrial and commercial applications in situations where equipment is likely to be exposed to chemicals.
- **Cryogenic properties**: fluoropolymers present excellent cryogenic properties, which makes them particularly suitable for use in high-tech applications such as aerospace, electronics or chemical industries.
- Separation / barrier properties: fluoropolymers have excellent moisture barrier and superior gas separation properties. Fluoropolymer membranes are essential to the production of clean hydrogen.

¹ See "A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers," Korzeniowski, Stephen H., et al., <u>Integrated Environmental Assessment and</u> <u>Management 19, 2 (2023): 326–354. DOI: 10.1002/ieam</u>; "A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers," <u>Integrated Environmental Assessment and Management</u>, <u>Henry, Barbara.J., et al.,14, 3 (2018): 316-334. DOI: 10.1002/ieam.4035</u>.

- **Dielectric properties**: dielectric properties cover low dielectric constant (Dk) and dissipation factor (Df) and are unaffected by fluctuations in temperature and humidity. This makes fluoropolymers a critical material for use in electronics and telecommunication applications.
- Weather resistance: fluoropolymers are able to maintain their physical properties even when exposed to harsh weather conditions, e.g., environmental degradation, including exposure to ozone, ultraviolet radiation and extreme temperatures. This makes them an essential material for architectural coating and films.
- **Durability**: fluoropolymers can withstand harsh conditions while maintaining their physical properties. This makes them particularly important for use in seals, gaskets, and wires and cables insulation.
- **Non-stick properties**: fluoropolymers prevent sticking, making them a material of choice for applications for which friction and adhesion are concerns is a concern.

This unique *combination* of properties underlies the irreplaceability of fluoropolymers in a wide range of applications, including those noted above. Alternative materials may be able to achieve comparable performance to fluoropolymers for one or a few specific parameters or properties, but overall, due to deficiencies in other properties, they have lower performance and other disadvantages as compared to fluoropolymers. Thus, while alternatives might be considered to be comparable in one or two areas of performance, they often fail to offer the combination of properties that fluoropolymers deliver. It is also important to highlight that, because fluoropolymers are generally more expensive than potential alternatives, for applications where the superior performance of fluoropolymers is <u>not</u> necessary, the market has already switched to non-fluoropolymer alternatives.

The unmatched performance of fluoropolymers across multiple areas of performance means that, for most applications in which fluoropolymers are used, attempting to substitute other materials for fluoropolymers will result in a loss of reliability and durability that in many instances will have negative effects on health, safety and the environment as well as negative economic impacts. For example, if a seal or gasket fails in a piece of heavy equipment or a heavy-duty vehicle due to temperature, chemical and mechanical stresses, the failure of that seal could threaten worker safety and result in releases of chemicals into the environment, in addition to causing economic losses due to repair costs and equipment down time. These adverse impacts are averted by the use of fluoropolymers.

Similarly, if a household or commercial appliance fails because a printed circuit board in the appliance was not protected by a fluoropolymer coating and suffered an electrical short as a result, the repair costs and, perhaps collateral costs (e.g., from spoilage) will cause economic loss to the consumer, which will disproportionately impact members of disadvantaged communities. Alternatively, in such a circumstance, the affected appliance might be disposed of prematurely, creating unnecessary waste, unnecessarily occupying landfill space, and unnecessarily consuming virgin resources to manufacture a replacement machine.

Because of the favorable health and environmental safety profile of fluoropolymers, as well as their irreplaceability in a wide range of products and applications that are essential to the daily lives of Maine residents and the daily operations of Maine businesses, fluoropolymers [GPC Brick Code 10008165] should be designated as CUU. Moreover, because fluoropolymers are critical components in such a wide range of essential products and applications, as illustrated by the examples described above, we believe it is impossible to compile a comprehensive list of essential products for which fluoropolymers are CUU – which is why fluoropolymers themselves should be designated as CUU. In this regard, we urge DEP to heed the admonitions of the US Department of Defense in their recent report surveying uses of PFAS compounds that are critical to the national security of the United States.² In that report, the Department concluded that:

181

PFAS are critical to DoD mission success and readiness and to many national sectors of critical infrastructure, including information technology, critical manufacturing, health care, renewable energy, and transportation. . . . Most of the structurally defined PFAS are *critical to the national security of the United States*, not because they are used exclusively in military applications (although a few are) but because of the civil-military commonality and the potentially broad civilian impact. (emphasis in original)³

Importantly, many of the critical PFAS applications identified by DoD are fluoropolymer applications. These include:

- subcomponents in modern Li-ion batteries: electrolyte solutions, cathode binders, separator coatings, casing materials, and gaskets;
- semiconductor fabrication;
- microelectronics applications, including base laminate materials used in Radio Frequency (RF) and microwave circuits;
- printed circuit boards;
- mold release agents and films typically used in composite manufacturing processes;
- hoses, tubing, hydraulic system lines, O-rings, seals and gaskets, tapes, and cables and connectors widely used in civil and military aircraft, space systems, vehicles, weapon systems, utility systems, and other applications;
- resins for specialty high-temperature or weather-/UVresistant composites; and

² US Department of Defense, <u>Report on Critical Per- and Polyfluoroalkyl Substance Uses</u> (August 2023), available at: <u>https://www.acq.osd.mil/eie/eer/ecc/pfas/docs/reports/Report-on-Critical-PFAS-Substance-Uses.pdf</u> ("DoD report").

³ Id. at 15.

• specialty filters and membranes (e.g., aviation filters).⁴

Finally, it is noteworthy that the Department of Defense spent nearly \$100,000 and took more than one year to complete its report. Nevertheless, the Department highlighted that the information on critical uses contained in the report "represents a fraction of the mission critical PFAS uses" due to a lack of knowledge about the composition of products and components. Therefore, DoD noted, "a more complete understanding of PFAS essential uses would require an extensive and complex evaluation of the market, a gap analysis of current requirements for manufacturer-provided product information, and illumination of the value chain of products." In other words, identifying all currently unavoidable uses of PFAS is a herculean task, and the DoD's year-long effort to catalogue such uses touched only the tip of the iceberg.

182

For this reason and others articulated above, we urge DEP to designate fluoropolymers (and articles manufactured from fluoropolymers) as CUU, since it is impossible to identify all individual products and components in which the use of fluoropolymers is currently unavoidable. Nevertheless, should DEP disagree with this approach, we have attempted in this submission to identify a range of specific applications where the use of fluoropolymers is essential and should be designated as CUU, as well as representative products within those applications. This information is summarized in the table below, with more detailed information for each application provided as attachments to this letter.

Sector	Representative application(s)	Attachment
Transportation	 Cable and wire coatings and sheathing for civil and military aircraft, aerospace, motor vehicles, watercraft, and other transportation modes, including high temperature sensor cables (e.g., sensor cables for emissions reduction and improvement of engine efficiency) 	
	 Mold release film for composites used for aircraft and helicopter fuselage, wings, etc. 	
	 Coatings for aircraft exteriors and interiors and motor vehicle exteriors 	<u>A</u>
	 Fuel cell components including: polymer electrolyte, catalyst ink binder for Proton Exchange Membrane Fuel Cell (PEMFC), as well as humidifier/drier in balance of system for fuel cell vehicle to control moisture of incoming hydrogen required for reliable and efficient operation of the fuel cell. 	
	 Hoses and tubes, including brakes hoses, hydraulic hoses and fuel hoses to reduce evaporative fuel emissions in combustion engine vehicles 	

⁴ Id. at A1-A7.

Sector	Representative application(s)	Attachment
	 Oil seal components, piston rings, shock absorbers, bearings and gasket 	
	 Lubricants where other lubricants are not suitable, such as bushings for car door hinges, and trunk lids 	
	 In ABS and braking systems because of safety needs 	
	 Coatings for engine parts, protection film 	
	Semiconductors Molding assist film for power semiconductors packaging 	
	Coating for electronic semiconductor wires	
	\cdot Air and liquid filtration filters used in the semiconductor industry	
	 Molded products for semiconductor equipment, tubes/release sheets used during semiconductor processing 	
	Advanced Semiconductor Packaging	
	 Pellicles for Semiconductor chip manufacturing 	
	 Seals, gaskets, O-rings, packings, linings and coatings for pipes and joints for semiconductor manufacture 	
	 Encapsulating material for UVC LED chip 	
	 Surface coatings of fixing films 	
Electronics	 Batteries Solid-state lithium batteries for electric vehicles 	<u>B</u>
	 Printed Circuit Boards Mold release film in compression lamination of printed circuit boards, in semiconductors, optoelectronics components, standard packaging to protect memory chips and sensor devices used for mobile devices, data centers, and LED lens production 	
	Substrate for print circuit board	
	 Sound transmission membranes in circuit boards, antennas for mobile phones, technical / industrial linings, electromagnetic flowmeters 	
	Cables & Wire, Other	
	 Coating material for wires, coaxial cables and various other cables for chemical resistance conforming with international factory mutual standards (fire risk reduction) 	

Sector	Representative application(s)	Attachment
	 Heat-resistant sheath wire in electronic equipment operating at high frequencies and high temperature 	
	Optical fibers	
	 Antifouling and mold-release coating agent for touch panel glasses, lenses and mirrors; functional anti-smudge coatings applied to various substrates (e.g. glass, metal, plastic), removing sebum and fingerprints on exterior parts (e.g. cover glass, housing, camera module in portable devices) especially smart phones and other touchscreen applications; coatings for automotive use (e.g. instrument panels with touchscreen interface); adhesion prevention for glass and parts for multifunctional printers 	
	Plastic optical fiber (POF) in telecommunication	
	 Coating of special optical cables called "buffer tubes" 	
Communications	Coating of signal cables	<u>C</u>
	 Tubes and machine or injection molded parts, printed circuit boards material for use in high-speed communication technology 	
	Tubes, catheters, etc	
Medical devices and life sciences	 Catheters for intravenous and inside body interventions; small "non-kink" tubes; endoscopy; pancreatic and biliary stents; foreign body retrieval devices; balloon dilators; needles, brushes and specialty items; single use snares in colonoscopies; endoprostheses 	
	 Gaskets; diaphragms in medical ventilators/respirators and sterile syringe filters; membrane filters for sterile venting of gases, aggressive fluids, acids & non-aqueous solvents, gas filtration and aerosol sampling; humidifier/drier membranes used in CPAP (Continuous Positive Airway Pressure) machines; breath gas analyzers. 	<u>D</u>
	Artificial blood vessels	
	 Dialysis-related devices 	
	 Surface coating for medical devices 	
	 Packaging of terminally sterilized medical devices 	
	Coatings for biochip devices	
	Equipment & Manufacture	
	Laminate rubber stoppers	

Sector	Representative application(s)	Attachment
	Wire sheath material for medical equipment	
	Humidification or conditioning of various medical gasses	
	 Tubes, seals, gaskets, O-rings, lining of vessels, pipes, valves, hoses, process control devices, pumps, gas scrubbers, dryers, evaporators, heat exchangers and connectors for pharmaceutical manufacturing equipment Coating for image plate of medical printing film 	
	 Roofing and façade material for membrane structures such as train stations, sport stadia, shopping malls, airports, exhibition centers, bridges, greenhouses for commercial-scale growth of fruits, vegetables, flowers, etc. 	
	 Sports facilities and sewage disposal facilities 	
Construction and	 Light weight and composite constructions (development / future application) 	E
Infrastructure	Heat-resistant flexible wire	
	 Architectural coatings and paints 	
	Sliding bearings	
	Anti-graffiti overlay for traffic signage / safety	
	 Laminate films to provide antifouling and touch-proofing of metals, fire and heat resistance and oil resistance to kitchen hoods 	
	Food industry	
	 Seals, O-rings, gaskets, tubing and pipes, valves and fitments, tank linings, sensor covers, and non-adhesive coating for food equipment 	
Food Contact	Lining of food cans	F
and Processing	Ion exchange membranes	<u>1'</u>
	 Industrial-scale food and feed processing equipment, in seals, tubes, pipes, hoses, o-rings, gaskets, valves and fitments, conveyor belting, tank lining, filter membranes, sensor covers, lubricants and equipment specific to food and feed transport. 	
Energy	Oil & Gas and Mining	
	 Cables and cable outer "jackets", including sub-sea heating cables and self-regulating heating cables. 	<u>G</u>

Sector	Representative application(s)	Attachment
	Structural or fluid handling components	
	Coating resin material for electrical wires for crude oil drilling	
	 Wire insulation for downhole sensor cables, extract duct coating, trace heating for cold production areas, and self-regulating heating cables for cold areas 	
	 Dehumidification of sample gas for analysis 	
	 Packers, blow out preventers, seals, gaskets and O-rings 	
	Nuclear	
	 Cables and wires, including cables of control rooms, sensor cables, and general cables for the industry. 	
	Photovoltaics and Wind	
	 Building integrated photovoltaic (BIPV) modules, solar panels, molding wind turbine composites 	
	 Next-generation solar cells for BIPV and megasolar projects 	
	Coatings for PV modules	
	 Coatings for wind turbine blades and towers 	
	Hydrogen	
	 Proton Exchange Membrane Electrolyzer (PEMEL): water electrolysis, electromechanical hydrogen compressors and purification and electrolysis plant for renewable hydrogen production 	
	Other	
	 Separator for REDOX flow batteries 	
	 Exchange Membrane Electrolyzer for anion exchange membrane water electrolysis (AEM) 	
	Binders for electrode materials in batteries	
	 Release films used for photovoltaic cells, proton exchange membrane of fuel cells, Li-ion batteries 	
	 Key polymer electrolyte, also used as a key ingredient of catalyst ink's binder for Proton Exchange Membrane Fuel Cell (PEMFC)) 	
	· Coating of tidal power cables	
	Humidification or conditioning of various gases	

186

Sector	Representative application(s)	Attachment
	Chemical Industry	
	 Coating material for industrial wires, coaxial cables and various other cables 	
	 Hoses, tubes, gaskets and other seals 	
	Distillation column packings	
	 Rotolining or electrostatic coating, e.g., vessels, tanks, pipes, tubes, elbows, complex manifolds, pump casings and filter housings 	
	 Electrodialysis processes for wastewater treatment (desalination and salt concentration) and separation of organic components and inorganic salts (cosmetics, medicals, food, medicine, and purification of intermediates in inorganic synthesis) 	
	 Expansion joints, compensators and bellows 	
	 Bearings, ball joints, hinges, calipers, valves 	
Manufacture/	 Ion exchange membranes for production of caustic soda, potash, chlorine for use in end products such as: paper, aluminum, wind turbines, hydrazine used in fuel cells, rocket fuels, pharmaceuticals, antiseptics, nylon, EDTA, soaps, cleaning agents, household bleaches and germicides, and many organic and inorganic chemicals 	H
0	Metal Plating	
	 Acid recovery (acid and metal salt separation process by electrodialysis/diffusion dialysis) 	
	Water treatment	
	 Industrial water treatment; electrodialysis 	
	Lubricants	
	 Solid lubricants where other lubricants are not suitable; thread seal pastes 	
	 Coatings for improved rub and scuff resistance, reduction of friction, chemical inertness and temperature resistance and to impart release characteristics (e.g., mold release agents) 	
	Misc. Equipment	
	 Manufacturing equipment such as belts, rollers, heat-sealers in dying, laminating, drying processes 	
	 Dryers used to remove moisture from gas samples prior to analysis to improve signal resolution 	

Sector	Representative application(s)	Attachment
	 Dehumidification or humidification pretreatment in pneumatics or compressed gas 	
	 Manufacturing equipment, including seals, hoses, gaskets, o-rings, valves, linings in vessels, pipes, reactors, process control devices, pumps, gas scrubbers, 3D printers 	

188

We would welcome the opportunity to discuss this request with you, and we would be happy to provide you with additional information regarding the products and applications identified in this submission. Should you have any questions or concerns, please reach out to Ahmed El Kassmi at 610-423-4312 or by email at <u>ahmed.elkassmi@agc.com</u>.

Sincerely,

Christopher F. Correnti President and CEO AGC America, Inc.

t. St Km

Ahmed El Kassmi, Ph.D Director, Product Stewardship & Regulatory Affairs AGC Chemicals Americas, Inc.

Attachment A -- Transportation Applications

Safe, reliable and accessible transportation is the lifeblood of our economy and is an essential feature of modern life. Fluoropolymers perform critical and irreplaceable functions for all modes of transportation.

Fluoropolymers are used for sheathing for cable and wire used in motor vehicles (on- and offroad), civil and military aircraft, spacecraft, watercraft, and other modes of transportation. Fluoropolymers are essential for this application because they provide flexibility plus durable and reliable protection against extreme temperatures, aggressive fluids such as hydraulic fluids and fuels, humidity, vibration and compression. For example, aircraft wires must comply with the international standard SAE AS22759, which requires temperature resistance of -65 ~ 200 °C, and similar high performance is required for electric vehicle (EV) cables. Potential alternative materials, such as polyvinyl chloride, polyethylene, alkane-imide and polyamide are not suitable for these applications due to one or more of the following deficiencies: inadequate heat resistance, poor arc resistance, poor moisture resistance, or cracking. Similarly, fluoropolymers are essential to satisfying international standard for automotive cables, ISO 6722-2, which cannot be satisfied by these potential alternatives. Only SIR (silicone rubber), polyether ether ketone (PEEK), mica, and ceramic can provide similar heat resistance as compared to fluoropolymers, however they fail to ensure similar mechanical strength and chemical resistance. Thus, the use of potential alternatives would lead to premature deterioration of the wire sheath material (insulation degradation or insulation breakdown), which could lead to electrical leakage, resulting in equipment failure, electrical shock and fire hazards. Furthermore, fluoropolymers have superior electrical properties (low dielectric constant and low dielectric loss tangent) compared to potential alternatives (dielectric constant below 2,1 kHz and dielectric loss tangent below 0.0002 kHz). This becomes increasingly important as larger volumes of data are transmitted and the wavelengths used shift toward higher frequencies, which are more susceptible to attenuation during transmission. Fluoropolymers are the material with the least loss during this transmission and are the most suitable insulating material for high frequencies.⁵

Fluoropolymers also provide critical functionality for hoses, fuel lines and gaskets and seals (such as crankshaft seals, transmission seals, pinion seals, and shock absorber seals) which

⁵ Notably, only fluoropolymers can meet the following international standards for automotive cables: ISO 6722-1; ISO 6722-2; LV 112-1; LV 112-2; LV 112-3; LV 112-4; LV 122; LV 212; LV 213-1; LV 213-2; LV 216-1 and LV 216-2.

require the following combination of properties: durability, heat resistance, oil and fuel resistance, flexibility and sealing. These properties are essential to assure that vehicle fluids do not leak, resulting in potential safety concerns, human and environmental exposures, decreased reliability and increased repair costs. For consumers (and personal vehicles), increased repair costs would disproportionately impact disadvantaged communities. Only fluoropolymers can provide the required properties to satisfy the relevant standards for Rubber Products in Automotive Applications (ASTM D2000). According to the standard, in operating environments surpassing 250 °C, type H or higher (required heat resistance) and class K (required oil resistance) should be used, meaning that only fluoroelastomer-based rubber can meet the performance level. Non-fluorinated materials, such as silicone, do not provide the same level of performance, and do not fulfil industry standards. At the current time, there is no prospect of technically or economically feasible substitution.

In fuel lines, the use of fluoropolymers ensures the necessary flexibility without the need for a corrugated structure, which reduces the loss of efficiency due to air contamination and eliminates the need for replacement as there is no deterioration. The primary alternative, PA6 (polyamide 6), has poorer barrier performance therefore increasing the likelihood of fuel vapor leaking into the environment. This is essential as environmental requirements for motor vehicles, in terms of fuel emissions reductions, become increasingly stringent.

Fluoropolymer membranes are also essential for fuel cells used in transportation, providing essential release properties, chemical durability to solvents of catalyst ink, and non-contaminating to platinum supported carbon and ionomer binders for suitable catalyst layer formation of fuel cells. The operating conditions inside fuel cells are harsh, with OH radicals being constantly generated at operating temperatures of 60 to 100 °C. Non-fluorinated polymer materials can only be used for short periods of time, as the polymer decomposes, rendering operation impossible. For example, the Fenton test (test method for fuel cells) shows that hydrocarbon-based materials degrade five times more than fluorinated materials. If non-fluorinated materials such as PEEK-(Polyetheretherketone) based hydrocarbon electrolyte polymers are used in fuel cell vehicles, the critical components of the fuel cell (stack parts) will need to be replaced more frequently, which means that the operating time of the fuel cell vehicle would not be assured and the amount of waste generated considerably higher. Fluoropolymer membranes are the only materials that can withstand operation for tens of thousands of hours in the presence of radicals. They are also the only materials that allow the cell to operate at high power density.

13

190

The US Department of Energy (DOE)⁶ standard for fuel cell vehicles include high performance and continuous service life, and fuel cells using fluoropolymer ionomer membranes can be used continuously for more than 25,000 hours. In addition, vehicles need to be able to generate electricity instantaneously, which solid oxide fuel cells are not able to do, making them unsuitable for automotive applications. Hydrocarbon-based electrolytes are not durable for the required length of operation time in stationary applications such as back-up power for datacenter. Although other types of stationary power generation exist, such as SOFCs (solid oxide fuel cell) made of inorganic materials, they are not suitable for generating instantaneous power. Fluoropolymer humidifier/drier membranes are also essential in fuel cell electric vehicles to control moisture of the incoming hydrogen, which is necessary to ensure reliable operating conditions of the fuel cell.

Fluoropolymers are also essential to EV batteries, which need higher voltages and, in turn, require greater heat resistance and superior insulation properties for sealing materials. Fluoropolymers provide sufficient heat resistance and insulation to withstand high voltages associated with EV batteries. They are also essential for use as binders in EV batteries, due to their ability to function in strong oxidization environments. None of the potential alternatives to fluoropolymers simultaneously meet the required chemical, heat, and voltage resistance, as well as adhesion to the substrate. If used as binders, these alternatives will be oxidized and tattered. Fluoropolymers used as a binder in Li-ion batteries provide extended lifetime and performance over a broad range of conditions. Those batteries are the central component of EV and their use is expected to increase significantly until 2030 and beyond.

In addition, fluoropolymers are required to bring ORFBs (Organic Redox Flow Batteries) to the market, to provide superior performance to rechargeable batteries and reduce greenhouse gas emissions. The use of fluoropolymer anion exchange membranes will also offer high durability and stability in the ORFB application. These applications - highly dependent on the use of fluoropolymers - will be the cornerstone of the decarbonization of US transportation. Also, for power semiconductors used in fuel cell vehicles and battery electric vehicles, fluoropolymer film is essential to provide the required properties of non-adhesion, high melting point (200-280°C) and mechanical properties at molding temperatures (100-200°C). Those properties are needed to prevent contamination of semiconductors and protect molding equipment and therefore ensure high performance and energy efficiency of fuel cell vehicles and battery electric vehicles.

⁶ Fuel Cell Technologies Overview, US Department of Energy, Arlington V.A., 2023. <u>Fuel Cell Technologies Subprogram Overview</u> (energy.gov) <u>https://www.hydrogen.energy.gov/pdfs/review23/fc000_papageorgopoulos_2023_o.pdf</u>

Fluoropolymers are also essential for aircraft exterior coatings, to protect the aircraft from harsh environmental conditions during flights at high speed of about 800 to 900 km/h (e.g., temperature spikes and drops, atmospheric pressure, friction, strong ultraviolet rays, dust, rain, hail, etc.). They also prevent oxygen seepage, reducing the likelihood of corrosion of the fuselage. Fluoropolymer coatings also provide improved fuel efficiency due to reduced icing (wings and fuselage) and high resistance to physical friction (e.g., wind at the wing sections). Use of fluoropolymer exterior coatings also allows for reduced volatile organic compounds (VOC) and CO2 emissions by lengthening the period of re-coating, and reducing the energy demand required for repainting. Fluoropolymers are difficult to replace for this application due to the exacting industry standards required to be met.^{7,8,9,10} Fluoropolymer coatings are also important for aircraft interiors, to provide excellent stain resistance as well as color and gloss retention, while satisfying applicable smoke and fire prevention criteria.

192

There are no suitable fluorine-free alternatives available that would provide the same level of protection as fluoropolymer coatings. Only two-component polyurethane paints, that were used before the introduction of fluoropolymer coatings, have been identified as readily available and potential alternatives. However, using non-fluoropolymer materials that are less weather resistant than fluoropolymers will increase the maintenance frequency significantly. A comparison of high weather resistance, chemical resistance, and room temperature baking and manufacturing show that non-fluoropolymer material has a product lifecycle of approximately 5 years, compared to 10 years for fluoropolymer coatings.^{11,12}

Similarly, fluoropolymer-coated automotive films provide weather, heat and corrosion resistance that performs 3-5 times better than available alternative materials, ensuring the longest lifetime of vehicles, the least efforts and costs for removing and re-applying the film to protect the car's appearance in the long term. Non-fluorinated alternatives do not provide the same level of performance. For example, polyurethane film causes reduced performance (e.g., deteriorated dirt

⁷ Aerospace Industry Standards, NQA, <u>What Standards Apply to the Aerospace Industry? https://www.nqa.com/en-us/certification/sectors/aerospacehttps://www.nqa.com/en-us/certification/sectors/aerospacehttps://www.sae.org/standards/aerospacehttps://enhancequality.com/standards/aerospace</u>

us/certification/sectors/aerospacehttps://www.sae.org/standards/aerospacehttps://enhancequality.com/standards/aerospace -quality-standards/https://www.iso.org/ics/25.220/x/

⁸ Aerospace Quality Standards, QSE. <u>Quality Systems Enhancement | Aerospace Quality Standards (enhancequality.com)</u>

⁹ ISO-25.220, Surface treatment and coating including processes and equipment for surface treatment and coating. <u>ISO - 25.220</u> - <u>Surface treatment and coating</u>

¹⁰ ISO-25.220.60, Organic coatings. <u>ISO - 25.220.60 - Organic coatings</u>

¹¹ Wind Hullo Topcoat. <u>wind hullo.pdf (nttoryo.co.jp)</u>

¹² Wind Hullo Topcoat. <u>wind_hullo.pdf (nttoryo.co.jp)</u>

removal when insects adhere to the film), resulting in increased frequency of film replacement and manual cleaning. Acrylic films do not provide the same level of acid resistance that is required to protect the roof of a car. Finally, polyester films provide inferior protection of gloss in continuous accelerated weathering tests and natural exposure tests, and is inferior to fluoropolymers in terms of weather, heat and corrosion resistance, stain protection, and self-healing.

Representative GPC Brick Codes of CUU products:

As discussed previously, and consistent with conclusions of the Department of Defense, it is impossible to enumerate every individual product or product category in which the use of fluoropolymers is CUU. However, since DEP has requested that stakeholders identify CUU products by GPC Brick code or HTS code where available, provided below is a list of GPC Brick codes for products or product categories in the transportation sector that are representative of the range of products in that sector that are CUU.

GPC Brick Codes: 10008049; 10005232; 10005233; 10006383; 10006382; 10005131; 10006846; 10005132; 10003084; 10003083; 10003080; 10002906; 10003105; 10003106; 10003762; 10003029; 10006374; 10008291; 10006772; 10006373; 10006773; 10008339; 10008050

Attachment B – Electronics Applications

194

Safe, reliable, affordable and durable electronics and electrical components are essential to virtually all facets of modern life, and fluoropolymers are essential to enabling those technologies. This is exemplified by the CHIPS Act, which is intended to ensure US leadership in "the technology that forms the foundation of everything from automobiles to household appliances to defense systems."¹³

Semiconductors

Fluoropolymers are essential in the manufacturing of semiconductors, in wet cleaning and wet etch processing equipment, where high purity, high chemical and temperature resistance and low flammability are required. Fluoropolymer resins with an adhesive function provide the ability to bond to metals including copper and other polymers (e.g., polyimides and polyamides). Adhesive fluoropolymers provide critical benefits as coatings for chemical resistance. They are essential because of their ability to not react with other chemicals, not to leach contaminants that could potentially negatively impact yield and to be stable under process conditions including elevated temperature. Fluoropolymer tubing additionally presents the advantage of being highly flexible, which allows for easier design and implementation in wet etch processing equipment and fluoropolymer coating on metal parts provides corrosion protection, allowing for increased efficiency as no primer or adhesive interlayer is needed.

Fluoropolymers are essential as pellicle films used in the photolithography process for the protection of photomasks from particle contamination in semiconductor lithography processing. They provide practical light resistance for the excimer laser in an environment that is irradiated with exposure wavelength ArF (193nm) and KrF (248nm), and achieve superior light transmittance through extremely high transparency (>95%). Additional essential performance requirements for pellicle film provided by fluoropolymers are uniformity of film thickness which helps avoid the tearing of the film, and low refractive index, and extinction coefficient which ensures that the light maintains a straight path without losing power. Fluoropolymer film

¹³ The White House, *FACT SHEET: CHIPS and Science Act Will Lower Costs, Create Jobs, Strengthen Supply Chains, and Counter China* (Aug 9, 2022) available at <u>https://www.whitehouse.gov/briefing-room/statements-</u> releases/2022/08/09/fact-sheet-chips-and-science-act-will-lower-costs-create-jobs-strengthen-supply-chains-andcounter-china/

coatings to a thickness of a few sub-microns, are essential for semiconductor innovation and associated node size reductions.

195

Fluoropolymers are critical as a UVC transparent window material or encapsulant for UVC LEDs to extract higher levels of light (i.e., to optimize the use of energy/electricity) from the UVC LED chip. Fluoropolymers are the only material that can simultaneously achieve the performance required for transparent encapsulants and for UVC LEDs, namely UVC durability, electrical insulation and water vapor barrier properties, which also ensure the proper functioning of the UVC LED. Synthetic quartz is not a suitable alternative for UVC-LEDs as it requires adhesives to be used as the encapsulation materials, which easily deteriorates with strong UVC light. Other potential alternatives such as acrylic resin, generally absorb the UVC light and cannot be used for this application.

Top Anti-reflective coatings (TARC) are widely used in the semiconductor industry, particularly in the manufacturing of semiconductors, integrated circuits, printed circuit boards, and other related components. TARC helps to reduce unwanted reflection of light from the surface of these materials, thereby improving optical performance and increasing efficiency. This coating is crucial for enhancing the functionality and guality of various electronic devices, ensuring better performance, and reducing the losses caused by reflections. The performance requirements of TARC material and its raw polymer are to simultaneously meet low refractive index, low surface energy, and solubility in water and developer. TARC material made of fluoropolymers has a unique performance superiority, such as low refractive index, low surface energy, and simultaneous solubility in water and developer. These performance requirements are directly related to the yield of commercial semiconductor manufacturing and process suitability. To our knowledge, there is no suitable alternative to fluoropolymer TARC material on the market. Similarly, BARC (Bottom Anti Reflective Coating) is an inadequate alternative to TARC, since BARC is only used for the production of certain semiconductors that have narrow patterning made by ArF immersion or EUV, as it requires a completely different manufacturing process and setting from those utilizing TARC made of fluoropolymers. Therefore, BARC is not considered a realistic and viable option for most semiconductor manufacturers to replace TARC. Furthermore, BARC is generally an inorganic layer stuck to the wafer and needs dry etching process to be removed from the wafer surface. On the other hand, TARC is easily removed together with photoresist at once due to performance requirements.

Thermal processes such as rapid thermal processing, Low Pressure Chemical Vapor Deposition, oxidation, diffusion and lamp annealing in semiconductor manufacturing processes require

18

significant chemical and heat resistance. The ultra-high temperature (up to 260°C), plasma resistance (exposure to O2 plasma, F2 plasma or a mixture of both) and insulation properties (high breakdown voltage) of fluoropolymers make them invaluable for semiconductor fabrication processes (and other industrial extreme high-temperature areas) requiring elastomer seals. Also of critical importance, fluoropolymers do not form particle contaminants because they have high chemical bonding energy, making them resistant to plasma cleavage. This ensures that no particles adhere to the wafer, causing malfunctions. To our knowledge, there are no potential substitute materials that satisfy these requirements.

196

Fluoropolymers are also essential for the packaging of semiconductors, as they are the only material that can provide the necessary properties of high-temperature durability, anti-static, easy release, and mechanical properties (e.g. tensile elongation of 600% or above, elastic modulus of 70MPa or below) to package semiconductors without deforming or damaging chips, particularly at high temperatures ranging 150 – 220 °C. Other films, such as polyethylene, polybutylene telephthalate (PBT), and polyvinyl chloride (PVC) have inferior mechanical properties and less flexibility at high temperatures compared to fluoropolymer film and can cause damage/deformation of chips and decrease in productivity due to oligomer contamination.

Fluoropolymers also exhibit superior electrical properties (low dielectric constant and low dielectric loss tangent) compared to other potential alternatives (dielectric constant around 2,1 and dielectric loss tangent below 0.0002). Those properties maintain signal integrity and reduce transmission loss, and they also have a low thermal expansion coefficient as heat is generated. As increasing volumes of data are transmitted, the wavelengths used are shifting toward higher frequencies, with higher frequencies being more susceptible to attenuation during transmission. Modified polyimide and liquid crystal polymers have been evaluated as alternative materials, but none of these materials has achieved electrical properties comparable to those of fluoropolymers. The dielectric loss tangent of both "alternative" materials is more than 0.001. High-speed data communication requires higher frequencies, so there is a possibility that communication speeds may reach a ceiling if fluoropolymers are not used. To our understanding, no alternative has been found to be able to meet one or more essential functional quality characteristics of fluoropolymers such as adhesion, dielectric constant and ability to process, and there is no prospect of technically or economically viable alternatives at present.

In addition to the critical functions described above, fluoropolymers also play an essential role in assuring the "clean room" environment necessary for semiconductor manufacture. Specifically, fluoropolymer membranes are used to meet the high-performance filter standard EN 1822 (ULPA,

HEPA) which is essential for semiconductor and LCD related plants and equipment. These fluoropolymer membrane filters combine high air permeability and collection efficiency, and can reduce power costs compared to non-woven filters and glass filters made of other materials. In addition to their superior performance, fluoropolymer filters do not have the potential to leach boron (B), which is present with glass filter media, and can adversely affect the performance of semiconductors. Similarly, filters with both high chemical resistance and filtration performance are required for filtration of chemicals used in semiconductors. Fluoropolymer membranes are among the few materials that can satisfy these requirements. Ceramic, a potential alternative, has high chemical resistance but is very expensive and therefore difficult to replace for economic reasons.

For more information on the importance of fluorine materials used in the semiconductor manufacturing process, please refer to the technical documents available on SIA (Semiconductor Industry Association) website.

Batteries

Fluoropolymers are essential components of high-performance lithium-ion rechargeable and lithium metal rechargeable batteries. High power and energy dense batteries require very thin high-performance gaskets. For gaskets to function optimally, proper thermal functionality is essential, for which a stable and compressive polymer providing a high degree of insulation to withstand very high currents of up to 280 amps is needed. Chemical resistance is also a requirement. The high compressive and moisture properties of fluoropolymers are required to enable adequate, reliable gasket performance. Other potential methods and materials such as multilayer construction do not provide long-term and leak-proof lining systems and would lead to frequent maintenance intervals. In addition, materials such as high-alloy steels (e.g., hastelloy, inconel, titanium, zirconium) are not sufficiently chemical-resistant.

For nickel-metal hydride batteries, the binder is required to have strong alkali resistance and the polymers need to be dispersed. This essential functionality is provided by fluoropolymers, which also may be used in the electrodes of lithium-ion batteries, where chemical resistance and low flammability are key requirements. Furthermore, to meet increasing performance demands, next generation batteries with higher functionality will need binder materials that can meet more exacting requirements in terms of alkaline solution concentration and voltage (oxidation potential of the cathode). Fluoropolymers are essential for providing these functionalities.

Studies assessing alternatives to fluoropolymer binders have been conducted without finding promising non-fluorinated alternatives.¹⁴ None of the potential alternatives simultaneously meet the required chemical, heat, and voltage resistance, as well as the adhesion to the substrate at a level comparable to fluoropolymer materials. Within battery applications, fluoropolymers are mainly used as binder because of their ability to function in strong oxidization environments. For lithium-ion batteries at positive electrodes, more than 4V is occurring, which causes oxidization. When applying non-fluorinated polymers as binder, these polymers will be oxidized and tattered. As holes are generated these polymers lose their function as a binder.

198

Printed Circuit Boards

Fluoropolymers are essential components of copper-clad laminates (CCL), the key material in printed circuit boards, because they combine the critical performance characteristics required for this application: heat resistance (solder reflow endurance temperature 300 °C), solder resistance, water resistance, good adhesion to copper foil, and low dielectric constant. We are not aware of suitable alternatives that provide equivalent performance and reliability. Fluoropolymers are also used to coat printed circuit boards to provide protection against moisture or other contamination that might lead to short circuit and device failure.

Wire & Cable

Insulating fluoropolymer coatings are essential components of wire and cable, to assure the safety of the structures within which wire and cable are used, and to comply with factory mutual standards including FM 4922 – the Global Specification for ventilation/duct extract systems. Fluoropolymer sheathing is essential for this because of their superior chemical and heat resistance and their non-flammability.

Fluoropolymer coated wire is rated to at least 260 °C, which provides the necessary protection for use in automotive, aerospace and industrial high temperature applications. These include thermocouples, self-regulating heater cables and any location where a temperature of above 200 °C is needed for extended periods of time. In addition, fluoropolymer coated wire is used in high voltage, high frequency heating cables, needed in many subsea applications that require high temperature resistance, low dielectric losses and the ability to withstand electrical and chemical breakdown over a long service life. Fluoropolymers are critical for achieving these performance requirements. Similarly, self-regulating heater cables are used for freeze

¹⁴ Application for Derogation from PFAS Restrictions For Specific Uses in BATTERIES, Battery association of Japan, available at: <u>https://www.baj.or.jp/about/ades5k0000001vxx-att/ades5k0000001wa9.pdf</u>
protection and process maintenance. In high temperature and high chemical resistance heating, fluoropolymers are necessary to both conduct electricity in the inner layer of the cable, as well as provide insulation in the outer layers.

Because of their low dielectric constant, fluoropolymers used in wires and cables confer a low dielectric loss up to 250 °C. Potential alternatives such as polyolefin-based materials do not offer a viable substitution potential, as their applications are limited to temperatures below 80-100 °C. Polyimide (PI) and liquid crystal polymers (LCP) are also potential alternatives to fluoropolymers for wire and cable and electronics coatings more broadly. However, both PI and LCP are unsuitable for many applications, due to their high dielectric constant.

Finally, as a technology enabling future innovations, fluoropolymer coated wire and cable is ideally suited for use in electric engines in aerospace applications. These require high temperature, high voltage and high frequency low loss performance. Partial discharge issues affect these cables at high altitude so semi conductive fluoropolymers are a promising solution. As such, fluoropolymers will be a critical material in the long-term decarbonization of air-travel.

Other

Electronic equipment with touchscreen interfaces, such as smart phones and tablets, require a smudge-resistant, easy-to-clean surface to maintain optimal performance. Fluoropolymerbased functional coatings are both hydrophobic and oleophobic and provide excellent waterand oil- repellency to such surfaces by forming an extremely thin monomolecular layer on the surface. Moreover, fluoropolymer-based functional coatings impart these benefits with no change in optical properties and they provide high resistance to abrasion (e.g., steel wool), UV exposure (e.g., outdoor sun light), and chemicals (e.g., acid, base, and a set of solvents).

Conventional anti-fouling and mold-release coatings exhibit low abrasion resistance, which causes them to wear-off quickly from friction as they are used. This makes it necessary to apply overly thick coatings or reapply frequently to keep the desired effects. Additionally, some coating agents have no oil repellency, a drawback that makes them prone to build up fingerprints, sebum, and other oily smudges. Other possible alternatives include washing with mild soap or wiping with alcohol; however, these are liquid-based and moisture, or excessive wiping might cause damage to the equipment.

199

Representative GPC Brick Codes of CUU products:

As discussed previously, and consistent with conclusions of the Department of Defense, it is impossible to enumerate every individual product or product category in which the use of fluoropolymers is CUU. However, since DEP has requested that stakeholders identify CUU products by GPC Brick code or HTS code where available, provided below is a list of GPC Brick codes for products or product categories in the electronics sector that are representative of the range of products in that sector that are CUU.

200

GPC Brick Codes: 10005757; 10005754; 10005759; 10005758; 10005541; 10000546; 10000704; 10000548; 10008395; 10005211; 10008390; 10008394; 10005661; 10005662; 10005667; 10005559; 10008363; 10001122; 10001123; 10001125

Attachment C – Communications Applications

Fast, reliable data and voice communication is an essential feature of modern society, and a major contributor to health and safety. Fluoropolymers are irreplaceable in enabling this technology.

In the telecommunications sector, fiber optics is a critical technology allowing the fast transmission of large amounts of data. Amorphous fluoropolymers are used in plastic optical fiber cables due to their excellent light transmission. As data transmission speeds increase (>10Gbps), optical data transmission will become more efficient and low attenuation of light rays in the 650-1300nm laser wavelength range for data communication is required. Fluoropolymers provide this functionality. In addition, when wiring indoors or in automobiles or aircraft, data must be transmitted correctly and reliably even when the cable is bent because it passes through narrow spaces. Plastic optical fibers made of fluoropolymers enable the necessary flexibility and durability, whereas potential alternatives cannot provide that required functionality. For example, acrylic resin and quartz glass are considered as alternative candidates for optical fibers. However, acrylic resin is not suitable for high-speed data transmission due to its high transmission loss in the 650-1300 nm range. Meanwhile quartz glass is not suitable for installation in confined spaces, e.g., indoors, in automobiles and airplanes, because of safety risks stemming from reduced amounts of information being transmitted (i.e. information exchange in airplanes and cars is lost) and its intrinsic risk of fiber break due to bending.

Fluoropolymer "buffer tubes" are also used to hold and carry fiber optic cables to protect them from the potentially harsh adjacent environment and thereby enhance the reliability and integrity of data being transmitted. Similarly, fluoropolymer insulation is critically important for tidal power/signal cables, to provide temperature and chemical resistance necessary for protracted exposure to sea water. More generally, fluoropolymer sheathing also provides excellent dielectric properties and therefore improved performance for high-volume data transmission and connectivity.

Fluoropolymer coatings on circuit boards also ensure low signal loss, which is essential to the future of 5G or higher transmission speeds. By comparison, potential alternatives are inadequate. For example, Polyimide (PI) has a high dielectric constant of 3.0 due to the presence of polar groups in its structure and cannot be used for high-speed communications after 5G, while Liquid Crystal Polymer (LCP) has a high dielectric constant of 2.9 and also

201

cannot be used. Fluorine has low dielectric loss due to its low polarity and is essential in the 28 GHz band used for high-speed communications after 5G. In high-speed wireless communication signal transmission, the characteristic impedance of printed circuit boards must be matched to 50 Ω . For this purpose, it is important to have a low dielectric constant, as provided by fluoropolymers.

202

Representative GPC Brick Codes of CUU products:

As discussed previously, and consistent with conclusions of the Department of Defense, it is impossible to enumerate every individual product or product category in which the use of fluoropolymers is CUU. However, since DEP has requested that stakeholders identify CUU products by GPC Brick code or HTS code where available, provided below is a list of GPC Brick codes for products or product categories in the communications sector that are representative of the range of products in that sector that are CUU.

GPC Brick Codes: 10001379; 10001380; 10001382; 10003779; 10001385; 10001386; 10001198; 10001123; 10001122; 10001126; 10001172; 10001170; 10001124; 10001116; 10001141; 10001142; 10001145; 10006276; 10001147; 10006743

Attachment D – Medical and Life Sciences Applications

203

Medical devices and the equipment and devices needed for medical and life sciences research are, *per se*, essential to health. Many of these technologies would not be possible without fluoropolymers.

Fluoropolymers are essential components of endoscopes, catheters, laparoscopic devices, stents, balloon dilators, needles, brushes, pacemakers, artificial blood vessels, dialysis-related devices, stent surface coating and other items inserted or implanted into the body for diagnostic or therapeutic purposes. Fluoropolymers are necessary for these applications because of the combination of properties they possess. Specifically, they are biocompatible, resistant to contamination and easy to clean, resistant to bodily fluids as well as chemicals (such as chemical sterilizers) and irradiation, do not degrade in heat (and are therefore autoclavable), corrosion resistant, and have a low dielectric constant and therefore superior electrical insulating capabilities. Similarly, fluoropolymers do not stick to surfaces and are anti-kinking. These properties are of utmost importance for devices requiring high lubricity and flexibility in navigating human physiology. Potential alternatives cannot provide the same functionality as fluoropolymers in these critical applications. For example, the low mechanical strength and tearability of silicone-based materials agents can lead to higher risks of contamination.

Fluoropolymers are also used as wire coating materials for medical equipment. Medical equipment has many hinge parts that bend and stretch, requiring high mechanical strength in addition to insulation and flame resistance. Silicone materials are known as alternatives, but they are not used due to their low mechanical strength and tear resistance.

Biochip or analysis chips (microfluidic devices) for medical and DNA diagnostic applications use fluoropolymers to impart water and oil repellence and electrical insulation. By forming a fluoropolymer coating on a glass surface, it is possible to produce fine hydrophilic / hydrophobic patterns that serves as a dielectric, hydrophobic surface in electrowetting. The fine patterns ensure that a fluorescence observation can be carried out. Fluoropolymers also provide low autofluorescence and a refractive index which is close to that of water (1.34), which ensures that it can easily be read with a microscope. Furthermore, due to its wettability control, fluoropolymers enable a change of wetness under an electric voltage, which allows for the manipulation of microscopic droplets. Potential alternatives studied to date demonstrate inferior or inadequate performance. For example, Parylene and PDMS lack the required water and oil

repellency, anti-biofouling property, and chemical resistance for electrowetting on dielectric (EWOD) devices, and glass substrates lack the required high water and oil repellency, only reaching contact angle of 44 degree for water and 21 degree for oil (n-hexadecane).

204

Fluoropolymer membranes are also essential in gas analysis and applications requiring humidification and/or dehumidification. In the medical sector, breath gas analyzers are needed to monitor the effects of drugs on patients, metabolism and other diagnostic purposes. Humidifier / drier membranes have a key role in controlling the level of moisture in oxygen or other gasses administered to patients and can be used in moisture-wicking sampling lines for intubated and non-intubated patients in low-and high-humidity applications. There are no adequate substitutes for these applications. For example, hollow fiber humidification modules present risks of oxygen leakage. In addition, potential alternatives provide lower detection accuracy and response performance of capnography and asthma analyzers, leading to impaired patient monitoring. Fluoropolymers are needed for high water vapor selective permeability, high separation ratio with other component gases, and a non-porous membrane to prevent the permeation of bacteria.

Fluoropolymer coatings also play an important role in diagnostic imaging, by preventing contamination or soiling of the image plate. Without the protection of a fluoropolymer coating, if contamination occurs at the time of imaging, the patient may have to undergo additional imaging or, even worse, the distortion in an image may lead to misdiagnosis. To our knowledge there are no suitable alternatives for diagnostic imaging plates that provide the comparable protection against surface contamination.

Representative GPC Brick Codes of CUU products:

As discussed previously, and consistent with conclusions of the Department of Defense, it is impossible to enumerate every individual product or product category in which the use of fluoropolymers is CUU. However, since DEP has requested that stakeholders identify CUU products by GPC Brick code or HTS code where available, provided below is a list of GPC Brick codes for products or product categories in the medical and life sciences sector that are representative of the range of products in that sector that are CUU.

GPC Brick Codes: 10000849; 10000852; 10000847; 100005844; 10008118; 10000456; 10000457; 10000912; 10000922; 10000681; 10000901; 10000883; 10000916; 10000877; 10000878

Attachment E – Infrastructure and Construction Applications

205

Reliable construction and infrastructure form the backbone of modern society and are essential to its continued functioning and existence. Fluoropolymers play an essential role in preserving and protecting infrastructure and enabling the reliable, effective and sustainable construction practices that are essential to the continuation of modern society.

Fluoropolymer-based coatings (FBCs) offer superior performance, service life, sustainability, appearance and value for applications on a wide variety of metal substrates used in commercial and monumental building projects. These fluoropolymer-based systems include film-forming binder resins used in settings where extreme durability and lifespan of several decades or more are needed to provide substrate protection. FBCs extend the lifespan of the underlying materials and are a critical specification for certain products and end markets. FBCs can be applied to a variety of components used in projects ranging from pre-engineered metal buildings to municipal arenas and skyscrapers. Important properties that FBCs enable for construction include, but are not limited to the following:

- Adhesion, flexibility, formability, abrasion resistance, hardness and impact resistance;
- Resistance to chemicals, flame spread/surface burning; and
- Durability as demonstrated by UV-resistance, film integrity, low film erosion rate, humidity resistance and corrosion resistance.

FBCs have been shown not to be susceptible to attack by UV light, which results in a coating that is highly resistant to degradation upon exposure to sunlight, unlike virtually all other polymers. This property provides a very high resistance to fading and chalking as well as very good long-term maintenance of gloss and color. Apart from being highly resistant to UV light, the FBCs are also highly resistant to many chemicals and can have excellent stain resistance. Due to these superior qualities, FBCs also tend to carry a premium price compared to most other coating systems. Because of their solar reflectance, FBCs used on roofing also offer the additional benefits of lower energy usage from higher solar reflectivity and lower roof

temperatures and a lower carbon footprint, as well as lower maintenance costs and increased efficiency and longer lifespan of HVAC equipment.¹⁵

206

We are aware of no other coating technology that enables the performance parameters of durability and product longevity that are the defining characteristic of FBCs. Indeed, outdoor exposure testing demonstrates that FBCs have an erosion rate approaching 50 percent less than other coating technology options used in Infrastructure & Construction settings. This difference explains why FBCs have a life expectancy of 50 years or more in many settings compared to 20 years or less for some alternate technologies. This reinforces why FBCs are so unique and useful in the development of durable and essential building products.¹⁶ In addition, the FBCs long lifespan means less recoating is necessary and less VOC's are emitted (as a result of the recoating process) as compared to other alternatives.

Bridge structures clearly need durable coating performance to protect the painted metal substrate below and maintain the bridge's structural integrity. Any coating system must last a long time given how difficult, disruptive and expensive the recoat process is. Bridges are subject to highly adverse environmental conditions including high intensity sunlight, fog, rain, saltwater (coastal areas) spray and constant automobile exhaust among other stressor factors. The superior anti-weathering performance of fluoropolymers allows the paint system to prolong the bridge's service life and decrease the number of re-painting cycles, contributing to lower life cycle costs for municipalities (and residents) and reduced VOC emissions and lower CO2 generation. The same is true for water tanks and other large pieces of infrastructure. Available data conclusively establish that FBC's substantially outperform potential alternatives with respect to weather and corrosion resistance. For example, compared to commonly used urethane resin paints, the service life of this product can be expected to be three times longer, while reducing CO2 emissions by approximately 38% over 100 years and VOCs by about 50% in 100 years.¹⁷

Fluoropolymer films are used as essential structural elements, such as roofing, wall panels and canopies in a variety of buildings and structures, including large public structures such as sports stadiums, airports and other transportation hubs. The use of fluoropolymer films in this application has several essential benefits, including, crucially, a substantial reduction in the

¹⁵ White Paper on Fluoropolymers in Infrasturcture and Construction (December 2023), asvailable at https://fluoropolymerpartnership.com/wp-content/uploads/2023/12/PFP-White-Paper-on-Fluoropolymers-in-Infrastructure-and-Construction.pdf

¹⁶ Id.

¹⁷ Id.

volume of material, typically concrete, steel and/or glass, that would otherwise be required for a structure. The reduced use of concrete, steel and glass, in turn, results in lower CO2 emissions as well as less waste being generated and sent to landfill upon demolition of the structure. In addition, fluoropolymer films have excellent light harvesting properties for light with wavelengths from 300 to 2100 nm and at all angles of incidence. Several properties of fluoropolymer films, together, cause them to be uniquely suited to this application and therefore essential. These include:

207

- Excellent resistance to temperature extremes, weather, chemicals, stains and fouling ("self-cleaning");
- Superior durability -- retains at least 90% of its initial tensile strength and elongation after 30 years of exposure to rain and ultraviolet rays;
- Lightweight but strong, requiring minimal structural support, highly resistant to tear propagation, no breaking or splintering;
- Self-extinguishing, UL V-0 certified for combustion resistance, ASTM E 108 for Fire Test of Roof Coverings, designated as a non-combustible material (Japan), and European Combustion Test EU EN13501-1; non-flammable material certified B1 in DIN4202 part 1;
- Superior sound absorption.

Fluoropolymer film made of ETFE resin is also used in greenhouses, to improve the growth efficiency of fruits, vegetables and plants. This film has a higher light and UV transmission rate than glass, polyethylene or polycarbonate, allowing the full spectrum of sunlight to pass through the growing area. The result is increased production, earlier blooms, more colorful petals, sweeter fruit and higher quality vegetables.

Overall, potential alternatives to fluoropolymers (e.g., glass, PVC, fiberglass-impregnated membranes without a fluoropolymer layer for protection) are unsuitable. They present safety concerns in terms of increased flammability and degradation of components due to low flame resistance and low weatherability. They are also less weather resistant and require early replacement, which shortens the structure's lifespan by 15-20 years. For example, with glass and PVC, the product life is 10-50% of fluoropolymer film and the frequency of replacement is 2-10 times higher. They also contribute to greater CO2 emissions.

Representative GPC Brick Codes of CUU products:

As discussed previously, and consistent with conclusions of the Department of Defense, it is impossible to enumerate every individual product or product category in which the use of fluoropolymers is CUU. However, since DEP has requested that stakeholders identify CUU products by GPC Brick code or HTS code where available, provided below is a list of GPC Brick codes for products or product categories in the infrastructure and construction sector that are representative of the range of products in that sector that are CUU.

208

GPC Brick Codes: 100006895;10008143; 10005655; 10002687; 10002686; 10003942; 10003943; 10002433

Attachment F – Food Contact and Processing Applications

209

It is self-evident that food is essential to health. In modern society, it is also essential to be able to process, store, transport and prepare food in a manner that is sanitary and preserves the purity and cleanliness of our food. Fluoropolymers are an essential technology for achieving these requirements.

Fluoropolymers play an essential role in food production and processing, including in the applications listed below. Importantly, for all of these applications, the U.S. Food and Drug Administration (FDA) has extensively reviewed the safety and efficacy of the fluoropolymers in use, and has authorized their continued use.

- In food and feed production equipment, fluoropolymers are used as base film in ion exchange membranes for water treatment and separation of organic components and inorganic salts in the electrodialysis process.
- In linings of food cans, fluoropolymer film is laminated with steel plates and, due to their chemical and temperature resistance, function to prevent corrosion of the can.
- In tubes and hoses, fluoropolymers provide superior heat and water resistance and durability. This combination of properties is critical because sterile cleaning with high temperature steam is standard for food applications, and it is common to clean under high pressure steam conditions at 121 °C for 15 minutes (see, e.g., ISO 17665, JIS T 0816-1).
- In tubes, hoses, gaskets and other food processing and handling equipment, fluoropolymers provide excellent heat resistance, oil and chemical resistance, helping to assure the purity of foods being processed and prevent cross-contamination.
- In food contact surfaces including processing, storage and packaging, fluoropolymers provide non-stick efficacy, heat and chemical resistance, cleanability, wear (abrasion) resistance and superior friction coefficient. They are also highly effective mold release agents for plastic packaging, helping to assure the purity and physical integrity of the packaging.

Fluoropolymers are essential in these applications because of their unique combination of properties. For example, silicone materials have been tested but are not suitable due to their

low mechanical strength and tearability. Ceramic coatings provide sufficient heat resistance, but their release properties are inferior and insufficient. They are also more difficult to coat than fluoropolymers, making it difficult to coat complex and fine shapes evenly, and they are more expensive than fluoropolymers to coat. To our knowledge, no non-fluorinated material has so far been found with mold release and processability comparable to fluoropolymers coupled with heat resistance above 200 °C. Silicones and ceramics have been widely accepted and used for such applications in the past, but fluoropolymers have been used in applications where these materials are inadequate in terms of performance. Therefore, if the use of fluoropolymers is prohibited, the risk of process purity degradation, leakage and foreign material contamination due to accelerated component degradation will increase and have a significant impact on manufacturing control and maintenance systems.

210

Representative GPC Brick Codes of CUU products:

As discussed previously, and consistent with conclusions of the Department of Defense, it is impossible to enumerate every individual product or product category in which the use of fluoropolymers is CUU. However, since DEP has requested that stakeholders identify CUU products by GPC Brick code or HTS code where available, provided below is a list of GPC Brick codes for products or product categories in the food sector that are representative of the range of products in that sector that are CUU.

GPC Brick Codes: 10001951; 10001950; 10003690; 10003691; 10003694; 10003695; 10001938; 10002135; 10004016; 10004022; 10004054; 10004024;

10004054

Attachment G – Energy Applications

211

Modern society runs on energy. While we as a society seek to transition entirely to clean energy solutions such as solar, wind and clean hydrogen, until we complete that transition we rely on an "all of the above" approach to meeting our energy needs. Thus, the development, generation, capture, storage, transmission and distribution of all sources of energy are essential functions in our society, and fluoropolymers are essential to all of those activities.

Solar Panels

Fluoropolymers are critical components of solar panels. Lightweight, durable, transparent fluoropolymer films used on top of flexible or rigid solar modules have higher light transmittance than glass while providing long-term weather protection as well as a "self-cleaning" anti-fouling functionality. Moreover, because of their weather resistance, these fluoropolymer films retain their superior performance characteristics for more than 25 years. These functionalities combine to increase the electrical output of the solar panel by as much as 30%. In addition, because of their light weight in comparison to glass, fluoropolymer films open up more roof spaces to photovoltaic modules made with fluoropolymers, facilitating the expansion of solar panel deployment.

Because of their unique combination of properties, fluoropolymers are also uniquely well suited for use as back sheets (films) in photovoltaic solar panel construction. Back sheets are used on solar panels to help protect the solar cell from weather, humidity, and impact damage. They can also help provide electrical isolation for safety purposes. Thus, the proper choice of the back sheet can increase the panel life and reduce the cost of electricity generated from the panel over the solar panel cell's life. Materials used in this end-use should have significant UV resistance and stability, corrosion resistance and flexibility. Fluoropolymers satisfy all of these criteria. They are light in weight and have extended durability in full exposure to a variety of environmental conditions, including intense sunlight and heat.

Finally, fluoropolymers are essential components of mold release films and transport materials used in the production of solar cells. For example, in the production of solar cells, cell modules and surface materials such as glass are laminated with EVA (ethylene vinyl acetate resin) at 150 °C under vacuum. Because EVA is extremely adhesive under high temperatures, the

materials used for lamination and transport must have excellent non-adhesiveness and heat resistance. Furthermore, they must be organic materials that will not damage surface materials such as glass. At present, the only technically and economically feasible materials that provide these functionalities are fluoropolymers. For example, a material with excellent non-stick properties (low surface tension) is high-density polyethylene, but it does not have a heat resistance of 150°C and therefore is not a feasible alternative. The use of multilayer film, where several types of film are laminated together, has also been proposed as an alternative, but the technology to separate and recover each layer has not been established, making recycling difficult and reducing the recyclability after use.

Wind Turbines

Fluoropolymer coatings perform an essential function for wind turbines (both the blades and the turbine tower) by imparting weather resistance and durability as well as "self-cleaning" functionality. These properties are especially important for offshore windmills, to provide resistance to the corrosive effects of seawater. They are also especially important for the wind-cut parts of the blades in snowy locations, where snow would otherwise adhere to the blade and clump, forcing the turbine to stop operation due to the risk of falling snow.

Potential alternatives to fluoropolymer coatings are polyurethane and polysiloxane coatings. However, fluoropolymer coating systems are several times more durable than polyurethane resin coating system, meaning that polyurethane coatings would require several more recoatings during the 20-year design life of the wind turbine, as compared to fluoropolymer coatings. For wind turbines, which are often installed at high altitudes and in harsh environments, durability is an essential factor in their usefulness and efficiency.

Finally, fluoropolymers are essential components of mold release films and transport materials used in the production of wind turbine blades.

Clean Hydrogen

Fluoropolymers are an essential enabling material for several hydrogen technologies, including electrolysis membranes, electrodes, as well as sealing and lining equipment for hydrogen storage and transport equipment. Hydrogen is a highly flammable gas; therefore containing any potential leaks is essential for the safety of personnel and equipment. For this reasons, seals and linings in hydrogen transport and storage demand the superior chemical, heat and electrical resistance and overall durability of fluoropolymers.

212

The electrolyte membrane used in the PEM (Proton Exchange Membrane) water electrolyser that produces hydrogen from water is made of fluoropolymer, which is essential for the realisation of a hydrogen society because the PEM water electrolyser can operate at high current density, has high responsiveness to voltage fluctuations and is compact. Alternatives to hydrocarbon-based membranes have been proposed but they lack practical durability due to low thermal and chemical stability, difficulty in achieving high proton conductivity, low mechanical strength, etc. Without fluoropolymers, development and adoption of hydrogen generation, storage and transport technologies in the US will be severely constrained.

213

Batteries and Fuel Cells

As discussed more fully in Attachments A and B above, fluoropolymers are essential for use as binders, separator coatings, gaskets and seals, and electrolyte additives for batteries, due to their combination of chemical and heat resistance, dielectric properties, durability and adhesion to the substrate. None of the potential alternatives to fluoropolymers simultaneously meet these required performance characteristics.

In flow batteries, fluoropolymers provide the unique combined performance requirements for ORFB (organic redox flow batteries) systems, including (i) low voltage allowing for high energy efficiency; (ii) long lifespan, resulting in lower cost and environmental impact; and (iii) low activation crossover, allowing for higher efficiency and lower power consumption. Overall, fluoropolymers enable high retention of redox molecules, high chemical stability and good battery performance. ORFBs are set to replace vanadium-based RFBs (redox flow battery) on the market, with the following advantages:

- They do not use rare metals such as vanadium or rare materials
- The active materials can be synthesized organically, enabling significant cost reductions
- Higher voltage (up to twice)
- Higher durability, i.e. less waste generated
- Cost savings

Several non-fluorocarbon hydrocarbon anionic membranes have been tested for use in flow batteries. However, they cannot achieve the performance of fluoropolymers with respect to key parameters including voltage reduction, battery life and crossover reduction. Thus, there are no suitable alternatives for fluoropolymers in this application.

Nuclear

In nuclear generating facilities, fluoropolymers are essential for use in seals and wire jacketing, due to their heat resistance, chemical resistance, resistance to radiation, mechanical strength and insulation properties. This combination of properties is essential in the harsh environment of a nuclear reactor to mitigate against leakages and failure, and to assure safe and reliable operations. Potential alternatives are not suitable. For example, PE becomes brittle and breaks after irradiation, rendering it unusable. By comparison, fluoropolymers tested according to ASTM D2587 show that physical durability and integrity are maintained after 10[^]8 rads of irradiation.

214

Oil, Gas and Mining

Fluoropolymers are essential in a broad range of applications in the oil and gas extraction sector, as well as downstream, in transport and refining of petroleum products.

The "down hole" applications in which fluoropolymers are essential include packers, blow out preventers, seals, gaskets and O-rings, where heat resistance coupled with chemical resistance are required. Resistance to hydrogen sulfide is particularly important since it is a natural, poisonous by-product in many gas/oil wells and is highly corrosive. Fluoropolymers provide superior resistance to this chemical at high temperatures. In addition, high temperature steam is sometimes used to enhance the efficiency of oil well extraction particularly in older wells or where oil viscosity is high. Also in down hole applications, seals must be able to cope with a rapid gas decompression without losing seal integrity. In the worst case this could lead to an environmental incident or other safety-related issues. Explosive Decompression (ED) resistance or rapid gas decompression resistance is also a key property of fluoropolymers in these very harsh conditions. Fluoropolymers are unique in their ability to resist for prolonged periods the combination of stresses – chemical, thermal, and pressure – that are present in "down hole" applications. In many cases oil needs to be pumped up to the surface and "electrical submersible bags" are used in the drilling systems to house the pump mechanism. Fluoropolymers are used in the construction of this "electrical submersible bag", which needs to withstand the crude and other high temperature chemicals on the outside of the bag but also resist the "lubricating oil" from the pump on the inside. Fluoropolymers provide this dual resistance at high temperatures.

The internationally recognized industry standard for sealing materials used for oilfield equipment, i.e., NORSOK M-710, developed by the Norwegian Petroleum Industry, sets the

qualification requirements of non-metallic sealing materials and manufacturers, referencing ISO 23936. Fluoropolymers are the only polymers that can resist rapid expansion due to compressed gas absorption, which can cause seal failure, while maintaining necessary chemical resistance performance in environments where heat resistance is required above 200°C. Fluoropolymers are also used for wire sheathing in equipment used in these harsh operating environments where high heat and chemical resistance is required. Sometimes alternative materials such as polypropylene are mentioned, but they are poor at corrosion resistance and cannot be used in such environments, and no alternatives to fluoropolymers have been identified. Similarly, in the mining sector, fluoropolymers are essential to ensure the safe operation of equipment which needs to work continuously under extremely harsh and dangerous conditions with practically no margin for errors. Potential alternatives cannot meet the very high performance requirements for temperature (as high as 270°C), chemical and mechanical resistance.

Representative GPC Brick Codes of CUU products:

As discussed previously, and consistent with conclusions of the Department of Defense, it is impossible to enumerate every individual product or product category in which the use of fluoropolymers is CUU. However, since DEP has requested that stakeholders identify CUU products by GPC Brick code or HTS code where available, provided below is a list of GPC Brick codes for products or product categories in the energy sector that are representative of the range of products in that sector that are CUU.

GPC Brick Codes: 10008389; 10008393; 10008392; 10000546

Attachment H – Manufacturing & Processing Applications

216

Fluoropolymers are used in critical applications throughout the manufacturing sector, including the chemical industry, where they are essential because of their unique combination of performance characteristics. This section describes a representative cross section of the manufacturing and processing applications in which fluoropolymers play a critical role.

Fluoropolymers are essential for use in valve seals, pipe packing, gaskets and other seals in industrial processes that entail the use of hot, hazardous or corrosive liquids and gasses. Potential alternatives such as polyethylene or polyamide cannot provide the same degree of temperature and chemical resistance and mechanical strength as fluoropolymers, and their use in high stress industrial processes would result in an increased risk for leaks or catastrophic failures that could result in threats to human health and the environment. Compared to potential alternatives, fluoropolymers provide superior corrosion prevention, leak prevention, chemical emission reduction, lower maintenance costs and downtime, increased component life span, cleaner flue gas emissions and lower CO2 emissions, higher efficiency and production yield, improved quality and purity of products, and waste reduction.

In chemical, petroleum and pharmaceutical plants in particular, many systems need seals, linings, hoses, reactor vessels and other equipment that provide corrosion resistance, heat resistance, chemical resistance, mechanical strength and non-flammability. These critical functionalities are uniquely provided by fluoropolymers, which have a heat resistance of more than 250 °C, are chemically stable over a wide pH range of 1-13 and have virtually no leaching of impurities. In addition, fluoropolymers are particularly well suited to line complex shapes and parts in tanks, since they can be rotolined and spray coated. Fluoropolymers are similarly essential in for use as packing material in distillation processes, especially for very aggressive chemicals at high temperatures.

Potential alternative materials are not suitable, particularly for highly aggressive chemicals. In terms of heat resistance, ceramic and refractory fibers are sometimes used, but these materials create impurities and cannot be used in clean applications. Polyimide is inferior in terms of chemical resistance; silicones are inferior in terms of heat resistance; and PEEK which costs several times more than fluoropolymers, is difficult to process due to its high stiffness (flexural modulus 3,8 GPa) and high linear expansion coefficient (linear expansion coefficient 10.8).

Fluoropolymer ion-exchange membranes are essential for chlor-alkali electrolysis due to their low electric resistance and low susceptibility to impurities. These properties help achieve substantial energy savings, stable performance, and maintain 97-98% electrical current efficiency in the functioning of electrolyzers. Products made from chlorine and caustic alkaline are used in a variety of sectors, which include construction (PVC, aluminum, polyurethane thermal insulation), energy (e.g. wind turbines, hybrid car batteries purification, fuel cells), fertilizers and herbicides, health & personal care (water disinfection, soap manufacture, PVC blood bags, nylon surgical sutures), home care (dry cleaning, PVC windows, aluminum) pharmaceuticals (production e.g. aspirin, antibiotics, medicine packaging), safety (heat resistant and protective clothing police and fire services, Zinc chloride in forensic finger printing, sport (aluminum baseball bats, spandex, Aramid motor racing suits), technology (circuit boards, fiberoptics, semiconductors, smartphones), transportation (car parts, brake fluid, anti-freeze). This illustrates the importance and wide impacts of chlor-alkali electrolysis. The only potential alternatives to fluoropolymer ion-exchange membranes in this application require the use of either mercury or asbestos - both of which are highly restricted substances that present substantial risks to human health and the environment. Moreover, the mercury and asbestos technologies provide inferior performance (e.g., higher energy consumption, lower purity) than fluoropolymer ion-exchange membranes.

217

As discussed in Attachment G, above, fluoropolymer-based electrolysis membranes are also essential to the production of clean hydrogen, since membranes from alternative materials have lower chemical resistance and a much lower life span as well as significantly higher energy consumption (up to 50% higher) than those made from fluoropolymers. In addition, potential alternative hydrocarbon-based ion exchange membranes have low mechanical strength and are easily damaged during assembly, while fluoropolymer-based membranes have high mechanical strength which resists damage during assembly and maintenance (i.e. disassembly, cleaning, and inspection) and, thus, result in the creation of much less waste compared to non-fluorinated membranes. This is true for applications in all downstream sectors. Fluoropolymer membranes are also critical in wastewater treatment applications, for desalination of wastewater (where they can concentrate salinity to high concentrations while requiring low energy consumption, compared to potential alternatives) and metal plating (where due to their durability under oxidizing acid conditions and their chemical resistance more generally).

Fluoropolymers are also essential for various components used in a wide array of industrial applications, including:

40

- Plate heat exchangers, where fluoropolymers are typically used as gaskets or seals. Plate heat exchangers are used in many industrial applications to transfer heat between two fluids. Typical applications include: heating, ventilation and air conditioning (HVAC); refrigeration; engine or other mechanical cooling; food processing; oil production; boilers; aerospace, cryogenics; and pharmaceutical manufacturing. In many applications particularly those involving corrosive chemicals and high temperatures there are no suitable alternatives to fluoropolymers which, among other benefits, allow complex plate heat exchanger systems to run for much longer times at higher temperatures extending plant/production operation, reducing maintenance downtime and generating far less waste (spent gaskets) over the life of the production plant.
- **Stator/Mono pumps**, ranging from laboratory- to industrial-sized, particularly for operations involving corrosive chemicals, high temperatures or steam, where the chemical and temperature resistance of fluoropolymers is essential.
 - **Compressed gas storage and transportation equipment** which relies on the exceptional properties of fluoropolymers at cryogenic temperatures -- essential for equipment used in transporting, handling and storing liquefied gas (e.g., liquefied natural gas or liquefied hydrogen). At cryogenic temperatures (- 161 °C for liquid methane gas, -253 °C for liquid hydrogen) no other elastomeric materials are adequate.
- Hoses, tubes, gaskets and seals used in all types of industries for applications and processes that require: durability, flexibility, heat resistance (greater than 200 °C) and chemical resistance.
- **Rubber rollers** utilized in material handling, assembly, and manufacturing operations, especially those involving the use of acidic or alkaline chemicals and high temperatures, such as processes used in the manufacture of steel and aluminum.
- Wire and cable used in aggressive industrial environments. As discussed in Attachment A, above, fluoropolymers are essential in these applications because their unique combination of properties including durable and reliable protection against extreme temperatures, harsh chemicals, humidity, vibration and compression, as well as their flexibility and strength.

Lubricants used in bearings, ball joints, hinges, calipers, valves and other components utilized in a wide range of industries including automotive, aerospace, chemical processing, packaging, medical and mining, among many others.
Fluoropolymer lubricants impart superior surface lubricity and reduced wear over a wide temperature range; they are virtually immune from chemical attack, do not absorb water, have a wide temperature range (-190 °C to +260 °C), and have excellent weathering and aging characteristics.

219

- **Conveyor belts, coaters, and thermal processing devices** used in various manufacturing and processing applications where chemical and temperature resistance are necessary for example, in textile, upholstery, and carpet manufacture.
- **Humidifier / dryer membranes** used for compressed gasses, metals manufacturing and refrigeration units. Fluoropolymer membranes have high selective permeability to water vapor and high separation ratio with other component gases.

Representative GPC Brick Codes of CUU products:

As discussed previously, and consistent with conclusions of the Department of Defense, it is impossible to enumerate every individual product or product category in which the use of fluoropolymers is CUU. However, since DEP has requested that stakeholders identify CUU products by GPC Brick code or HTS code where available, provided below is a list of GPC Brick codes for products or product categories in the manufacturing sector that are representative of the range of products in that sector that are CUU.

GPC Brick Codes: 11040000; 11030000; 11020000; 10004016; 10005541;



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January 28, 2025

Commissioner Melanie Loyzim Maine Department of Environmental Protection State of Maine 17 State House Station Augusta, Maine 04333

Submitted via email: rulecomments.dep@maine.gov

Re: SUPPLEMENTAL COMMENTS -- Posting Draft Proposed Rule, Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances (December 20, 2024)

Dear Commissioner Loyzim:

AGC Chemicals Americas Inc. ("AGCCA") and its parent company, AGC America, Inc., (together, "AGC") offers the attached addendum to provide addition context for comments submitted earlier today, urging that "identical products should be regulated in the same manner" and that, more specifically, components of products exempt under Section 4(A)(5) through (13) should be exempt when used to perform the same or similar function in other products.

Thank you again for the opportunity to submit these comments. Should you have any questions, please reach out to Ahmed El Kassmi at 610-423-4312 or by email at <u>ahmed.elkassmi@agc.com</u>.

Christopher F. Correnti President and CEO AGC America, Inc.

Sincerely,

t. St Km

Ahmed El Kassmi, Ph.D Director, Product Stewardship & Regulatory Affairs AGC Chemicals Americas, Inc.

Addendum

DEP should ensure that products and product components exempt under Section 4 of the proposed regulations ("covered product components" below) are uniformly exempt and are not arbitrarily banned from commerce when used in some industry sectors ("covered sectors" below) but not others ("currently excluded sectors" below).

Regulation	Covered Sectors	Covered Product Components	Currently Excluded Sectors
§4(A)(7)	Products for public health, environmental or water testing	Cables, wires, sheathing, hoses, tubes, gaskets, seals, O-rings, optical fibers, gas exchange membranes, ion exchange membranes, distillation column packings, linings for vessels, tanks, pipes	Products intended to improve or protect public health and the environment (e.g., wastewater and water treatment equipment)
§4(A)(9)	Motor vehicles & equipment (e.g., cars, off-road vehicles)	Cables, wires, hoses, fuel lines, seals, gaskets, bearings, high performance coatings, specialty lubricants	Locomotives and railroad equipment; construction equipment; factory & warehouse equipment
§4(A)(12)	Non-consumer electronics (e.g., data center equipment; telecommunications equipment; business servers)	Cables, wires, sheathing, optical fibers, optical cable buffer tubes, sound transmission membranes, printed circuit boards, microprocessors, monitors, touchscreens, anti-fouling coatings	Laptops, cell phones, plenum cables in residential buildings; automated equipment for residential use
§4(A)(12)	Non-consumer laboratory equipment (e.g., analyzers, detection devices, measurement devices, fermentation and reaction vessels & equipment)	Hoses, tubes, gaskets, seals, O-rings, optical fibers, gas exchange membranes, ion exchange membranes, distillation column packings, linings for vessels, tanks, pipes	Manufacturing equipment for the chemical and life sciences industries; wastewater and water treatment equipment
§4(A)(13)	Equipment directly used to manufacture exempt products (e.g., manufacturing equipment and components for motor vehicles, aircraft, watercraft, non- consumer electronics)	Cables, wires, sheathing, hoses, tubes, gaskets, seals, O-rings, expansion joints, compensators, bellows, bearings, ball joints, hinges, calipers, valves, lubricants, pumps, process control devices, pipes, vessel linings, 3D printers, high performance coatings, belts, rollers, heat sealers, gas driers, moisture control and ion exchange membranes	Manufacturing equipment for all other sectors, including chemical industry, energy sector, non-transportation durable goods, "consumer" electronics, food processing, recreational equipment



January 28, 2025

Submitted via electronic mail

Kerri Malinowski Farris Maine Department of Environmental Protection 17 State House Station Augusta, ME 04333-0017

Re: Chapter 90 Draft Rule

Dear Ms. Malinowski Farris:

On behalf of the Association of Home Appliance Manufacturers (AHAM), I would like to provide recommendations with respect to the proposed rule from the Maine Department of Environmental Protection (MDEP) for the "PFAS in Products Program" sales prohibition on cookware and the currently unavoidable use process. Our comments are specifically with regards to the 2026 prohibition of intentionally added PFAS for cookware outlined in 38 MRSA §1614.

AHAM represents manufacturers of major, portable and floor care home appliances, and suppliers to the industry. AHAM's members produce hundreds of millions of products each year. They design and build products at the highest levels of quality and safety. As such, they have demonstrated their commitment to strong internal safety design, monitoring, and evaluation/failure analysis systems. AHAM supports the intent to protect consumers against all unreasonable risks, including those associated with the exposure to potentially harmful chemicals. AHAM also firmly supports the appropriate use of PFAS chemicals in appliances. Together with industry design practices, test requirements, and redundant safety mechanisms, PFAS chemicals play an important role in the safety of household appliances.

AHAM appreciates the ongoing conversations addressing compliance challenges caused by the law's provisions impacting cookware. However, the language around cookware in the proposed rule is much broader than the law and raises significant concerns that could potentially threaten appliance product safety and product availability for Maine residents.¹ AHAM requests the following four items related to cookware be included in the Final Rule, and we would like to discuss these matters in more detail with MDEP:

¹ "Cookware product" as defined at 38 M.R.S. § 1614(1) (A-10) is limited to houseware intended to be in direct contact with food or beverage. Cookware does not encompass items intended for use in and market exclusively for use in commercial, industrial, or institutional settings.

- 1) Narrow and Specify Products Under Prohibition
- 2) Cookware Ban Should Exclude Internal Components and Non-Cooking Surfaces
- 3) Exempt Spare/Replacement Parts from Prohibition
- 4) Clarify Currently Unavoidable Use Exemption Process

Narrow and Specify Products Under Prohibition

The Department of Environmental Protection, in this rulemaking, has not appropriately clarified the definition and product scope of cookware, creating compliance uncertainty such that it could be interpretated broadly to include "any durable houseware intended to be in direct contact with food or beverages." This broad statement raises serious concerns about what products would be incorporated into this prohibition. Contrary to the law's intent, this overly broad language could even include several major appliances, including refrigerators, microwaves, stoves and even a dishwasher that contacts food as it cleanses dishware of food waste.

The term "cookware" typically refers to products designed to be used primarily on a stovetop or inside an oven and not the cooking appliance itself. These regulations must provide the needed focus and clarity of what products and what parts of the product are in scope. Otherwise, there are risks of inconsistent interpreting and enforcement of which products are included in the 2026 cookware product prohibitions. The Minnesota Pollution Control Agency (MPCA) clarified that the prohibition on PFAS cookware was for the specific products identified in the law, which is like California's² and Colorado's³ implementation of their cookware PFAS laws. MPCA also specifically excluded coffee makers as an example of the type of product that did not fit the law's definition of cookware.⁴ Ultimately, the product scope included in the Draft Rule, is entirely too broad. Manufacturers and suppliers want to consistently comply with the law and a clear product scope is essential which means including the clear list of products as listed in the law (pots, pans, skillets, baking molds). This ultimately ensures increased compliance across all cookware product manufacturers and prevents any negative impacts from inconsistent interpretations of a potentially limitless scope.

Cookware Ban Should Exclude Internal Components and Non-Cooking Surfaces

The proposed language is unjustifiably expansive to include any product that touches food, including internal components. While several states have enacted PFAS prohibitions, Maine would be the first and only state to include internal components for cookware. This raises significant

² <u>https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202120220AB1200</u>

³ <u>https://leg.colorado.gov/bills/hb22-1345</u>

⁴ <u>https://www.pca.state.mn.us/sites/default/files/20240725-presentation-pfas-prohibitions.pdf</u>

concerns for manufacturers, primarily because there may not necessarily be safe, tested, and validated alternatives to PFAS use in internal components and electronics. Further aggravating the problem is that compliance is based on a short January 2026 timeline, instead of 2032, which is the intent of Minnesota's PFAS prohibitions. This additional time is needed to identify substitutes, and even if a substitute is found, manufacturers need time to test, design, retool, and restock global supply. Regrettably, failing to make necessary corrections could lead to manufacturers limiting or restricting essential household products that Maine residents rely on. This could jeopardize the health and safety of Maine residents who rely on our cookware products for their daily cooking needs.

Appliances are complex products with wirings, circuit boards, and numerous internal components. Other products included in the 2026 prohibition are not complex but homogenous products, such as cosmetics, dental floss & ski wax. The internal components of an appliance do not contact food, or otherwise present risks to consumers, and PFAS use may even be necessary for product safety and performance in the case of electrical components. The rapidly approaching 2026 deadline will require manufacturers to make quick product planning decisions, given the lead-time needed from design to production of appliances, which can take several years. Because of the inclusion of internal components, manufacturers may not have time to identify substitutes that have a similar level of safety protection and performance. Rushing substitutes can lead to regrettable substitutes for products that manage water, gas, electricity, and high-speed motors. AHAM appreciates the law's exemption for semiconductors, but this does not go far enough. Maine should make clear and exempt all internal components for cookware products from the 2026 prohibition.

Minnesota enacted the nation's first prohibition on PFAS used in cookware products. In subsequent guidance documents, the Minnesota Pollution Control Agency (MPCA), specified that surfaces that do not come into contact with food are excluded.⁵ AHAM respectfully requests Maine similarly exclude all surfaces that do not come into contact with food. The prohibition should also exclude external surfaces that do not come into direct contact with food and beverages during cooking. This provides further common-sense clarity of the law to manufacturers on the prohibition. AHAM's suggested language is included below.

Exempt Spare/Replacement Parts from Prohibition

AHAM respectfully requests special consideration for replacement or spare parts. Products, such as electric skillets and grills, may have replacement parts for products sold prior to the ban. Manufacturers are required to store replacement and spare parts for several years to ensure the purchased product can function based on the original design and ensure the continued safe operation of the product. If there is no exemption for spare and replacement parts, consumers may have to discard fixable cookware and manufacturers may have to dispose of these parts, which would impact the waste stream. Indeed, the State of Vermont is looking at their PFAS Law and has encouraged such exemption:

The following are exempt from the requirements of this chapter:

⁵ <u>https://www.pca.state.mn.us/sites/default/files/c-pfas-rule1-00a.pdf</u>

Replacement parts for products manufactured prior to the ban imposed by section 2 7604 of this title.⁶

Proposed Regulatory Language

AHAM's proposed revision for the regulations, as explained above, are articulated below:

<u>Cookware product</u>. "Cookware product" as defined at 38 M.R.S. § 1614(1) (A-10) is limited to houseware food or beverage contact surfaces while cooking that contain intentionally added PFAS intended to be in direct contact with food or beverage. Cookware does not encompass items intended for use in and marketed exclusively for use in commercial, industrial, or institutional settings. Cookware means the specifically listed items, or different forms of the listed items in 38 M.R.S. § 1614(1) (A-10) and includes a heated, direct food contact surface containing intentionally added PFAS. Internal components and non-cooking surfaces are exempt from the 2026 cookware prohibition. Cookware products under this prohibition do not include repair or replacement parts.

Except as provided in subsection H and section 9(B), effective January 1, 2026, a person may not sell, offer for sale or distribute for sale in the State of Maine:

(2) A cookware product <u>surface that is intended to be in direct contact with food or beverage while</u> <u>cooking and contains</u> intentionally added PFAS.

Clarify Currently Unavoidable Use Exemptions Process

Regarding the "Currently Unavoidable Use Exemptions" (CUU) process, AHAM appreciates that Maine has a process to determine exemptions. The unavoidable use of a PFAS substance that is essential for health, safety, or the functioning of society should be considered for an exemption. However, with respect to prohibitions that begin January 1, 2026, there is not enough time for the exemption process to be useful or effective. If manufacturers and suppliers are not provided with a determination of exemption well in advance of the January prohibition, it would make the exemption process meaningless. With the current language of the proposal, the Department will likely receive many CUU requests specific to product scope and internal components.

Manufacturers are given very limited time in the current process between the Department's anticipated timeline for the CUU process and the January 1, 2026, compliance date for many products. The Department anticipates that manufacturers would not be able to register CUU products for the 2026 sales prohibitions until "Fall/Winter 2025," which could be mere days or weeks before the January 1, 2026, compliance date. Failing to provide additional compliance lead time for any products under an active CUU evaluation creates significant commercial disruptions for manufacturers, retailers, and consumers. Manufacturers could be forced to withhold any distribution of cookware in Maine until a final CUU determination is made.

Additionally, any product that was denied a CUU exemption should be given approval lead time. Manufacturers that were denied exemptions right before or after January 1, 2026, should be given

⁶<u>https://legislature.vermont.gov/Documents/2026/Workgroups/House%20Environment/Water%20Quality/W~Ma</u> <u>tt%20Chapman~PFAS%20Overview~1-22-2025.pdf</u>

226

additional time to comply with the prohibitions. Otherwise, manufacturers would need to anticipate not receiving the exemption, which again eliminates any meaningful benefit of the CUU process.

AHAM requests the Department review potential interim exemption approvals which allow for a meaningful exemption process and give manufacturers certainty while the Department evaluates the merits of a CUU exemption. We also request that the Department grant additional time to comply with any CUU exemptions denials. We suggest making the following amendments to the Chapter 90 request, and/or the Department to implement through enforcement discretion:

- The moment a CUU is submitted, that manufacturer or supplier would receive an automatic interim exemption, up to 180 days, which would allow the Department to review and evaluate all submissions.
- Once the Department makes a determination:
 - If it is approved, the manufacturer would register its products to receive the valid exemptions.
 - If rejected, the manufacturers would be granted potentially up to one or two years from the date of the final CUU notification to meet the applicable prohibition(s). The Department could also use enforcement discretion to delay enforcement of the provisions of the applicable prohibition for any products that were denied a CUU exemption.

Request for Consideration around Fluoropolymers/PTFE

The term PFAS encompasses in some instances as many as 12,000+ substances and not all are the same. One chemical that is used in the home appliance industry and is included in the current broad definition of PFAS is fluoropolymers. Fluoropolymers are used nearly everywhere, in almost every major manufacturing sector due to their inert and thermally stable properties. Polytetrafluoroethylene (PTFE) is a fluoropolymer that is used in certain appliances and may be included in material that contacts food. Manufacturers use coatings that include a small amount of PTFE for water, scratch resistance, heat resistance, with a good flexibility in manufacturing stage, as well as a long-life durability in use. PTFE pipes for transferring hot water are used because of their unique combined resistance to high pressure, high temperature and high durability under these conditions. Unlike non-polymeric PFAS, which are mobile, can bioaccumulate, and can have toxicity concerns, fluoropolymers have not been demonstrated to have negative health concerns and are a material of choice for sensitive applications such as medical devices. In fact, since the 1960s, the Food and Drug Administration has authorized fluoropolymers for use in food contact applications. More recently, the Environmental Working Group has publicly stated that non-stick cookware is not a major source of exposure: "But even though it's always been the poster child for PFAS exposure, is not anticipated to be a major source of exposure."⁷ As a result,

⁷https://www.ewg.org/news-insights/news/2024/02/forever-chemicals-top-3-ways-lower-yourexposure?utm_source=newsletter&utm_campaign=202501JanNews10&utm_medium=email&utm_content=default

fluoropolymers require special consideration relative to any prohibition. Just last year, Connecticut Governor Ned Lamont in signing Public Act 24-59, An Act Concerning the Use of PFAS in Certain Products, which includes a 2028 ban on cookware with intentionally added PFAS, asked that there be an exemption process for nonstick coating based on polytetrafluoroethylene (PTFE).⁸ Legislation has already been filed in Connecticut to help alleviate this issue. As this process moves forward, we request special consideration for fluoropolymers in this prohibition.

AHAM appreciates the opportunity to comment. We would be happy to discuss all of these details further.

Respectfully submitted,

John Kene

John Keane Manager of Government Relations

AHAM represents manufacturers of major, portable and floor care home appliances, and suppliers to the industry. AHAM's membership includes over 150 companies throughout the world. In the U.S., AHAM members employ tens of thousands of people and produce more than 95% of the household appliances shipped for sale. The factory shipment value of these products is more than \$30 billion annually. The home appliance industry, through its products and innovation, is essential to U.S. consumer lifestyle, health, safety, and convenience. Through its technology, employees and productivity, the industry contributes significantly to U.S. jobs and economic security. Home appliances also are a success story in terms of energy efficiency and environmental protection. New appliances often represent the most effective choice a consumer can make to reduce home energy use and costs.

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January 28, 2025

Commissioner Melanie Loyzim Maine Department of Environmental Protection State of Maine 17 State House Station Augusta, Maine 04333

Kerri Malinowski Farris Maine Department of Environmental Protection State of Maine 17 State House Station Augusta, ME 04333

Submitted via email to: rulecomments.dep@maine.gov

Re: Posting Draft - 06-096 Ch. 90 Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS)

Dear Commissioner Loyzim and Ms. Malinowski Farris:

These comments are submitted by the Air-Conditioning, Heating, and Refrigeration Institute (AHRI) regarding the Maine Department of Environmental Protection's (DEP) rule "Ch. 90 Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances" in compliance with amended *The Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution* (38 M.R.S. §1614), published on December 20, 2024.

AHRI represents more than 330 manufacturers of heating, ventilation, air conditioning, refrigeration (HVACR) and water heating equipment. It is an internationally recognized advocate for the HVACR and water heating industry and certifies the performance of many of the products manufactured by its members. In North America, the annual economic activity resulting from the HVACR and water heating industry is more than \$211 billion. In the United States alone, AHRI member companies, along with distributors, contractors, and technicians employ more than 704,000 people.

HVACR and water heating equipment provide critical services to society by providing life-saving climate control and ventilation in most buildings, notably homes, hospitals, schools, and elder care facilities. The cold chains for both food and medicines depend on transportation and storage provided by transport and commercial refrigeration equipment manufactured by our members.

AHRI members greatly appreciate DEP's response to feedback from the previous rulemaking. AHRI thanks DEP for exempting a critical electrical component (semiconductors) and for excluding refrigerants for servicing that are subject to acceptable use conditions pursuant to the U.S.

Environmental Protection Agency's (EPA) Significant New Alternatives Policy (SNAP). This will allow Maine consumers continued access to the newest generations of low global warming potential refrigerants and refrigeration equipment.

AHRI continues to note the practical challenge of complex product manufacturers complying with the proposed regulations. Merely identifying the use of chemicals in supply chains is an exceptionally challenging and often unsuccessful task for manufacturers of complex systems, due to the general lack of transparency around component composition and the number of chemicals (approximately 9,000) included in the overly broad definition of PFAS the State of Maine continues to use as the basis for this regulation. This is exacerbated by confidentiality claims by component manufacturers and suppliers and the lack of clarity on whether this regulation will impact chemicals embedded in the polymer matrix of equipment components.

AHRI urges Maine to focus its efforts on the regulation of persistent, bioaccumulative, and toxic (PBT) chemicals in high-exposure products.

Maine's broad definition of PFAS includes approximately 9,000 known chemicals. Although the focus of Maine's legislation are PBT PFAS that pose a risk to human health and the environment, Maine's definition of PFAS includes many chemicals that do not all share these three critical properties. For example, most low global warming refrigerants (A2Ls) used in HVACR and water heating systems are proven to have low levels of toxicity.¹ The EPA Significant New Alternatives Policy (SNAP) criteria for evaluating alternatives for acceptable use conditions includes assessments of the potential exposure risks, toxicity and environmental impact of the refrigerant.² The EPA SNAP approval process has determined that the chemical makeup of A2L refrigerants presents minimal risk to humans and the environment. Moreover, HVACR and water heating products are hermetically sealed and tend to have a useful life over 15 years. Additionally, certain polymers that meet Maine's definition of PFAS (i.e., fluoropolymers such as polytetrafluoroethylene (PTFE)) are used in a wide variety of consumer products with unlikely potential for human or environmental release or exposure during use of the product, therefore, presenting minimal risk associated with the actual product itself.

AHRI is concerned that Maine is at risk of being overwhelmed by incomplete datasets for the millions of unique products and components in the scope of this rule. AHRI's Directory of Certified Product Performance³ alone lists over 4 million unique products with over 9 million new products sold and installed annually in homes and businesses. AHRI members must parse through tens of thousands of stock-keeping units (SKUs), each having hundreds of associated components and spare parts, to better understand whether their products will be affected by this draft regulation. This introduces hundreds of millions of potential chances for any given product or component to contain one of the thousands of PFAS included in Maine's PFAS definition. AHRI's members have discovered in previous chemical reporting that frequently, component suppliers are unable to disclose the chemical composition of their components to their manufacturer customers, as the chemical composition is considered confidential intellectual property.

¹ ANSI/ASHRAE Standard 34-2022

² EPA Significant New Alternatives Policy- Criteria for Evaluating Alternatives, <u>https://www.epa.gov/snap/about-snap-review#criteria</u>. (Last accessed on January 28, 2025).

³ AHRI's Directory of Certified Product Performance, <u>https://www.ahridirectory.org/</u>. (Last accessed on January 27, 2025).

While the draft regulation provides a process by which suppliers may substantiate these claims, AHRI is concerned that compliance challenges will inevitably complicate and delay the implementation of this regulation. Even for industries with strong knowledge of the chemical make-up of components, it is extremely difficult to ensure an accurate dataset of chemicals within their supply chains. The HVACR and water heating industry must request, accumulate, and summarize information on chemicals in components to even determine if their final products contain PFAS and to fully understand the effects of this draft regulation. Focusing the regulation of non-polymer PBT PFAS will ensure Maine is able to protect human health and the environment from PFAS pollution, without putting unnecessary and ineffective burden on industries whose products may contain low-exposure PFAS that are not PBT chemicals.

AHRI urges DEP to clarify the definition of "Cooling, heating, ventilation, air conditioning or refrigeration equipment."

While we appreciate Maine's creation of a category of "Cooling, heating, ventilation, air conditioning or refrigeration equipment" in LD 1537 (2024), this wording creates regulatory ambiguity for the HVACR and water heating industry. This category does not specify that water heating, water cooling, dehumidifiers, air cleaners, and all other space conditioning equipment are also included in the scope of the category. AHRI requests DEP to clarify that the scope of "cooling, heating, ventilation, air conditioning or refrigeration equipment" includes all equipment used to heat or cool water and improve the indoor air environment.

AHRI again thanks Maine for excluding refrigerants for servicing that are subject to acceptable use conditions pursuant to EPA's SNAP but notes that some HVACR and water heating applications are not regulated under EPA's SNAP. As such, AHRI requests that DEP provide a compliance pathway for products which utilize these refrigerants for applications that are not covered under EPA's SNAP.

AHRI urges DEP to amend its language regarding the effective date of the regulation.

Due to the ambiguity of the scope of "Cooling, heating, ventilation, air conditioning or refrigeration equipment," AHRI is concerned with language in the draft regulation stating DEP's intent to make the prohibition of products containing intentionally added PFAS effective immediately for all covered products, including those already in the stream of commerce. AHRI strongly recommends DEP amend the prohibition to be effective on products containing intentionally added PFAS entering the stream of commerce at a date no earlier than one year from the publication of the final rule based on the manufacture date of the product. This kind of advanced notice would allow affected parties to contact suppliers and gather the most accurate data available to report to DEP. Additionally, without this lead time, inventory can become stranded causing a shortage of equipment and increasing costs to consumers in Maine. This additional time will also allow DEP to effectively staff and train the personnel who will manage reporting and certification requirements.

AHRI notes that recent chemical restrictions have focused on prohibiting the introduction of chemicalcontaining products to commerce, rather than prohibiting what is already in the stream of commerce. For example, EPA, in its recently finalized restrictions on perchloroethylene (PCE),⁴ based its

⁴ 40 CFR Part 751

restrictions on the manufacture, processing, and entry into commerce of PCE-containing products, but does not prohibit the sale of existing PCE-containing products in the marketplace.

AHRI requests DEP to clarify the exclusion of embedded components in the regulation.

AHRI asks DEP to clarify the exclusion of components embedded within complex products.

Maine's statute defines products as:

"*an item manufactured, assembled, packaged or otherwise prepared for sale to consumers, including its product components.*"

Section 3 – Notification states:

"For product components for which the Department has previously received notifications, which are used in more complex products containing the reported components, <u>the</u> <u>manufacturer of the more complex product shall either report PFAS in the product</u> <u>including its components or refer to the supplier's submitted notifications for product</u> <u>components</u> and any PFAS in the remainder of the product."

However, Section 6 (A) – Fees, states,

"Notifications are required only for products which are subject to a currently unavoidable use determination and are sold, offered for sale, or distributed for sale in the State of Maine. <u>Product components that are incorporated into complex products which</u> <u>are sold, offered for sale, or distributed for sale in Maine are not subject to the</u> <u>notification requirement</u>, even when information regarding the product components is provided as part of that product's notification submission."

The statutory definition of "products," Section 3, and Section 6 (A) provide conflicting directions regarding notification requirements for embedded components. AHRI supports the exclusion of embedded components within complex products from the reporting requirements as described in Section 6 (A). We request that DEP resolve the inconsistencies described above to clarify the exclusion of embedded components from the reporting requirements.

AHRI requests DEP to clarify the definition of "complex product" in the regulation.

AHRI also notes that DEP does not define "complex product" in this regulation. AHRI requests DEP consider adding a definition of "complex product" that aligns with Directive 98/71/EC of the European Parliament and of the Council (Directive - 98/71).⁵ Directive - 98/71 defines "complex product" as a product which is composed of multiple components which can be replaced permitting disassembly and reassembly of the product. It is important to address the definition of complex products to remove any ambiguity as to the reporting requirements.

⁵ Directive 98/71/EC of the European Parliament and of the Council. <u>https://eur-lex.europa.eu/eli/dir/1998/71/oj/eng</u>. (Last accessed on January 27, 2025).

AHRI urges DEP to reduce the financial burden of PFAS reporting fees in the regulation.

AHRI notes that the proposed fee required per product could result in a significant financial burden to manufacturers, depending on what is considered an individual product, especially if it includes products in the same product line but different model numbers/identifiers. To reduce the financial burden of reporting fees in Maine, AHRI supports the ability for manufacturers to bundle notifications of the same product lines or use cases, so our industry can continue to provide Maine consumers with product diversity. AHRI also supports the recognition by DEP of notifications previously submitted for the same use case. AHRI opposes the collection of notification fees for exempted equipment.

Products or components containing *de minimis* levels, less than 0.1% by weight, of any PFAS should be exempt from the regulation.

PFAS in electrical and other components are difficult for manufacturers to track. Manufacturers have limited visibility and control over complex, multi-tiered, global electronics supply chains. Manufacturers must rely on the accuracy of reporting from every supplier throughout their entire supply chain on trace amounts of a chemical, even those that are present unintentionally. AHRI notes there are common components in use by the HVACR and water heating industries that could be manufactured at the same facilities producing components for industries that can contain PFAS. This could result in unintentional cross-contamination and the continued presence of *de minimis* quantities of PFAS in components used in HVACR and water heating equipment. AHRI continues to urge DEP to exempt articles that contain only *de minimis* quantities of PBT or non-PBT PFAS of 0.1% by weight or less, which will allow for a practicable regulation that is reasonably implementable. Not having a *de minimis* exemption puts an unreasonable burden on manufacturers, and therefore, DEP should provide permanent regulatory relief.

Conclusion

AHRI thanks DEP for incorporating our previous feedback to acknowledge the complexity of HVACR and water heating products and the critical role they serve in the functioning of modern society. AHRI maintains that there is minimal opportunity for exposure to the chemicals used in HVACR and water heating equipment. Chemicals in HVACR and water heating components are not disposed of in waterways, nor do they result in exposure through drinking water. HVACR and water heating equipment are maintained and serviced by qualified professionals and the chemicals used in HVACR and water heating equipment and components are not generally accessed by the public. The burden for this type of regulation would be impossible or nearly impossible for manufacturers to comply with.

AHRI thanks DEP for the opportunity to comment on the Maine Chapter 90: PFAS in Products Program and requests a discussion regarding ways to protect public health and the environment while considering the practical challenges to compliance with this proposed rule.

We look forward to discussing this important matter with you at your earliest convenience.

Sincerely,

Makenzie Horrigan Senior Manager of International & Domestic Policy

cc: Mark Margerum

234

Alliance of Nurses for Healthy Environments Bringing Science and Passion to the Environmental Health Movement

January 28 2025

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Comments on Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

The Alliance of Nurses for Healthy Environments (ANHE) appreciates the opportunity to comment on the proposed rule Chapter 90 to establish criteria for currently unavoidable uses of intentionally added PFAS in products.¹ With nurse members in all 50 states, including Maine, ANHE is the only national nursing organization focused solely on the intersection of health and the environment. Nurses have been ranked the most trusted profession for 22 consecutive years² and are led by our professional obligations³ which make addressing health, environment, and safety a professional focus of ours.

Nurses consistently see evidence of the health harms of toxic environmental exposures in our everyday work and are often the "eyes and ears" of the care teams in which we work. The ubiquitous nature of PFAS contamination underscores the need to curb all pathways of PFAS exposure and sources of pollution. The National Academies of Science, Engineering and Medicine has published in their guidance that there is <u>sufficient evidence</u>⁴ that certain PFAS are associated with health outcomes including:

- decreased antibody responses (in adults and children),
- dyslipidemia (in adults and children),
- decreased infant and fetal growth, and
- increased risk of kidney cancer (in adults)

Because of Maine's leadership on addressing PFAS issues, please find the following comments on the draft rule and suggested changes.

1) Under the definition of "cookware" the draft states "NOTE: The definition of cookware is limited to houseware. Cookware does not encompass items intended for use in and market exclusively for use in commercial, industrial, or institutional settings." "Cookware product" is defined as a durable houseware product intended to be used to prepare, dispense or store food, foodstuffs or beverages, including, but not limited to, a pot, pan, skillet, grill, baking sheet, baking mold, tray, bowl and cooking utensil (LD 1537, Section A-10). There is no exemption for industrial or commercial cookware and to do so goes against the legislative intent of the law.

¹ Maine Department of Environmental Protection. *Chapter 90: Products containing Perfluoroalkyl and Polyfluoroalkyl substances*. <u>https://www.maine.gov/tools/whatsnew/index.php?topic=dep-rulemaking&id=13139124&v=govdel</u>

² American Nurses Association. (Jan 22 2024). America's most trusted: Nurses continue to rank the highest.

https://www.nursingworld.org/news/news-releases/2024/americas-most-trusted-nurses-continue-to-rank-the-highest/

³ American Nurses Association. (2020). *Nursing: Scope and Standards of Practice (4th ed.)*. Standard 18: Environmental Health. ANA: Silver Spring, MD.

⁴ National Academies of Sciences, Engineering, and Medicine (NASEM). (2022). Guidance on PFAS Exposure, Testing, and Clinical Follow-Up. Washington, DC: The National Academies Press. <u>https://doi.org/10.17226/26156</u>.


2) In the definition of semiconductor, part of the definition states "intended to perform electronic and other related functions" which is very broad. Because this will be an exemption from the law, this definition should be clarified and strengthened. The semiconductor definition should specify the purpose to avoid an unnecessarily broad definition.

3) The draft definition states that a PFAS alternative is "reasonably available" if "readily available in sufficient quantity and at a comparable cost to PFAS." Cost should not be the focus of this definition and "comparable" costs do not seem easily measurable, given that the cost implications can vary dramatically from product to product. **Because of the health implications of PFAS exposure, it is important that cost not be considered with regards to "reasonably available."** The definition also includes "intended to replace and perform as well as or better than PFAS in a specific application of PFAS in a product or product component." This part of the definition regarding performance is irrelevant to the concept of "reasonably available" and should be removed.

4) In the currently unavoidable use (CUU) section A(3)(b) the draft states "The required specific characteristic or combination of characteristics that necessitate the use of PFAS chemicals." A **justification for the need for PFAS for the function of the product alone should not be sufficient for a currently unavoidable use (CUU) exemption.** Additional information should be required as to why this characteristic(s) is necessary for the products' function in health, safety, or the functioning of society. We recommend establishing clear criteria for making CUU decisions and that criteria align with international scientific work reflected in the EU guiding principles and criteria for the essential use concept.

5) Section A(4)(e) "A comparison of the known risks to human health and the environment between PFAS and the materials identified in Subsection a". It makes no sense to require risk based criteria to get a currently unavoidable risk designation. When the law was passed, it was passed because there is agreement that the use of any PFAS is a problem and that use of PFAS should be stopped wherever possible. This is the essential use concept. The law was not intended to set up a risk-based framework and setting up this process opens the law to allow for unnecessary CUU designations impacting public health. It also goes against the intent of the law that any use of PFAS must be necessary for the "health, safety, and functioning of society."

Thank you for the opportunity to provide input on this important draft rule.

Sincerely,

Katie Huffling, DNP, RN, CNM, FAAN Executive Director, Alliance of Nurses for Healthy Environments katie@enviRN.org



January 21, 2025

Maine Department of Environmental Protection 17 State House Station Augusta, Maine 04333-0017

Dear Ms. Malinowski Farris,

Thank you for the opportunity to comment on the State of Maine's Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances draft regulations.

The Business and Institutional Furniture Manufacturers Association (BIFMA) and its members worked together to address this important regulation. BIFMA supports over 150 small businesses as well as many mid-size and large businesses impacted by this regulation. We are experiencing a proliferation of PFAS regulations at the state level, all slightly different, creating challenges for our members. In light of the current challenges facing our industry, including supply chain disruptions, economic pressures from increased fees and reporting requirements, and the evolving landscape of complex regulations, we appreciate the opportunity to provide additional written comments for your consideration.

Several comments address reporting requirements that may be applicable in 2032 - the full PFAS ban. For example, furniture containing electronics, motors, and/or other parts may contain intentionally added PFAS for 5 to 10 more years based on current supplier information.

• Section 3. Notification

- CAS level and chemical name reporting A.(d)
 - Comment: Suppliers often will not disclose information due to confidentiality and/or variability in specific chemical added. BIFMA recommends a yes/no in terms of PFAS inclusion.
- **PFAS Concentration B.(e)**
 - Comment: Laboratories are making progress in determining concentrations and chemical identification; however, the capabilities are extremely limited, expensive, and vary in quality. Furthermore suppliers may change added PFAS for a variety of reasons (supply, quality, economics) which increases variability. BIFMA recommends a range-based disclosure for upholstered furniture.
- Single notification C.: A manufacturer may submit a single notification to the Department for multiple products if all the products are covered by the same currently unavoidable use determination found in section 9(B).
 - Comment: BIFMA supports this approach as it creates efficient data collection and record keeping.

• Section 5. Prohibition of the Sale of Products Containing Intentionally Added PFAS.

- *C. Except as provided in subsection H and section 9(B), effective January 1, 2026, a person may not sell, offer to for sale or distribute for sale in the state of Main: (9) Upholstered furniture containing intentionally added PFAS.*
 - Comment: Section 5. B. prohibits fabric and fabric treatment containing PFAS by January 1, 2023. BIFMA supports this prohibition as manufacturers control the supply of fabric and fabric treatments on their products. The prohibition of non-fabric components containing PFAS including electronics, gear lubricants, and mechanical parts to reduce friction is exponentially more difficult to meet. These parts are purchased from large industries which furniture manufacturers do not control nor influence given the low purchasing power. Alternatives, if presented by a supplier, must be evaluated to ensure quality and safety standards are met.
 - To date, few if any alternatives are available that meet quality and safety requirements. BIFMA recommends the date to meet this prohibition align with other states and industries. Maine's proposed prohibition of most products by 2032 allows for multiple industries, including those much larger and influential, to implement no intentionally added PFAS alternatives for electronics, gear lubricants, and mechanical components designed to reduce friction. BIFMA recommends this date for non-fabric items within upholstered furniture.
- Section 6. Fees.
 - A. Fee amount.... pay a fee of \$1,500 for each notification submitted. For the purposes of calculating fees, each submission...will be considered a separate notification.
 - Comment: BIFMA supports the product grouping and notification process which reduces costs and reporting burdens. States are increasingly adding reporting requirements and fees for PFAS, extended product responsibility, and other regulatory requirements. These cost manufacturers in terms of real dollars as well as people costs. BIFMA recommends a lower submission fee of \$500. BIFMA also urges Maine to ensure a level playing field in terms of reporting and costs. Without proper oversight, internet retailers and other businesses may inadvertently or intentionally fail to remit the required fee, potentially due to lack of awareness or other factors. This leads to a competitive disadvantage for those meeting the regulation.

Thank you for the opportunity to provide these comments. BIFMA welcomes the opportunity to discuss this further and provide additional information. Please contact Steve Kooy, BIFMA Technical Director Health and Sustainability, at <u>skooy@bifma.org</u> or +1.616.591.9797.

On behalf of BIFMA,

AT 23

Steve Kooy Technical Director Health and Sustainability BIFMA



GENERAL DYNAMICS²³⁸ Bath Iron Works

> Jason M. Gasper Director, Occupational Safety & Environmental

January 28, 2025

VIA: rulecomments.dep@maine.gov

TO: MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION

RE: Comment on Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

Bath Iron Works Corporation ("BIW") appreciates the opportunity to comment on the posting draft of the proposed Chapter 90 Rule: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances ("Proposed Rule") that implements Public Law 2021, c. 477, *An Act To Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution* (LD 1503, 130th Legislature), 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 "Acts"), codified at 38 M.R.S. § 1614.

BIW respects the efforts of the legislature and the Department to address the public's growing concern with PFAS in consumer products and the real-world impact of their regulations on industry, including revisions made by Department Staff between the Concept Draft and the posted Proposed Rule in response to stakeholder comments. 38 M.R.S. § 1614(7)(A). However, BIW is submitting these comments to request further clarification on the scope and applicability of the Proposed Rule to BIW's suppliers and to the component parts of its ships (and their packaging). In short, BIW is concerned that without the clarifications and revisions proposed below, the Proposed Rule will have unintended impacts on market dynamics and the supply chain, resulting in a loss of BIW's access to critical supplies and therefore a loss to the U.S. of mission critical warships.

BIW is a full-service naval shipyard that designs, builds, and supports complex surface combatant ships for the U.S. Navy, a unit of the U.S. Department of Defense ("DOD"). BIW must build its ships to certain specifications established in regulations and contracts with the Navy. These ships are highly complicated and include thousands of component parts. Furthermore, the number of suppliers able to manufacture these critical components of the ships is restricted because of U.S. laws and regulations (including export control laws, such as ITAR/EAR; the Buy American Act; and the Federal Acquisition Regulations & Defense Federal Acquisition Regulations).

The Proposed Rule does acknowledge BIW's unique position, exempting from its requirements products required to meet standards or requirements of the DOD and watercraft products.

Proposed Rule at §§ 4(A)(8) and 4(A)(10)-(13). However, as explained in our August 29, 2024 comments on the August 5, 2024 Chapter 90 Concept Draft (enclosed herein), the scope of the Proposed Rule must be clarified so that it does not unintentionally prohibit the sale of products to BIW in Maine that are required to meet those specifications established in regulations and contracts with the Navy.

1. The equipment exemption must be expanded to include all parts involved in the manufacture or development of exempted products.

The exemption of "semiconductors," "non-consumer electronics," and "equipment directly used in the manufacture or development" of combatant ships does not go far enough. Proposed Rule at §§ 4(A)(10)-(13). While it is reasonable to assume that the product components that comprise a naval warship also are excluded, particularly given the definition of "watercraft" in Title 12¹ and the §§ 4(A)(10)-(13) exemptions, this is not clear in the Proposed Rule.

Indeed, the note to the Proposed Rule following Subsection (11) specifically states that "Manufacturers of electronic equipment are still subject to sales prohibitions, currently unavoidable use determinations, and notification requirements on the balance of their product which is not comprised of semiconductors." This suggests that "equipment," while an undefined term, could be interpreted to exclude some of the component parts of an exempted product. For example, certain switchboards, motor controllers, and current limiting devices are primarily electronic in nature and contain semi-conductors. They also come contained in metal cabinets or boxes, contain other types of hardware, and some have insulation or sound dampening or shock dampening material contained within the cabinets. So, theoretically, under the current proposed regulations, the semi-conductors themselves would be exempt from the rule, but the rest of the material (which in some cases is significant in both amount and importance to functionality) would have to be evaluated for PFAS. This would be unnecessarily complicated and defeats the purpose of exempting the semi-conductors. Accordingly, we suggest the following language in Section 4(A)(13), which mirrors the definition of "watercraft," to clarify that BIW's ship components are not products or product components subject to the Proposed Rule:

¹ The Proposed Rule cites to 32 M.R.S. § 13001(28) for the definition of "watercraft." That section does not exist, so BIW assumes that the DEP intended to cite to 12 M.R.S. § 13001(28), which defines "watercraft" as "any type of vessel, boat, canoe or craft capable of being used as a means of transportation on water, other than a seaplane, *including motors, electronic and mechanical equipment and other machinery, whether permanently or temporarily attached,* that are customarily used in the operations of the watercraft" (emphasis added).

(13) Equipment and product components, including motors, electronic and mechanical equipment and other machinery, whether permanently or temporarily attached, directly used in the manufacture or development of products, or in the final products themselves, described in subsections 5 through 12, above.

2. Internal inconsistencies regarding textiles and refrigerants must be corrected.

The Section 4(A)(8) and 4(A)(10) provisions excluding from those exemptions "any textile article or refrigerant that is included in or as a component part of" exempted combatant ships is internally inconsistent with Section 4(A)(10) itself, which defines "watercraft" by reference to a statutory definition that includes "motors, electronic and mechanical equipment and other machinery, whether permanently or temporarily attached, that are customarily used in the operations of the watercraft." Refrigerants in particular are necessary components of many electronic and mechanical equipment. So too do Sections 4(A)(8) and 4(A)(10) directly contradict the ban provision in Section 5(C)(7)(b), which states that the 2026 ban on textile articles does <u>not</u> include "a textile article that is included in or a component part of a watercraft."

Similarly, the 2040 ban on refrigerants and foams in Section 5(F) contains a limitation on such products used in servicing equipment acceptable pursuant to the Significant New Alternatives Program ("SNAP"). While the task of reviewing each product and product component's acceptability to SNAP is onerous, and the responsibility for this task unclear, it is likely that the refrigerants or foams used in ships constructed for the DOD or watercraft more generally would fall under this exemption, rendering the exclusion of refrigerants in Sections 4(A)(8) and 4(A)(10) unnecessary.

Because textile articles and refrigerants are necessary to the construction and functioning of BIW's exempt product² and because these necessary product components are explicitly excluded

² See DOD Report on Critical Per- and Polyfluoroalkyl Substance Uses at Sections IV.5 and V, enclosed with BIW's August 29, 2024 comments on the Concept Draft. For example, chemical resistant bearing greases and marine lubricants are necessary for the construction and function of BIW's product. Halogenated PTFE Lubricant (MIL-G-27617 Type III or DOD-L-24574 Type III) is necessary to lubricate parts and threads of refrigerants or valves during reassembly. As DOD explains, the use of textiles and refrigerants, both directly and indirectly, is "critical to the national security of the United States." Excluding these "mission critical" PFAS uses from the exemption, which would "have unintended impacts on market dynamics and the supply chain, resulting in the loss of access to mission critical uses of PFAS . . ." poses risks to DoD operations and the defense industrial base supply chain. This certainly is not the intent of the Acts.

from products prohibited from sale in Sections 5(C)(7)(b) and 5(F), it is BIW's position that textiles and refrigerants used in combatant ships are not subject to any ban.

The Proposed Rule should be revised such that these internal inconsistencies do not cloud the explicit Section 5 constraints on textile and refrigerant prohibitions, by removing the Section 4(A)(8) and 4(A)(10) provisions excluding from those exemptions "any textile article or refrigerant that is included in or as a component part of" exempted combatant ships.

3. The packaging exemption must be clarified.

Finally, the Proposed Rule must clarify that a product's exemption extends to its and its components' packaging. While packaging of products such as lubricants, cleaners, industrial chemicals, paint thinners, etc. is generally exempt, that exemption does not extend where the packaging is a fluorinated container or container that otherwise contains intentionally added PFAS. *See* Sections 4(A)(2) and 5(B), (C), (E), and (F). Determining which of its product components arrive in such excluded packaging would be unduly burdensome for BIW. Because packaging ingredients are not listed on SDSs, it is impossible to know which components are arriving in banned packaging and which are not. While we are unaware of any specific product containers in use or to be supplied that contain PFAS, such a determination would require extensive inquiry through BIW's entire supply chain, suppliers within which would then need to make further inquiries to their packaging suppliers.

Furthermore, the Section 4(A)(2) prohibition on "the package of a product prohibited from sale, offer for sale, or distribution for sale pursuant to sections 5(B), (C), (E), or (F) if that package is a fluorinated container or container that otherwise contains intentionally added PFAS" is inconsistent with the exclusions from the Sections 5(B), (C), (E), or (F) prohibitions. For example, Section 5(C)(7)(b) excludes from the January 1, 2026 prohibition on the sale of textile articles containing intentionally added PFAS those textiles that are included in or a component of a watercraft such as BIW's combatant ships. Logically, then, the packaging of that textile that is a component part of a combatant ship remains within the Section 4(A)(2) exemption for packaging, even if that packaging is a fluorinated container.

To avoid having to provision-hop to understand what is and what is not excluded from the Proposed Rule, BIW proposes that the Department simply make it clear upfront that textiles, refrigerants, and their packaging (fluorinated or not) is exempt, as follows:

(8) A product, <u>including its component parts and including its packaging</u>, <u>notwithstanding</u>. <u>Sections 4(A)(2) and 5(B)</u>, (C), (E), and (F), required to meet standards or requirements of the FAA, the National Aeronautics and Space Administration (NASA), the United States Department of Defense (DOD) or the United States Department of Homeland Security (DHS);

(10) A watercraft as defined in <u>12</u> M.R.S. § 13001(28)(2), <u>including its component parts</u> and <u>including its packaging</u>, notwithstanding Sections 4(A)(2) and 5(B), (C), (E), and (F), or a seaplane;

Thank you for considering these comments, and we look forward to continuing to work with the Department to develop reasonable regulation of PFAS in consumer products.

Sincere Jason M. Gasper

Enclosure

cc: Laura M. O'Hanlon Esq. Deputy General Counsel, BIW Lisa Gilbreath, Esq., Pierce Atwood ENCLOSURE

243

GENERAL DYNAMICS 244 Bath Iron Works

Jason M. Gasper Director, Occupational Safety & Environmental

August 29, 2024

VIA EMAIL - PFASproducts@Maine.gov

General Dynamics Bath Iron Works Corporation ("BIW") appreciates the opportunity to comment on the proposed Chapter 90 Rule: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances ("Proposed Rule") that implements Public Law 2021, c. 477, *An Act To Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution* (LD 1503, 130th Legislature), 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 "Acts"), codified at 38 M.R.S. § 1614 (the "statute").

BIW respects the great efforts of the legislature and the Department to address the unintentional ban of hundreds of thousands of products in which the use of PFAS is essential for health, safety, or the functioning of society under the 2021 Act. 38 MRS § 1614(7)(A). However, BIW is submitting these comments to request further clarification on the scope and applicability of the Proposed Rule to BIW's operations, the component parts of its ships, and its suppliers. In short, BIW is concerned that without the clarifications and revisions proposed below, the Proposed Rule will have unintended impacts on market dynamics and the supply chain, resulting in a loss of BIW's access to critical supplies and therefore a loss to the U.S. of mission critical warships.

1. Applicability of Proposed Rule Still Must Be Clarified

BIW is a full-service naval shipyard that designs, builds, and supports complex surface combatant ships for the U.S. Navy, a unit of the U.S. Department of Defense ("DOD"). BIW must build its ships to certain specifications established in regulations and contracts with the Navy. These ships are highly complicated and include thousands of component parts. Furthermore, the number of suppliers able to manufacture these critical components of the ships is restricted because of U.S. laws and regulations (including export control laws, such as ITAR/EAR; the Buy American Act; and the Federal Acquisition Regulations & Defense Federal Acquisition Regulations).

Despite BIW's unique position – it is subject to significant federal government regulation, its naval warship "products" are not typical "products," and its "consumers" are the U.S. government – all products and product components are not "consumer products" as defined in the Proposed Rule because they are not intended to be used primarily for personal, family or household purposes. They are strictly used for military purposes as prescribed by the DOD. While the Legislature clearly intended the Acts and the statute, titled "SALE OF CONSUMER PRODUCTS AFFECTING THE ENVIRONMENT," to be limited to consumer products, this limitation has been overlooked across the multiple iterations of draft Chapter 90. In fact, the term "consumer products" does not appear in the Proposed Rule outside of the definitions section. The only usage of the concept of consumer products is in the Section 4(A)(12) exemption for "Non-consumer electronics and non-consumer laboratory equipment not ordinarily used for personal, family or household purposes."

VIA EMAIL - PFASproducts@Maine.gov August 29, 2024 Page 2

Potential applicability of the Proposed Rule to BIW's restricted suppliers and component parts is not the intent of the Legislature. The Legislature in the 2024 Act made clear that BIW's ships are exempt from the Proposed Rule under Sections 4(A)(8) and 4(A)(10)-(13), as its ships are required to meet standards or requirements of the DOD and are watercraft comprised of thousands of components. The scope of the Proposed Rule must be clarified, however, so that it does not unintentionally prohibit the sale of products to BIW in Maine that are required to meet those specifications established in regulations and contracts with the Navy. Accordingly, we suggest the following language to clarify that BIW's ship components are not products or product components subject to the Proposed Rule.

Applicability. Unless exempted in Section 4, this Chapter applies to all new and unused <u>consumer</u> products and <u>consumer</u> product components sold, offered for sale, or distributed for sale in the State of Maine which contain intentionally added perfluoroalkyl and polyfluoroalkyl substances.

2. Limitations of Exemptions

As previously noted, the products BIW manufactures – naval warships – are exempt from the Proposed Rule under Sections 4(A)(8) and 4(A)(10)-(13). It is reasonable to therefore assume that the product components that comprise a naval warship also are excluded, particularly given the definition of "watercraft" in Title 12¹ and the exclusions of semiconductors, non-consumer electronics, and equipment directly used in the manufacture or development of exempt products. But this is not made clear in the Proposed Rule.

To the contrary, the Section 4(A)(8) exemption suggests that the manufacturer of an exempt product must still investigate the presence of PFAS in that product (defined to include its components) and, upon request, "provide sufficient justification that the product containing intentionally added PFAS is necessary to meet said requirements." Section 4(A)(8)(a). That makes no sense, as it effectively removes an exempt product and its components from an exemption that expressly acknowledges that federal standards or requirements mandate what products/product components may be manufactured. Furthermore, it has the effect of foisting a currently unavoidable use ("CUU") determination upon a product or its components to ensure that a product and its components will not be subject to a ban. And it is unclear who would have the CUU determination and reporting obligations – each individual supplier of BIW that manufactures a naval warship's component parts or BIW itself. In short, Section 4(A)(8)(a) has the effect of rendering Section 4(A)(8) potentially meaningless.

¹ The Proposed Rule cites to 32 M.R.S. § 13001(28)(2) for the definition of "watercraft." That section does not exist, so BIW assumes that the DEP intended to cite to 12 M.R.S. § 13001(28)(2), which defines "watercraft" as "any type of vessel, boat, canoe or craft capable of being used as a means of transportation on water, other than a seaplane, *including motors, electronic and mechanical equipment and other machinery, whether permanently or temporarily attached*, that are customarily used in the operations of the watercraft" (emphasis added).

VIA EMAIL - PFASproducts@Maine.gov August 29, 2024 Page 3

Section 4(A)(8)(a) also renders the Section 4(A)(8) exemption in conflict with the Section 4(A)(10) and 4(A)(13) exemptions, which exempt the component parts of and equipment² used to manufacture a watercraft. Section 4(A)(8) should be revised for consistency and clarity by striking Section 4(A)(8)(a) and adding "product components" at the outset of the exemption:

(8) A product, <u>including its component parts</u>, required to meet standards or requirements of the FAA, the National Aeronautics and Space Administration (NASA), the United States Department of Defense (DOD) or the United States Department of Homeland Security (DHS), except that the exemption under this Subsection does not apply to any textile article or refrigerant that is included in or as a component part of such products;

Excluding textile articles or refrigerants that are included in or as a component part of Sections 4(A)(8) and 4(A)(10) exempt products is further problematic. Again, the exempt product here is a naval warship. At no point will this product, or any of its components, be used for personal, family, or household purposes. But such product components are necessary to the construction and functioning of the exempt product.³

Nevertheless, Section 4(A)(8) and 4(A)(10) remove from the respective exclusions "any textile article or refrigerant that is included in or as a component part of such products." Note that for watercraft, Section 4(A)(10) directly contradicts the ban provision in Section 5(C)(7)(b), which states that the 2026 ban on textile articles does not include "A textile article that is included in or a component part of a watercraft." Accordingly, it is BIW's position that textiles used in combatant ships are not subject to the 2026 ban.

Similarly, the 2040 ban on refrigerants and foams in Section 5(F) contains a limitation on such products used in servicing equipment acceptable pursuant to the Significant New Alternatives Program ("SNAP"). While the task of reviewing each product and product component's acceptability to SNAP is onerous, and the responsibility for this task unclear, it is likely that, the refrigerants or foams used in ships constructed for the DOD or watercraft more generally would fall under this exemption, rendering the exclusion of refrigerants in Sections 4(A)(8) and 4(A)(10) unnecessary.

² "Equipment" is an undefined term that could be interpreted to include product components. See, e.g., NOTE at Section 4(A)(11) explaining that "electronic equipment" is a product subject to the Proposed Rule.

³ See DOD Report on Critical Per- and Polyfluoroalkyl Substance Uses at Sections IV.5 and V, enclosed herein. For example, chemical resistant bearing greases and marine lubricants are necessary for the construction and function of BIW's product. Halogenated PTFE Lubricant (MIL-G-27617 Type III or DOD-L-24574 Type III) is necessary to lubricate parts and threads. These synthetic fluorinated lubricants are used in extreme conditions, such as continuous high temperatures. They are chemically inert and safe for use around hazardous chemicals, these lubricants are nonflammable, are silicone free and do not damage plastics or elastomers, or cause corrosion to metals. As DOD explains, the use of textiles and refrigerants, both directly and indirectly, is "critical to the national security of the United States." Excluding these "mission critical" PFAS uses from the exemption, which would "have unintended impacts on market dynamics and the supply chain, resulting in the loss of access to mission critical uses of PFAS ... pose[s] risks to DoD operations and the defense industrial base supply chain." This certainly is not the intent of the Acts.

VIA EMAIL - PFASproducts@Maine.gov August 29, 2024 Page 4

Finally, the Proposed Rule must clarify that a product's exemption extends to its components' packaging. While packaging of products such as lubricants, cleaners, industrial chemicals, paint thinners, etc. is generally exempt, that exemption does not extend where the packaging is a fluorinated container or container that otherwise contains intentionally added PFAS. *See* Sections 4(A)(2) and 5(B), (C), (E), and (F). Determining which of its product components arrive in such excluded packaging would be unduly burdensome for BIW. Because packaging ingredients are not listed on SDSs, it is impossible to know which components are arriving in banned packaging and which are not. While we are unaware of any specific product containers in use or to be supplied that contain PFAS, such a determination would require pulsing BIW's entire supply chain, which would then need to pulse their packaging suppliers.

For these reasons, BIW proposes that the Department strike the language excluding from the exemption of any textile article or refrigerant that is included in or as a component part in Sections 4(A)(8) and (10) and add language that the exemption extends to all packing of the exempt product, as follows:

(8) A product, <u>including its component parts and including its packaging, notwithstanding Sections</u> <u>4(A)(2) and 5(B), (C), (E), and (F)</u>, required to meet standards or requirements of the FAA, the National Aeronautics and Space Administration (NASA), the United States Department of Defense (DOD) or the United States Department of Homeland Security (DHS);
(10) A watercraft as defined in 32 M.R.S. § 13001(28)(2), <u>including its component parts and</u> <u>including its packaging, notwithstanding Sections 4(A)(2) and 5(B), (C), (E), and (F)</u>, or a seaplane;

Thank you for considering these comments, and we look forward to continuing to work with the Department to develop reasonable regulation of PFAS in consumer products.

Sincerely Jason M. Gasper

cc: Laura M. O'Hanlon, Esq., Deputy General Counsel, BIW Lisa Gilbreath, Esq., Pierce Atwood

Enclosure

Report on Critical Per- and Polyfluoroalkyl Substance Uses

Pursuant to Section 347 of the James M. Inhofe National Defense Authorization Act for Fiscal Year 2023 (Public Law 117-263)



August 2023

Office of the Assistant Secretary of Defense for Energy, Installations, and Environment

Office of the Assistant Secretary of Defense for Industrial Base Policy

The estimated cost of this report or study for the Department of Defense is approximately \$83,000 in Fiscal Year 2023. This includes \$47,900 in expenses and \$45,100 in DoD labor. Generated on 20230718 RefID: 1-22557AD

Table of Contents

Acro	onyms		iii	
I.	Intro	duction		
II.	Definitions			
	II.1	Per- and	Polyfluoroalkyl Substances	
	II.2	Critical	to the National Security	
	II.3	Sectors (Considered 4	
III.	Data	Collectio	on Methodology	
	III.1	CMRMI	P Data Call	
	III.2	Additior	nal Industry Engagement	
	III.3	OASD(I	BP) Industry Sector Data Collection Process	
IV.	Resu	lts		
	IV.1	Kinetic (Capabilities	
	IV.2	Energy S	Storage and Batteries	
IV.3 Microelectronics and Semiconductors			ectronics and Semiconductors7	
	IV.4 Castings and Forgings and Strategic and Critical Minerals			
	IV.5 Additional Mission Critical PFAS Uses			
		IV.5.1 Re	efrigeration and Air Conditioning, Cooling, and Electronics Thermal Control 10	
IV.5.2 Fire Suppression in Naval Vessels, Aircraft and Ground Combat Vehicles			re Suppression in Naval Vessels, Aircraft and Ground Combat Vehicles10	
		IV.5.3 A	queous Film Forming Foam11	
		IV.5.4 Li	nes, Hoses, O-Rings, Seals and Gaskets, Tapes, and Cables and Connectors11	
IV.5.5 Electronic/Dielectric Fluids IV.5.6 Advanced Oils, Greases, Fluids, and Lubricants			ectronic/Dielectric Fluids	
			dvanced Oils, Greases, Fluids, and Lubricants	
		IV.5.7 Pr	recision Cleaning Fluids	
		IV.5.8 De	egreasing/Cleaning Fluids	
		IV.5.9 A	dhesives	
		IV.5.10	Insulation and Foam Blowing	
		IV.5.11	Resins for Specialty Materials	
		IV.5.12	Specialty Filters and Membranes	
		IV.5.13	Fabrics, Fabric Liners, and Fabric Barriers	
		IV.5.14	Customized Applications	

<u>Figure</u>

Figure:	Overview of PFAS Groups	(refined from OECD 2021))
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<u>Appendix</u>

Appendix: Summary of Know	n Mission Critical PFAS	Uses A-1

<u>Acronyms</u>

AFFF	Aqueous film forming foam
AIM Act	American Innovation and Manufacturing Act of 2020
CMRMP	Chemical and Material Risk Management Program
DoD	Department of Defense
ECTFE	Ethylenechlorotrifluoroethylene
EPA	U.S. Environmental Protection Agency
EU	European Union
F3	Fluorine-free foam
FY	Fiscal Year
HFCs	Hydrofluorocarbons
HFOs	Hydrofluoroolefins
Li-ion	Lithium-ion
MCMEU	Mission-critical military end use
MilDep	Military Department
NDAA	National Defense Authorization Act
NDT	Non-destructive testing
OASD(IBP) ODASD(E&ER) OECD	Office of the Assistant Secretary of Defense for Industrial Base Policy Office of the Deputy Assistant Secretary of Defense for Environment and Energy Resilience Organisation for Economic Co-operation and Development
PA&T	Policy, Analysis, & Transition
PFA	Perfluoroalkoxy alkanes
PFAA	Perfluoroalkyl acid
PFAS	Per- and polyfluoroalkyl substances
polyFAA	Polyfluoroalkyl acid
PTFE	Polytetrafluoroethylene
PVDF	Polyvinylidene fluoride
SOTA	State-of-the-Art
Sotp	State-of-the-Practice
U.S.	United States
USS	United States Ship
UV	Ultraviolet

I. Introduction

Section 347(a) of the James M. Inhofe National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2023 (Public Law 117-263) directs the Secretary of Defense, in consultation with the Defense Critical Supply Chain Task Force (i.e., the Office of the Assistant Secretary of Defense for Industrial Base Policy (OASD(IBP))) and the Chemical and Material Risk Management Program (CMRMP) of the Office of the Assistant Secretary of Defense for Energy, Installations, and Environment (OASD(EI&E)), to submit to the Committees on Armed Services of the House of Representatives and the Senate a report outlining the uses of per- and polyfluoroalkyl substances (PFAS) that are critical to the national security of the United States. This report focuses on critical uses in the sectors outlined in the February 2022 Department of Defense (DoD) report titled *Securing Defense-Critical Supply Chains* and sectors of strategic importance for domestic production and investment to build supply chain resilience.

PFAS are common chemicals used across DoD. Most weapons platforms incorporate PFAS, and PFAS are found throughout the defense industrial base in roles supporting mission critical component production and supply. PFAS uses may be direct, where a PFAS is a constituent in a consumable item or is incorporated into an article (e.g., end item), or indirect, where a PFAS is used to formulate another chemical or is part of a manufacturing process. These uses and processes are necessary to the production of key components of the defense industrial base, such as microelectronic chips and lithium-ion (Li-ion) batteries.

PFAS are chemically quite stable, and many are water and oil repellent, heat resistant, and/or stain resistant, often leading to non-stick surfaces on various materials. Examples of applications of PFAS are in plastics, o-rings, gaskets, lubricants, coolants, and fabrics. DoD is reliant on the critically important chemical and physical properties of PFAS to provide required performance for the technologies and consumable items and articles which enable military readiness and sustainment. Losing access to PFAS due to overly broad regulations or severe market contractions would greatly impact national security and DoD's ability to fulfill its mission, and impact domestic defense industrial base manufacturing and supply.

This report provides details on what is currently known about direct and indirect mission critical PFAS uses that could impact mission readiness if the substances are no longer available. It also highlights the challenges and costs related to finding and qualifying equal or improved performing alternatives to existing PFAS materials in sectors of strategic importance to DoD. It is important to note that the information contained in this report is limited to what was available at the time of its drafting. As such, the information presented represents a fraction of the mission critical PFAS uses due to a lack of knowledge of the complete chemical composition in consumables and articles (e.g., end items)¹. In addition, there is significant uncertainty regarding

¹ A consumable is defined as "an item of supply or an individual item (except explosive ordnance and major end items of equipment) that is normally expended or used up beyond recovery in the use for which it is designed or

the presence of PFAS in products that make up a complex value chain. A more complete understanding of PFAS essential uses would require an extensive and complex evaluation of the market, a gap analysis of current requirements for manufacturer-provided product information, and illumination of the value chain of products.

II. Definitions

For purposes of this report, the terms used within section 347(a) of the NDAA for FY 2023 are defined in the following sub-sections.

II.1 Per- and Polyfluoroalkyl Substances

There is currently no consensus definition of PFAS as a chemical class.² Congress did not define PFAS within section 347(a) of the NDAA for FY 2023 for purposes of this report.³ While there is no consensus definition, regulators in the European Union (EU) and the United States have proposed, but not yet adopted, different chemical-structure-based (rather than hazard- or risk-based) definitions. In anticipation of the most stringent future regulatory actions, DoD used the definition put forward by the Organisation for Economic Co-operation and Development (OECD) in its 2021 report, *Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance*,⁴ for collecting data and developing this report. OECD states "The term 'PFASs' is a broad, general, non-specific term, which does not inform whether a compound is harmful or not, but only communicates that the compounds under this term share the same trait for having a fully fluorinated methyl or methylene carbon moiety." OECD cautions that this definition should not be used in deciding how to group and manage PFAS in regulatory actions; however, future PFAS legal and regulatory frameworks may disregard the OECD caution and seek to restrict the use of PFAS based on chemical structure.

https://one.oecd.org/document/ENV/CBC/MONO(2021)25/En/pdf.

intended. An end item is the "final combination of end products, component parts, or materials that is ready for its intended use, e.g., ship, tank, mobile machine shop, or aircraft." *DoD Supply Chain Terms and Definitions* (February 21, 2023). <u>https://www.acq.osd.mil/log/LOG_SD/.policy_vault.html/DoD_Supply_Chain_Terms_and_Definitions.pdf</u>.

² Per- and Polyfluoroalkyl Substances (PFAS) Report: A Report by the Joint Subcommittee on Environment, Innovation, and Public Health, Per- and Polyfluoroalkyl Substances Strategy Team of the National Science and Technology Council, March 2023.

³ Congress previously defined PFAS in the NDAA for FY 2021 for purposes of establishing the interagency working group to coordinate federal activities related to PFAS research and development. Section 332(g)(1) defines PFAS broadly as (A) man-made chemicals of which all of the carbon atoms are fully fluorinated carbon atoms; and (B) man-made chemicals containing a mix of fully fluorinated carbon atoms, partially fluorinated carbon atoms, and nonfluorinated carbon atoms. William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Pub. L. 116-283 (2021).

⁴ "PFASs are defined as fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e., with a few noted exceptions, any chemical with at least a perfluorinated methyl group (–CF3) or a perfluorinated methylene group (–CF2–) is a PFAS." OECD, *Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance* (Series on Risk Management No. 61), July 9, 2021.

The figure below provides an overview of the PFAS groups based on the OECD definition. This very broad definition encompasses more than 38,000 individual PFAS chemicals.⁵ DoD uses are represented in each major category of PFAS (i.e., perfluoroalkyl acids (PFAAs) and polyfluoroalkyl acids (polyFAAs)), PFAA precursors, and other PFAS (e.g., fluoropolymers, fluoroelastomers).



Figure: Overview of PFAS Groups (refined from OECD 2021)

II.2 Critical to the National Security

Congress did not define "critical to the national security of the United States" within section 347(a) of the NDAA for FY 2023. The term "mission-critical military end use (MCMEU)," however, is defined in regulations promulgated by the U.S. Environmental Protection Agency (EPA) under the American Innovation and Manufacturing Act of 2020 (AIM Act).⁶ The AIM Act addresses the phasedown of production and consumption of hydrofluorocarbons (HFCs) (e.g., regulated substances). MCMEUs are "[t]hose uses of regulated substances by an agency of the Federal Government responsible for national defense that have a direct impact on mission capability, as determined by the U.S. Department of Defense, including, but not limited to uses necessary for development, testing, production, training, operation, and maintenance of Armed Forces vessels, aircraft, space systems, ground vehicles, amphibious vehicles, deployable/expeditionary support equipment, munitions, and command and control systems."⁷

The MCMEU definition focuses on *regulated substances*. As with HFCs, PFAS are undergoing increased regulation. But in addition to regulation, market forces can directly impact mission capability by limiting DoD's ability to source and use PFAS and PFAS-containing

 ⁵ Williams, et al. 2022. Assembly and Curation of Lists of Per- and Polyfluoroalkyl Substances (PFAS) to Support Environmental Science Research. *Front. Environ. Sci.* 10:850019. doi:10.3389/fenvs.2022.850019.
 ⁶ 42 U.S. Code 7675.

⁷ See 40 Code of Federal Regulations 84.3, "Phasedown of Hydrofluorocarbons" (October 5, 2021).

products. The most recent example is 3M's decision to phase out production of PFAS and PFAS-containing products by 2025.⁸

For purposes of data collection and report development, DoD used the MCMEU definition with the recognition that both market forces and increased regulation can have a direct impact on mission capability.

II.3 Sectors Considered

Section 347(a) of the NDAA for FY 2023 directs DoD to focus this report on critical PFAS uses in the four focus areas identified in DoD's February 2022 report *Securing Defense-Critical Supply Chains.*⁹ The four focus areas—kinetic capabilities, energy storage and batteries, microelectronics, and castings and forgings—have critical supply chain vulnerabilities posing the most pressing threats to national security. In addition, this report focuses on semiconductors—a sector of strategic importance for domestic production and investment to build supply chain resilience—and strategic and critical minerals. These areas are described as:

- **Kinetic capabilities**: Current missiles systems and advanced and developing missile capabilities, including hypersonic weapons technology, as well as directed energy weapons.
- **Energy storage and batteries**: High-capacity batteries, with a particular focus on lithium batteries.
- **Microelectronics and semiconductors**: State-of-the-Practice (SOTP) and legacy microelectronics, State-of-the-Art (SOTA) microelectronics, and semiconductors.
- **Castings and forgings**: Metals or composites developed into key parts and manufacturing tools through high-intensity processes.
- **Strategic and critical minerals**: Minerals to supply U.S. military, industrial, and essential civilian national emergency needs, with emphasis on those that are not produced in sufficient quantities in the United States.

III. Data Collection Methodology

Data collection efforts for this report were led by the CMRMP of the ODASD(E&ER) and the OASD(IBP) and included engagement with the DoD Components and Military Departments (MilDeps), industry, and industry associations.

⁸ "3M to Exit PFAS Manufacturing by the End of 2025" (December 20, 2022). <u>https://news.3m.com/2022-12-20-3M-to-Exit-PFAS-Manufacturing-by-the-End-of-2025</u>.

⁹ Securing Defense-Critical Supply Chains: An Action Plan Developed in Response to President Biden's Executive Order 14017 (February 2022). <u>https://media.defense.gov/2022/Feb/24/2002944158/-1/-1/1/DOD-EO-14017-REPORT-SECURING-DEFENSE-CRITICAL-SUPPLY-CHAINS.PDF</u>.

III.1 CMRMP Data Call

In March 2023, the CMRMP asked the DoD Components and MilDeps to provide information about its critical uses of PFAS, to include use of neat PFAS, use of PFAS-containing products, the functionality provided by the PFAS, specific uses and applications, and availability of alternatives (if known).

III.2 Additional Industry Engagement

The CMRMP held engagement sessions with various industries and industry associations to obtain information about the PFAS and PFAS-enabled products that they (or their member industries) manufacture and how DoD uses those products. The CMRMP shared this information with the DoD Components and MilDeps to inform their data collection efforts.

III.3 OASD(IBP) Industry Sector Data Collection Process

The Kinetic Capabilities Team at Policy, Analysis, & Transition (PA&T), OASD(IBP), engaged with PA&T Industry Sector leads and their industry partners to identify PFAS uses that are critical to U.S. national security. These sectors include Kinetic Capabilities, Energy Storage and Batteries, Microelectronics and Semiconductors, Castings and Forgings, and Strategic and Critical Materials. The Sector leads identified PFAS uses in industry, operation, manufacturing, processes, components, parts, and materials. They also discussed how and where losing access to PFAS could have significant mission readiness impacts and what they could do or are doing to mitigate those impacts.

IV. <u>Results</u>

DoD's known critical uses of PFAS are summarized in the following sub-sections, organized by focus area, and in the Appendix. The complexities in dissecting the defense industrial base value chain and supply chain dependencies, in addition to the lack of transparency in chemical and material content data, prevented the CMRMP from gathering comprehensive data on all critical PFAS uses.

Critical PFAS uses were identified in almost every major weapon system category including but not limited to fixed wing aircraft (trainers, fighters, bombers, transports, refuelers, ground support, unmanned, and associated support equipment); rotary wing aircraft (attack, transports, heavy lifts, search-and-rescue, and associated support equipment); surface ships (combat, destroyers, aircraft carriers, cutters, landing crafts); submarines; missiles (air-to-air, ground-to-air, air-to-ground, ballistic); torpedo systems; radar systems; and battle tanks, assault vehicles, and infantry carriers.

IV.1 Kinetic Capabilities

Kinetic capabilities represent a direct use of PFAS, as PFAS are found in a variety of applications across the DoD munitions portfolio. About a dozen fluoropolymers, including

fluoroelastomers, are ingredients in polymer bonded explosives, pyrotechnics, and propellant components used in munitions, decoy flares, and chaff. They serve as high temperature resistant binders and resins. These uses, which represent some of the few purely military PFAS applications, include:

- Unique binder materials specifically developed for use in the energetic portion of conventional and strategic weapons platforms.
- Fluoroelastomers, such as VitonTM, used as a binder in explosive and booster charge formulations integrated into many DoD munitions.
- Fluoropolymers, such as TeflonTM, used in pyrotechnics and as a material used in the manufacture of munitions for a variety of missile systems.

PFAS are used in a variety of applications during energetics processing and testing. Currently, non-PFAS alternatives do not exist for most of these applications, and the likelihood of developing alternatives for these uses is estimated to range from moderate to almost impossible. If available, alternatives require multi-year processes and cost program offices millions of dollars to requalify every missile system that used the material, even if products are similar.

IV.2 Energy Storage and Batteries

Impacts to national security from PFAS applications in energy storage and battery applications are indirect. Manufacturers use fluoropolymers (e.g., polytetrafluoroethylene (PTFE)) and polyFAAs in multiple subcomponents in modern Li-ion batteries. They serve as heat transfer materials or insulation and provide weather resistance and ultraviolet (UV) light resistant functionalities to final components. Military applications rely on Li-ion battery technologies that are largely innovated in the civilian sector. Manufacturers use PFAS in the electrolyte solutions, cathode binders, and separator coatings; and, to a lesser extent, PFAS are found in casing materials and gaskets due to their deterioration resistance properties.

PFAS materials also play an important role in battery manufacturing. Filters and other components of manufacturing equipment are essential to battery production. The battery industry's ability to make products for a broad range of commercial and military applications would be greatly impacted if PFAS were no longer available for use in these components. The significant time and money needed to identify and qualify alternatives as replacements would cause ripple effects throughout the economy as consumers and users absorb the additional cost.

Fully eliminating PFAS from energy storage in the U.S. economy would likely take more than 10 years. Energy storage is a broad issue for U.S. industrial competitiveness as well as an important part of Federal initiatives around combating climate change. DoD is not the primary consumer of batteries in the United States, but battery supply chain issues would impact the ability to produce missiles and field military vehicles that increasingly rely on batteries.

IV.3 Microelectronics and Semiconductors

The semiconductor industry produces the chips that drive modern electronic devices. The microelectronics packaging and assembly industry integrates these chips into the electronic products used every day across the defense enterprise. In the semiconductor industry, fluoropolymers, fluoroelastomers, polyFAAs, and other fluorochemicals are used in a number of applications and at every stage of semiconductor fabrication. These uses include etching materials (photoresists), etching coolants, masks in photolithography processes, packaging materials that provide heat dissipation for the chip, and cleaning gases at various stages in the microchip production process. Examples of specific PFAS in the semiconductor industry include polyvinylidene fluoride (PVDF; a fluoropolymer), ethylenechlorotrifluoroethylene (ECTFE; a fluoropolymer), FKM/FFKM (fluoroelastomers), and perfluoroalkoxy alkanes (PFAs).

One significant use of PFAS in semiconductor manufacturing is during the photolithography process, where the patterns that define the microchip circuitry are developed onto bare silicon surfaces. Manufacturers use photolithography specialty formulations containing fluorinated compounds in various steps of this process to ensure final chip quality and reduce the probability of defects. PFAS are ideal for these purposes due to their low surface tension and compatibility with other chemicals. The PFAS materials used in these processes are typically no longer present in the finished product, except in some specific applications, such as imaging chips used in cameras, displays, and some medical devices.

Similar to the energy storage industry, PFAS are essential for semiconductor manufacturing equipment and factory infrastructure. The exceptional combination of heat and chemical resistance and chemical inertness allows fluoropolymers to be used both in equipment components (e.g., tubing, gaskets, containers, filters) and lubrication (e.g., various oils and greases). These same properties are also needed to ensure the functioning of the surrounding infrastructure.

In wider microelectronics applications, PFAS remain key industrial materials in applications that integrate microchips into electronic products, such as printed circuit boards. PTFE and PFA base laminate materials are currently used in many radio frequency (RF) and microwave circuits, as they provide unique properties related to isolating RF and microwave signals. Identifying and qualifying potential replacement materials will require significant time, particularly for use in fielded systems. There currently are no available drop-in replacement materials for a PTFE designed printed board. Lack of access to PTFE laminate will necessitate the redesign and requalification of the printed board, the assembly, and potentially the system.

Several PFAS-containing vapor phase soldering and flux removal products are used in the manufacture of printed circuit boards. Vapor phase soldering is used primarily for printed board assembly when there is a high thermal mass, in combination with advanced technologies such as fine-pitch features, or when there are temperature sensitive components used. Alternative materials are not currently identified and would need to be evaluated for performance and safety. New equipment may be required to implement new vapor phase soldering liquids. PTFE cable jackets are used in printed circuit board and other electronic systems in connectors and wire. PTFE has unique properties as a wire insulator including fire, smoke, and chemical resistance to mitigate the risk of wire exposure in harsh environments. PTFE can withstand 450°C and is used widely in products that have been developed to meet MilSpec applications. Manufacturers also use fluoropolymers as electronics sealants and encapsulants to protect microelectronic components from degradation due to environmental, chemical, or UV-light exposure. Vapor degreasing solvents, used in a variety of cleaning processes during microelectronics production, contain hydrofluorocarbons (HFCs) and hydrofluoroolefins (HFOs), which, in many cases and in the broadest sense, are defined as PFAS. These materials impart fire suppression properties to the degreasing solvent, creating safer manufacturing environments for workers.

Currently, no alternatives to PFAS have been identified that can provide the functional properties required for photolithography or some applications in semiconductor manufacturing equipment. Even if alternative chemicals and technologies were discovered today, due to the extremely complex qualification process throughout the value chain, it would take another 15 years to deploy them in high-volume manufacturing. Therefore, continued access to PFAS is a prerequisite for high-volume and advanced semiconductors. Lack of continued access to PFAS could lead to an inability to produce and supply semiconductor manufacturing technology.

Replacing most PFAS uses in semiconductor fabrication would require industry-wide retooling and other process innovations, at a minimum. Some might be achievable within 10 years, but many would not. As stated above, there are some PFAS uses for which no alternatives are known. For these uses, it may be necessary to invent novel chemistries and processes. Replacing PFAS in semiconductor fabrication could be a 25-year effort and may not succeed in all respects if alternatives cannot be identified or qualified at the microchip level.

Consideration must also be given to the resultant impact on DoD programs. It is highly probable that manufacturers would need to change semiconductor manufacturing processes to accommodate PFAS replacements. This change has the potential to result in the costly requalification of specific components. For example, radiation hardened microelectronics applications typically mandate requalification if a manufacturer substantively alters the fabrication process, which can easily exceed \$10 million; many programs lack intrinsic funding for requalification.

IV.4 Castings and Forgings and Strategic and Critical Minerals

Specialty fluorochemical gases and fluids are used for advanced metalworking, casting, and fabrication due to the temperature and wear resistance functionalities they provide. These gases and fluids are used in the production of advanced metal parts throughout U.S. industry, including military-specific parts. Requiring a move to PFAS-free alternatives in under 10 years may make construction using certain alloys impossible and require returning to previous methods

of construction leading to lower performance, shorter life, and higher weight of constructed parts.

In both the casting and forging and strategic and critical minerals industries, loss of access to PFAS is an indirect threat to national security and a potential source of significant disruption to supply chains vital to the DoD mission. These industries depend on PFAS in products used during normal business operations. A product used as a liquid cold spray in castings and forgings or coolant in drilling operations for critical minerals may contain PFAS, but the product user would not know that PFAS are present until the product is discontinued. Both industries are at risk of losing critical capabilities with little warning, as there are limited requirements for companies to provide composition information for the materials used to create the products they sell to DoD or on the commercial market. The risk for these industries is particularly high, even if the probability is low, because there may be no warning for critical product obsolescence and no ability to develop and qualify alternatives in a timely fashion.

PFAS are also contained in mold release chemicals and release films typically used in composite manufacturing processes. Loss of access of PFAS would impact the commercial composites manufacturing industry and, indirectly, the DoD who is reliant on the commercial industry for applications.

Mold release chemicals are applied to mold hardware to prevent the composites from strongly adhering to the mold hardware during cure. The mold release chemicals typically contain PFAS chemicals or a PTFE polymer spray. Peel plies are used to prevent attachment of vacuum bag materials and other disposable molding materials to the composite part and to impart a textured surface to the molded component to improve adhesion in secondary bonding or painting. Peel plies are typically made of non-PFAS polymers, such as polyamides and polyesters; however, to prevent adhesion of the composite to the peel ply, PFAS modification (most commonly) or silicone modification is done to the fabric. Additionally, if high cure temperatures are required, PTFE and PVDF peel plies are typically used. Polymer release films are similar to peel plies but are generally used with composite resins that need to release gasses during cure. Many of these release films are polyethylene, polypropylene, or other polyolefins and work well for many applications; however, certain applications (typically higher temperature curing systems) require use of fluoropolymers, such as PTFE, PVDF, and others. Pre-preg release film is used to keep individual layers of pre-pregs (e.g., fabrics that are pre-impregnated with a fully curable, mixed resin system during manufacture) separated from each other within the rolls of materials that are prepared and transported for use in composites manufacturing facilities. Fluoropolymer release films are generally used to ensure the releasability of the release film during composite layup. Silicones are also useable for this application but are generally not used because of the low rigidity of silicone films.

IV.5 Additional Mission Critical PFAS Uses

Mission critical PFAS uses extend beyond the five industries discussed to this point. DoD identified a range of additional critical uses for which the potential risk of supply chain disruption would undercut not only mission readiness but the U.S. economy. These uses are discussed in more detail in the following sub-sections.

IV.5.1 Refrigeration and Air Conditioning, Cooling, and Electronics Thermal Control

Most refrigerants used in civil and military cooling and refrigeration applications can be classified as PFAS. Many next-generation refrigerant alternatives adopted by U.S. industry (and U.S. households) between now and the end of 2025 are also PFAS. Under the AIM Act and EPA technology transition regulations, the U.S. economy is in the process of switching from one set of PFAS-classified refrigerants (e.g., HFCs) to a new generation of refrigerants (e.g., HFOs), which are also, in the broadest definitions, considered to be PFAS. Known non-PFAS alternatives (e.g., hydrocarbon or ammonia alternatives) pose flammability, toxicity, or high-pressure concerns. The same PFAS that are used in quantities of several hundred million pounds per year throughout the U.S. economy for cooling applications are used in much smaller quantities (i.e., a fraction of one percent) for military cooling and military thermal control of all kinds.

IV.5.2 Fire Suppression in Naval Vessels, Aircraft and Ground Combat Vehicles

Fluorochemical specialty gases are used in "clean agent" fire suppression in naval vessels, aircraft, and ground combat vehicles. Most known clean agent, low-corrosion, low-weight, low-toxicity alternatives will likely be classified as PFAS, broadly defined.

Since the advent of regulations against halogenated agents, Naval vessels commonly utilize an HFC clean agent in compartments subject to flammable/combustible liquid fuel fires such as engine modules and hazardous material storage spaces. For new U.S Naval ship designs, the Navy continues to move to alternate fire suppression technologies (e.g., water mist) where suitable, however limited use of HFC remains for those spaces where the alternatives are not appropriate. For existing ship HFC uses, there is no "drop-in" replacement for these HFC agents.

Well over 10 million pounds of PFAS fire suppressants are installed in civil aircraft engine, cargo compartment, and lavatory fire suppression systems, and in hand-held aircraft fire extinguishers, worldwide. This includes halons (which meet PFAS definitions but are frequently excluded from draft PFAS regulations because they are separately covered by ozone depleting substance regulations) and all currently implemented aviation replacements for halons. In 2022, Working Paper 96 presented at the 41st Assembly of the International Civil Aviation Organization recommended considering PFAS use in aircraft fire suppression an essential use in prospective PFAS regulations to maintain progress in replacing halons.¹⁰

¹⁰ International Civil Aviation Organization (ICAO), Working Paper 96: Aircraft Halon Replacement, A41-WP/96, 28 July 2022. <u>https://www.icao.int/Meetings/a41/Documents/WP/wp_096_en.pdf</u>.

IV.5.3 Aqueous Film Forming Foam

Mission critical ocean-going vessels employed by DoD and the Military Services continue to use aqueous film forming foam (AFFF) containing PFAS for combating Class B (flammable/combustible liquid) fuel spill fires. U.S. Navy ships are required to use AFFF qualified to MIL-PRF-24385. MIL-PRF-24385 qualified AFFF provides the capability to rapidly control and extinguish shipboard fires. AFFF is critical for fire emergencies on flight decks where aircraft movement, fueling, launch/recovery, and weapons loading occur, and substantial risk exists for loss of aircraft, ship, and life if a fire is not rapidly controlled and extinguished.

Past flight deck fires, such as those that occurred on the United States Ship (USS) FORRESTAL, USS ENTERPRISE, and USS NIMITZ, all demonstrate the potential for such catastrophic events to occur. The risk of devastating loss of life and warfighting capability in incidents such as these, and the more recent fire emergency which resulted in the loss of the USS BONHOMME RICHARD, necessitates the use of the most effective firefighting agents available.

Beyond the potential for the immediate loss of life and impacts to operational capability that can result from an uncontrolled fire on a warship, the defense industrial base has limitations with respect to repairing or delivering replacement national security assets, including ordnance, aircraft, and ships. It could take a decade or longer to replace large amphibious assault ships and aircraft carriers.

Currently available fluorine-free foams (F3s) have significant limitations compared to AFFF that preclude their use on DoD ocean-going vessels, including the U.S. Navy fleet. Those limitations include reduced firefighting performance; chemical and physical properties that make them unsuitable for use with existing ship firefighting foam storage and delivery systems; and cross-agent compatibility issues. There are currently no equivalent, fully performing firefighting alternatives to AFFF for shipboard use.

DoD continues to sponsor research and development for F3 technologies to address these limitations, with the goal that continued technology improvements will support efforts toward a future path for use on ships. To date, DoD has invested approximately \$45.8M since 2017 toward the development and qualification of F3 technologies.

Until such time that a capable F3 alternative is found, the safety and survivability of naval ships and crew from shipboard fires depends on the continued availability of MilSpec AFFF products and their PFAS-containing constituents, which were formulated, tested, qualified, and implemented in order to save lives and military assets.

IV.5.4 Lines, Hoses, O-Rings, Seals and Gaskets, Tapes, and Cables and Connectors

Dozens of different fluoropolymers (e.g., PVDF, ECTFE, PTFE) and fluoroelastomers (e.g., FKM/FFKM) are critical to modern UV-resistant, ozone-resistant, weather-resistant,

temperature-resistant, high pressure-resistant, chemical-resistant "rubberized" fuel lines. They are also key materials in hoses, tubing, hydraulic system lines, O-rings, seals and gaskets, tapes, and cables and connectors widely used in civil and military aircraft, space systems, vehicles,

weapon systems, utility systems, and other applications. Alternatives are not as resistant to embrittlement and break-down and have a much shorter useful life, leading to more frequent part replacement, which is not feasible for space or satellite uses.

IV.5.5 Electronic/Dielectric Fluids

Fluorochemicals are found in electronic and dielectric fluids that are used in civil and military radars and high-power electronics and electrical system/utility system components because of their dielectric and heat transfer properties. Industry and DoD have repeatedly investigated alternatives for these applications. Known alternatives have high global warming potential (e.g., sulfur hexafluoride) or may pose health/environmental risks (e.g., the polychlorinated biphenyls banned by the U.S. Toxic Substances Control Act and the Stockholm Convention on Persistent Organic Pollutants). Examples of PFAS-containing electronic/ dielectric fluids used by DoD include 3MTM FluorinertTM Electronic Liquids FC-40, FC-72, FC-770, and FC-3283.

IV.5.6 Advanced Oils, Greases, Fluids, and Lubricants

PFAS are used in many advanced turbine engine oils, greases, fluids, and lubricants due to their wear- and heat-resistant properties. These uses are common throughout the most demanding applications in the U.S. civil transportation, industrial, and space sectors. Analogous PFAS-containing oils, lubricants, and fluids are used in military critical ground, sea, air, and space applications. Previous generations of oils, fluids, and lubricants approached, but did not equal, the performance of PFAS additives that have become more prevalent in high performance oils, greases, fluids, and lubricants over the past 20 years.

Castrol Braycote 640AC is an example of a PFAS-containing grease, designed to be oxidizer and propellant compatible for use in aerospace vehicles, spacecraft, rocket and aircraft engines, and associated ground support equipment, oxygen equipment, and transport equipment. Braycote 640AC is typically used to lubricate threaded fasteners, connectors, valves, gaskets, elastomers, and bearings. Perfluorinated greases, in general, exhibit excellent shelf lives due to their intrinsic inertness.

Two additional examples of PFAS-containing greases used by DoD (and original equipment manufacturers and the maintenance, repair, and overhaul industry) are NYCO GREASE GN25013 and NYCO GREASE GN617. PTFE is used as a thickener in both products and perfluoropolyether is used as the base stock for GN617.

IV.5.7 Precision Cleaning Fluids

Fluorochemicals are used in precision cleaning applications, including the cleaning of sensitive oxygen systems in civil and military aerospace.

IV.5.8 Degreasing/Cleaning Fluids

The MilDeps reported the use of PFAS-containing degreasing/cleaning products and contact cleaners (e.g., 3MTM NovecTM Engineering Fluids, 3MTM NovecTM Contact Cleaners, 3MTM NovecTM Contact Cleaner/Lubricant) in vapor degreasing and flux removal.

The Army reported the use of FCC2 Enhanced Fiber Connector Cleaner and Preparation Fluid, which contains butane, 1,1,1,2,2,3,3,4,4-nonafluoro-4-methoxy, for cleaning fiber optic connectors in secure link manager assemblies and primary modem assemblies.

The MilDeps reported the use of fluorinated non-destructive testing (NDT) solvent cleaner/remover for precleaning before NDT and for removing excess surface penetrant from an inspection area before applying developer during liquid penetrant testing.

The MilDeps also reported that PFAS-containing degreasers are used to effectively remove grease, oil, tar, and other substances from military equipment to increase its operating efficiency. These degreasers leave no residue, have no flash or fire point, and serve as an alternative to legacy solvents (e.g., n-propyl bromide, trichloroethylene, tetrachloroethylene).

IV.5.9 Adhesives

The MilDeps reported the use of the following adhesives, which contain PFAS: 3M[™] Super Foam Fast Spray Adhesive 74-Orange, 3M[™] Hi-Strength Spray Adhesive 90 (aerosol), and 3M Scotch-Weld Epoxy Adhesive DP420 Off-White, Part A.

IV.5.10 Insulation and Foam Blowing

Fluorochemicals are components of insulation and foam blowing products used in civil and military aircraft and space vehicles/rocket motors.

IV.5.11 Resins for Specialty Materials

Fluoropolymers are used in resins for specialty high-temperature or weather-/UVresistant composites due to their temperature-, pressure-, wear-, and chemical-resistance properties. Fluoropolymers are also used in high cleanable, high weathering and chemical resistant coatings for military assets. Many aircraft topcoats contain fluoropolymer resins due to their UV and chemical resistance properties. PFAS are not actually in the coatings themselves but are used in fluoropolymer resin manufacturing.

Moving to alternatives in under 10 years may require a return to previous methods of parts construction which produced shorter life and higher weight composites with lower performance characteristics.

IV.5.12 Specialty Filters and Membranes

Fluoropolymers are used in specialty filters and membranes (e.g., aviation filters) due to their temperature-, pressure-, and wear-resistance properties. PFAS are also found in several air filtering masks and air filtering respirators used by DoD.

IV.5.13 Fabrics, Fabric Liners, and Fabric Barriers

A variety of textiles used in uniform clothing and footwear items, tents, and duffle bags are treated with PFAS to repel water and oils while providing durability to laundering, UV light exposure, and temperature cycling. The main PFAS used on textiles are fluoropolymers, such as PTFE and short chain PFAS, known as C6 or C4 chemistries. PFAS can be incorporated as an additive mixed into individual fibers or sprayed as a coating onto finished fabrics during manufacturing or after sale and are present in/on textiles in two forms: a non-polymerized compound that can be washed out or evaporated or as a molecule integrated into a fluorine free polymer network via covalent bonds. The MilDeps reported the use of PFAS in chemical, biological, radiological, and nuclear protective equipment (the Uniform Integrated Protection Ensemble Family of Systems) and in a number of uses within health care communities.

Coretech, the biological protective fabric lining used on the Joint Biological Agent Decontamination System, includes a barrier layer for biological protection during the decontamination of aircraft. The barrier layer contains PFAS.

IV.5.14 Customized Applications

Customized applications like gyroscope suspension fluids and analytic gases and fluids for thermometric and other sensors use specialty fluorochemicals because of their pressure-resistant, wear-resistant, and temperature control properties. These applications require very small quantities of specialty PFAS and are particularly susceptible to disruptions in PFAS supply chains due to challenges in attracting manufacturers to develop low-volume commodities.

V. Conclusions

This report summarizes known direct and indirect uses of PFAS that are critical to the national security of the United States, but it is not comprehensive. Also highlighted are the challenges and costs related to finding and qualifying alternatives to existing PFAS materials in sectors of strategic importance to DoD. The information contained in this report is limited to what was available at the time of its drafting. As such, the information presented represents a fraction of the mission critical PFAS uses due to a lack of transparency in the chemical composition in consumables and articles. In addition, there is significant uncertainty regarding the presence of PFAS in products that make up a complex value chain. A more complete understanding of PFAS essential uses would require an extensive and complex evaluation of the market, a gap analysis of current requirements for manufacturer-provided product information, and illumination of the value chain of products.

PFAS are critical to DoD mission success and readiness and to many national sectors of critical infrastructure, including information technology, critical manufacturing, health care, renewable energy, and transportation. DoD relies on an innovative, diverse U.S. industrial economy. Most of the structurally defined PFAS are *critical to the national security of the United States*, not because they are used exclusively in military applications (although a few are) but because of the civil-military commonality and the potentially broad civilian impact. This report provides details on what is currently known about direct and indirect mission critical PFAS uses that could impact mission readiness if the substances are no longer available.

Emerging environmental regulations focused on PFAS are broad, unpredictable, lack the specificity of individual PFAS risk relative to their use, and in certain cases will have unintended impacts on market dynamics and the supply chain, resulting in the loss of access to mission critical uses of PFAS. These market responses will impact many sectors of U.S. critical infrastructure , including but not limited to the defense industrial base. Collectively, international and U.S. regulatory actions to manage PFAS' environmental impacts and identify and eliminate PFAS from the market, and the resulting market changes, pose risks to DoD operations and the defense industrial base supply chain. In addition, impacts to the global PFAS supply chain will present risks to the DoD Foreign Military Sales program and to North Atlantic Treaty Organization interoperability.

The Department will continue to oversee coordinated lines of effort to expeditiously identify essential uses of PFAS, prioritize actions according to vulnerabilities to national security, and address mission readiness associated with the potential loss of access to PFAS. Actions include:

- Implementing DoD PFAS policy directing the DoD Components and MilDeps to determine the PFAS content in DoD weapon systems, to the extent feasible, and enabling continued access to mission critical uses, while encouraging safe use by DoD personnel and adoption of PFAS-free alternatives.
- Engaging with industry to identify PFAS content in other materials commonly used within the DoD to assess potential obsolescence risks and potential PFAS alternatives.
- Engaging with industry and federal agencies during routine meetings to assess obsolescence risks, mission criticality, and potential PFAS alternatives.
- Investing in research, development, and qualification efforts required to demonstrate conformance with Military Standards or Specifications.
- Collaborating across the Federal Government to develop a long-term research plan for the most challenging applications where it will take a decade or more to find viable replacements.
- Investing in research to support advanced manufacturing approaches by improving purification, deconstruction technologies, scale-up of sustainable materials design and manufacturing, and circularity for the most critical and irreplaceable PFAS.

Concurrent with efforts to identify essential uses of PFAS, the Department is phasing out non-essential and non-critical PFAS uses in accordance with NDAA requirements where there is no mission impact (e.g., in food packaging, cookware, furniture, personal protective firefighting equipment). Additionally, per the 2023 U.S. Government Accountability Office (GAO) recommendations,¹¹ the Department is developing an approach to implement the April 2023 prohibition for military exchange resale procurements. The Department is also updating DoD Instruction 4105.72, *Procurement of Sustainable Goods and Services*, to include procedures specifically targeted to implementing the provisions of Executive Order 14057, *Catalyzing Clean Energy Industries and Jobs Through Federal Sustainability*, with respect to limiting the procurement of items containing PFAS.

Eliminating PFAS from non-essential uses is an important step toward addressing public concerns and protecting human health and the environment. Mission critical PFAS uses provide significant benefits to the framework of U.S. critical infrastructure, and national and economic security. DoD will consider future policy actions to manage non-essential and essential PFAS uses and will implement these actions with the intent of protecting human health and the environment while ensuring no adverse impacts to U.S. critical infrastructure and national security.

If future PFAS legal and regulatory frameworks ignore the OECD caution on the use of its PFAS definition and seek to broadly restrict the use of PFAS based on chemical structure, there could be extensive economic, industrial competitiveness, and quality-of-life impacts to U.S. society. The PFAS universe is structurally and physiochemically diverse and subgroups of PFAS may be more or less stable, persistent, and/or bioaccumulative compared to well-studied PFAS such as perfluorooctane sulfonate and perfluorooctanoic acid.¹² Congress and the Federal regulatory agencies should avoid taking a broad, purely "structural" approach to restricting or banning PFAS. It is critical that future laws and regulations consider and balance the range of environmental and health risks associated with different individual PFAS, their essentiality to the U.S. economy and society, and the availability of viable alternatives.

¹¹ U.S. Government Accountability Office (GAO). Persistent Chemicals: Actions Needed to Improve DoD's Ability to Prevent the Procurement of Items Containing PFAS. GAO-23-105982. April 2023.

¹² EPA Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS) (Public Review Draft), EPA-822-P-23-003 (March 2023).

PFAS	Application	Functionality	Availability of Alternatives	Time Frame / Cost to Develop and Qualify Alternatives*		
Kinetic Capabilities						
Fluoropolymers (e.g., Teflon™)	Ingredients in binders and resins used in PBX, pyrotechnics, and propellant components that are used in a	High temperature resistance	NA*	NA		
Fluoroelastomers (e.g., Viton TM)	variety of applications across the DoD munitions portfolio.					
PFAS	Used in energetic slurry processing.	Enables high levels of mixing between key energetic components.	NA	NA		
Fluorinated performance fluids (e.g., 3M [™] Fluorinert [™] fluids)	Enable energetics laboratory research. Are critical for developing and transitioning new energetic materials.	NA	NA	NA		
Energy Storage and Bat	Energy Storage and Batteries					
Fluoropolymers (e.g., polytetrafluoroethylene (PTFE)) Polyfluoroalkyl acids (PolyFAAs)	Multiple subcomponents in modern Li-ion batteries: electrolyte solutions, cathode binders, separator coatings, casing materials, and gaskets.	Serve as heat transfer material or insulation. Provide weather-resistance, UV light-resistance, and deterioration-resistance properties.	NA	Fully eliminating PFAS from energy storage in the U.S. economy would likely take 10+ years.		
PFAS	Battery manufacturing: filters and other components essential to production.	NA	Possibly available	Time and cost to identify and qualify alternatives would be significant and have ripple effects throughout the economy.		
Microelectronics and Semiconductors						
Fluoropolymers Fluoroelastomers PolyFAAs	Semiconductor fabrication: etching materials and masks in photolithography processes;	Dielectric, heat transfer, and insulation functionalities.	Currently no alternatives to PFAS for photolithography.	NA		
Other PFAS	cleaning gases.					

269 Appendix: Summary of Known Mission Critical PFAS Uses

PFAS	Application	Functionality	Availability of Alternatives	Time Frame / Cost to Develop and Qualify Alternatives*
Fluoropolymers	Semiconductor manufacturing equipment and factory infrastructure: equipment components (e.g., tubing, gaskets, containers, filters) and lubrication (various oils and greases).	Heat and chemical resistance, and chemical inertness.	Currently no alternatives for some applications in semiconductor manufacturing equipment. Replacing most PFAS uses in semiconductor fabrication would require industry-wide re-tooling and other process innovations. Some might be achievable within 10 years, but many would not.	Development of alternatives for some uses may require the invention of novel chemistries and processes. Due to the extremely complex qualification process, it would take another 15 years to deploy alternatives, once developed, in high-volume manufacturing. Replacing PFAS in semiconductor fabrication could be a 25-year effort and may not succeed in all respects if alternatives cannot be identified or qualified at the microchip level. Replacing PFAS has the potential to initiate costly requalification of specific components. Example: radiation hardened microelectronics applications typically mandate requalification if a manufacturer substantively alters the fabrication process, which can easily exceed \$10 million.

270 Appendix: Summary of Known Mission Critical PFAS Uses

PFAS	Application	Functionality	Availability of Alternatives	Time Frame / Cost to Develop and Qualify Alternatives*
PTFE	Microelectronics applications: base laminate materials used in many RF and microwave circuits.	Provide unique properties related to isolating RF and microwave signals. Used in radar, antenna, guidance systems, 5&6 G infrastructure, and other network/ transmission applications.	There is no drop in alternative material. Any material replacement for fielded systems would require redesign of the printed board and potentially the electronic system to account for material property differences. Fielded systems that have been redesigned may require requalification.	Developing and or identifying suitable alternative materials and qualifying them could be a forward-looking action for all future DoD systems. This however does not address sustainment of existing systems. There will continue to be a need to have PTFE laminate materials available for system sustainment until all systems currently designed with PTFE are retired.
PFA				
PFAS	Manufacture of printed circuit boards (PCBs): vapor phase solder and flux remover products.	Vapor phase soldering process is used for PCB assemblies with high thermal mass, fine- pitch structures, and temperature-sensitive components to minimize risk to materials, structures and components. The material stability and flame retardant qualities are well suited for the enclosed high temperature operation of the process.	It is unknown if there are suitable materials that can be used, however it is likely that current equipment may need to be replaced or modified to accommodate the replacement materials.	Developing and evaluating new materials could take 5 years or more. Equipment replacement would add time and have a cost impact.
PTFE	PCBs: cable jackets used in PCB connectors.	Used because it has excellent fire, smoke, and chemical resistance. Wide temperature range -200 to 260C constant use and up to 450C for peak exposure.	It is unknown if there are suitable replacement materials for all of the applications for PTFE wire jacket material. PTFE is higher cost than some other wire jacket materials. When it is selected for use there are typically no other suitable replacement materials.	Qualification of alternatives will be both costly and time consuming. Many materials will require new UL or other certification body approval before they can be implemented. Many current products are MilSpec certified.
271 Appendix: Summary of Known Mission Critical PFAS Uses

PFAS	Application	Functionality	Availability of Alternatives	Time Frame / Cost to Develop and Qualify Alternatives*
Castings and Forgings a	nd Strategic and Critical Miner	als	•	•
Specialty fluorochemical gases and fluids	Advanced metalworking, casting, and fabrication processes used in the production of advanced metal parts throughout U.S. industry, including military- specific parts.	Temperature and wear resistance.	NA	Moving to alternatives in under 10 years may require returning to previous construction methods and may make construction using certain alloys impossible.
PTFE, PVDF, other PFAS	Mold release chemicals and release films typically used in composite manufacturing processes.	Prevent composites from strongly adhering to mold hardware.	NA	NA
Refrigeration and Air Conditioning, Cooling, Electronics Thermal Control				
HFOs	Next-generation refrigerant alternatives (to HFCs) used in civil and military cooling and thermal control applications.	NA	Known non-PFAS alternatives (e.g., hydrocarbon or ammonia alternatives) pose flammability, toxicity, or high-pressure concerns.	NA
Fire Suppression in Aircraft and Ground Combat Vehicles				
Fluorochemical specialty gases	"Clean agent" fire suppression in aircraft and ground combat vehicles.	NA	Most known clean agent, low- corrosion, low-weight, low- toxicity alternatives will likely be classified as PFAS, broadly defined.	NA
Aqueous Film Forming Foam (AFFF)				
PFAS	AFFF use to combat Class B (flammable/combustible liquid) fuel spill fires on mission critical ocean-going vessels employed by DoD and the Military Services.	MIL-PRF-24385 qualified AFFF provides the capability to rapidly control and extinguish shipboard fires.	Current F3s have significant limitations compared to AFFF that preclude their use on DoD ocean-going vessels, including the U.S. Navy fleet.	NA

272 Appendix: Summary of Known Mission Critical PFAS Uses

PFAS	Application	Functionality	Availability of Alternatives	Time Frame / Cost to Develop and Qualify Alternatives*
Lines, Hoses, O-Rings, S	eals and Gaskets, Tapes, and C	ables and Connectors		•
Fluoropolymers (e.g., PVDF, ECTFE, PTFE)	Critical to modern "rubberized" fuel lines. Key materials in hoses, tubing, hydraulic system lines, O- rings, seals and gaskets, tapes,	Functionalities include UV- resistance, ozone-resistance, weather-resistance, temperature-resistance, high pressure-resistance, and chemical resistance.	Alternatives are not as resistant to embrittlement and break-down and have a much shorter useful life, leading to more frequent part replacement, which is not feasible for space or satellite uses.	NA
Fluoroelastomers (e.g., FKM/FFKM)	and cables and connectors widely used in civil and military aircraft, space systems, vehicles, weapon systems, utility systems, and other applications.			
Electronic/Dielectric Flu	uids			
Fluorochemicals	Used in electronic and dielectric fluids used in civil and military radars, high- power electronics, and electrical system/utility system components.	Provide dielectric and heat transfer properties.	Industry and DoD have repeatedly investigated alternatives in these applications. Known alternatives have high global warming potential (e.g., sulfur hexafluoride) or may pose health/environmental risks (e.g., the polychlorinated biphenyls).	NA
Advanced Oils, Greases, Fluids, and Lubricants				
PFAS	Used in many advanced turbine engine oils, greases, fluids, and lubricants common throughout the U.S. civil transportation, industrial, and space sectors. Analogous oils, lubricants, and fluids are used in military critical ground, sea, air, and space applications.	Wear- and heat-resistant properties. Perfluorinated greases exhibit excellent shelf lives due to their intrinsic inertness.	Previous generations of oils, fluids, and lubricants approached, but did not equal, the performance of PFAS additives that have become more prevalent in high performance oils, greases, fluids, and lubricants over the past 20 years.	NA

273 Appendix: Summary of Known Mission Critical PFAS Uses

PFAS	Application	Functionality	Availability of Alternatives	Time Frame / Cost to Develop and Qualify Alternatives*
Precision Cleaning Fluid	ls	•	•	•
Fluorochemicals	Precision cleaning applications such as cleaning of sensitive oxygen systems in civil and military aerospace.	NA	NA	NA
Degreasing / Cleaning F	luids			
PFAS	Degreasing/ cleaning products and contact cleaners used in vapor degreasing and flux removal.	NA	NA	NA
	Non-destructive testing solvent cleaner/remover used for precleaning and for removing excess surface penetrant before applying developer during liquid penetrant testing.	NA	NA	NA
	Degreasers used to effectively remove grease, oil, tar, and other substances from military equipment to increase its operating efficiency.	Leaves no residue, has no flash or fire point, and serves as an alternative to chlorinated solvent-based cleaners (e.g., 1,1,1-trichloroethane).	NA	NA
Butane, 1,1,1,2,2,3,3,4,4- nonafluoro-4-methoxy	Connector cleaner and preparation fluid used for cleaning fiber optic connectors in secure link manager assemblies and primary modem assemblies.	NA	NA	NA
Insulation and Foam Blowing				
Fluorochemicals	Components of insulation and foam blowing products used in civil and military aircraft and space vehicles/rocket motors.	NA	NA	NA

274 Appendix: Summary of Known Mission Critical PFAS Uses

PFAS	Application	Functionality	Availability of Alternatives	Time Frame / Cost to Develop and Qualify Alternatives*
Resins for Specialty Con	nposites	•	•	•
Fluoropolymers	Resins for specialty high- temperature or weather-/UV- resistant composites.	Temperature-, pressure-, wear-, and chemical-resistance properties.	NA	Moving to alternatives in under 10 years may require a return to previous methods of parts construction and an acceptance of lower performance, shorter life, and higher weight composites.
Specialty Filters and Me	mbranes	I	I	I
Fluoropolymers	Used in specialty filters and membranes (e.g., aviation filters); and in air filtering	Temperature-, pressure-, and wear-resistance properties.	NA	NA
PFAS	respirators used by DoD.			
Fabrics, Fabric Liners, I	Fabric Barriers			1
PFAS	 Fabrics used in a variety of uniform clothing and footwear items, tents, and duffle bags. Reported use in chemical, biological, radiological, and nuclear protective equipment. Used in the biological protective fabric lining used in the Joint Biological Agent Decontamination System. 	Water and oil repellency.	NA	NA
Customized Applications				
Specialty fluorochemicals	Used in customized applications like gyroscope suspension fluids and analytic gases and fluids for thermometric and other sensors.	Pressure-resistant, wear-resistant, and temperature control properties.	NA	NA

* NA = no information provided through data collection efforts.



THE COOKWARE & BAKEWARE ALLIANCE

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PFAS Advocacy & Education

A Statement from the Alliance

We are facing unique and challenging times in our industry as we work to understand and comply with enacted state legislations regarding PFAS chemicals. Knowledge is powerful. This is a key element in why The Cookware & Bakeware Alliance was formed back in 1922, to collect and share important information and create safe consumer products.

For years we have answered questions and shared resources on important topics facing our industry. Many times, only part of the answer, or one viewpoint is shared. Our Good Science (<u>https://cookwareandbakeware.org/good-science/</u>) site has been created to help provide resources and access to more information on important topics.

In an effort to help educate those who are either involved in deciding on PFAS legislation, or for consumers looking to purchase our products, we created an education series on PFAS. The series is shared on the Good Science site and helps explain key differences of fluorochemicals vs fluoropolymers, life cycle assessment, alternatives, and the science on the impact of fluoropolymers on human health.

<u>Part 1</u>: **Cookware & Bakeware, PFAS, and PTFE,** the definition of PFAS involving a large family of substances with significantly varied properties and uses, was discussed. PFAS was divided into two distinct groups: non-polymeric and polymeric. The polymeric PFAS (fluoropolymers) are neither water soluble, nor mobile, nor bioavailable, nor bio accumulative.

Part 2, **Fluoropolymers and Human Health** it was shown that fluoropolymers do not present an unacceptable risk to human health and are classified as polymers of low concern. PTFE coated cookware and bakeware are assessed by authorities in the US and Europe as safe for the user. In addition, the emissions of PFAS (of concern) into the environment during the production of PTFE coated cookware is negligible, and more importantly manageable.

<u>Part 3</u>: A Closer Look at PFAS in Cookware & Bakeware: other contested issues with fluoropolymers are discussed such as, Environmental Emissions of PFAS, End of Life of Nonstick Cookware, Feasibility of Alternatives to PTFE.

Highlights from the Series

In the series, you will read about and find links to resources that present information and evidence that:

- Fluoropolymers do not present an unacceptable risk to human health.
- Use of fluoropolymers in cookware and bakeware does not lead to negative health impacts.
- Fluoropolymers, including PTFE, are widely used in other applications, such as medical devices, with no evidence of negative health effects.

DISCLAIMER: The Information compiled here Is not to be considered legal advice. This Information Is Intended to help understand Important Industry news and provide what the Alliance and/or affiliated experts understand of the situation.



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- Polymeric PFAS (fluoropolymers), such as PTFE, which are used in nonstick cookware and bakeware coatings, are not water soluble, and have documented safety profiles. They are thermally, biologically, and chemically stable. They are also nonmobile, non-bioavailable, non-bioaccumulative, nontoxic, and most importantly, they are not soluble in water. Although fluoropolymers fit the current PFAS structural definition, they have very different physical, chemical, environmental, and toxicological properties when compared with other PFAS of concern.
- PTFE is the most stable fluoropolymer and has a continuous use temperature of 500°F (260°C). (Plastics Safe Handling Guide 2018). This temperature is well above temperatures realized during normal cooking and baking activities when a nonstick housewares article is used per the manufacturers' use and care instructions.
- There is no scientific basis that PTFE-coated cookware and bakeware poses a hazard or risk to humans or the environment when used under normal conditions. Therefore, in our opinion it is safe to use and should not be restricted.
- There are negligible emissions of non-polymeric fluorochemicals in landfill due to PTFE-coated cookware.
- Using the best-available technology and appropriate temperatures, PTFE and other fluoropolymers are of no concern for emissions of PFAS into the environment.
- Important points regarding PTFE-based nonstick coatings:
 - 1. PTFE-based nonstick coatings will retain their nonstick properties for as long as the coating is present on the coated article. This is due to the inherent nonstick properties of PTFE, a fluoropolymer. Alternative nonstick coating technologies will lose the nonstick characteristics over time.
 - 2. PTFE-based nonstick coatings are unaffected by household dishwashers.
 - 3. PTFE-based nonstick coatings emit very low levels of volatile organic compounds (VOCs) during the coating application process.
 - 4. The risk of PTFE-based nonstick coatings releasing low molecular weight PFAS substances of concern or any other substance that might adulterate food during normal use is very low.
- Not enough is scientifically known about the full lifecycle of ceramic or sol-gel coated cookware to declare this a viable alternative to PTFE coated cookware and bakeware. The risk of a regrettable substitution is significant.
- PTFE-coated cookware and bakeware has throughout its full lifecycle a negligible risk for PFAS emissions into the environment and is safe to use for the consumer. Therefore, there is no foundation to restrict its manufacturing, usage, or recycling.

In the 100+ years of our Alliance, we have stood by good science to create the standards for all our products. We have been dedicated to consumer safety and will continue to do so now and into the future.

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PFAS EDUCATION

277

PART 1: COOKWARE, PFAS, AND PTFE



The CBA is a not-for-profit trade association owned by its membership: manufacturers of cookware, bakeware and kitchenware with substantial operations and headquarters in the United States. The CBA began in the early 1920s as the Aluminum Wares Association, became the Metal Cookware Manufacturers Association in the 1960s, and in the 1970s changed its name to the Cookware Manufacturers Association in recognition of its representation of all types of cookware and bakeware materials. The CBA's mission is to inform and

promote the industry to its members, their customers and to the general public.

The members of The Cookware & Bakeware Alliance (CBA) develop standards to promote the welfare of the cookware industry and improve its service to the public. The CBA Engineering Standards are continually updated to reflect changes in materials and technology and include test methods for nonstick finishes on cookware that when followed ensure coating performance and durability.

Nonstick cookware and bakeware manufactured according to CBA Standards use only US FDA food contact compliant materials for surfaces. CBA supports the responsible manufacturing and safe uses of PTFE and other fluoropolymers, and a science-based approach to regulations that benefit human health and the environment. CBA supports labeling provisions to alert consumers to the presence of PFAS, but based on current science, considers it unnecessary to prohibit sales and eliminate consumer choice.



Your cookware and bakeware industry resource.

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Science site has been created to help provide resources and access to more information on important topics. We now bring all of this information to our website to share and promote Good Science. <u>Visit the Good Science webpage to explore.</u>

For questions, please contact Fran Groesbeck, Managing Director (fran@cookware.org).

Thank you for your interest in Good Science!

279 PART 1: Cookware, PFAS, and PTFE

Per- and polyfluoroalkyl substances (PFAS) are a diverse group of chemistries that contain carbon-fluorine bonds, the strongest chemical bonds in organic chemistry. Due to their unique and useful properties, PFAS are widely used and critical to enabling numerous technologies.

The term PFAS encompasses in some instances as many as 12,000+ substances. However, it is estimated that roughly 5% of all PFAS substances are in commercial use today. Further, not all PFAS are the same. The chemistries currently in commercial use have very different physical and chemical properties, health, and environmental profiles, uses, and benefits.



Large family of substances

Significantly varied properties

Subgroups have unique and specific differences

They can be considered part of a universe of fluorinated organic substances with varying physical, chemical, and biological properties including polymers and non-polymers; solids, liquids, and gases.[1]

A subgroup of PFAS having specific characteristics and properties is called fluoropolymers. The discovery of the first fluoropolymer, polytetrafluoroethylene (PTFE),

occurred in 1938 [2], and it led to its use in the most critical and demanding applications known. Aerospace and military applications were first to use fluoropolymers to insulate cables or create impermeable seals because it can withstand the harshest conditions and it replaces materials that have a high risk of failure due to a deterioration of properties. Uses in conditions where other materials fail due to corrosion and extreme temperature are the hallmark of fluoropolymers, often making them irreplaceable.

The first nonstick cookware appeared in the US in 1961.[3] Fluoropolymers are used in cookware, for their non-stick and barrier properties. To ensure food contact substances are safe for their intended use, the FDA conducts a rigorous scientific review before they are authorized for the market.[4]

PFAS can be divided into two distinct groups: non-polymeric and polymeric PFAS. Furthermore, the non-polymeric, ie fluorochemicals, are water soluble, versus the polymeric, ie fluoropolymers, are not.

The non-polymeric PFAS (fluorochemicals) are typically used for food contact materials (FCM), such as fast-food



packaging and microwave popcorn bags, as well as a number of other applications and industries. The FCM examples referenced can indirectly contribute to dietary exposure through the migration of PFAS into food, which can be a food safety concern [5]. Because they are water soluble, consumers have the potential to be exposed through foods and/or drinking water.

Whereas the polymeric PFAS (fluoropolymers), such as PTFE, which are used in nonstick cookware and bakeware coatings, are not water soluble, and have documented safety profiles. They are thermally, biologically, and chemically stable. They are also nonmobile, non bioavailable, non bioaccumulative, nontoxic, and most importantly they are not soluble in water. Although fluoropolymers fit the current PFAS structural definition, they have very different physical, chemical, environmental, and toxicological properties when compared with other PFAS.[6]

Fluorochemicals	Characteristic	Fluoropolymer (used in cookware)
Yes	Water Soluble	Νο
Yes	PFAS of Concern	No
Yes	Transported in Air	No
Yes	Toxicity	No
Yes	Persistence/ Non-Degradable	Yes

[1] Identification and classification of commercially relevant per- and poly-fluoroalkyl substances (PFAS) Robert C. Buck,Stephen H. Korzeniowski,Evan Laganis,Frank Adamsky; First published: 14 May 2021 <u>https://doi.org/10.1002/ieam.4450</u>

[2] https://www.aps.org/publications/apsnews/202104/history.cfm

[3] ibid

[4] Authorized Uses of PFAS in Food Contact Applications <u>https://www.fda.gov/food/chemical-contaminants-food/authorized-uses-pfas-food-contact-applications</u>

[5] Schaider, L.A.; Balan, S.A.; Blum, A.; Andrews, D.Q.; Strynar, M.J.; Dickinson, M.E.; Lunderberg, D.M.; Lang, J.R.; Peaslee, G.F. Fluorinated Compounds in U.S. Fast Food Packaging. Environ. Sci. Technol. Lett. 2017. [CrossRef] [PubMed] <u>https://www.mdpi.com/2304-8158/10/7/1443</u>

[6] A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and Fluoroelastomers. Stephen H. Korzeniowski,Robert C. Buck,Robin M. Newkold,Ahmed El kassmi,Evan Laganis,Yasuhiko Matsuoka,Bertrand Dinelli,Severine Beauchet,Frank Adamsky

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PFAS EDUCATION

283

PART 2: FLUOROPOLYMERS AND HUMAN HEALTH





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PFAS Education Series

PART 2: Fluoropolymers and Human Health

Definition of Fluoropolymers:

Fluoropolymers are defined according to Buck et a.l⁽¹⁾ as a distinct subset of fluorinated polymers, based on a carbon-only polymer backbone with fluorine atoms directly attached to it, e.g., polytetrafluoroethylene (PTFE), fluorinated ethylene propylene (FEP) and perfluoroalkoxy polymer (PFA). Many fluoropolymers have been approved for food contact applications by regulators, including the US FDA (21 CFR 175.1550), the European Union through Regulation (EU) 10/2011 and also through specific national regulations such as German BfR recommendation LI.

Fluoropolymers do not present an unacceptable risk to human health.

The current OECD definition of PFAS includes thousands of substances with wide ranges of properties, including classes such as fluoropolymers which have traditionally been differentiated from legacy non-polymeric PFAS (PFOA or PFOS). In 2021, the OECD wrote, "The term "PFASs" is a broad, general, non-specific term, which does not inform whether a compound is harmful or not, but only communicates that the compounds under this term share the same trait for having a fully fluorinated methyl or methylene carbon moiety".⁽²⁾

A typical restriction on a substance or material requires the demonstration of "unacceptable risk", and fluoropolymers do not meet this standard, as demonstrated by years of research:

- The OECD is a central source of definitions for global chemical regulation (including the definition of PFAS) and classifies polymers with "insignificant environmental and human health impacts" as polymers of low concern.⁽³⁾
- PTFE is not soluble in water (or any other common solvents) and is not mobile in the environment.⁽⁴⁾
- Fluoropolymers have been repeatedly found to meet all of the OECD characteristics of polymers of low concern,⁽⁵⁾ based on their stability, lack of bioavailability, lack of bioaccumulation, and general absence of observed ill effects.



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 In a scientific opinion published in 2016 relating to the risk analysis of chemical products in food, the scientific committee of the European Food Safety Authority (EFSA) specified that the risk analysis of polymers used in food additives must consider the molar mass of the polymer in question. For fluorinated polymers, EFSA proposed a threshold of 1,500 Daltons. Beyond this threshold, EFSA indicated that it is unlikely that the polymers will be absorbed through the gastrointestinal barrier and therefore considered that they do not present a health hazard.⁽⁶⁾ By comparison, PTFE for food contact applications is characterized by sizes ranging from hundreds of thousands to several million Daltons. This recent opinion from EFSA shows that fluorinated polymers and in particular PTFE used for food contact materials like nonstick coated cookware do not pose a concern for health authorities.

Studies have consistently shown that fluoropolymers do not pose a risk to human health, largely due to their inertness, insolubility, and lack of reactive functional groups.

- A 2016 study by Naftalovich et al. shows that PTFE ingestion to increase satiety was both successful and safe. They also reviewed the biological safety of PTFE.⁽⁷⁾
- A 2022 study by Lee et al. shows that fluoropolymers such as PTFE are safe when ingested. For example, no toxic effects were observed from PTFE exposure in mice. No traces of PTFE were observed in the blood of mice even though they were exposed to very large amounts of PTFE.⁽⁸⁾
- The International Agency for Research on Cancer (IARC) has repeatedly investigated the carcinogenicity and toxicity of PTFE, finding it has no toxicological impact, and cannot be classified according to its carcinogenicity (IARC Group 3).⁽⁹⁾

Use of fluoropolymers in cookware and bakeware does not lead to negative health impacts.

The evidence does not indicate that use of fluoropolymer-coated cookware exposes users to non-polymeric PFAS.

- In a study on articles in the Korean market, Choi et al show that only a very limited number of articles (3 out of 139 fry pans) show migration of low molecular weight PFAS and only in the first migration experiment with no detection in later experiments. All detected quantities were significantly below the level of concern.⁽¹⁰⁾
- Studies of PTFE-coated cookware have detected no or for some products only traces of low molecular weight PFAS in the first migration experiment. The French consumer association 60 millions de consommateurs (n°579, April 2022), published a study on 9 non-stick coated articles. Despite detecting very low levels of low molecular weight PFAS, the author conceded that these substances "were probably not used in the manufacturing of the pans



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but could have been introduced in an accidental manner during manufacturing, packaging or transport". $^{(1)}$

- PTFE is known to start to deteriorate at an extremely slow rate above 260 °C (500°F). Above 360 °C (680°F), the degradation of PTFE starts to be measurable. However, according to the German Federal Office for Risk Assessment (BfR), the concentration of these emissions while normally using PTFE-coated cookware is so low that there is no health risk for the user.⁽¹²⁾
- It should be noted that degradation temperatures for fats and oils are typically lower than 200 °C (392°F), consequently at a much lower temperature than when fluoropolymers would begin to degrade. For instance, emission of volatiles, such as aldehydes, from coconut, safflower, canola, or extra virgin olive oil are measured by Katragada et al. from 180 °C (356°F).⁽¹³⁾ This suggests that regular usage of fluoropolymer-coated cookware would not result in sufficient temperatures for fluoropolymer degradation.

Studies and expert reports consistently evaluate PTFE coated cookware as safe for users.

- The European Food Safety Authority (EFSA) published a 2020 report assessing the safety of PFAS in food contact materials, primarily focusing on non-polymeric legacy PFAS (PFOA and PFOS).^[14] The study assessed the use of PTFE in cookware, saying it may contribute to human exposure on the scale of micrograms per kilogram, a level far below background exposure from eating fish, meat, eggs, and fruit (among the most common sources of exposure to PFAS).
- The American Cancer Society considers the use of fluoropolymer-coated cookware safe, saying "there are no proven risks to humans from using these products. While PFAS can be used in making some of these coatings, it is not present (or is present in extremely small amounts) in the final products".⁽¹⁵⁾

Fluoropolymers, including PTFE, are widely used in other applications with no evidence of negative health effects.

PTFE is widely used in medical devices, including implanted devices, which are highly regulated and thoroughly studied for any negative health impacts. Evidence demonstrates the use of PTFE in these devices is safe, suggesting it does not pose a health risk for humans in other uses such as in cookware.

• The US-based independent research and innovation organization ECRI (Emergency Care Research Institute) was tasked by the US Food and Drug Administration (FDA) to carry out a review of the scientific literature and produce a report on the state of knowledge of the biocompatibility of PTFE-based (medical devices in terms of local and systemic host



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response. The analysis covered a total of 52 studies. The analysis found no local response to PTFE in implanted devices, and no exaggerated or fatal systemic responses.⁽¹⁶⁾

The general consensus of researchers is that PTFE and fluoropolymers do not present a health risk to humans.

- Their suitability for direct use in the human body is a central reason for their role in medical devices, and many researchers have argued that PTFE should be considered a polymer of low concern by meeting or exceeding all OECD criteria. This view is reinforced by regulatory agencies in the EU and the United States in multiple reviews and meta-analyses.
- The scientific literature on the health impacts of fluoropolymers, PTFE particularly as used in cookware, suggests that the use phase does not pose a risk to human health, as the fluoropolymers themselves are not absorbed by the body (not biologically available) and have no indicated harmful effects, and other non-polymeric PFAS are not present in meaningful quantities in the final products.

Beyond fluoropolymers, exposure to non-polymeric PFAS in other applications nonetheless presents a risk to health.

• According to the European Chemicals Agency (ECHA), the largest sources of PFAS contamination in the environment come from non-polymeric applications such as fluorinated refrigerants or waterproof coatings [e.g., treatments and finishes], which then raise concerns for exposure to humans through the food and water supply.⁽¹⁷⁾ Regulatory solutions for PFAS exposure should be guided by the scientific consensus, while considering categories like fluoropolymers which have been consistently shown to be safe and result in minimal exposure.

Where or why does nonstick cookware come into all this?

PTFE, or polytetrafluoroethylene, is the PFAS material that makes nonstick coatings non-stick. As we discussed in Part 1 – PTFE is a fluoropolymer: it is non-water soluble, it is non-toxic, and it is not mobile or bio-accumulative. It has a certain level of persistence, but as with other fluoropolymers, it is this trait that makes it beneficial in so many applications.

Fluoropolymers do not fit any of the new classifications such as:

- PBT : Persistent, Bioaccumulative, Toxic
- vPvB : very Persistent, very Bioaccumulative
- PMT : Persistent, Mobile, Toxic
- vPvM : very Persistent, very Mobile



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Looking at PTFE from a high level, it offers many benefits to the products that use it. It is an insulator, so it reduces heat transfer. It reduces friction, which is what allows it to aid products from cookware to cars. Also, we must remember this is one of the non-water soluble PFAS types, so water contamination is not possible.

288

Fluoropolymers, like PTFE, are stable under normal, foreseeable use conditions. Stability is resistance to physical, chemical, or biological breakdown. Fluoropolymers, in general, have very good chemical and thermal stability due to the strength of the Carbon to Fluorine bond. (Henry et al: 2018).⁽⁵⁾

PTFE is the most stable fluoropolymer and has a continuous use temperature of 500°F (260°C). (Plastics Safe Handling Guide 2018).⁽¹⁸⁾ This temperature is well above temperatures realized during normal cooking and baking activities when a nonstick housewares article is used per the manufacturers' use and care instructions.

Consumer Nonstick Housewares Products

Fluoropolymers, mainly PTFE, are the principal ingredients in traditional nonstick coatings for housewares. In most cases, these coatings are water-based, liquid coatings. The PTFE has to be stable in this liquid mixture in order to be applied to a product like a piece of cookware. PTFE, as helpful as it is, is extremely stubborn when it comes to mixing with water. In order to get PTFE to be stable in a water mixture, a surfactant is needed as a dispersing aid. Historically, the surfactant used to make PTFE stable in water was a fluorinated surfactant (i.e. fluorochemical).

You don't need a lot of the fluorochemical to make this work. A good analogy is if you had an Olympic size swimming pool, you would need to add a thimble-sized amount of the fluorosurfactant to make the PTFE stable. To put this small amount into another perspective, it translates to just over a minute in a century, or 0.00000025%

Aqueous film forming foams (AFFF) used to fight petroleum-based fires can often contain as much as 3.0% of fluorochemicals which are PFAS of true concern. To contrast these amounts, it would require 2 million years of cookware production to equal the environmental exposure caused by 1 year's use of AFFF.⁽¹⁹⁾

There are PTFE manufacturers that are committed to the reduction of emissions from polymerization aid/surfactant technology used in the fluoropolymer manufacturing process, the adoption of state-of-the-art emission reduction technologies, and informing downstream users of fluoropolymers about their safe handling, use, and prevention of environmental release.⁽²⁰⁾



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Conclusion:

There is no scientific basis that PTFE-coated cookware and bakeware poses a hazard or risk to humans or the environment when used under normal conditions. Therefore, in our opinion it is safe to use and should not be restricted.

More from the PFAS Education Series

In the other parts in this series by CBA, we discussed several topics around PFAS and Cookware & Bakeware.

Part 1: Cookware, PFAS, and PTFE, the definition of PFAS involving a large family of substances with significantly varied properties and uses, was discussed. PFAS was divided into two distinct groups: non-polymeric and polymeric. The polymeric PFAS (fluoropolymers) are neither water soluble, nor mobile, nor bioavailable, nor bio accumulative.

Next in the series:

Part 3: A Closer Look at PFAS in Cookware & Bakeware: other contested issues with fluoropolymers were discussed such as, Environmental Emissions of PFAS, End of Life of Nonstick Cookware, Feasibility of Alternatives to PTFE.

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PFAS EDUCATION

292

PART 3: A CLOSER LOOK AT PFAS AND COOKWARE & BAKEWARE



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PFAS Education Series

PART 3: A Closer Look at PFAS and Cookware & Bakeware

In previous parts of this series by CBA, we discussed several topics around PFAS and Cookware & Bakeware.

- In Part 1 the large group of PFAS was divided into non-polymeric fluorochemicals and polymeric fluoropolymers. Fluoropolymers such as PTFE, which is used in nonstick coatings of cookware and bakeware, have very different properties compared to fluorochemicals. Existing legal restrictions of legacy fluorochemicals such as PFOA or PFOS should not be extended to fluoropolymers without scientific justification.
- 2. In <u>Part 2</u>, it was shown that fluoropolymers do not present an unacceptable risk to human health and are classified as polymers of low concern. PTFE coated cookware and bakeware are assessed by authorities in the US and Europe as safe for the user. In addition, the emissions of PFAS into the environment during the production of PTFE coated cookware is negligible.
- 3. In Part 3 we will have a closer look at the complete lifecycle of PTFE coated cookware and bakeware and current alternatives.

Lifecycle Assessment

Any lifecycle of consumer goods can be separated into four different sections: 1. Manufacturing of raw materials, 2. manufacturing of the product, 3. use of the product and 4. end-of-life.

It is important to point out that in the case of PTFE coated cookware phases 1, 2 and 4 are carried out by professionals with clear and elaborate OSHA safety and EPA environmental regulations.

Only phase 3 is carried out by non-professional consumers.

In Part 2 it was shown that PTFE coated cookware is of no or negligible concern during phases 2 and 3. Using existing best-available technologies emissions of these PTFE coated products are insignificant and will even be reduced in the coming years.

In phase 1 chemical manufacturers produce fluorinated monomers such as TFE (tetrafluoroethylene) and transform them into fluoropolymers using both fluorinated and non-fluorinated polymerization aids. There are technical and scientific indications that either of these production steps can be done without any non-polymeric PFAS emissions to the environment. A fluoropolymer industry-led initiative includes a platform to promote the adoption of commercially available state of the art technologies to minimize non-polymeric PFAS emissions during manufacturing.⁽¹⁾



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It can be summarized that based on phases 1 – 3 of the full lifecycle PTFE-coated cookware should not be restricted.

End-of-Life

Landfill, incineration or recycling are viable options for PTFE-coated cookware and bakeware used by consumers or professionals at the end-of-life.

A RIVM (Dutch National Institute for Public Health and the Environment) incineration review states that PTFE is stable at 260 °C without loss of mass. A PTFE coated article in **landfill** would therefore not decompose at the temperatures found in this environment

(https://rivm.openrepository.com/handle/10029/625409). In addition, fluoropolymers such as PTFE are not soluble in water, not mobile, stable to most chemicals

(https://setac.onlinelibrary.wiley.com/doi/10.1002/etc.5182) and UV radiation.

Therefore, it can be expected that there are negligible emissions of non-polymeric fluorochemicals in landfill due to PTFE-coated cookware.

Incineration and recycling can be discussed together because in both cases the fluoropolymer is thermally treated. Several studies have shown that it is possible to destroy or mineralize the fluoropolymers including undesired decomposition products such as problematic fluorochemicals (Utah 2023

https://www.wastedive.com/news/clean-harbors-incinerator-pfas-forever-chemicals/640829/, Dutch RIVM https://rivm.openrepository.com/handle/10029/625409, Karlsruhe Institute of Technology 2019 and 2023 https://doi.org/10.1016/j.chemosphere.2019.03.191).

Therefore, using the best-available technology and appropriate temperatures, PTFE and other fluoropolymers are of no concern for emissions of PFAS into the environment.

Due to the significant reduction of carbon footprint using recycled aluminum and stainless steel compared to their primary materials, it is strongly recommended to use an existing collection scheme or to implement a new scheme for PTFE-coated cookware at its end-of-life. Based on a rough estimate by FEC (European Federation for Cookware, Cutlery and Houseware Industry) more than 100 Mio. pieces of coated cookware is sold in Europa annually. The recycling of PTFE-coated aluminum cookware at end-of-life would reduce the carbon footprint by more than 250'000 tons $CO_{2 eq}$, per year.

Conclusion

PTFE-coated cookware and bakeware has throughout its full lifecycle a negligible risk for PFAS emissions into the environment and is safe-to-use for the consumer. Therefore, **in our opinion**, there is no foundation to restrict the manufacture, usage or recycling of products made with fluoropolymers.



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Alternatives to PTFE-coated cookware

There are alternatives to PTFE-coated cookware and bakeware. The options can be split into two sub-groups: with and without nonstick coating. According to the 2023 Consumer Outlook Report, published by HomePage News, 72% of consumers indicated that they have a preference for products with nonstick coatings⁽²⁾. Therefore, stainless steel, cast iron or enameled cookware are not an equivalent alternative because they possess no nonstick property.

Nonstick is not only a function that simplifies the life of the user, it also reduces the risk of burning food with undesirable by-products that might be unhealthy. In turn, this also reduces the potential of food waste. It is an obvious feature of nonstick cookware that the cleaning is easier, and less cleaning agents and water is needed. Overall, nonstick cookware has a lower environmental footprint during its usage compared to alternatives without this property.

An example of nonstick alternatives are silicone-based coatings which are mainly used for bakeware. They are a low performance alternative to fluoropolymer systems, both in terms of temperature and damage resistance and nonstick performance. To avoid deterioration of silicones, temperatures of 230°C/446°F should not be exceeded during use [BfR recommendation, https://www.bfr.bund.de/cm/349/LI-Temperature-Resistant-Polymer-Coating-Systems-for-Frying--Co oking-and-Baking-Utensils.pdf].

The best-known nonstick alternative to PTFE based nonstick coatings are ceramic or sol-gel coatings. Ceramic refers to the material from which the coating is made of and sol-gel to the production technique being used. Today, there are two points in assessing this alternative:

- PTFE is a 100% defined material (polytetrafluoroethylene), but ceramic nonstick coatings can be made with a variety of materials. Thereby, the final ceramic coating and its composition varies from manufacturer to manufacturer.
- The ceramic coating itself has usually no nonstick performance and needs additional additives such as silicone oils.

To avoid any regretful substitution of PTFE-coated nonstick cookware, it is mandatory to carry out a study of the full lifecycle of ceramic coatings. To our best knowledge, no such analysis exists, and these coatings have been studied a lot less due to their limited applications compared to PTFE.



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Important points regarding PTFE-based nonstick coatings:

- 1. PTFE-based nonstick coatings will retain their nonstick properties for as long as the coating is present on the coated article. This is due to the inherent nonstick properties of PTFE, a fluoropolymer. Alternative nonstick coating technologies will lose the nonstick characteristics over time.
- 2. PTFE-based nonstick coatings are unaffected by household dishwashers.
- 3. PTFE-based nonstick coatings emit very low levels of volatile organic compounds (VOCs) during the coating application process.
- 4. The risk of PTFE-based nonstick coatings releasing low molecular weight PFAS substances of concern or any other substance that might adulterate food during normal use is very low.⁽³⁾

Conclusion

Not enough is scientifically known about the full lifecycle of ceramic or sol-gel coated cookware to declare this a valuable alternative to PTFE coated cookware and bakeware. The risk of a regretful substitution is significant.

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conservation law foundation

January 28, 2025

Kerri Farris Maine Department of Environmental Protection 17 State House Station Augusta, Maine 04333

RE: Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

Dear Ms. Farris,

Thank you for the opportunity to submit comments regarding the Department of Environmental Protection's (DEP) new proposed rule, Chapter 90, to establish criteria for currently unavoidable use of intentionally added perfluoroalkyl and polyfluoroalkyl substances (PFAS) in products. The following comments are submitted on behalf of the Conservation Law Foundation (CLF). CLF's mission is to conserve natural resources, protect public health, and build healthy communities in Maine and throughout New England. CLF has been a staunch supporter of the PFAS in Products Program since its inception. CLF generally supports this draft rule with a few strong recommendations on how to strengthen the proposed criteria for a Currently Unavoidable Use (CUU) determination.

Ensuring that the criteria for a CUU determination are adequately precise and rigorous is critical to achieving the program's goal—to protect Maine's environment and residents from the further contamination of PFAS, a class of over 15,000 chemicals that are toxic to humans in very small concentrations. PFAS are linked to a wide array of health harms such as cancers, learning and behavioral problems in children, fertility and pregnancy complications, hormonal disruption, high cholesterol, heart disease, immunotoxicity, and liver, thyroid, and pancreatic dysfunction. PFAS are used in countless products, many of which to this day are untested and unknown. These chemicals do not stay contained in consumer products: they leach from products into our sewers and waterways, into the air we breathe. Given the importance of the PFAS in Products Program, it is imperative that any products containing intentionally added PFAS only receive a CUU determination if the products are truly essential for health, safety or the functioning of society, and no alternatives are readily available. 38 M.R.S. §1614(1)(B-1). This determination should be made using standardized criteria that can continue to align with emerging scientific developments.

297



Recommendations to Strengthen the Currently Unavoidable Use Determination Criteria:

- (1) As a general recommendation, the DEP should consider adopting the criteria proposed by the European Commission for how to determine if a use is essential for "health or safety" and, separately, for "the functioning of society."¹ Adopting such criteria would ensure that applications for CUU determinations aim to meet all such criteria, thus limiting the burden on the agency to seek out additional information and clarifying the determination process for those employees tasked with assessing CUU. Using such criteria would also align the agency's decision-making with international scientific principles and knowledge.
- (2) In the CUU Section 9.A (2), the draft should clarify that the CUU requester must show that the product itself is essential for health, safety or the functioning of society, and then *also* show why the availability of PFAS identified in the specific product is essential for health, safety or the functioning of society. This would conform with the statute which stipulates that one must show that a product becoming unavailable would result in one or more of the negative consequences enumerated in 38 M.R.S. §1614(1)(B-1).
- (3) In the Section 9.A(2), the draft states, "This may include or take the form of a description of the negative impact that would be caused by the unavailability of PFAS for use in the product and the subsequent unavailability or unsatisfactory performance of the product." "May" should be replaced with "must" to conform with the requirements of the statute. 38 M.R.S. §1614(1)(B-1) requires a showing that if the PFAS in the given product were unavailable there would be either a "significant increase in negative health outcomes", or, "an inability to mitigate significant risks to human health or the environment", or "a significant disruption of the daily functions on which society relies." Therefore, a

¹ European Commission, Communication from the Commission – Guiding Criteria and Principles for the Essential Use Concept in EU Legislation Dealing with Chemicals, April 25, 2024, available at https://op.europa.eu/en/publication-detail/-/publication/90926c62-0365-11ef-a251-01aa75ed71a1/language-en.

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description of the above negative impact of the aforementioned unavailability is not an option, it is *required* when requesting a CUU determination.

(4) In the CUU Section 9.A(3)(b), the draft states, "The required specific characteristic or combination of characteristics that necessitate the use of PFAS chemicals." To conform this rule more closely to the text and intent of the statute, this provision should first require a description of "the specific characteristic or combination of characteristics that necessitate the use of PFAS chemicals" and next require a description of why that characteristic or combination of characteristics is *necessary for the product to perform as intended*. 38 M.R.S. §1614(1)(B-1). Otherwise, the description may merely show that a certain characteristic of the product depends on PFAS, without showing that this characteristic is actually essential for this product to function. Of course, the availability of the product itself must first be shown to be essential for health, safety of the functioning of society, as required by Section 9. A(2) of the draft rule and as currently defined by 38 M.R.S. §1614(1)(B-1). The criteria for assessing what is essential for health, safety or the functioning of society should conform with those outlined by the European Commission.

Thank you for your consideration of the above recommendations on how to strengthen and streamline the currently unavoidable use determination process. We generally support this draft rulemaking and commend the department on this rigorous and critical endeavor in protecting our state from forever chemicals.

Respectfully submitted,

NonBerth

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January 21, 2025

Ms. Kerri Malinowski Farris 17 State House Station Augusta, ME 04333

VIA EMAIL: pfasproducts.dep@Maine.gov

RE: Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

Dear Ms. Malinowski Farris:

The Can Manufacturers Institute (CMI) appreciates the opportunity to comment on the Maine Department of Environmental Protection's (DEP) December 20, 2024, proposed "rule to establish criteria for currently unavoidable uses of intentionally added PFAS in products and to implement the sales prohibitions and notification requirements for products containing intentionally added PFAS but determined to be a currently unavoidable use pursuant to the amended 38 M.R.S. 1614." CMI submitted comments in August 2024, specifically regarding a "note" to the definition of *product.* We are disappointed that our comments were not incorporated in the recent draft. CMI resubmits our comments and asks that they be incorporated into the new rule.

The draft concept language under consideration includes the following "note" to the definition of *product*:

NOTE: Product includes packages, packaging components, and food packaging as defined in 32 M.R.S. § 1732, when sold individually or in bulk and not used in marketing, handling, or protecting a product.

This language is not in the underlying statute and should be removed because food packaging is specifically exempt under the statute. Maine has a separate law, enacted in 2019, that addresses PFAS in food packaging—REDUCTION OF TOXICS IN PACKAGING, 32 M.R.S. 1731-1738 (Chapter 26-A). The 2021 law 38 M.R.S. 1612 – 1614 clearly excludes products subject to the food packaging law (Title 32, chapter 26-A or 26-B).

Food packaging is not intended to be within the scope of the law at 38 M.R.S 1612 - 1614 and DEP should ensure that the implementing rule does not blur the line between the two laws. The

definition of product in the rule should not vary from the definition in the statute and should be the following, without any additional language: "Product" is defined at 38 M.R.S. §1614(1).¹

The "note" on food packaging in the concept draft is unclear but could be read to mean that the law's exemption only applies to the food packaging once it contains food and that sale of empty packaging materials would not be exempt. To the contrary, such food packaging is under the purview of the food packaging law², and exempt from this one. Straying from the statutory definition and exemption would cause confusion for companies providing food and food packaging in Maine, with no apparent purpose. If DEP has a specific aim or concern regarding the law's exemption for food packaging, we would be happy to discuss it.

CMI asks that DEP adopt the statutory definition of product and delete the draft "note." In all matters, DEP should be clear that food packaging is covered under 32 M.R.S. 1731-1738 and exempt from this rulemaking and any other rules under LD 1503 (as amended by LD 1537), as dictated by the statute.

CMI thanks you for the opportunity to comment on the draft concept rule. Please let me know if CMI can answer any questions.

Sincerely,

hul emaha

Michael Smaha Vice President of Government Relations Can Manufacturers Institute

¹ G. "Product" means 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.

² The law for food packaging has clear coverage with its definition of food package at 32 MRSA section 1732: "Food package" means a package that is designed for direct food contact. "Food package" includes, but is not limited to, a food or beverage product that is contained in a food package or to which a food package is applied, a packaging component of a food package and plastic disposable gloves used in commercial or institutional food service.





January 28, 2025

Melanie Loyzim, Commissioner Maine Department of Environmental Protection 17 State House Station Augusta, Maine 04333-0017 <u>rulecomments.dep@maine.gov</u>

Re: Proposed Chapter 90 Rule Regarding Products Containing PFAS; Ten Recommendations from the Complex Consumer and Durable Goods Supply Chain

Dear Commissioner Loyzim:

The Complex Products Manufacturers Coalition (CPMC or Coalition) appreciates this opportunity to provide these comments to the Maine Department of Environmental Protection (MDEP or Department) on implementing Maine's statute regulating per- and polyfluoroalkyl substances (PFAS) in products as amended by 38 M.R.S. § 1614.¹ The Coalition brings together trade associations and individual businesses, many with in-state locations, most of whom distribute goods and equipment in commerce in Maine that include appliances, vehicles, vessels, motors, lighting, heating, ventilation, cooling, refrigeration, and water heating equipment (HVACR-WH), electronics, and their replacement parts.

Members manufacture equipment and products that have complex supply chains and assemble tens to hundreds or thousands of parts, components, and raw materials to provide, in many cases, products and services critical to the health, safety, and functioning of society. Their products support vital sectors of the economy including government, the military, law enforcement, first responders, 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, critical manufacturing, the defense industrial base, conservation, and life-saving climate control and ventilation in homes, hospitals, schools and universities, eldercare facilities, food preservation and processing, and laboratory and life sciences facilities. These comments provide recommendations for ensuring that vital products and services, which are essential to the health, safety, and functioning of society, remain available to Maine's citizens.

I. Executive Summary

The Coalition supports many aspects of the proposed rule, including:

- 1. <u>The ability to rely in part on Section 3 notifications by component suppliers</u>: For product components for which MDEP has previously received notifications, which are used in more complex products containing the reported components, the manufacturer of the more complex product may refer to the supplier's submitted notifications for product components and any PFAS in the remainder of the product in Section 3(A)(1)(e).
- 2. <u>Options for quantity reporting in Section 3</u>: Information on a concentration range may be more readily available and is an accepted practice in many government reporting programs and reduces the need to identify and protect formulations as confidential business information (CBI). The Coalition urges

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

Maine to drop the requirement for Department-approved ranges, which represents an added administrative burden on MDEP that is not necessary for effective implementation of the law. The Coalition also appreciates the option, similar to that provided in the TSCA Section 8(a)(7) PFAS Reporting Rule,² to submit information on the total weight of the goods if other information is not available. This flexibility is important to the Coalition because experience shows that the documentation provided to complex goods manufacturers and importers by their suppliers frequently does not include low concentrations of a PFAS or other chemicals.

- 3. <u>Flexibility in the use of product identifiers in Sections 3 and 9</u>: The proposed rule allows the use of the Harmonized Tariff System (HTS) code as an alternative to Global Product Classification (GPC) brick codes. Often, companies do not use GPC brick codes.
- 4. <u>Opportunities for information waivers in Section 3</u>: The Coalition supports waivers from currently unavoidable use (CUU) notification where the information is already available.
- 5. <u>Submitting CUU exemptions individually or collectively for product categories and industry sectors in</u> <u>Section 9(A)</u>: The proposed rule allows a manufacturer to submit requests individually or collectively and group combinations of products in a single category.
- 6. <u>Limited reporting for degradation products</u>: The Coalition thanks the Department for the interpretation in Section 2 that "intentionally added PFAS" excludes degradation byproducts which do <u>not</u> provide functionality. MDEP is prevented from excluding them entirely by the definition in 38 M.R.S. § 1614. An exclusion based on lack of functionality is supported by the statute. The Coalition appreciates MDEP doing what it can. The clarification is important, given that many downstream companies will not have the expertise or knowledge to identity degradation byproducts. Excluding degradation byproducts from having to be addressed in CUU exemption requests, providing they do not serve a functional purpose or technical effect within the product or its components, will be useful in this regard.

The following ten recommendations to improve this rule are provided here and explained in further detail in the "Recommendations" section below:

- Improve public understanding of nonconsumer electronics, and HVACR-WH exclusions and broaden consideration of replacement parts. "Electrochemical" should be added to the definition of "electronics" in Section 2 and examples provided as listed in these comments. Confirmation of the exempt status of certain equipment types are requested. A risk-based approach for fluoropolymers allimportant for implementing this rule. The Coalition also seeks assurance that statutory and CUU exemptions for durable goods include their replacement parts.
- 2. <u>Maintain MDEP's commitment to the exclusive use of Chemical Abstracts Service Registry Numbers (CASRNs) for Section 3 notification, specify a date in Section 5 for this notification, and streamline Section 3 notification in line with information provided pursuant to Section 9.</u> It is inconsistent with MDEP's prior interpretations to broaden Section 3(A)(d) to include "(ii) In the absence of this number the chemical name following the nomenclature of the international union of pure and applied chemistry (IUPAC)." This provision expands reporting to an unknown and significant degree. The Coalition would appreciate clarification on the date by which Section 3 notifications will be required, as the "applicable effective date listed in section 5" is not readily apparent. Since CUU determinations under Section 9 precede Section 3 notifications, information requirements should be coordinated and streamlined where possible.
- 3. <u>Allow all CUU exemption requests to be submitted at any point in time once the final rule is issued in</u> <u>Section 9</u>. Maine can prioritize and process these requests according to the deadlines required by law.

² EPA, Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, 88 Fed. Reg. 70516 (Oct. 11, 2023).

- 4. <u>Require a standardized form for CUU exemption requests in Section 9</u>. MDEP is requiring a standardized form for making CUU notifications in Section 3(B). Similarly, a standardized form for making a CUU exemption request should be added to Section 9 to streamline reporting, avoid inconsistent or incomplete submissions, and make it easier to review requests.
- 5. <u>Include due process considerations in Section 9</u>. A due process mechanism is necessary for companies to ask for reconsideration of a denial of a CUU exemption request. Due process also requires that Section 9 incorporate the criteria for granting CUU determinations.
- 6. <u>Streamline CUU request information in Section 9</u>. The Coalition finds the information in Section 9(A)(5) through (7) either non-essential or duplicative and recommends needed information be consolidated in Section 9(A)(4). MDEP should reconsider Section 9(A)(9). The Coalition requests the inclusion of a 0.1% *de minimis* exemption from the 2032 ban to make the number of applications Maine receives more manageable.
- 7. <u>Retain flexibility on the length of CUU exemptions in Section 9(B)</u>. The statute does not require CUU determinations to be time-limited and has exemptions that are not time-limited.
- 8. <u>Do not penalize companies for submitting CBI claims in Section 9.</u> Language in the proposed regulation which directs companies not to submit CBI in CUU requests should be removed. State and federal law provide for the right to make CBI claims.
- 9. <u>Adopt definitions for the terms "complex consumer goods" and "complex durable goods.</u>" These terms should be used instead of the catch-all term "complex products."
- 10. <u>Further simplify other administrative burdens</u>. A further reduction in notification fees should be considered to meet the nominal standard of the law, considering that notifiers may have to report numerous products. The Coalition asks MDEP to clarify that testing is not required and confirm that the "significant change" provision applies to a final product.

With this rulemaking, MDEP has taken on the task of developing the first rulemaking in the country (and the world), to implement legislation that seeks to ban PFAS in most products. As with its statute, many other states (and countries) are looking at Maine when considering similar regulations. We hope that MDEP will strive to make this regulatory process an example to follow.

II. Recommendation 1: The Coalition Supports MDEP's Implementation of the Statutory Exemptions in the Proposed Rule and Asks for Examples to be Provided.

The Coalition appreciates and supports the statutory exemptions which eliminate the need to make a CUU exemption request for many commercial and industrial complex durable goods and their associated components and replacement parts. The Coalition supports MDEP's recognition of these exemptions in the proposed rule. With respect to the exemption for "nonconsumer electronics and nonconsumer laboratory equipment not ordinarily used for personal, family or household purposes," the Coalition appreciates MDEP's decision to propose a definition of the term "electronics." "Electronics" is defined to mean "technology having electrical, digital, magnetic, wireless, optical, electromagnetic, or similar capabilities."

The Coalition asks MDEP for two improvements to this definition. The term "*electrochemical*" should be added before "electromagnetic". According to Merriam Webster, this term is an adjective for the interconversion of chemical and electrical energy. It most accurately describes the industrial technology of a Coalition member. In addition, the Coalition asks Maine to use the same approach as the definition of juvenile products and list the following electronics as examples in the definition:

- Outdoor, commercial, and industrial lighting;
- Residential light fixtures (luminaires);
- Electric hydrogen technology;

- Lithium and other batteries;
- Personal and commercial communication devices;
- Smart home systems;
- Global positioning and navigation systems;
- Solar panels;
- Electrical equipment such as but not limited to power grid equipment, motors and generators, arc welding equipment, electrical conduits, fuses, enclosures, connectors, wiring devices, low voltage distribution equipment, power electronics, residential and commercial controls, wires and cables, industrial automation controls, electric vehicle, and transportation management equipment; and
- Food manufacturing equipment.

The Coalition asks for MDEP to acknowledge that medical imaging equipment is exempt under Section 4(A)(5) as "[a] prosthetic or orthotic device or any product that is a medical device, drug or biologic or that is otherwise used in a medical setting or in medical applications that are regulated by or under the jurisdiction of the United States Food and Drug Administration."

Similarly, the Coalition is grateful for the statutory time extension until 2040 for "cooling, heating, ventilation, air conditioning or refrigeration equipment" and its inclusion in the proposed rule. In particular, the Coalition is grateful to Maine for exempting the use of certain refrigerants from this deadline altogether, specifically ". . . refrigerants used in servicing such equipment as long as the refrigerant is listed as acceptable, acceptable [sic] subject to use conditions or acceptable subject to narrowed use limits by the EPA pursuant to the Significant New Alternatives Program at 42 U.S.C. 82(G), as long as the refrigerant, foam, or aerosol propellant is sold, offered for sale or distributed for sale for the use for which it is listed pursuant to that program." In addition, the Coalition respectfully asks MDEP to specify in this part of the rule that the following water heating equipment are within the scope of this provision:

- Water heaters;
- Heat pumps; and
- Related residential, equipment.

Maine's approach on refrigerants reflects a risk-based approach to PFAS regulation. We urge Maine to adopt a risk-based approach to fluoropolymers more broadly when considering CUU exemption requests. These are large, highly stable molecules, which are insoluble in water, do not break into smaller pieces in environment, and are not bioaccumulative. Fluoropolymers play a vital role in countless consumer products that are essential for the health, safety, and functioning of society.³ This request was endorsed during MDEP's January 16, 2025, public hearing, by the testimony from the Performance Fluoropolymer Partnership group of the American Chemistry Council (ACC), and AGC Glass Company North America.

Accommodations in the proposed rule for replacement parts appear limited to automotive maintenance and cooling, heating, ventilation, air conditioning or refrigeration equipment parts and servicing needs. Manufacturers maintain replacement parts for years to ensure that complex consumer and durable goods can remain operational and meet product warranties. The Coalition asks MDEP to write a specific provision in the CUU exemption section of the rules that companies may request exemptions for replacement parts for other types of exempt products.

III. Recommendation 2: Section 3 CUU Product Notifications Should be Exclusively by CASRN and Should Not Duplicate Information Already Provided.

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

³ An extensive study funded by the U.S. Department of Energy that discusses fluoropolymers and the feasibility of replacements is Stephanie Jacobs, David S. Kosson, *Assessment of Fluoropolymer Production and Use with Analysis of Alternative Replacement Materials* (January 2024).

number." The FAQ confirmed 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 August Concept Draft stated "38 M.R.S. § 1614 requires notification of intentionally added PFAS by CAS number." It is inconsistent with these prior statements to broaden Section 3(A)(d) to include "(ii) In the absence of this number the chemical name following the nomenclature of the international union of pure and applied chemistry (IUPAC)." The Coalition urges MDEP not to backtrack on its commitment to CASRNs and remove Section 3(A)(d)(ii) on this basis. This provision expands reporting to an unknown and significant degree.

Section 3(A) provides that "the applicable effective date" of notification will be "listed in section 5." However, the Coalition was unable to locate this date or a proposed placeholder provision for it in proposed Section 5.

Moreover, it is the understanding of this Coalition that Section 3 notification applies exclusively to products that have secured a CUU exempt determination from Maine under Section 9. This means that the CUU exemption process will *always precede* the need to submit a Section 3 notification. Therefore, the Coalition asks MDEP to consider the extent to which Section 3 notification can be streamlined by the proposed requirement in Section 3(A)(1)(g) to provide "[i]dentification, by citation to a specific section of this Chapter, of the applicable determination by the Department that the use of PFAS in the product subject to the notification if a currently unavoidable use." For example, both Section 3 and Section 9 require a brief description of the product that includes the GPC or HTS code, the intended use of the product, and the purpose of the PFAS. It is not clear why companies should re-submit this information unless it has changed.

IV. Recommendations 3 - 8: The Coalition Supports a CUU Exemption Process that is Open to All from the Outset of the Effective Date of the Rule, Incorporates Due Process Considerations, and is Streamlined in its Requirements.

The proposed rule for Chapter 90 includes strict, late-stage deadlines to apply for CUU exemption determinations, extensive information requirements for these applications, recognized statutory exemptions from the 2032 ban, and establishes limited notification for products determined to be a currently unavoidable use pursuant to the amended 38 M.R.S. 1614. The following recommendations concern the CUU exemption request application process.

1. <u>Comments on Proposed Timeframe</u>

The Coalition is gravely concerned with not allowing CUU exemption request applications to be filed until 18 to 36 months before the 2032 ban for most products. There are four key steps in the process: a company files a CUU exemption request; MDEP makes an affirmative determination (which triggers the notification requirement); the company submits the required notification; MDEP determines that the notification is sufficient (including the accompanying fee). Only after these four steps are completed will the product(s) in question be permitted for sale: the law expects every one of these steps to be completed before the effective date of the ban for a particular product.

For most products that will be eligible for a CUU exemption, the timing for only one of these steps is known (18-36 months for the first step). However, as noted above, the proposed rule assumes these other three steps will be completed in the same timeframe. Entities with a prohibition effective as of January 1, 2026, have only six months to accomplish all of these steps. The proposed timing for implementing this important aspect of Maine's law places enormous pressure on MDEP and the regulated community and may not even be feasible. Please rethink this process and allow more time.

Furthermore, this schedule freezes access to this critical regulatory process for important products such as consumer lighting and communication devices and forces them into a state of limbo that will last for years. Regulatory uncertainty can have a dramatic and negative effects on market stability, product sales, and business planning that we are confident Maine does not seek to impose.
In commercial terms, it is detrimental for companies to wait until a comprehensive product ban is almost in effect to find out whether they can continue to sell their product. For manufacturers of complex durable goods, such as those represented by this Coalition, the developmental lead time for new product formulations is necessarily years or even decades. This is because manufacturers must complete three lengthy, resource-intensive stages: 1) determine the presence of PFAS throughout its complex international supply chain and manufacturing processes; 2) find a suitable alternative (if one is available); and 3) implement the alternative by performing the rigorous testing necessary to meet existing safety, regulatory, functionality, and consumer demands.

These efforts may affect hundreds or thousands of products, both directly and indirectly through the products in which they are used.⁴ The Coalition is also concerned that MDEP is underestimating the number of requests that will need to be submitted with respect to complex consumer goods. It is possible, and very likely, that the proposed timeframes will not allow MDEP sufficient time to complete its evaluations and make CUU exemption determinations before the 2032 statutory ban becomes effective.

The Coalition urges MDEP to allow all CUU exemption requests to be submitted at any point in time once the final rule is issued. Maine has discretion to prioritize and process these requests according to the deadlines required by law. MDEP should include a due process mechanism for a company to request reconsideration if a CUU exemption request is denied. During MDEP's January 16, 2025, public hearing, Emerson Electric and the Maine Chamber of Commerce testified to endorse these types of considerations.

2. Comments on the Need for a Risk-Based Approach

Certain chemicals that fall within the scope of the broad structural definition used by Maine to define the term PFAS present a low human health and environmental risk. The Coalition recommends that MDEP applies a *risk-based approach* to consider both hazard *and* exposure. In many cases, the PFAS will be encased in the products that are eligible for CUU determinations, such that they present little to no risk of exposure to consumers. The associated product lifespans and disposal and reclamation practices are such that there is a negligible risk of unintentional or unmitigated release to the environment.

On the whole, CUU eligible products are an important class of products that deserve priority attention: to be eligible for a CUU determination, these products must be essential to health, safety, and the functioning of society. The companies who manufacture these products should be allowed an opportunity earlier in the implementation of Maine's law to provide information on whether replacements exist and the time involved to transition to alternatives, where this is even possible and necessary.

Commercial certainty is of significant importance, and we think CUU requests should be favorably received. Nevertheless, Maine's system must also account for denials as well as approvals. The time needed to withdraw from the market in response to a denial is not taken into account by the proposed rule. MDEP has left out any opportunity to appeal a negative CUU determination, so that due process requirements are not met.

The Coalition supports a "*de minimis*" exemption as part of a risk-based approach. MDEP should include an exemption from the 2032 ban and the need for a CUU determination for 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 internal component contributes to exposure, which must be considered in any risk determination. Furthermore, there has been much

⁴ For example, an extensive study prepared under an agreement with and funded by the U.S. Department of Energy, discusses the poor availability of alternatives for fluoropolymers and the low feasibility of replacements. Stephanie Jacobs, David S. Kosson, *Assessment of Fluoropolymer Production and Use with Analysis of Alternative Replacement Materials* (January 2024).

308

scientific debate over whether it is actually possible to achieve 100% confidence in any formulation. Lastly, there is precedent in international, federal, and state law for providing *de minimis* exemptions. The Coalition urges MDEP to extend that relief to this rule as well.

3. Comments on Proposed Application Requirements

The Coalition asks for MDEP to issue a standardized form to submit CUU exemption requests. Such a form would streamline reporting and lower the potential for inconsistent and incomplete submissions. A standard form would make it easier for MDEP to review requests.

The Coalition asks Maine to add a provision to Section 9 which specifies the criteria it will use to make CUU determinations. While many important aspects of the statute are incorporated into the proposed rule, the CUU decisional criteria are noticeably absent. MDEP must find that a use is "essential for health, safety, or the functioning of society and for which alternatives are not reasonably available." This determination is a three-part test:

- First, "the function provided by the PFAS is necessary for the product to perform as intended". This requires information sufficient to understand how the PFAS functions in the product.
- Second, "the unavailability of the PFAS . . . would cause the product to be unavailable". This requires information on product performance and competing alternatives.
- Third, the unavailability of the product would result in either "a significant increase in negative health outcomes," "an inability to mitigate significant risks to human health or the environment," or "a significant disruption of the daily functions on which society relies." This requires information on the purpose of the product and an outcomes assessment if it were no longer available in Maine.

The above criteria will essentially drive all CUU determinations. The Coalition asks Maine to ensure that companies should not have to look outside of the rule to find these important criteria.

Furthermore, the Coalition asks Maine to reduce the information required for a CUU exemption request. The information required should be limited to that necessary to make the finding required by the statute. As proposed, the current level of information presents a substantial and undue burden on industry submitters. MDEP has not explained the necessity and relationship of the proposed information elements to these decision criteria. Specifically, the CUU decision criteria can be met without forcing companies to comprehensively explain to MDEP how products are regulated in Section 9(A)(5) through (7).

With respect to Section 9(A)(5), explaining the comprehensive PFAS regulatory landscape is a complex task. This should have little bearing on whether the product is essential in Maine. If MDEP considers the information supplied by a submitter insufficient, an otherwise valid CUU exemption request could be denied, even though this information is not required by statute to obtain a CUU determination. This is public information that regulators are well-positioned to know.

Regarding Section 9(A)(6) and 9(A)(7), information on competing products and their availability is duplicative of the information required by Section 9(A)(4) on alternatives and these provisions should be consolidated.

In addition, proposed Section 9(A)(9) asks for information known or reasonably ascertainable by the manufacturer regarding the impacts on human health or the environment of PFAS in the product. As described above in "<u>Comments on the Need for a Risk-Based Approach</u>", the Coalition supports a riskbased approach to regulating PFAS and appreciates that this provision reflects the intention by Maine to take a risk-based approach in these determinations. However, the Coalition respectfully submits for consideration that the Legislature did not list health and environmental effects as a consideration for reaching a CUU determination. While Maine's law otherwise directs MDEP to address the impacts of PFAS on humans and the environment, the CUU determination is an exception for essential uses if there are no current alternatives. MDEP should consider removing this provision to reflect the Legislature's deliberate omission of this information. The proposed rule specifies that "upon the expiration date listed in s 9(B) [sic], a currently unavoidable use determination is no longer applicable, and all sales, offers for sale, or distributions for sale are immediately prohibited." The Coalition urges MDEP to retain the discretion for deciding whether a CUU determination should be time-limited or not. The statute does not require that CUU determinations be time-limited and includes several exemptions that are not time-limited. Specifically, the Coalition asks MDEP to consider making 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 and alternatives cannot be identified. When time limits are considered, this Coalition has provided information documenting that the time needed to make a single chemical substitution could take approximately 20 years, as described in Section 1, "Comments on Proposed Timeframe" above.

Finally, the Coalition urges MDEP to remove language in the proposed regulation which encourages companies not to submit CBI information. 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 states that it will make a determination that there is insufficient publicly available information to justify a rulemaking. MDEP "strongly recommends" that CUU proposals do not include CBI claims. It is highly inappropriate for a government to advise citizens not to exercise a right provided by law. 38 M.R.S. § 1310-B(1) and (B)(2) permit CBI claims. In addition, MDEP's instructions run counter to federal law, such as the ability to assert CBI for PFAS on the TSCA Confidential Inventory and under the Uniform Trade Secrets Act. Absent the ability to claim information as CBI, companies may choose to refrain from making CUU exemption requests. This may result in harm to Maine's consumers, if products that are essential for the health, safety and functioning of society, would not be available anymore because companies prefer to withdraw from the market rather than risk disclosing proprietary business information.

V. Recommendation 9: The Coalition Asks MDEP to Distinguish Complex Consumer Goods from Complex Durable Goods Instead of Using the Term "Complex Product."

The distinction between complex consumer goods and non-consumer complex durable goods is an essential component of Maine's law. Generally speaking, many complex consumer goods will require CUU exemptions to stay in commerce in Maine, while there are permanent or extended time exemptions for most complex commercial and industrial (B2B) durable goods.

The proposed rule uses the term "complex product" in referring to the notification program that will be required for CUU exempted products. Maine does not define this term. Unfortunately, the definition of a "product" in Maine's statute blurs the inherent distinction between consumer and nonconsumer facing goods in Maine's law. The statute defines a "product" 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." In this definition, a consumer is virtually any consumer – individual and business alike.

The Coalition asks MDEP to use the terminology "complex consumer good" to refer to products in which individual consumers and households are the intended recipient, and the term "complex durable good" to refer to commercial and industrial business-to-business (B2B) equipment. The blended consumer concept in the statute makes the use of the term "complex product" in the proposed rule misleading. In relation to CUU determination notifications, its use inaccurately includes many products intended for commercial and industrial use that are already exempt from the 2032 ban by statute. Implementing a definition for "complex durable good" and a separate definition for "complex consumer good" provides a clear frame of reference for exempt products such as nonconsumer electronics in the former category.

The request to distinguish consumer from nonconsumer durable goods in the language of this rule is consistent with Section 6(c)(2)(D)(ii)(I) and (II) of the federal Toxic Substances Control Act (TSCA) and a recent proposal by the State of Vermont on PFAS legislation. In TSCA, "complex consumer goods" are

distinguished from "complex durable goods" in terms of the number of components, product lifespan, and the intended recipient of the product (i.e., consumers versus non-consumers). Moreover, in November 2024, the Vermont Agency of Natural Resources released a report on PFAS in Consumer Products and recommended legislation that defines and excludes "complex durable goods" from its scope. The proposed definition for a "complex durable good" in Vermont is "a consumer product that is a manufactured good 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. This includes replacement parts for complex durable goods not subject to a phase out under this chapter." Notably, the scope of Vermont's proposed legislation is a "consumer product", which in this context is limited to items for personal, family and household use, and "product categories that are normally used by households but sold to businesses (e.g. commercial carpets or commercial floor waxes)." Thus, the Vermont proposal excludes all other commercial and industrial durable goods, complex consumer goods like computers and cell phones, and replacement parts. As one of the reasons for taking this approach, Vermont pointed to the challenges experienced by Maine.

VI. Recommendation 10: Simplify Other Administrative Burdens.

The Coalition would like to thank MDEP for removing the \$5,000 fee proposal for making a CUU exemption request that was in the Concept Draft. The proposed fee of \$1,500 should be reduced to \$150 or less for notification and re-notification once a CUU determination is granted. Small businesses should not be asked to pay a fee.

Subsection 6 supports the assessment of a nominal filing fee for these notifications. However, the proposed fee level remains high for Maine businesses and will exceed the nominal stipulation quickly for companies that must notify numerous product categories. A nominal administrative fee should not look like a tax for keeping products that are essential for health, safety, or the functioning of society on the market. Fees can deter companies from selling essential products in Maine. The Maine Chamber of Commerce expressed concerns with the proposed fee when testifying during MDEP's January 16, 2025, hearing on this rule.

In addition, the Coalition asks MDEP to clarify that testing is not a requirement of this rule. Testing would be cost-prohibitive and difficult because test methods are still under development. Finally, the Coalition seeks guidance from MDEP on the "significant change" in composition concept. The Coalition would like to confirm that for companies that manufacture and report a final piece of equipment, the 10% change in composition should be calculated based on the entire piece of equipment. Without this clarification, this added layer of complexity will make compliance and verification more challenging.

*

Thank you for your consideration. For questions, the contact for the CPMC is Martha Marrapese, Partner, Wiley Rein LLP, 2050 M Street, N.W. Washington, D.C. 20036, (202) 719-7156, <u>mmarrapese@wiley.law</u>.





January 28, 2025

Submitted Via Email to rulecomments.dep@maine.gov

Kerri Malinowski Farris 17 State House Station Augusta, ME 04333

Re: Comments on Proposed Chapter 90 Rule re: Currently Unavoidable Use Designation of Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

Dear Ms. Farris:

Established in 1933, CropLife America (CLA) represents the developers, manufacturers, formulators, and distributors of pesticides and plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell, and distribute nearly all pesticide and biotechnology products used by American farmers.

Responsible Industry for a Sound Environment (RISE)[®] is the national trade association representing manufacturers, formulators, distributors, and other industry leaders engaged with the specialty pesticide and fertilizer products used by professionals and consumers.

CLA and RISE appreciate the opportunity to provide comments on the Maine Department of Environmental Protection (DEP) December 20, 2024 proposed rule, Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances (Proposed Rule), which is designed to implement the PFAS in Products Program established by 38 MRSA § 1614.¹ The Proposed Rule represents an opportunity for DEP to limit the negative public health and economic impacts of this law. CLA and RISE reiterate their request that DEP exempt pesticides from the requirements of 38 MRSA § 1614. In the alternative, CLA and RISE urge DEP to issue a Currently Unavoidable Use (CUU) determination for all pesticides and, because the Maine Board of Pesticides Control (BPC) already possesses formulation information for every pesticide sold in Maine, DEP should exempt pesticide manufacturers from notification requirements of 38 MRSA § 1614. We also describe below our continued concern about how DEP proposes to collect confidential business information. CLA and RISE previously commented on these issues and are

¹ Also referred to as the Products Containing PFAS law.





concerned that DEP's Proposed Rule is not a reasonable exercise of the agency's discretion or authority.

A. CLA AND RISE REQUEST THAT PESTICIDES BE EXEMPT FROM 38 MRSA § 1614 OR, IN THE ALTERNATIVE, A CUU DETERMINATION FOR ALL PESTICIDES

CLA and RISE reiterate our request² that pesticides be exempt from all requirements of 38 MRSA § 1614. This should be accomplished by listing pesticides in Section 4(A) of the rule. In the alternative, DEP should issue a CUU determination for all pesticides in Section 9(B) of the rule. Pesticides are essential for health, safety, and the functioning of society and are heavily regulated at the federal and state level to ensure safe use and avoid unreasonable adverse effects to the environment.

1. Pesticides are essential for health, safety, and the functioning of society

Access to a wide range of pesticide products with different modes of action for different pests, application situations, and users is essential for health, safety, and the functioning of society. While not an exhaustive list, we provide these examples of the fundamental role pesticides play in food production, quality of life, commerce, and environmental protection. Pesticide products are:

- Necessary for producing a safe, predictable, and adequate food supply as well as for producing essential fiber and fuel crops. In Maine, pesticides are essential to producing nutritious and abundant food crops available to residents in local supermarkets and farmers markets and for producing commodity crops such as potatoes and blueberries. Pesticide products protect crops from weeds, insects, fungi, rodents, and other pests in the field, after harvest, and during processing, storage, and transportation.
- Crucial for public health protection and controlling and eradicating life threatening, harmful and nuisance pests. Certain pesticide products manage and eradicate ticks, mosquitos, cockroaches, bedbugs, and rodents in homes, hotels, parks, schools, and restaurants. Harmful nuisance and invasive species such as the brown tail moth and emerald ash borer require pesticides for effective control.
- Indispensable for controlling and eliminating poisonous, noxious, and invasive nonnative plants such as poison ivy, oak, sumac, rag weed, Japanese barberry, oriental

312

² See July 18, 2022 CLA and RISE Comments on "Concept Draft for the Maine PFAS in Products Program," Implementing Reporting Provisions of 38 MRSA Section 1612; November 10, 2022 CLA and RISE Comments on "Second Concept Draft for the Maine PFAS in Products Program," Implementing Reporting Provisions of 38 MRSA Section 1612; May 19, 2023 CLA and RISE Comments on Posting Draft for Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances.







bittersweet, Russian olive, Eurasian milfoil, purple loosestrife, Japanese knotweed, and others on the Department of Agriculture, Conservation and Forestry's (DACF) Advisory List of Invasive Plants that threaten public health, safety, and ecosystems.

- Critical for maintaining safe and accessible green space, including parks, ornamental landscapes, and golf courses. Well maintained turf and landscapes reduce glare, dissipate heat, improve soil restoration and retention, and offer noise abatement. In addition, these areas offer extensive aesthetic benefits contributing to quality of life and mental well-being of residents and tourists. Well maintained golf courses specifically offer recreational activities including physical exercise and overall substantial economic value back into the Maine economy.
- Essential for effective subterranean termite control in homes and commercial buildings, and verification of pesticide treatment for these pests could be necessary to obtain a home mortgage.
- Integral to shielding Maine's energy, transportation, and other public infrastructure from damage and degradation from weeds, insects, rodents, and other pests.
- Protective of public infrastructure as a tool for creating firebreaks, clearing highway and railway rights of way and sight lines of vegetation, and managing noxious and invasive aquatic plants and algae in shipping lanes, lakes, ponds, and other aquatic ecosystems.

As a coastal and border state, Maine and its residents are uniquely subject to increasing pest pressures and disease threats introduced into the state through trade, weather, and other factors. Effective use of pesticides by Maine's agricultural producers, public health officials, forestry and vegetation management professionals, and residents is the first line of effective defense against these extraordinary pressures.

In addition, a wide variety of pesticide formulations with different modes of action are necessary for preventing and managing pesticide resistance in target species. Resistance can develop over time when pesticides with the same mode of action are applied in the same area. The practice of Integrated Pest Management (IPM) ensures pesticide applicators have the tools they need to effectively manage pests and avoid creating resistance. IPM is defined in three federal statutes: the 1996 Food Quality Protection Act (PL 104-170), the Children's Health Act of 2000 (PL 106-310), and the Food, Conservation, and Energy Act of 2008 (PL 110-234), and define it as "a sustainable approach to managing pests by combining biological, cultural, physical, and chemical tools in a way that minimizes economic, health, and environmental risks." IPM allows Maine's growers and pesticide applicators to make their own, case-by-case decisions to meet pest management needs.

2. Pesticides are among the most heavily regulated chemical substances at the federal level





Pesticides are already comprehensively regulated by the U.S. Environmental Protection Agency (EPA) under two federal statutes, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food Drug and Cosmetic Act (FFDCA). Both statutes require pre-market approval ("registrations" under FIFRA and, for food uses, "tolerances" or "tolerance exemptions" under the FFDCA) before a pesticide may be sold and used in the United States and before any state agency may approve the pesticide for sale or use in that state.

Pursuant to FIFRA, EPA independently evaluates chemical-specific data for active ingredients and all of the components of the formulation applied by the end-user to ensure that pesticides can be used safely and without unreasonable adverse effects to the environment³ when label directions are followed. EPA's rigorous data review includes analyzing a broad range of toxicity and exposure data and conducting comprehensive risk assessments drawing on all these data, *e.g.*, a human health risk assessment, including worker exposure, dietary risk for proposed food uses, and other aspects of human health, and an ecological risk assessment for pesticides proposed for outdoor use. EPA carefully reviews the scope and specific wording of the labels, which often are dozens of pages long, to ensure that the detailed directions for how, when, and where the pesticide may be used, worker protection, and other aspects of the label carefully and clearly circumscribe the way the pesticide may be used to protect human health and the environment.

As part of this review, EPA has access to detailed confidential, competitive information about the formula, which is carefully protected from public disclosure under federal law. Importantly, EPA is also required to review each registered pesticide at least every 15 years to ensure that each pesticide continues to meet current federal requirements. As part of this registration review, EPA often seeks additional scientific information from registrants to ensure that EPA has the necessary scientific information to conduct its review, based on current standards. EPA can, and often does, require changes to the pesticide or its use as a result of that review.

In addition, specifically with regard to dietary risk, EPA examines proposed food uses under the FFDCA's reasonable certainty of no harm safety standard.⁴ No pesticide may be approved for a food use under FIFRA unless it also meets the FFDCA safety standard, again based on extensive toxicity and exposure data and a human health risk assessment. EPA expresses its assessment

⁴ 21 U.S.C. § 346a(b)(2)(ii).

 $[\]frac{3}{2}$ FIFRA defines the term "unreasonable adverse effects on the environment" to mean: "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21." 7 U.S.C. § 136(bb).





by issuing a tolerance (the amount of pesticide residue that can be safely present in food) or a tolerance exemption.

All pesticides, including those formulated with fluorinated chemistry, must already be registered by the EPA before an entity may apply for and receive a state registration for sale and use; before pesticides enter commerce in a state, they must already be deemed safe for that use by EPA. To approve a new pesticide product, EPA must determine, based on data, that the pesticide will not, when used according to the label, and with commonly recognized practice, cause unreasonable adverse effects on the environment under FIFRA and for food uses provides reasonable certainty of no harm to human health under the FFDCA. EPA subjects all new pesticide products to rigorous human health and environmental review and testing requirements to satisfy these standards. The testing requirements include, depending on the type of pesticide, reviews of the following:

- Product chemistry
- Acute toxicity
- Ecological effects
- Applicator exposure
- Physical and chemical properties
- Environmental fate
- Efficacy testing (for public health uses), and
- Residue chemistry (for food uses).

EPA's scientific review of the data required for registering pesticides takes years to complete and products are continually re-evaluated to ensure they meet current scientific standards. This risk-benefit evaluation, in which the benefits must outweigh the risks, involves detailed scientific scrutiny. A finding of "currently unavoidable use" is supported by this wellestablished, comprehensive federal regulatory oversight of pesticides.

3. Pesticides are already regulated by BPC

At the state level, pesticides also are stringently regulated by the BPC through the Maine Pesticides Control Act. Pesticide manufacturers registering products in Maine already meet the criteria proposed in the Proposed Rule under a pesticide-specific law – LD 264. We urge DEP to defer to the expertise of the BPC in this matter. Precedent also exists for deference to the state lead agency for pesticide regulation. The state of Minnesota passed a similar product reporting and prohibition law, H.F. 2310, during its 2023 legislative session. That state's legislators gave express authority in the matter of PFAS substances and pesticide regulation to the Commissioner of the Department of Agriculture, recognizing the existing regulatory framework





and agency expertise for pesticide products. In Maine, we suggest that DEP defer to BPC by exempting pesticide products from all requirements of 38 MRSA § 1614.

4. The Proposed Rule fails to address variability in PFAS chemistries

The Proposed Rule incorporates the Act's definition of PFAS: any "substances that include any member of the class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom." 38 MRSA § 1614(1)(F). This definition is based solely on chemical structure and thus disregards the remarkably different physical, chemical, and biological properties that shape the potential human and ecological risk profiles of chemistries that meet that definition. The Proposed Rule fails to adopt a priority or risk-based approach to defining PFAS, which will result in an arbitrary application of 38 MRSA § 1614, including the CUU determination process. Pesticides should be exempt from the law's requirements, or, at the very least, a CUU determination should be implemented for fluorinated pesticides, as those products are essential to human health, safety, and the functioning of society, as detailed elsewhere in these comments.

5. The use of PFAS in certain pesticides is essential to their function

Certain pesticide products may contain fluorinated chemistry that meets the state's definition of this chemistry to enhance performance where there is a desire for additional selectivity, specificity, and stability. Such chemistry supports control of only the target pest and ensures formulated products maintain efficacy and integrity as they move through the product supply chain to application.

At a minimum, "currently unavoidable use" should include fluorinated pesticides because their ongoing federal and state regulated uses are "essential for health, safety, or the functioning of society." Pesticides are critical in controlling pathogens and disease vectors, protecting homes and infrastructure, and safely growing crops.

B. CLA AND RISE REMAIN CONCERNED ABOUT PROTECTION OF CONFIDENTIAL BUSINESS INFORMATION

Virtually all pesticide formulations constitute highly sensitive confidential business information (CBI) that demands protection by the State (and is protected under federal law). The importance of protecting this information is evidenced throughout Maine's laws and must be equally protected under the Proposed Rule.

1. The Proposed Rule Requires Disclosure of Protected Information



Under the Proposed Rule, in order to request a CUU determination, a company would need to submit certain information to DEP, including the following:

- A description of the product, including physical structure, appearance, how it functions, and identifying codes such as the North American Industry Classification System (NAICS) code for the sector or sectors in which the products containing intentionally added PFAS will be utilized;
- An explanation as to why the availability of PFAS in the product is essential for health, safety or the functioning of society; and
- A description of how the specific use of PFAS in the product is essential to its function.

In order to continue selling the product subject to a CUU determination beyond the restriction date, a company would then need to submit a notification to DEP containing the following information:

- A description of the product, including the Global Product Classification (GPC) brick category and code;
- The product's type and intended use;
- The NAICS code for the sector or sectors in which the products containing intentionally added PFAS will be utilized;
- The purpose for which PFAS are used in the product;
- The precise identity of each PFAS used in the product, by chemical abstracts service (CAS) registry number or international union of pure and applied chemistry (IUPAC) nomenclature;
- The exact quantity of each PFAS in the product as a concentration (or in the alternative, the total organic fluorine); and
- The name and address of the reporting manufacturer, and the name, address, email address, and phone number of a responsible official for the manufacturer.

The key elements typically are contained in the Confidential Statement of Formula (CSF) document required to be submitted to federal regulators as part of a pesticide registration application. Such documentation is required for all pesticides, and identifies the specific ingredients in detail, including the amount allowed to be used and the source of the ingredient. In addition, applicants must provide detailed information to federal regulators about the manufacturing process.

As written, the Proposed Rule does not provide adequate assurances that this information will be protected from public disclosure, or how DEP plans to do so. Without a higher degree of confidence in the protection of CBI, it is foreseeable that important pesticide products may not





be available to Maine's agricultural producers, professional applicators, public health officials, and consumers, particularly to address resistance and emerging and future pest pressures.

2. Pesticide-Related CBI Is Protected Under State Law

The importance of protecting CBI from disclosure is underscored by the legislature's inclusion of CBI protections in the Products Containing PFAS law. 38 MRSA § 1614(12) ("Proprietary information submitted to the department by a manufacturer pursuant to the requirements of this section . . . is confidential and must be handled by the department in the same manner as confidential information is handled under section 1310 B.")

3. CLA and RISE Urge Coordination with Maine BPC

When LD 264, the pesticide-specific law, was first enacted, it required the submittal of the same information provided to EPA about formulations to register pesticides with the state. CLA and RISE participated throughout the available opportunities for public comment and public hearings, providing suggestions for how the information could be submitted and protected. BPC ultimately developed an approach to address those concerns. CLA and RISE are available to discuss BPC's actions to ensure appropriate protection in accordance with state and federal law and to support compliance with LD 264.

C. DEP SHOULD EXEMPT PESTICIDE MANUFACTURERS FROM NOTIFICATION REQUIREMENTS

The Proposed Rule would require pesticide manufacturers subject to a CUU determination to submit considerable information to DEP, including CBI, and continue to update that information if there are significant changes or upon request by DEP. Because BPC already has access to confidential formula information submitted pursuant to LD 264 and LD 2019, all pesticide manufacturers should be exempt from the duplicative notification requirements contained in the Proposed Rule.

CONCLUSION

Because pesticides are essential to the health, safety, and the functioning of society, and are subject to science-based federal regulation that requires a comprehensive human health and environmental risk assessment, it is appropriate to exempt pesticides from the requirements of 38 MRSA § 1614. This would be most efficiently accomplished by listing pesticides in Section 4(A) of the rule. In the alternative, DEP should issue a CUU determination for all pesticides in Section 9(B) of the rule and exempt pesticide manufacturers from the rule's notification





requirements. To the extent any final rule would require pesticide manufacturers to submit CBI to DEP, we ask you to work with us to ensure that CBI is adequately protected.

As representatives of developers, manufacturers, formulators, and distributors of pesticides for agriculture and pest management in the United States, CLA and RISE appreciate the opportunity to provide these comments on the Proposed Rule. Please contact us if we can provide further information or if you have questions.

Sincerely,

Mun

Karen Reardon

Manojit Basu, Ph.D. Vice President, Regulatory Affairs CropLife America Tel. (202) 296-1585 www.croplifeamerica.org

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320

January 28, 2025

Maine Department of Environmental Protection 17 State House Station Augusta, ME 04333-0017 Submitted via email: rulecomments.dep@maine.gov

Re: Chapter 90 Draft Rule: Products Containing perfluoroalkyl and Polyfluoroalkyl Substances

To whom it may concern:

The Cookware Sustainability Alliance (CSA) appreciates the opportunity to submit comments to the Maine Department of Environmental Protection's ("DEP") Chapter 90 Draft Rule to implement certain provisions of the Maine PFAS in Products law, P.L. 2024, c. 630. We represent a diverse membership of cookware manufacturers who are committed to promoting sustainable practices and ensuring compliance with regulatory standards. Specifically, we write to support the Department's efforts to clarify the definition of "cookware" in the draft rules and to recommend revisions that explicitly exclude polymer-coated durable items from this definition. Such clarification is critical to ensure the final rules align with the law's intent, provide regulatory certainty for industry stakeholders, and avoid unintended burdens on products that do not pose the types risks to human health and the environment for which the PFAS in Products law was enacted to address.

Issue Overview

Per- and poly-fluoroalkyl substances ("PFAS") are a large group of compounds composed of fluorinated carbons. Importantly, the physical and chemical properties of the individual chemicals within this large group of compounds vary widely. Their use, how they behave in the environment, and their potential risk to human health vary significantly as well.

Non-stick cookware is made using a specific subfamily of compounds called fluoropolymers, primarily polytetrafluoroethylene ("PTFE"). Fluoropolymers are characterized as a PFAS under Maine's expansive definition, i.e., any fluorinated organic compound containing at least one fully fluorinated carbon atom. However, unlike non-polymeric PFAS of concern, fluoropolymers are extremely large and stable compounds that do not pose the same risks to human health or the environment. Extensively studied and approved for use in food preparation by the U.S. Food & Drug Administration and various European regulatory bodies, fluoropolymers have a decades-long record of safety supported by sound scientific research.

CSA was established to address misconceptions surrounding fluoropolymers and ensure that policies targeting PFAS focus on substances of actual concern, rather than safe and well-regulated products like non-stick cookware Today, fluoropolymers used in cookware that come into contact with food are not a concern for human health or the environment for the following reasons:

- They have a decades-long history of safe and essential use, including in healthcare where fluoropolymer coatings are used on medical implantation devices like pacemakers and catheters.
- They are not water-soluble, thus potential exposure through drinking water is not a concern.
- PTFE and similar fluoropolymers are highly stable and are not shown to degrade under normal use conditions.

Including cookware in Public Law 2023, c. 630 disregards the unique physicochemical characteristics of fluoropolymers that make the subfamily benign with respect to potential health effects and environmental impact. Policies aimed at prohibiting certain PFAS compounds deemed harmful to human health and the environment, along with the rules implementing them, must fairly evaluate chemical-specific properties and carefully avoid inadvertently regulating compounds like fluoropolymers, which are essential to modern society and have been demonstrated through scientific research to be safe for use in consumer products such as non-stick cookware.

Accordingly, we submit the following limited proposed amendments to portions of the Chapter 90 Draft Rule pertaining to the definition of cookware and the prohibition on the sale of cookware containing intentionally added PFAS:

2. Definitions.

Cookware product. "Cookware product" as defined at 38 M.R.S. § 1614(1)(A-10) is limited to houseware intended to be in direct contact with food or beverage. Cookware does not encompass items intended for use in and market exclusively for use in commercial, industrial, or institutional settings, nor does it include any polymer-coated durable items which the United States Food and Drug Administration authorizes for food contact.

5. Prohibition on sale of products containing intentionally added PFAS. This subsection governs sales of products containing intentionally added PFAS.

C. Except as provided in subsection H and section 9(B), effective January 1, 2026, a person may not sell, offer for sale or distribute for sale in the State of Maine:

(2) A cookware product <u>surface that is intended to be in direct contact with food or beverage</u> <u>while cooking and</u> containing intentionally added PFAS. <u>This prohibition under this subparagraph</u> <u>does not include polytetrafluoroethylene (PTFE), fluorinated ethylene propylene (FEP), and</u> perfluoroalkoxy alkane (PFA) used on food contact surfaces of cookware.

Supporting Data

1. Government Agencies Have Deemed PTFE Cookware Safe

Since the 1960's, federal regulations at the U.S. Food & Drug Administration (21 CFR 175.300) have authorized specific types of PFAS substances for use in food contact applications. The FDA has determined that PTFE cookware is safe to use due to the "highly polymerized coating bound to the surface of the cookware and studies showing negligible amounts of PFAS in this coating migrating to food, and that polymerized or large molecule PFAS are not absorbed by the human body when ingested." (updated 2024).

Similarly, the European Food Safety Authority (EFSA) has found that PTFE, due to its molecular size, will not likely be absorbed through the gastrointestinal barrier, and therefore concludes it does not present a health hazard (2016).

The properties that make some non-polymer PFAS a concern for human health and the environment include their water solubility and wide-spread environmental occurrence, bioaccumulation potential, and potential toxicity. Fluoropolymers do not have these properties, as the following further details.

2. Fluoropolymers Have No Measurable Bioaccumulation Potential

Available empirical data indicates that fluoropolymers such as PTFE, do not bioaccumulate. Bioaccumulation potential is generally assessed on empirical evidence (bioaccumulation factor > 2000) and/or prediction using the octanol-water coefficient (e.g., log Kow > 3). Fluoropolymers such as PTFE are insoluble in octanol and water (Henry et al., 2018). Therefore, the bioaccumulation potential of fluoropolymers cannot be predicted from a log Kow measurement. Measured biota tissue, water, and sediment concentrations indicate that there is no evidence of bioaccumulation in aquatic food webs (Bour et al., 2018; Sfriso et al., 2020).

3. Fluoropolymers Show No Evidence of Toxicity

Fluoropolymers such as PTFE have not been shown to be toxic to humans. A summary of available data examining the toxicity of PTFE on test animals is provided in Radulovic and Wojcinski (2014). Acute oral toxicity of PTFE in rats is low/negligible with reported LD50 greater than 11,280 mg/kg. Researchers also found no adverse effects in rats exposed to up to 25% PTFE in their diet for up to 90 days (Naftalovich et al., 2016; Radulovic & Wojcinski, 2014). Additionally, a four-week repeated dose study of PTFE fed to mice in their diet reported no effects at any dose level, and no PTFE was detected in the blood (Lee et al., 2022). The dose level fed to mice without any adverse effects would be equivalent to approximately 9,720 mg/kg for a 60 kg (~132 pounds) adult. Manufacturer material safety data sheets for PTFE indicate that dermal contact with PTFE does not cause skin irritation in humans. PTFE is not genotoxic, and the World Health Organization's International Agency for Research on Cancer concluded that organic polymeric materials (such as fluoropolymers) as a group, are not classifiable as to their carcinogenicity to humans (IARC, 1999).

4. Fluoropolymers Are Not Water Soluble

Fluoropolymers are not environmentally mobile. Fluoropolymers such as PTFE are not water soluble and even if released to the environment, are not likely to result in widespread environmental impacts (Korzeniowski, et al. 2022).

5. Fluoropolymer Cookware Show No Significant Emissions Upon Disposal

Fluoropolymers from food contact applications are unlikely to result in significant environmental emissions during the end-of-life phase. Recycling and treatment of PTFE-treated metal cookware offers the greatest assurance that the used cookware is most properly controlled in the end of life. Incineration at typical temperatures of municipal waste incinerators can result in full mineralization of the fluoropolymers, thereby preventing degradation into non-polymeric PFAS. Landfilling PTFE cookware prevents PFAS emissions due to the stability of the polymer and the absence of high enough temperatures in landfills to cause polymer degradation.

Our Industry is Engaged in Responsible Manufacturing

It is important to acknowledge that since the mid-20th century, PTFE has played a vital role in the technological advancements of many industrial and consumer products. Moreover, over the past several years, PTFE manufacturers have implemented significant changes to their manufacturing processes. Technologies now exist and are implemented to manufacture PTFE without the use of fluorosurfactant processing aids. Also, those manufacturers who may continue to make fluoropolymers via the use of fluorosurfactant processing aids now include additional steps to ensure negligible remaining non-

polymer PFAS are entrained in the final fluoropolymer product. These recent developments in the manufacturing process for PTFE and other fluoropolymer cookware ensure that they are not a health effects concern to humans or the environment.

In sum, the physicochemical factors and health effects research should lead policymakers to conclude that fluoropolymers in PTFE cookware, even those that come into contact with food being cooked in pots, pans, skillets, and utensils, are NOT appropriate chemical focus areas for regulation under the Chapter 90 Draft Rule.

Sincerely,

Stephen D. Burns

Stephen D. Burns President, Cookware Sustainability Alliance

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January 28, 2025

Kerri Malinowski Farris Maine Department of Environmental Protection 17 State House Station Augusta, ME 04333 <u>PFASproducts@Maine.gov</u>

Re: CTA Comment on Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

Dear Ms. Farris,

On behalf of the Consumer Technology Association (CTA), we respectfully submit these comments on the Maine DEP proposed rule <u>Chapter 90: Products Containing Perfluoroalkyl and</u> <u>Polyfluoroalkyl Substances</u> ("Rule"). The Rule provides regulations to implement the <u>PFAS in</u> <u>Products law</u> (the Act) which will impact nearly the entire technology and electronics sector. CTA is North America's largest technology trade association. Our members are the world's leading innovators – from startups to global brands – helping support millions of American jobs. Our member companies have long been recognized for their commitment and leadership in innovation and sustainability, often taking measures to exceed regulatory requirements on environmental design and product stewardship. We appreciate the opportunity to provide these comments on the Rule and welcome continued dialogue with the Department as it begins implementing this complex law.

We have structured our comments in order of the sections provided by the Rule:

Section 3. Notification

<u>Section 3(A)</u>: The ban on product sales will apply to products or components in the stream of commerce on the day the ban goes into effect. This will mean that any spare parts, which are considered new or unused, for products that are out of production will be subject to the ban. Products that consumers are using in Maine may not be serviceable once the ban goes into effect if spare parts become unavailable. We ask that the Department include an exemption for spare parts in the Rule.

Section 3(A)(1)(b): This section requests companies to submit an estimate of the number of units sold annually. We ask the Department to clarify specifically what information will be required in the estimate. CTA has significant reservations concerning an obligation for companies to report sales data, which is often treated by companies as confidential. If sales data reporting is required, it should be limited to aggregated data within a past year and not include future forecasts. In addition, recent historic sales data should be explicitly protected as CBI by DEP.

325

Consumer Technology Association[®] Producer of CES[®] Section 3(A)(1)(e): This section governing the notification on the amount of each of the PFAS in the product or component still requires a lot more clarification. The Department has not specified how an exact concentration can be calculated. For example, if a finished good is sold into Maine and PFAS is within one of that product's components, is the concentration calculated based on the entire finished good? The Department should provide examples and details on calculation. The Department should provide further clarification in the Rule about the phrase "falling within a range approved by the Department" and how this will be implemented. There are also currently no standardized methods to calculate the use of PFAS in complex goods like electronics. Therefore, we would also like clarity as to what constitutes "commercially available analytical methods" as outlined in this Section.

<u>Section 3(A)(1)(d) CAS Numbers</u>: The rule should require the Department to issue a complete list of CAS Numbers subject to the notification obligation at least 12 months before the reporting deadline. This will help manufacturers streamline their compliance processes.

<u>Section 3(C)</u>: The Rule should clarify that affiliates and subsidiaries under the same corporate parent manufacturer may submit combined reports.

Section 5. Prohibition of Sale of Products Containing Intentionally Added PFAS

Section 5(H): This states that Section 5 does not apply to a retailer unless it sells a product containing intentionally added PFAS for which the retailer has received a notification that the sale of the product is prohibited. The Rule should clarify whether or not *only* the retailer will be held responsible for violation of the Rule in this circumstance.

Section 6. Fees

Section 6(A): The Note in 6(A) states that notifications are not required for product components that are incorporated into complex products. DEP should clarify whether this applies to product components sold as replacement parts for finished goods. We encourage the Department to avoid duplicative reporting and not require separate notification for replacement parts.

Section 9. Currently Unavoidable Use

<u>Section 9(A) Timeline</u>: The proposed timeline for submission of a CUU determination is between 36 and 18 months prior to the effective date of a product ban. We are concerned this will leave manufactures with little time to comply with CUU determinations that are released close to the deadlines out line in the Act. We recognize that DEP will receive many CUU proposals, and it may take considerable time for the Department to process them all. There is no assurance that DEP will process CUU determinations with sufficient time before a sales ban goes into effect.

Manufacturers of products awaiting CUU determinations should have an exemption period while DEP is evaluating a CUU proposal. After the grant or denial of a CUU determination, manufacturers should have sufficient time to comply. If a CUU is granted, manufacturers will need time to prepare for the necessary notification requirements. If one is denied, manufacturers will need time to comply with a sales ban.

The industry is still gathering information on the uses of PFAS across the supply chain, and we respectfully ask that CUU proposals be received after the 18-month mark up to the sales prohibition. If a manufacturer has a CUU proposal ready, it should be able to submit before the 36-month window. For renewing an expired CUU determination, the proposed 12-24 month timelines have the same problems expressed above for 9(A). We ask for additional flexibility with renewing expired determinations. Instead of treating the process as a new determination, we ask that the Department treat it as a renewal.

<u>Need for Broader CUU Categories</u>: The Rule suggests that manufacturers submit CUU proposals by using GPC/HTS codes in NAICS sectors. We ask that CUU proposals be submitted for broader product categories than the proposed codes. When CTA submitted CUU proposal categories under DEP's prior rulemaking, we found over 600 relevant HTS codes for electronics products. Instead of granting CUUS for hundreds of different codes, we believe it would be simpler to issue CUUs based on industry sector. The proposed individual CUU determinations based on suggested codes are costly for the Department and inefficient for industry compliance.

<u>Section 9(A) Information</u>: The proposed requirements under Section 9(A) call for more information than the statute requires, and the compliance burden for much of the proposed data would exceed what a regulator needs to make a CUU determination. The Department should consider making some of these requirements optional if they are not necessary to determine whether a use of PFAS is unavoidable.

Section 9(A)(2)-(3): The Department should provide clearer guidance regarding what qualifies as "essential for health, safety, or the functioning of society."

<u>Section 9(A)(4)</u>: The Department should provide clearer guidance regarding what standard will be applied to determine if an alternative is "reasonably available."

Conclusion

Thank you again for the opportunity to provide these comments on the Rule. If you have any questions about, please don't hesitate to contact me at <u>dmoyer@cta.tech</u>.

Sincerely,

Dan Moyer Sr. Manager, Environmental Law & Policy Consumer Technology Association

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January 28, 2025

VIA EMAIL RULECOMMENTS.DEP@MAINE.GOV

Kerri Malinowski Farris Maine Department of Environmental Protection 17 State House Station Augusta, Maine 04333

Re: Comment on Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

Dear Ms. Farris:

The Chemical Users Coalition (CUC) is providing comments in response to Maine DEP's proposal of a new rule, Chapter 90, to establish criteria for currently unavoidable uses of intentionally added PFAS in products and to implement the sales prohibitions and notification requirements for products containing intentionally added PFAS but determined to be a currently unavoidable use pursuant to the amended 38 M.R.S. 1614.

CUC is an association of companies from diverse industries interested in chemical management policy from the perspective of those who use, rather than manufacture, chemical substances.¹ CUC encourages the development of chemical-regulatory policies that protect human health and the environment while simultaneously fostering the pursuit of technological innovation in the context of international markets and the global economy.

The CUC appreciates your consideration of these comments. If you have any questions relating to this submission, please feel free to contact me.

Sincerely,

Judil Pren

Judah Prero

Enclosure cc: L. Culleen

¹ The members of CUC are Airbus S.A.S., The Boeing Company, Carrier Corporation, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, the National Electrical Manufacturers Association, RTX Corporation, Sony Electronics, Inc., and TDK U.S.A. Corporation.

Before the Maine Department of Environmental Protection Proposed Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substance under Maine's Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution, 38 M.R.S. § 1614

Comments of the Chemical Users Coalition

Introduction

Chemical Users Coalition ("CUC") appreciates the opportunity to provide these comments in response to Maine's Department of Environmental Protection's ("DEP" or "Department") proposed rule for notification requirements, sales prohibitions and currently unavoidable use determinations for products containing intentionally added PFAS under Maine's Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances [PFAS] Pollution (the "Proposed Rule"). CUC's members will likely be adversely affected by the proposed changes being considered. CUC is an association of companies from diverse industries that typically acquire and use, rather than manufacture, chemical substances. CUC has consistently supported measures that protect health and the environment in a manner that enables the regulated community to pursue technological innovation simultaneously with economic development in the United States. CUC members produce and distribute highly complex materials and products, including critical semiconductor devices to major devices, appliances and intricate equipment. To thrive in a competitive global economy, our members depend on the availability of certain existing substances as well as products that incorporate such substances, which are necessary components of a reliable pipeline for our members' production of innovative new products upon which the consumer, commercial, industrial, health care, defense, space, and transportation sectors consistently rely. Consequently, our members encourage the Department when implementing PFAS related restrictions or requirements to develop regulatory approaches that responsibly consider existing (and developing) products and technologies on which the US economy and the departments of the US government depend. The availability of such products and the development of new technologies will be unintentionally and adversely restricted if DEP does not develop certain implementation strategies that provide exceptions and varying compliance schedules to enable the continued distribution and use of such materials and products.

Comments

CUC welcomes this opportunity to provide comments on this next step in the rule promulgation process. We note that with regard to many of the areas on which CUC previously commented (enclosed), there has been little to no substantive change, despite the significant policy and practical issues that have been raised. CUC asks that the Department carefully consider comments received by CUC and other stakeholders, implement the requested changes, and upon the issuance of final regulations, explain how and why the issues raised in these comments were addressed in the final rules. Failure to implement these changes will adversely affect the availability of certain products and materials that are of critical importance.

The comments below follow the organizational structure of the Proposed Rule:

Applicability

• The revised Applicability section states that the Chapter applies to all new and used products sold, offered for sale, etc. and removes the reference to product components being subject to the regulations. However, there are references to product components in other sections of the Proposed Rule. For example, the Notification section states that the purpose for which PFAS are used in a product, including PFAS in any component must be reported. It also states that "For product components for which the Department has previously received notifications, which are used in more complex product scontaining 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." This implies that component manufacturers are subject to the notification requirements. DEP needs to clarify this extremely important detail and harmonize the regulations in this regard throughout.

CUC supports exempting components from the notification requirements as this will address significant compliance challenges. There is a lack of transparency within the value chain concerning the chemical content of manufactured articles, especially with respect to complex products and manufactured items with multiple component parts. Suppliers often are reluctant or unable to provide information on composition of components to customers, often due to confidentiality concerns within and among the value chain. For these reasons, CUC supports removal of "components" from the notification requirements, and the Proposed Rule should ensure that this is appropriately reflected throughout.

• The revised Applicability section states that the Chapter applies to new products. CUC supports the Proposed Rule's terms that the sales prohibitions do not apply to used products. CUC suggests that the prohibition also should not be applicable to replacement parts that are needed for routine repair and maintenance of existing (and used) products throughout their projected lifecycle. This is especially critical for complex and durable goods (such as consumer use appliances) which if properly maintained can have a lengthier period of use and reduce waste through the unnecessary disposal of such goods. Moreover, as discussed further below, CUC recommends that the regulations be modified to state directly that wholesale and retail distribution of products that were imported or manufactured prior to the effective date of a particular prohibition may continue to be distributed in Maine until existing stocks of such previously manufactured items can be "sold through" without enforcement concerns.

Definitions

• **Commercially available analytical method** The Proposed Rule defines "Commercially available analytical method" as any test methodology used by a laboratory that performs analyses or tests for third parties to determine the concentration of PFAS in a product. Commercially available analytical methods do not need to be performed at a third-party laboratory; however, the method must remain unmodified when not performed by a third-party laboratory.

Many laboratories are using certain tests for Total Organic Fluorine ("TOF") as opposed to methods that can identify the presence of specific PFAS. There are currently no standardized methods to identify and calculate the quantity of PFAS present in complex goods. DEP should therefore clarify what constitute "commercially available analytical methods" under these circumstances.

- **Product** The Proposed Rule notes that Product is intended to include packages and packaging components. This is reinforced in Exemptions, 4(A)(2), where the Proposed Rule states that if packaging contains intentionally added PFAS, it is prohibited. CUC believes that product packaging should be exempt, at least until the 2032 prohibitions take effect. Considering how industries and supply chains are still trying to gather information on the use of PFAS in the products themselves, imposing the same requirements on product packaging presets significant compliance challenges and substantially increases the burden on regulated entities.
- Semiconductor CUC appreciates the Department's revisions to the definition in an attempt to ensure consistency with the federal definition of semiconductor chip product that appears at 17 U.S.C. §901(a)(1). However, CUC believes that additional changes are warranted. Specifically, the text appearing in the final sentence of the proposed semiconductor definition which describes materials that semiconductors "do not include" should be omitted. In its stead, the final sentence should read, "Semiconductor means both a semiconductor material and a type of product that is a discrete assembled functional object containing semiconductor material which is capable of being incorporated into electronic equipment, such as a CPU." Such changes will ensure the final rule makes clear that a semiconductor is not just an etched and layered material, but also a type of assembled functional product described in the semiconductor exemption in section 4.A.(11) of the Proposed Rule, and capable of being "incorporated into electronic equipment".

In addition, CUC requests that the "NOTE" appearing immediately below the semiconductor definition on page 7 of the Proposed Rule be removed. As currently drafted, its intent is unclear, it does not add any needed information and is likely to simply create confusion.

Notification

• The contents of the notification to be required for materials subject to Currently Unavoidable Use (CUU) determinations can and should be minimized given the extent of

information that already will be in DEP's possession as a result of the CUU application process and the materials concerning the product's contents provided in the application.

- Section 3(A) states that the prohibitions would take effect even for products that are already in the stream of commerce. This imposes a challenge, particularly for manufactured goods that may have a longer shelf life, and which may be with a distributor or retailer for an appreciable amount of time after the manufacturer has sold the item. Furthermore, imposing a sales prohibition on products that have already entered the stream of commerce will result in manufacturers, wholesalers, distributers, and retailers potentially having to discard manufactured products, needlessly creating waste. CUC therefore requests that a sell-through provision be provided.
- Section 3(A)(1)(a) requires information on "the general type of the product." CUC requests that DEP clarify the intent of this provision. Is DEP looking for information on industrial vs consumer use, specific product category, category of use (juvenile vs. adult)?
- Section 3(A)(1)(b) requires companies to submit an estimate of the number of units sold annually. CUC requests that DEP clarify the intent of this provision. Is DEP requiring information relating to the sales from the past calendar year prior to the notification submission date or requiring sales projections for the coming calendar year. Sales projections are often confidential business information, and disclosure of such creates significant economic harm. Accordingly, DEP should focus on the historical data (in ranges), and explicitly state such in the final rules.
- Section 3(A)(1)(d) states that for PFAS substances in which the specific CASRN is unknown, DEP would require the identification of PFAS by a nomenclature of the IUPAC. Suppliers of substances to customers often communicate the use of PFAS without specifying the CASRN or even a generic chemical name due to trade secret (confidentiality) reasons. CUC therefore requests that, in those instances DEC would approve a submission that simply indicates "the use of a PFAS."
- Section 3(A)(1)(e) requires notification of the amount of each PFAS used in the product or product component reported as an exact quantity as a concentration. CUC requests that DEP clarify how an exact concentration can be calculated. If a finished good is sold into the state of Maine, and PFAS is contained within one of the product components that make up the finished good, then is the concentration calculated based on the entire finished good, or is it based on a component?

Furthermore, this section requires reporting on the TOF in a product if the amount of each PFAS is not known or easily reasonably ascertainable, determined using commercially available analytical methods. While TOF is often used to indicate presence of PFAS, it may detect organofluorine chemicals that are not PFAS. As such, TOF does not conclusively indicate the presence of PFAS nor the quantity of any such PFAS, and CUC questions the value of requiring that this number be provided.

Lastly, this provision concludes by stating "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." As mentioned above, the applicability section removed components. Consequently, this provision needs to be eliminated or clarified as to its intent. On its face, however, it is unclear how a product manufacturer would even know if a component manufacturer submitted a notification to rely upon for compliance with the notification requirement.

Exemptions

• Section 4(A)(8) states that an exemption from the requirements of the regulations applies to a product required to meet standards or requirements of the FAA, the National Aeronautics and Space Administration (NASA), the United States Department of Defense (DOD) or the United States Department of Homeland Security (DHS), except that the exemption under does not apply to any textile article or refrigerant that is included in or as a component part of such products.

DEP should provide a rationale as to why notifications are needed for these particular components and what purpose such reporting serves or otherwise simply exempt items. All these products have detailed specifications, including for textile article and refrigerant content. Furthermore, DEP needs to provide clarification as to how and when notifications are to be submitted for these textile and refrigerant parts (which themselves are presumably "components").

CUC requests that such textiles and refrigerants be exempted when present in such items to avoid confusion and reduce the complexity of the regulations and simplify the administrative burden on Maine DEP.

Prohibition on Sale of Products Containing Intentionally Added PFAS

- Subsection E states that the sales prohibitions do not apply to the sale or resale of a used product. As mentioned above, CUC suggests that the prohibition should also not be applicable to replacement parts that are needed for routine repair and maintenance of existing (and used) products throughout their projected lifecycle. Furthermore, products which are leased following their original manufacture (e.g., rental cars) should be considered within the scope of the exemption for "used" products.
- Subsection H states that the prohibitions do not apply to a retailer in the State of Maine unless the retailer sells offers for sale or distributes for sale in the State of Maine a product containing intentionally added PFAS for which the retailer has received a notification pursuant section 8(2) that the sale of the product is prohibited.

CUC requests confirmation that if a company notifies a retailer that certain products cannot be sold starting 2026, and the retailer continues to sell the PFAS-containing

products despite the company's notification, that only the retailer be held responsible for violating the prohibition rule.

CUC also requests that clarification should be given with regard to the status of wholesalers and distributers of manufactured products.

Manufacturers or articles that contain multiple components work utilize vast supply chains that may be composed of potentially thousands of suppliers. These suppliers, usually located outside of the United States, are often not aware of new regulatory requirements. Consequently, time and resources are required to ensure this awareness and to facilitate needed disclosure of PFAS presence to downstream customers. It is probable that even with due diligence, an end-product manufacturer may only become aware of the presence of PFAS in their products after the restriction deadline has passed. CUC therefore asks that DEP add a provision that explicitly states that manufacturers will not be penalized in such cases as long as the manufacturers have made a good - faith effort to reasonably ascertain the presence of PFAS their products prior to selling the finished product in the state after the effective date of a specific prohibition.

Fees

• CUC appreciates that DEP has lowered the fee amount. However, for companies that must submit many notifications, the financial burden could still be high. CUC suggests that a single fee be imposed on each reporting entity, regardless how many product notifications are submitted by that entity.

Currently Unavoidable Use

• The Proposed Rule states that The Department will not consider any Proposed Rules for an initial currently unavoidable use determination prior to 36 months in advance of the applicable sales prohibition and no later than 18 months prior to the applicable sales prohibition. Accordingly, it appears that if a product will be subject to the 2032 prohibition, the earliest that proposed CUU can be submitted is Jan. 2029, and the latest is June 2030. CUC believes that the proposed timeframe is too narrow and inflexible. Regulated companies are reviewing uses of PFAS and PFAS alternatives are still being studied. A company may need significant lead time in the event a CUU determination is denied, and 36 months is not sufficient. In the alternative, companies studying alternatives may not have all the needed information to submit 18 months before the applicable sales prohibition.

CUC requests that additional flexibility be provided for "resubmission" of CUC determinations, and that such should not be considered as new submissions but rather renewal of the existing determination. Furthermore, DEP should streamline the regulations because requests for renewal should have minimal information requirements as such details would have been previously provided to DEP.

• The Proposed Rule provides that a CUU Proposed Rule must contain a significant amount of information on alternatives to the PFAS currently in use and information on the human and environmental effects of the PFAS used in a product. For complex product manufacturers, there is a strong likelihood that they will not possess such information. While the Proposed Rule does state that "known or reasonably ascertainable" information is to be provided, clarification as to the actual level of due diligence required is needed (and the consequences of not being able to supply such information) to determine how practical and/or burdensome this requirement will be.

• The Proposed rule requires Proposed Rules to contain product descriptions based on HTS/GPC and NAICS combinations. Due to the ubiquitous nature of PFAS, CUC suggests that Proposed Rules could be based on industry sector instead (e.g., electronics sector). As the definition of PFAS encompasses more than 10,000 substances, it will take a significant amount of time to understand the uses of PFAS within many industries, and a broader product classification will provide for a simpler process.

Proprietary Information

- The Proposed Rule states that because CUU's must be determined through a rulemaking, it is DEP's position that CUU determinations will not be issued for submissions that contain confidential information. This is simply untenable and impracticable for numerous reasons. For example, the composition of a product is very likely to be considered by the applicant to be confidential (for the protection of highly-important trade secrets), and if DEP will not allow such confidential information to be submitted (or will deny a CUU application on the basis of it having confidential content), the CUU exemption process will be unusable for many product manufacturers, who will then be forced not to sell into Maine. DEP's position also is completely unworkable for products that may have uses that are critical to national security and are subject to a variety of secrecy requirements (which often may extend to numerous products that go beyond those specific items that are exempt due to DOD, NASA, or FAA specifications requirements)
- The provision to which DEP cites in the December Proposed Rule concerning the Department's ability to protect confidential information is not specifically applicable to the underlying PFAS-in-products law (38 M.R.S. § 1614). DEP must explain how confidentiality will be guaranteed under the Proposed Regulations and the statutory authority for this interpretation.

Conclusion

CUC appreciates the opportunity to submit the foregoing comments and, as mentioned, reserves its right to submit additional or modified comments at a later date. We would welcome the opportunity to meet with DEP staff to address our comments and to assist in refining the Proposed Rule prior its finalization.



Solutions for a Toxic-Free Tomorrow

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336

January 28, 2025

Re: Comments on the Concept Draft for PFAS in Products Program

Dear Board of Environmental Protection,

Thank you for the opportunity to provide comments on the draft rules for Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances. Below you will find Defend Our Health's detailed comments on the draft rule. Please don't hesitate to contact us if you have any follow up questions or would like clarifications of these comments.

We appreciate the work that the Department has done to draft this language. We do, however, have concerns with some of the language in the draft. None of the amendments and updated language we suggest require legislative update of the statutory language.

Specific Comments on Draft Rule by Section

Definitions

The draft rule defines "chemically formulated" as "a process 1. that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources": This does not take into account where PFAS doesn't chemically "change" the natural substance but is still added to the substance. For example, PFAS added to the surface of cotton fabric to make it stain resistant does not necessarily change the chemical composition of the cotton. Additionally, the term "naturally occurring biological processes" is concerningly vague. Does that include biological processes artificially induced in a lab? What about the use of chemical substances that facilitate or speed up a naturally occurring biological process? This should be amended to more clearly read "...a process that chemically changes the properties of a substance extracted from naturally occurring plant, animal, or mineral sources except that such term does not apply to substances created by living organisms through normal metabolic processes".

- DEFEND 2. Under the definition for "commercially available analytical method" the Department states that "commercially available analytical methods do not need to be performed at HEALTH a third-party laboratory". We disagree with this. Industry must not be allowed to test their own materials; history has shown us that industry has not been trustworthy when Solutions for a Toxic-Free Tomorrow it comes to the health impacts of PFAS¹ or the use of PFAS in certain products. They absolutely should be required to use a third-party laboratory to test to prove that the information is correct, valid, and unbiased. Products must be tested in independent third-party laboratories, and reporting on both the methods used and the results should be required to be reported in full. We have related concerns with the statement that "method must remain unmodified when not performed by a third-party laboratory" - the question is "unmodified" from what? Third-party labs may have slight variations in their protocols; it's possible there won't necessarily be an exact standard accepted protocol. There should be full transparency in reporting the methods for every test done, and all tests must be conducted by third-party labs to avoid the inherent and well-documented reliability issues that come from lab testing conducted internally by industry, where conflicts of interest between scientific accuracy and business priorities unavoidably skew results²⁻⁶.
- 3. Cosolvent is defined as "substances added to a primary solvent in small amounts to increase the solubility of a poorly soluble compound". Cosolvents can be used in a wide range of concentrations so the "small amounts" should be removed from the definition. Also, the "poorly soluble" is unnecessarily restrictive. We recommend the more concise and easily applicable definition of: "Cosolvent" means substances added to a primary solvent to increase the solubility of a compound.
- 4. Under the definition of "cookware," the draft states "*NOTE: The definition of cookware is limited to houseware. Cookware does not encompass items intended for use in and market exclusively for use in commercial, industrial, or institutional settings.*" However, LD 1537 in section A-10 states that the definition of cookware "Cookware product" means a *durable houseware product intended to be used to prepare, dispense or store food, foodstuffs or beverages, including, but not limited to, a pot, pan, skillet, grill, baking sheet, baking mold, tray, bowl and cooking utensil."* There is no exemption for industrial or commercial cookware. To do so goes against the clear intent of the legislature and the specific wording of the law; this commercial/industrial/institutional exemption must be removed from the draft rules.
- 5. Regarding fluorinated containers, the draft defines a fluorinated container as "*any container which has been treated with fluorine atoms to create a permanent barrier.*" The statute makes no exceptions for the purpose for which containers are fluorinated. To restrict the scope of the term based on purpose is therefore contrary to statute. Fluorinated containers should be covered regardless of whether they are fluorinated to create a permanent barrier, to prevent odor, to prevent distortion, or for any other purpose. The agency does not have the authority to narrow the definition of a statutory term. Therefore, the definition should simply read "*any container which has been treated with fluorine atoms*".
- 6. For the definition of semiconductor, part of the definition states "*intended to perform electronic and other related functions*". This definition is incredibly broad and would potentially expose Mainers to significant unnecessary PFAS exposure well beyond the intent of the legislature and the statute. Given that this will be an exemption from the law, this definition needs to be extremely clear and limited to only the exemption intended by the law. To be eligible for exemption, only semiconductor devices "whose primary purpose is to control the flow of electric current, amplify signals, act as a switch, or perform energy conversions" should be considered exempt^{7,8}.

- 7. The concept draft definition proposes that "significant change" would include a specific percentage change in the amount of PFAS included in the product. Defining "significant change" by means of a percentage change creates challenges for Solutions for a compliance and fails to provide useful information to the public. For example, a 10% change in a product with 1 ppt, may be difficult to measure or predict from inputs opposed to a 10% change in a product with 1000 ppm. Instead, we urge that a significant change of quantity of PFAS be defined as a change that would result in moving between the Department's defined reporting ranges. This standard is much easier for industry to comply with, for Department staff to regulate and review, and for the public to understand.
 - 8. The draft definition states that a PFAS alternative is "reasonably available" if "readily available in sufficient quantity and at a comparable cost to PFAS." We do not think cost should be the focus of this definition and find the concept of a "comparable" cost too vague, given that the cost implications can vary dramatically from product to product. For instance, an alternative may initially be more expensive than PFAS but as demand increases, the cost may fall. Indeed, a ban on the use of PFAS may drive an increase in demand for an alternative and so it is important that cost is not considered with regards to "reasonably available". The definition also includes "intended to replace and perform as well as or better than PFAS in a specific application of PFAS in a product or product component". This part of the definition regarding performance is irrelevant to the concept of "reasonably available" - it and the "at a comparable cost to PFAS" clauses of this definition should be removed. We recommend the following definition: "Reasonably available" means an alternative to the use of PFAS or to the product containing PFAS which is readily available in sufficient quantity or can become readily available in sufficient quantity in the relevant timeframe"

Currently Unavoidable Use

- 1. The draft does not make clear the criteria that the agency will use to determine CUU and how the requested information will relate to that decision. We would recommend that the state establish clear criteria for how they will make CUU decisions and then have the information that they are asking for directly connect to each of the criteria and state how it will inform the decision. Any other information requests should be removed as to not increase work for both sides and to not create confusion as to what information is going to be used to make a decision. It is very important that the criteria align with international scientific work on this, which is also reflected in the EU guiding principles and criteria for the essential use concept⁹.
 - a. For example, under section A(9), the draft asks industry to provide information regarding "the impacts on human health or the environment of PFAS in the product". Given that the CUU determination as legislatively defined is to be based only on whether the use of PFAS in the product is necessary for the health, safety, or functioning of society, any data on the impacts of PFAS itself on health and the environment would be unnecessary (PFAS are harmful to human health and the environment, which is why the statute only permits ongoing use under the CUU criteria). We recommend removing A(9) and any other requirements of risk-based or exposure-related information (see below) to prevent industry applications that waste state resources and staff time reviewing irrelevant attempted industry justification for the use of PFAS in a product that has not met the actual CUU definition.



Toxic-Free Tomorrow

b. We recommend simplifying section A(4) to exclusively focus on requiring evidence to demonstrate that there are no safer alternatives to PFAS, inclusive to alternative designs or products that achieve the same primary function. Most importantly, we recommend removing A(4)(d) and A(4)(e).



Section A(4)(e) states "A comparison of the known risks to human health and the environment between PFAS and the materials identified in Subsection a". It makes no sense to require risk based criteria to get a currently unavoidable use designation. When the law was passed, it was passed because there is agreement that the use of any PFAS is a serious concern and that we need to stop all uses that we can. This is the essential use concept. This law was not intended to set up a risk-based framework. By setting up this process, it opens up the law to allow for unnecessary CUU designations and harms public health. This goes against the clear intent of the law that any ongoing use of PFAS must be permitted only when necessary for the "health, safety, and functioning of society".

While we believe that this section sets up a risk-based criteria that is not the purpose or intent of this law, if you decide to move forward with it, there must be criteria in place. For this section and for some of the other assessments in this section – what is the criteria for completing such a comparison/assessment? There needs to be clear criteria laid out so that industry cannot cherry pick studies that show what they want. Further, rather than ask for an open-ended comparison of risks, industry should be required to demonstrate that each of the alternatives listed in 4(a) have higher risks to human health and the environment than PFAS, in order to justify the use of PFAS.

- 2. In the currently unavoidable use section A(3)(b) the draft states "The required specific characteristic or combination of characteristics that necessitate the use of PFAS chemicals." They should have to provide additional information as to why this characteristic(s) is necessary for the products' function in health, safety, or the functioning of society. Or said more clearly: Why the absence of this characteristic(s) will negatively affect the function of the product and the resulting effect on the health, safety, functioning of society. A justification for the need for PFAS for the function of the product alone should not be sufficient for a currently unavoidable use (CUU) exemption.
- 3. The draft states on page 20 that "Information submitted to the Department must contain sufficient detail or supporting documentation to satisfy the requirements of the currently unavoidable use as essential for health, safety, or the functioning of society for which alternatives are not reasonably available." There should be very specific criteria for supporting documentation: such as primary literature citation, copy of any cited studies, results and methodology of a systematic literature review, data analysis, and other scientific methodology.

Solutions for a Toxic-Free Tomorrow



Thank you once again for the opportunity to provide these comments. We look forward to continuing discussions with the Department on its implementation of this critical law. Please feel free to contact me at SWoodbury@DefendOurHealth.org if we can provide additional information.

Sincerely,

Sarah Woodbury Vice President of Policy and Advocacy Defend Our Health

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Emily Carey Perez de Alejo President and CEO January 16, 2025

Chair Lessard and Members of the Board of Environmental Protection. My name is Sarah Woodbury. I am the Vice President of Policy and Advocacy for Defend Our Health. Defend is a Maine-based non-profit that works to make sure everyone has equal access to safe food, safe drinking water, healthy homes, and toxic-free, climate-friendly products. We have been working on the issue of PFAS contamination since 2017. Thank you for the opportunity to provide comments on the draft rules for Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances.

We will submit more in-depth written comments by the January 28th deadline but did want to take a moment to make a couple of comments on the draft rule. The PFAS Products law passed last session was the result of weeks of hard work and compromise between the Department, legislators, industry, and advocates like me. We appreciate the work that the Department has done to draft this language. Overall, we think this is a good rule and we would urge the board to avoid any attempts to weaken the reporting requirements that are laid out by the Department for industry to obtain a currently unavoidable use designation. We do, however, have concerns with some of the language in the draft.

Specific Comments on Draft Rule by Section

Definitions

1. The draft rule defines chemically formulated as "a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources": This does not take into account where PFAS doesn't chemically "change" the natural substance but is still added to the substance. For example, PFAS added to the surface of cotton fabric to make it stain resistant does not necessarily change the chemical composition of the cotton.

2. Under the definition for "Commercially available analytical method" the Department states that "Commercially available analytical methods do not need to be performed at a third-party laboratory". We disagree with this. Industry should not be allowed to test their own materials. History has shown us that industry has not been trustworthy when it comes to the health impacts of PFAS or the use of PFAS in certain products. They absolutely should be required to use a third-party to test to prove that the information is correct and valid.



4. For the definition of semiconductor, part of the definition states "intended to perform electronic and other related functions". This definition is incredibly broad. Given that this will be an exemption from the law, this should be strengthened. The primary purpose of semiconductor devices is: "control the flow of electric current via amplification of signals, switching, or energy conversion". The definition should specify the purpose to avoid an unnecessarily broad definition.

Currently Unavoidable Use

1. In the currently unavoidable use section A(3)(b) the draft states "The required specific characteristic or combination of characteristics that necessitate the use of PFAS chemicals." They should have to provide clear information as to why this characteristic(s) is necessary for the products' function in health, safety, or the functioning of society. Or said more clearly: Why the absence of this characteristic(s) will negatively affect the health, safety, functioning of society.

2. Under section A(4)(e) "A comparison of the known risks to human health and the environment between PFAS and the materials identified in Subsection a". For this section and for some of the other assessments in this section – what is the criteria for completing such a comparison/assessment? There needs to be criterial laid out so that industry cannot just cherry pick studies that show I would want to avoid allowing industry to cherry pick studies that show what they want.

Once again, we will have much more detailed comments for the January 28th written comments deadline. This is just a few of the concerns we have but we wanted to be brief. Thank you for your service and attention to this issue.

DEFEND

HEALTH
28 January 2025

Maine Department of Environmental Protection

Re: Comments on Maine Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

Dear Colleague:

Electric Hydrogen is pleased to submit comments on Maine's Draft Rule <u>Chapter 90</u>: <u>Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances</u> (PFAS). With a team of more than 300 people with operations in California and Massachusetts, Electric Hydrogen manufactures, delivers and commissions the world's most powerful electrolyzers for critical industries to produce green hydrogen, Our mission is making molecules to decarbonize our world and helping advance critical industries like steel, aviation, maritime shipping, and heavy-duty transportation by making green hydrogen an economic inevitability.

343

The importance of electrolyzers to critical industries and the clean energy transition has been recognized by the U.S. Department of Energy and governments around the world. In Europe which was the first jurisdiction to propose broad PFAS product restrictions, the European Chemicals Agency (ECHA) and five national authorities issued a progress update regarding the EU REACH PFAS restriction proposal. It indicates the potential for electrolyzers, along with fuel cells and batteries, to be eligible for an alternative to a broad restriction, in order to avoid disproportionate socio-economic impacts. EU Commissioners overseeing REACH revisions have also indicated <u>support</u> for continued use of PFAS in critical industrial applications. In the U.S., the Vermont Agency of Natural Resources has developed <u>proposed legislation</u> on PFAS that defines and differentiates "complex durable goods" from the scope of the legislation.

Comment 1: Regarding the exemption for "non-consumer electronics" in section 4.A.(12), we appreciate the addition of a definition of "electronics" in section 2. While the definition of "electronics" covers numerous technologies, it would benefit from the addition of "electrochemical" technology to be more comprehensive.

For example, under <u>Legislative Document 1775</u>, the Maine Public Utilities Commission has been tasked with overseeing a pilot program to produce clean hydrogen. The latter is commonly produced with water electrolysis, an electrochemical process of using electrical energy to produce chemicals (hydrogen and oxygen). While electrolysis already falls under the "electrical" technology in the section 2 definition of "electronics", it can be called more precisely an "electrochemical" technology. Explicitly adding "electrochemical" to the list of technologies included in the exemption for non-consumer electronics, will enhance certainty for green hydrogen project developers in Maine, including those considering participating in the Maine PUC pilot program.

The same is true of fuel cell technology, which is an electrochemical device that converts chemical energy into electrical energy. As with electrolyzers, fuel cells are used in a variety of non-consumer applications involving power generation and energy storage.

- Suggested edit in red for section 2: "Electronics. "Electronics" means technology having electrical, digital, magnetic, wireless, optical, electromagnetic, electrochemical, or similar capabilities."

Comment 2: Regarding the "Proposal for Currently Unavoidable Use Determinations" in section 9.A., we suggest clarifying that products covered under a CUU determination are exempt from prohibition for the life of the product, including maintenance of the product which may involve repair or replacement of individual components.

For example, durable industrial products such as electrolyzers and fuel cells have a product lifetime that significantly exceeds the duration of the CUU determination. As part of maintaining the product over its warranty and service life, individual components such as cells or stacks may need to be repaired or replaced past the duration of the CUU determination. As non-consumer products, these maintenance activities are professionally managed and enable product stewardship and resource conservation.

Because the CUU determination covers exemption from prohibition of "sale, offer for sale, or distribution for sale", we understand that maintenance activities are not in the scope of the prohibition. However, it would be helpful to further clarify this in section 9.A.

Suggested edit in red in section 9.A.: "Upon the expiration date listed in Section 9(B), a currently unavoidable use determination is no longer applicable, and all sales, offers for sale, or distributions for sale are immediately prohibited.
 Products sold under a CUU determination are exempt from prohibition for the life of the product, including maintenance of the product."

Please do not hesitate to reach out directly with any questions regarding these comments.

Sincerely,

Signed by: Parikhit Sinha

Parikhit Sinha, Ph.D. Director of Sustainability Electric Hydrogen Co. psinha@eh2.com | (480) 619-3960 Attachment: Life Cycle Fluoropolymer Management in Proton Exchange Membrane Electrolysis





Article Life Cycle Fluoropolymer Management in Proton Exchange Membrane Electrolysis

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Abstract: Concerns over the life cycle impacts of fluoropolymers have led to their inclusion in broad product restriction proposals for per- and poly-fluorinated alkyl substances (PFAS), despite their non-bioavailable properties and low exposure potential in complex, durable goods such as nonconsumer electrical products. Based on the hypothesis that manufacturers are most able to manage the environmental impacts of their products, practical engineering approaches to implementing life cycle fluoropolymer stewardship are evaluated to bridge the ongoing debate between precautionary and risk-based approaches to PFAS management. A life cycle thinking approach is followed that considers product design and alternatives, as well as the product life cycle stages of material sourcing, manufacturing, field deployment, and end-of-life. Over the product life cycle, the material sourcing and end-of-life stages are most impactful in minimizing potential life cycle PFAS emissions. Sourcing fluoropolymers from suppliers with fluorosurfactant emissions control and replacement minimizes the potential emissions of bio-available PFAS substances. A stack-as-service approach to electrolyzer operations ensures a takeback mechanism for the recycling of end-of-life fluoropolymer materials. Retaining electrolytic hydrogen's license to operate results in over USD 2 of environmental and health benefits per kilogram of hydrogen produced from reduced greenhouse gas and air pollutant emissions compared to conventional hydrogen production via steam methane reforming.

Keywords: renewable energy; PFAS; product stewardship; recycling



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1. Introduction

1.1. Fluoropolymers and PFAS

Fluoropolymers are a widely commercialized group of organofluorine substances, consisting of repeated fluorinated organic monomers (Table 1). They are part of a broader family of per- and poly-fluorinated alkyl substances (PFAS) that are becoming subject to increased regulation globally. Historically, such regulation has focused on non-polymer PFAS such as perfluorooctane carboxylate (PFOA) and perfluorooctane sulfonate (PFOS), which are small molecules that exhibit hazardous and bio-accumulative properties at low concentrations. The International Agency for Research on Cancer (IARC Volume 135) classifies PFOA and PFOS as carcinogenic to humans (Group 1) and possibly carcinogenic to humans (Group 2B), respectively. In contrast, fluoropolymers are large, insoluble, inert solids that are not hazardous or bio-accumulative [1,2]. However, concerns have been raised about the life cycle of fluoropolymers, specifically regarding the use of hazardous non-polymer PFAS (fluorosurfactants) during fluoropolymer production, and concerning end-of-life hazards from fluoropolymer disposal [3]. These concerns are leading to broad-based regulatory frameworks that may group the two classes (non-polymer and polymer) together under the PFAS umbrella.

In addition to focusing on non-polymer PFAS, historical regulation has also focused on dispersive uses, where PFAS comes into direct contact with consumers and/or the environment. For example, PFAS in cosmetics, cookware, and textiles has been regulated in some jurisdictions (e.g., State of California). The regulatory focus on PFAS with hazardous properties (high hazard) and dispersive applications (high exposure potential) follows a risk-based approach, where risk is the product of hazard and exposure [4]. Hazard and exposure potential are also the basis for the chemical prioritization process in the U.S. Toxic Substances Control Act (TSCA) [5].

Table 1. PFAS types and examples, with the focus of this study (ionomers) shown in bold.

Class	Subclass	Definition	Example	
Non-polymer _	Per-fluorinated alkyl substances	Compounds with fully fluorinated carbon atoms	Perfluorooctane carboxylate (PFOA) (C ₇ F ₁₅ COOH); Perfluorooctane sulfonate (PFOS) (C ₈ F ₁₇ SO ₃ H)	
	Poly-fluorinated alkyl substances	Compounds with at least one fully fluorinated carbon atom	Fluorotelomer alcohol (FTOH) (C ₁₀ F ₂₁ CH ₂ CH ₂ OH)	
			Fluoroplastics (e.g.,): Polyvinylidene fluoride (PVDF) (C ₂ H ₂ F ₂) _n	
	Fluoropolymers	Carbon-only polymer backbone with fluorines directly attached to carbon	Fluoroelastomers (e.g.,): Tetrafluoroethylene-propylene co-polymer (FEPM)	
Polvmer		·	Specialty flouroplastics (e.g.,): Perfluorinated sulfonic-acid (PFSA) ionomers	
,	Polymeric perfluoropolyethers	Carbon and oxygen polymer backbone with fluorines directly attached to carbon	Perfluoropolyalkylether	
	Side-chain fluorinated polymers	Nonfluorinated polymer backbone, with fluorinated side chains	Fluorinated urethane polymers	

Recently, a precautionary alternative to the risk-based approach has been proposed for PFAS regulation, in which the entire family of PFAS types (substances with at least 1 fully fluorinated carbon atom) and applications has been proposed for restriction and phaseout [6]. An argument for the precautionary alternative has been that targeted regulation does not address the full life cycle of hazards and exposures from PFAS materials [3]. While broad chemical family bans can reduce future PFAS emissions, they are not based on risk assessment science and so can result in adverse cost–benefit outcomes, where the cost of compliance is high and the health benefit is low.

1.2. Complex, Durable Goods and Proton Exchange Membrane (PEM) Electrolysis

Complex, durable goods are a class of products defined under the U.S. Toxic Substances Control Act (TSCA; 15 U.S. Code § 2605) as 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. Use of fluoropolymers in a complex, durable good, such as a non-consumer electrical product, is an example of low-risk PFAS usage, given the low chemical-specific hazard in non-dispersive applications.

In addition to the low exposure potential in the use phase of complex, durable goods, the objective of this study is to show how potential exposure to PFAS can be minimized over the full product life cycle. A specific evaluation of proton exchange membrane (PEM) electrolysis is used to demonstrate life cycle management.

PEM water electrolysis (PEMWE) technology is used to produce green hydrogen (H₂) when operated with renewable electricity. H₂ is a versatile commodity that can be used as either a chemical feedstock or energy carrier for heat, power, or storage. For example, one of the most widely deployed and industrially important chemical reactions globally is the Haber–Bosch process that produces ammonia fertilizer from H₂ and N₂.

Most H₂ is produced from natural gas via steam methane reforming (SMR), resulting in byproduct CO₂ emissions. Green H₂ from renewable water electrolysis is a low-carbon fuel that can be used to decarbonize hard-to-abate industries, such as shipping, chemicals, refining, steel, and long-haul transport. The energy transition to low carbon fuels is dependent on cost and scale, with the U.S. Department of Energy (DOE) setting targets of a USD 150/kW PEM electrolyzer uninstalled system cost and a USD 1/kg green H₂ cost by 2031, compared to USD 1000/kW and >USD 3/kg, respectively, in 2022 [7].

1.3. Objectives and Problem Formulation

The reason for selecting the specific evaluation of PEMWE is that it represents a potentially adverse cost-benefit outcome of a broad PFAS chemical family ban. The evaluation is intended to show ways in which product life cycle management can achieve the same goals (PFAS health and environmental impact mitigation) as a broad PFAS ban, without the adverse technology impact.

Product-stewardship-based approaches to environmental management have been evaluated for other renewable energy technologies such as wind [8] and solar [9], but not for renewable hydrogen. In these studies, design, production, and end-of-life strategies have been shown to be effective in minimizing life cycle product environmental impacts. The underlying hypothesis is that manufacturers are most able to manage the environmental impacts of their products. Therefore, they do not have to assume only a passive role in complying with environmental regulations governing their products but can play a proactive role in minimizing the environmental impacts of their products.

Prior research has focused on precautionary approaches to fluoropolymer management that advocate for broad product bans to minimize PFAS emissions [3], and risk-based approaches that focus on managing PFAS substances and applications with high hazard and exposure potential, respectively [1,2]. The objective of this study is to bridge this ongoing debate between precautionary and risk-based approaches to PFAS management with practical engineering approaches to implementing stewardship over the product life cycle and to identify which actions are most impactful in minimizing potential emissions.

2. Materials and Methods

Methods follow the "life cycle thinking" approach in the U.S. National Academies framework for alternatives assessment [10]. It includes consideration of product design and alternatives, as well as the product life cycle stages of material sourcing, manufacturing, field deployment, and end-of-life. Best practices in life cycle fluoropolymer management are identified based on principles of sustainable procurement, resource efficiency, and circular strategies. Sustainable procurement promotes minimization of environmental impact in raw material production, resource efficiency minimizes the material intensity of manufacturing, and circular strategies promote recycling and the use of recycled content. Material intensity refers to the quantity of materials per unit of production (e.g., kilograms of fluoropolymer usage per megawatt of electrolyzer capacity), which is a function of system power density.

Life cycle product stewardship falls under the broader concept of extended producer responsibility, where manufacturers expand the scope of responsibility for their environmental impacts. Instead of confining responsibility to within their manufacturing operations and product use, responsibility is expanded to include upstream sourcing of raw materials and downstream management of product end-of-life (cradle-to-grave).

In addition to life cycle management, the life cycle environmental and health benefits of electrolytic hydrogen production are compared to conventional hydrogen production with steam methane forming. The comparison helps quantify the benefits of retaining electrolytic hydrogen's license to operate. Life cycle benefits follow the approach of Wiser et al. [11] used for evaluating the environmental and public health benefits of solar energy in the U.S. These methods use environmental damage factors (USD per kg of pollutant) for air pollutants and greenhouse gases from the U.S. Environmental Protection Agency (EPA).

The environmental damage factors for air pollutants (NO_x, PM_{2.5}, SO₂) are from the U.S. EPA regulatory impact analysis for the California region [12], adjusted from 2011 to 2020 dollars using a 3% discount rate. The damage factors for greenhouse gases (CO₂, CH₄, N₂O) are from the U.S. EPA regulatory impact analysis in 2020 dollars for emission year 2020 [13]. The damage factor for a given pollutant is multiplied by its life cycle emissions (kg pollutant per kg H₂ production) to yield the environmental cost (USD per kg H₂ production).

While the environmental damage factors are obtained from U.S. EPA, the life cycle emissions are obtained from the Argonne National Laboratory GREET model. Life cycle emissions for SMR are from Argonne National Laboratory's R&D GREET1_2023 model and impacts for PEMWE are from the R&D GREET2_2023 model [14]. Both R&D GREET models utilize the Excel platform, and life cycle environmental and health benefits are also estimated in Excel.

For SMR, a 480-ton-per-day plant with steam export is modeled, along with the fuel cycle of natural gas (extraction, processing, compression, and transportation). For PEMWE, a 998 kW plant with 97% capacity factor is modeled with 7 year lifetime for the cell stack and 20 year balance of plant lifetime, assuming 55.5 kWh of renewable electricity per kg of H_2 production.

For additional comparison, life cycle emissions for alkaline electrolysis are also obtained from the R&D GREET2_2023 model [14]. For alkaline electrolysis, a 3836 kW plant with a 90% capacity factor is modeled with 10 year lifetime for the cell stack and 20 year balance of plant lifetime, assuming 51.8 kWh of renewable electricity per kg of H₂ production. For all three technologies (SMR, PEMWE, and alkaline electrolysis), default model parameters are used in the GREET model, representing the typical scale and duration of commercial operations. Results are analyzed per kg of H₂ production for comparability.

3. Results and Discussion

The results of the "life cycle thinking" approach to fluoropolymer management in PEMWE are summarized below. Best practices are identified across the life cycle stages of product design and alternatives assessment, material sourcing, manufacturing, field deployment, and end-of-life (Figure 1), and discussed in turn.



Figure 1. Life cycle stewardship approach to PFAS management in PEMWE.

3.1. Product Design

At the core of the PEMWE technology is the electrolyzer cell (Figure 2), which consists of an anode where water is split to produce O_2 and protons (H⁺), and a cathode where protons combine with electrons to produce H₂ gas. The PEM at the center of the cell acts as a channel for protons and insulator against electrons and gases (O₂).





The specific membrane materials used in PEMWE are fluoropolymers of perfluorinated sulfonic acid (PFSA ionomers), which are fluoropolymers with pendant sulfonic acid groups. The fluoropolymer backbone is hydrophobic, while the negatively charged ionic side chains are conductive for positively charged ions (H⁺; protons). The membranes are cast as thin, solid sheets, that are typically <100 μ m in thickness. In order to function in water electrolysis, the membrane needs to be insoluble in water and selectively conductive while durable in harsh operating conditions (Table 2).

Table 2. PEM electrolyzer stack operating conditions [15,16].

Property	Value
Temperature	Up to 90 °C
Pressure	Up to 30 bar
pН	Acidic
Redox conditions	Oxidizing
Operating hours	40,000-80,000

As shown in Table 1, PFSA ionomers are part of the fluoropolymer family [2]. Some chemical, physical, and toxicological properties of PFSA ionomers are summarized in Table 3. In addition to their use in electrolysis, PFSA ionomers in ion exchange membranes have been identified as the best available technology for one of the chemical industry's fundamental chemical processes, chlor-alkali production, which produces chlorine and sodium/potassium hydroxide through the electrolysis of brine. The use of ion exchange membranes is a safer alternative compared to historic chlor-alkali production with asbestos diaphragm cells or mercury electrode cells [17].

Fluoropolymer material usage in PEM electrolyzer stacks is ~14 metric tons per GW capacity (Figure 3). For perspective, the DOE Hydrogen Program Record (Record 24001) indicates total installed capacity of PEM electrolyzers in the U.S. of ~0.1 GW in 2024, with an additional ~0.7 GW under construction and a planned future firm capacity of ~3.8 GW. Fluoropolymer usage per GW in PEM electrolyzer stacks is 1–3 orders of magnitude lower than the annual fluoropolymer use in the other main downstream use categories in Europe (Figure 3). Design strategies for reducing fluoropolymer usage include increased

electrolyzer system power density, which reduces fluoropolymer usage per unit of system capacity and per kg of H_2 production. Increased power density means that fewer stacks are needed to achieve the rated electrolyzer system capacity, thereby reducing fluoropolymer and other material demand.

Table 3. PFSA ionomer properties [2].





Figure 3. Annual fluoropolymer sales to European downstream product categories [18] compared to usage in PEMWE (1GW) [19].

3.2. Alternatives

Research on replacing conventional perfluorinated ionomers with fluorine-free materials has been conducted for decades, but commercialization has been limited by degradation related to poor oxidation stability in industrial operating conditions [20]. Example alternative PEMWE materials include hydrocarbon membranes, polysulfone, sulphonated polyetheretherketone (SPEEK), and electrospun polybenzimidazole-type materials. Due to the lack of durability from oxidation by oxygen radicals, the technical suitability of these alternatives is, at present, unclear, and the alternatives are not yet available for large-scale application [21]. Durability has both technical and environmental benefits, since durable materials require fewer replacements over the system life. Overall, factors such as safety, availability, performance, cost, and life cycle environmental and social impacts factor into alternatives assessment [10]. As part of sustainable design practices, alternatives should be revisited when substitute materials show potential for achieving performance comparable to incumbent materials, factoring in the above ~decade-long timeline required to introduce new materials at commercial scale.

With regards to competing electrolysis technologies, alkaline electrolysis operates by transporting hydroxide ions (OH⁻) through an alkaline liquid electrolyte (sodium or potassium hydroxide) from the cathode to the anode, with hydrogen being generated at the cathode. Compared to PEMWE, alkaline electrolysis yields a lower-purity product due to higher gas crossover rate; it is not suitable for intermittent power sources like renewables due to a narrow acceptable current density range, and it uses corrosive chemicals during operation [15]. Alkaline electrolysis is currently dependent on fluoropolymer use for production of the alkaline liquid electrolyte. Specifically, sodium hydroxide and potassium hydroxide are manufactured with the chlor-alkali production process which uses fluoropolymer-containing materials in membranes, gaskets, gas-diffusion electrodes, and other construction materials [2].

Newer approaches to alkaline electrolysis use solid alkaline exchange membranes (AEM) as the electrolyte but have had lower energy efficiencies and poor durability due to chemical instability [2]. Steam reforming of natural gas emits significant amounts of greenhouse gases in conventional hydrogen production. Overall, these alternative technologies differ in their flexibility, performance, and product quality characteristics compared to PEM water electrolyzers.

3.3. Material Sourcing

The PFSA ionomer used in the PEM membrane is produced using emulsion polymerization, with fluorosurfactants used as a processing aid. The fluorosurfactants are non-polymer PFAS (Table 1), which pose a higher hazard than the fluoropolymers being produced. In response to concerns over fluorosurfactant hazards, major fluoropolymer producers have collectively committed to achieving low emissions of these substances. Table 4 shows the commitment levels and target dates for emissions to air and water. Emissions controls used to achieve these levels include thermal oxidation for air emissions and several approaches for water emissions, including activated carbon, reverse osmosis, ion exchange, and nano-filtration.

Table 4. Emissions control commitments (average emission factors) for non-polymeric processing aid PFAS residues in fluoropolymer manufacturing. Average emission factors are calculated as annual emission of added or generated non-polymeric processing aid PFAS residues/total annual amount of fluoropolymers produced on site [22].

Target Year	Average Emissions to Air	Average Emissions to Water
End 2024	0.009%	0.001%
End 2030	0.003%	0.0006%

In addition to emissions controls, some fluoropolymer producers have committed to phasing out fluorosurfactant use as processing aids in fluoropolymer production [23]. In general, for downstream users, fluorosurfactant emissions control and replacement are sustainable procurement criteria for life cycle fluoropolymer management. Downstream users can facilitate innovation in the supply chain with a collaborative approach that involves testing early engineering samples and providing some flexibility in specifications to de-risk new fluoropolymer production processes.

3.4. Product Manufacturing

The core assembly of a PEMWE cell is the catalyst-coated membrane (CCM) (Figure 2). The CCM is composed of catalyst/fluoropolymer composite film layered with fluoropolymer membranes. The catalyst layers are usually cast from polymer dispersions blended with catalysts, while the membranes can be extruded or cast from fluoropolymer dispersion. Over 90% of input fluoropolymer and catalyst materials are incorporated into products. The remaining materials are reclaimed and reused through captive reclamation hydrometallurgical recycling methods [24]. These methods can be used to recover catalysts from electrolyzer membrane systems, allowing for the separate recovery of critical minerals and fluoropolymers from the electrolyzer, and return to the initial manufacturing process (Figure 4). In addition, water used for testing the electrolyzer is purified with reverse osmosis, recirculated in the cell stack, and consumed during operation to produce H_2 and O_2 .



Reuse or third-party refining

Figure 4. Schematic process flow for fluoropolymer and catalyst separation from catalyst-coated membranes in PEM electrolyzer cells.

A key step in enabling recovery of unused materials is the material flow mapping of the inputs, outputs, and byproduct streams in manufacturing by a process tool. The mapping process facilitates proper segregation of byproducts by material type for subsequent reclamation. In the case of reclaiming unused catalyst-coated membranes (CCM; Figure 4), effective separation of fluoropolymers from catalyst metals is necessary to maximize reuse potential for both materials.

3.5. Field Deployment

Electrolyzers split water to produce H_2 and O_2 gas as their only reaction products. Electrolyzer stacks are designed for 40,000+ h of operation (Table 2), during which water is purified, recirculated within the electrolyzer, and consumed to produce H_2 and O_2 (Figure 5). Wastewater is generated upstream of the electrolyzer stack operation in the form of reject water from the reverse osmosis/deionizer (RODI). Water is consumed at a stoichiometric rate of 9 L per kg H_2 , with water molecules recirculated numerous times in the enclosed loop before being converted to H_2 and O_2 . The reverse osmosis/deionizer runs intermittently to make up water consumed in the electrolysis process. Operating conditions (e.g., voltage, current density, temperature) are continuously measured at individual cell and/or stack level to monitor performance and degradation.

In the case of fluoropolymer management, water recirculation ensures closed-loop operation, minimizing both water consumption and wastewater generation. In Figure 5, flows of water are indicated in blue, showing output from the RODI water purification system, input into the electrolyzer stack, and water recirculation. Water efficiency can be measured in comparison to the above stoichiometric consumption rate, with differences primarily due to losses from water purification and water vapor lost with O₂ release.



Figure 5. Schematic process flow of electrolyzer plant operation, with flows of water, electricity, hydrogen, and oxygen shown in blue, purple, red, and green, respectively.

3.6. End-of-Life

Hydrometallurgical recycling methods used to reclaim materials during manufacturing can also be used for critical mineral and fluoropolymer recovery from end-of-life electrolyzer stacks. The presence of high-value components in the stack's cells (Table 5) provides a strong economic incentive for takeback over disposal. End-of-life fluoropolymers can be recycled or reused (Figure 4). A closed-loop system for metal and fluoropolymer recovery from electrolyzers is being developed under the H2CIRC consortium funded by the U.S. Department of Energy [25].

Table 5. Quantities of high-value components in PEM electrolyzer stacks [19].

Cell Stack Component	Target Material Recycled	Quantity (kg/MW)
Membrane–electrode assembly	Fluoropolymer	14
	Iridium	0.6
	Platinum	0.4
	Titanium	57
Bipolar plate	Titanium	108

The cell stacks within an electrolyzer plant can be viewed partly as a product and partly as a service. Because the stack lifetime (Table 2) is less than the plant lifetime (~20 yrs), the plant owner/operator needs to develop a stack maintenance schedule prior to commissioning the plant. Under this schedule, the stack equipment producer provides availability for stack replacement to ensure operating performance within specifications. Under such an arrangement, when stacks need refurbishment or replacement at the end of their expected lifetime, they are exchanged with the stack manufacturer during installation of the new stack. This stack-as-service approach ensures a takeback mechanism for end-of-life fluoropolymers and other stack materials.

3.7. Life Cycle Benefits

The advantage of life cycle product stewardship compared to precautionary product restrictions is to minimize environmental impacts from fluoropolymer usage, while preserving license to operate. The latter maintains the life cycle benefits of renewable electrolysis over conventional H_2 production with natural gas SMR. As shown in Figure 6, PEM renewable electrolysis has lower life cycle impacts by 1 to 2 orders of magnitude for environmental categories of air pollution, carbon and water footprint, and energy use.



Figure 6. Life cycle impacts of hydrogen production from PEMWE with renewable electricity and steam methane reforming via natural gas for air pollution, greenhouse gas, water, and energy environmental impact categories [14]. Abbreviations: VOC—volatile organic carbon; PM—particular matter; BC—black carbon; OC—organic carbon; GHGs—greenhouse gases.

As shown in Table 6, renewable PEMWE also has 2–3 times lower life cycle environmental impacts compared to renewable alkaline electrolysis. The difference is because alkaline systems are more material-intensive, with stack and balance of plant weights of 23 and 40 metric tons per MW, respectively, compared to 0.7 and 19 metric tons per MW, respectively, for PEMWE [19].

In addition to life cycle environmental impacts, the environmental costs associated with those impacts can be estimated using environmental damage factors. For example, in the case of NO_x emissions, the life cycle impact for natural gas SMR (4.930 g NO_x/kg H₂) can be multiplied by the environmental damage factor for NO_x (USD 31,633/metric ton NO_x or USD 0.0316/g NO_x) to estimate the environmental cost of NO_x emissions. When the same is undertaken for NO_x emissions from PEMWE and subtracted from the result for SMR, the environmental benefit of replacing SMR with PEMWE is USD 0.15/kg H₂, as shown in Table 6. Overall, there are over USD 2/kg in environmental benefits from switching from conventional SMR to renewable PEMWE, mostly related to greenhouse gas (CO₂, CH₄, N₂O) emissions avoidance (Table 6).

The main factor contributing to the life cycle environmental benefits of PEMWE is USD $1.62/\text{kg H}_2$ in benefits from avoided CO₂ emissions. These are based on an environmental damage factor of USD 190 per metric ton CO₂ from U.S. EPA [13], which reflects the benefit to society of reducing CO₂ emissions by a metric ton with regards to the physical, ecological, and economic impacts of climate change. Carbon pricing in the form of a carbon tax or

cap-and-trade program would be needed to monetize these benefits. In the European Union (EU), a carbon border adjustment mechanism (CBAM) has been adopted for assessing and taxing the excess carbon intensity of H_2 imported into the EU, relative to the domestic EU baseline carbon intensity [26].

Table 6. Life cycle impacts and environmental costs of hydrogen production from PEM and alkaline electrolysis with renewable electricity and steam methane reforming via natural gas for air pollution, greenhouse gas, water, and energy environmental impact categories.

	Life Cycle Impacts of PEM Renewable Electrolysis [14]	Life Cycle Impacts of Alkaline Renewable Electrolysis [14]	Life Cycle Impacts of Natural Gas SMR [14]	Environmental Damage Factor (2020 Dollars/Metric Ton) [12,13]	Environmental and Health Benefit of Replacing SMR with PEMWE (2020 Dollars/kg H ₂)
VOC $(g/kg H_2)$	0.011	0.030	1.582		
$CO(g/kgH_2)$	0.051	0.152	4.114		
NOx $(g/kg H_2)$	0.035	0.068	4.930	USD 31,633	USD 0.15
$PM_{10} (g/kg H_2)$	0.007	0.017	0.240		
$PM_{2.5} (g/kg H_2)$	0.004	0.009	0.229	USD 532,008	USD 0.12
SOx (g/kg H ₂)	0.288	1.231	1.482	USD 136,597	USD 0.16
BC $(g/kg H_2)$	0.0002	0.0004	0.021		
$OC(g/kgH_2)$	0.001	0.001	0.050		
$CH_4 (g/kg H_2)$	0.075	0.154	27.350	USD 1900	USD 0.05
$N_2O(g/kgH_2)$	0.002	0.003	0.198	USD 55,000	USD 0.01
CO_2 (kg/kg H ₂)	0.035	0.063	8.581	USD 190	USD 1.62
GHGs (kg $CO_2 eq/kg H_2$)	0.038	0.069	9.461		
Water consumption $(L/kg H_2)$	0.755	0.860	17.962		
Energy use (MJ/kg H ₂)	0.544	0.989	30.997		
Total					USD 2.12

In addition to air pollution and climate impacts, multi-criteria life cycle assessment indicates factor of ~3 reduction in human toxicity impacts from PEMWE relative to natural gas SMR per kg of H₂ produced. Specifically, advanced PEMWE can reduce life cycle non-cancer and cancer human toxicity impacts by ~5 × 10⁻⁸ and ~1 × 10⁻⁸ comparative toxic units for humans (CTU_h) per kg H₂, respectively, compared to natural gas SMR [27]. CTU_h represents the estimated increase in morbidity (adverse health cases) in the population per unit mass of chemical. In California, natural gas SMR facilities have a combined production capacity of approximately 840,000 metric tons H₂ per year as of 1 January 2024 [28]. Given this production capacity, replacement of California SMR facilities with advanced renewable PEMWE facilities would correspond to ~1000 avoided adverse health cases over a 20-year plant operating period (16.8 billion kg H₂ over 20 years • ~6 × 10⁻⁸ CTU_h per kg H₂). While these quantitative health estimates are approximate due to uncertainty in modeling life cycle human toxicity, SMR facilities and PEMWE facilities have important differences in local air quality impacts, with the former being a local source of criteria air pollutants and the latter having zero emissions of criteria air pollutants.

4. Conclusions

Because not all PFAS substances are bioavailable and not all PFAS uses are dispersive, broad PFAS product restrictions can have technology impacts that are disproportionate to risk, as exemplified by fluoropolymer use in complex, durable goods such as PEM electrolyzers. As a best practice, concerns over the fluoropolymer life cycle should be addressed by life cycle product stewardship that minimizes non-polymer PFAS emissions during fluoropolymer production, uses enclosed systems in product manufacturing and use, and establishes circular strategies for manufacturing and end-of-life fluoropolymer materials. Life cycle management can minimize environmental impacts of fluoropolymer materials, while maintaining the considerable environmental benefits (>USD 2/kg H₂ from reduced greenhouse gas and air pollutant emissions) of renewable electrolysis over

conventional H₂ production with steam methane reforming. Life cycle management also represents specific engineering strategies for working collaboratively with the supply chain and policymakers on PFAS stewardship. Out of the various life cycle product stewardship strategies, the material sourcing and end-of-life stages are most impactful in minimizing life cycle PFAS emissions. Sourcing fluoropolymers from suppliers with fluorosurfactant emissions control and replacement minimizes potential emissions of bio-available PFAS substances. A stack-as-service approach to electrolyzer operations ensures a takeback mechanism for recycling of end-of-life fluoropolymer materials.

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January 27, 2025

VIA ELECTRONIC SUBMISSION:

rulecomments.dep@maine.gov pfasproducts.dep@Maine.gov

Maine Department of Environmental Protection Attention: Kerri Malinowski Farris

Re: Chapter 90 - Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

The Truck and Engine Manufacturers Association (EMA) hereby submits comments on the proposed rule: Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances (proposed rule) that was noticed on December 20, 2024. EMA previously submitted comments to The Maine Department of Environmental Protection (MDEP) on November 4, 2022, on May 19, 2023 and September 18, 2024.

MDEP is proposing a new rule, Chapter 90, to establish criteria for currently unavoidable uses of intentionally added Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) in products and to implement the sales prohibitions and notification requirements for products containing intentionally added PFAS but determined to be a currently unavoidable use pursuant to the amended 38 M.R.S. §1614.

EMA represents worldwide manufacturers of internal combustion engines and onhighway medium and heavy-duty vehicles (greater than 10,000 pounds gross vehicle weight rating). EMA member companies design and manufacture internal combustion engines that are used in a wide variety of applications, including: trucks and buses (including school buses); farm, construction, and industrial equipment; marine vessels; locomotives; lawn, garden and utility equipment, and electric generators and other stationary applications. PFAS is widely used in a variety of applications to provide products with strength, durability, stability, and resilience. It is also known to be used for its flame retardant properties. Additionally, it is used in refrigerants that are subject to approval by EPA's Significant New Alternatives Policy (SNAP) Program that was established under Section 612 of the Clean Air Act for EPA to identify and evaluate acceptable alternatives in end-uses that have historically used ozone-depleting substances. Some alternatives that are approved for use by EPA under the SNAP program (HFO-1234yf and HFC-134a) are subject to bans in the Maine PFAS rule. Consequently, EMA's members are significantly and directly impacted by the Proposed Rule.

We understand that the scope of reporting obligations has been narrowed to include only those products subject to a ban, for which a currently unavoidable use (CUU) determination has been obtained. Although we support the narrowed focus of reporting obligations, we are concerned that the draft language is confusing and does not clearly communicate the timing and scope of product bans and the associated obligations that accompany CUU determinations.

359

360

Specifically, we would appreciate clarification of the language in section 5.E. and section 5.F. Timing of bans for specific products are indicated both by exclusion from the scope of specific sections and inclusion in subsequent sections. This approach is confusing and, unnecessarily complex. Section 5.F. bans refrigerants from 2040, and combined with section 5.E. language that carves out "Products subject to subsection F, below." Confusingly, the language in section 5.E. also includes a list of the other sections which identify banned products but does not include subsection "F" in that list. We suggest that 5.E. state that "any product that is not prohibited for sale under subsections A, B, C, D, F, or G". This simply strikes "already" and adds subsection "F" to the existing list. The subsequent reference to "Products subject to subsection F, below", would not be necessary.

In addition, the language in section 7 related to failure to provide notice, must be read with section 3 which references "effective date listed in section 5". The language in section 7.A. seems to indicate a need to report in 2032, even though products (like refrigerants) are not banned until 2040. Section 7 should include clarifying language to indicate that it applies to "prohibited" product containing intentionally added PFAS.

More fundamentally, the requirements related to refrigerants containing PFAS should be revised to allow the use of refrigerants approved under the SNAP program. The proposed language allows continued use for parts and other servicing needs but should also include refrigerants in new products i.e. vehicles, when there is not a SNAP approved alternative available. The timelines proposed for seeking a CUU determination may not accommodate the extensive time required to complete development, industrialization, and SNAP approval of currently unidentified PFAS-free alternatives, which can take as long as ten years to complete. Specifically, section 9.A. states a CUU request submitted more than 36 months prior to a ban taking effect will not be considered.

The scope of information required for submission of a CUU proposal is extremely challenging and will necessitate the expertise of chemical industry experts, health effects specialists, product engineers, and environmental experts, at a minimum. The onerous nature of the process may prevent CUU determinations in instances where PFAS performs a critical function and no reasonable alternative exists. The nature of the information requested in section 9.A.9 is that which should have been evaluated prior to imposing a broad ban on PFAS. It seems like the CUU determination process is being used to gather information that should have been considered and informed the scope of the PFAS rulemaking, and the burden is falling directly on the shoulders of those seeking CUU determinations.

As we have stated in prior comments, PFAS, as broadly defined in the proposed rule, may also include some refrigerants, like HFO-1234yf and HFC-134a. There has been a shift to HFO-1234yf because of its extremely low global warming potential. It is not clear that the CUU determination process as proposed will provide a feasible and reasonable path to ensure that vehicles and equipment that may contain PFAS as part of refrigeration, heating and cooling (including cooling functions for batteries in electric vehicles) and motor vehicle air conditioning systems, will not be impacted by the 2040 ban on PFAS containing refrigerants.

We appreciate the opportunity to provide these comments. Please do not hesitate to contact Dawn Friest at (519) 999-4480 (or at <u>dfriest@emamail.org</u>) if you have any questions.

Respectfully submitted,

TRUCK & ENGINE MANUFACTURERS ASSOCIATION

138530.3



January 28, 2025 By E-Mail: <u>rulecomments.dep@maine.gov</u>

Subject: Comments on Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

Emerson Electric appreciates the opportunity to respond to the Maine Department of Environmental Protection's (DEP's) Chapter 90 rulemaking process, addressing products containing Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS).

We commend the DEP for allowing industry participation in this vital process and recognize the significance and purpose of this rule in protecting both people and the environment. We also acknowledge the importance of responsibly managing and using PFAS materials, particularly in unavoidable cases where their performance and functionality are critical for challenging applications essential to everyday life.

Emerson Electric, headquartered in St. Louis, Missouri, is a global leader in automation with extensive operations across the United States, including over 29,000 employees and 50 manufacturing sites. The company is dedicated to producing Industrial Automation Monitoring & Control (IAMC) products that are safe for both end-users and the environment, aligning with the goals of the DEP. IAMC equipment forms the backbone of modern manufacturing, energy systems, and infrastructure, with PFAS, particularly fluoropolymers and fluoroelastomers, playing a vital role as essential enablers of the technology.

Emerson's primary concern with the Chapter 90 Products draft rule centers on the timing for awarding Currently Unavoidable Uses (CUUs) for the 2032 PFAS prohibition. The proposed rule permits companies to apply for a CUU determination 36 months before the product ban takes effect. Emerson recommends extending this period to 60 months to provide companies with sufficient time to prepare and adapt.

1. Industrial Automation Monitoring & Control (IAMC) Equipment is Indispensable for Delivering Operational Excellence, Innovation, and Positive Sustainability Outcomes.

IAMC equipment consists of complex electromechanical products that measure a variety of parameters such as temperature, humidity, pressure, corrosion and density as well as process control products such as valves, actuators, flow measurement devices and regulators, per the following and Figure 1 (Right):

- Pressure, Flow, Level and Temperature Measurement
- Corrosion, Erosion & Heat Trace Monitoring
- Energy Monitoring & Management
- Industrial Test & Measurement
 Instruments
- Density & Viscosity Measurement
- Liquid, Flame, & Gas Detection
- Machinery Monitoring, Protection & Maintenance



Figure 1. IAMC Equipment

- Marine Measurement & Analysis
- Distributed Control Systems
- Hygienic & Sanitary Measurement
- Vibration Sensors & Welding Machines
- Electrical Power Distribution & Control
- Valves, Regulators, and Actuators

IAMC equipment is vital for optimizing processes across manufacturing and other industries. It helps boost operational efficiency, enhance safety and reliability, minimize costs and downtime, and fulfill key applications, as outlined below:

• Enhanced Data-Driven Decision Making for Optimal Operational Efficiency

- Real-time parameter monitoring enables proactive adjustments for optimal process control, minimizing manual intervention, ensuring consistency, and maximizing throughput.
- Real-time monitoring collects critical process data, which can be analyzed to optimize performance, forecast throughput and maintenance, and improve quality control.

• Safety and Reliability Control

- Real-time parameter monitoring identifies and mitigates potential plant failures, reducing risks and unplanned downtime.
- IAMC systems prevent human exposure to hazardous environments, ensuring workplace safety.
- Scalability Control
 - IAMC equipment enables operational scale efficiency providing adaptability to changing demands and for allowing the integration of new technologies such as IoT and AI
- Key Applications Fulfillment
 - IAMC is critical in sectors like energy, pharmaceuticals, food processing and chemicals.

• Key enabler of complex activities such as precision manufacturing, sustainable energy control systems, and smart energy grid stability and control.

2. Fluoropolymers are Key Enablers of IAMC Technology

IAMC equipment must be designed with substantial robustness to operate reliably in industrial processes, demanding the use of high-performance materials and high safety margin designs, often specified by industry standards such as ATEX or IECEx.

Fluoropolymers and fluoroelastomers, which are vital as an engineering material class, not because of one particular characteristic, but because of the multiple properties any one of them simultaneously possesses, are perfectly suited for IAMC products. This is demonstrated in Figure 2 below where IAMC requirements and fluoropolymers/fluoroelastomers performance are overlayed. The overlap in performance across this specific array of properties is what sets fluoropolymers/fluoroelastomers apart from other materials and makes them a requirement for many IAMC applications.



Figure 2. IAMC's Operating Profile Requirements Overlap with Fluoropolymers Performance

Fluoropolymers' and fluoroelastomers' most commonly leveraged properties include:

- Broad chemical resistance to virtually all chemicals
- Low temperature performance down to -328°F
- High temperature performance up to 500°F
- Corrosion Resistance
- Intrinsic flame resistance
- Excellent electrical properties
- Low friction
- Purity
- Good oxidative stability

A range of different PFAS (such as PTFE, PCTFE, EFTE, PFA, FEP, FKM and FFKM are used in critical components of IAMC equipment, such as liners, coatings, seals, valve packing, valve seats, wire and cable insulation, as well as electronic components.

3. Advanced Planning for Projects Involving IAMC Equipment and PFAS is Necessary.

Policymakers and regulators must consider the critical role of PFAS and the impact of a ban on extended planning timelines, as their availability heavily impacts long-term business investments. The following justification outlines these considerations.

Delaying CUU Awards for the 2032 PFAS Prohibition Presents Challenges for Companies Considering Long-Term Investment Decisions

In Emerson's experiences in servicing industrial manufacturing customers and building its own manufacturing facilities, long-term investments in infrastructure, such as building a new manufacturing facility or modernizing an existing one, are typically planned several years in advance, with timelines often ranging from 5 to 10 years. These timelines are influenced by factors such as the scale and complexity of the project, regulatory and permitting approvals, and market conditions. Consequently, businesses are making crucial investment decisions now for future projects in states like Maine.

With a PFAS ban scheduled for 2032 and without accelerated timelines for awarding CUUs, Maine could encounter difficulties attracting high-tech opportunities where PFAS are vital to the manufacturing facilities, particularly in the equipment and machinery used in production in key sectors like life sciences and sustainable technologies, including hydrogen, batteries, wind, and solar.

We believe without a near-term CUU determination, the 2032 PFAS prohibition will represent a significant challenge for businesses planning long-term investments in states like Maine, particularly in terms of PFAS regulatory implications. The following are some factors we believe based on our experiences companies may consider during their investment decision-making process for manufacturing locations where PFAS is being banned.

- **High Financial Risk:** Investments made in developing and deploying products and technologies that rely on PFAS are at risk of becoming obsolete, resulting in loss of investment and/or diluted revenue.
- Weakened Competitive Position: Given the current landscape of available PFAS material substitutes, a prohibition could place companies at a significant competitive disadvantage in product usage where PFAS offers key performance attributes.
- **Uncertainty in the Supply Chain:** The PFAS ban, without the appropriate CUUs, will disrupt supply chains, affecting the availability of critical materials needed for manufacturing processes. This uncertainty makes it difficult to plan investments in new products and technologies that rely on PFAS.

PFAS Materials are an Important Factor in Long-Term Investment Decisions

PFAS are high-performance materials that drive technological advancements in products, delivering significant financial and societal benefits globally. Renowned for their exceptional

performance, reliability, and role in ensuring safe manufacturing operations, PFAS are critical in many applications.

- **Performance:** PFAS materials provide an unmatched combination of properties to unlock performance attributes in products across the spectrum of industrial applications, including low surface energy, resistance to a wide temperature range, and excellent chemical resistance.
- **Safety and Reliability:** Their ability to thrive in harsh environments makes PFAS essential for meeting demanding operational profiles and for providing reliable solutions which in turn lead to safer environments for workers.

These positive attributes are enabled by PFAS materials, compelling companies to carefully assess their future availability in the regions where investments are being planned.

Advancing the Timeline for Awarding PFAS CUUs May Position Maine as a Favorable Destination for Investment

As stated previously, Emerson recommends advancing the timeline for awarding CUUs for the 2032 PFAS prohibition to 60 months. This new timeline would help create a stable Maine regulatory environment, potentially stimulating economic growth and driving technological innovation.

The benefits of advancing the CUU timeline include:

- **Enhanced Planning Clarity:** Provides companies with greater clarity and confidence in planning their investments.
- **Reduced financial risk:** Protects investments made in developing and deploying products and technologies that depend on PFAS.
- **Optimized resource allocation:** Accelerates the receipt of CUU submissions, informing the Maine PFAS team of the full scope of work.

To minimize disruption with the 2026 prohibition, a function-based approach that categorizes uses by sector could be implemented, with priority and timeline concessions given to CUU awards for industrial products, which typically have the longest lead items.

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Comments on the proposing new rule, Chapter 90 : Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

January 2025

We welcome the opportunity to submit public comments on the Maine Department of Environmental Protection's (MDEP) proposed new regulations to implement the Maine law restricting PFAS in products (38 M.R.S. section 1614, as amended by LD 1537). We have prepared and organized our comments as follows.

The "A. Proposal for Currently Unavoidable Use Determinations." under "9. Currently Unavoidable Use." in this proposed concept draft describes the information required to make a proposal for Currently Unavoidable Use (CUU) determinations. As explained below, the information requirements imposed on CUU applicants are excessive and difficult to obtain by the applicant alone, and imposing such excessive information requirements will excessively raise the hurdle for CUU applications and lead to the loss of benefits originally derived from products and uses that should be determined as CUU. This in turn leads to a loss of opportunity to protect what is essential for health, safety or functioning of society for Maine, which is the original purpose of CUU. We believe that Maine would be better served by setting the realistic requirements for CUU applications and by opening the door for applications more widely.

1. Potential violation of antitrust law.

The "A. Proposal for Currently Unavoidable Use Determinations." under "9. Currently Unavoidable Use." in this proposed concept draft indicates the following that must be included in the proposal.

(4) A description of whether there are alternatives for this specific use of PFAS which are reasonably available including:

(a) Identification of specific compounds, classes of materials, or combinations of materials identified as potential alternatives including the removal of PFAS without substitution;

(b) An assessment of how the materials in Subsection a, above, meet or fail to meet the criteria identified in Subsection 3(b) above;

(c) An assessment if materials identified in Subsection a, above, are available in sufficient quantities to meet production needs without regard to cost;

(d) An assessment of the cost difference between obtaining PFAS for use in a product and obtaining the material identified in Subsection a, above, for the same purpose;

(e) A comparison of the known risks to human health and the environment between PFAS and the materials identified in Subsection a; and

(f) An assessment of whether there are feasible changes to the manufacturing process of the product that would eliminate the need for PFAS.

(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.

Proposals may be submitted by manufacturers individually or collectively, according to the proposal. For example, if a PFAS manufacturer prepares a proposal, the potential substitute could be manufactured by a competitor. (4) (c), (d) and (8) are information on production volume and cost, which is very difficult to obtain and the exchange of information with competitors may be taken as an agreement and judged to be in violation of antitrust laws. Therefore, it is practically impossible for a manufacturer of PFAS to provide this information, and it is not a requirement that should be imposed on the proposer.

2. Possibility of omission of information due to heavy burden on the proposer.

The "A. Proposal for Currently Unavoidable Use Determinations." under "9. Currently Unavoidable Use." in this proposed concept draft indicates the following that must be included in the proposal.

(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.

(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;

Obtaining this information would require very extensive research, which is an overly high hurdle for the proposal. Imposing such excessive information request obligations will lead to an excessively high hurdle for CUU applications and the loss of benefits that would otherwise accrue from products and uses that should be determined as CUU. This would result in the loss of the opportunity to protect what is essential for health, safety or functioning of society for Maine, which is the original purpose of CUU. In addition, there is a risk of omission of information by some proposers. Therefore, these information collections should be conducted by the authorities themselves, for example by appointing neutral experts and consultants, so that the information can be used objectively.

Even when these information collections are conducted by a third party, we believe that the following points should be noted. (5)(a)(ii) should not be included in the mandatory requirement because the business status varies by product category and industry, and therefore, it does not necessarily mean that the applicant has applied to other states, and the intention to understand the status of submission to other states is not clear. (6) and (7) are not necessarily substitutable in Maine applications for products offered for sale in other states because of the wide range of product specifications. Simply the fact that the product is offered for sale in another state should not be the sole basis upon which a CUU should be determined. If the potential for substitutability is to be investigated, it should not be included in the mandatory requirement because it is duplicative of (4)(a) and (b).

3. Information should be allowed to be submitted at the CBI.

The "A. Proposal for Currently Unavoidable Use Determinations." under "9. Currently Unavoidable Use." in this proposed concept draft contains the following note.

NOTE: While 38 M.R.S. § 1614(12) and Section 10 provide a mechanism for the protection of proprietary information, currently unavoidable use determinations are subject to the Department's rulemaking process including approval by the Board of Environmental Protection in a public meeting and response to public comments. Should a proposal for a currently unavoidable use determination contain claims of confidentiality, the Department may determine that there is insufficient publicly available information to justify a rulemaking. The Department strongly recommends that all proposals for currently unavoidable use determinations do not contain claims of confidentiality.

It is inconsistent to require information equivalent to Confidential Business Information (CBI), such as information on distribution volumes and product characteristics, while not recommending

the application of CBI. In addition, by not recommending the application of CBI, it is questionable whether the correct information is available; we believe that allowing the application of CBI and obtaining the correct information is more necessary to CUU's decision to provide an opportunity to protect what is essential for health, safety or functioning of society for Maine's citizens. Therefore, the provision of information through CBI should be allowed.

4. Lastly.

We recognize that Maine is one of the states in the US that is about to adopt the most stringent regulations regarding PFAS. Extremely stricter regulations than other states would result in the loss of essential PFAS applications (especially those related to fluoropolymers) and lead to an exodus of industry to other states. For the further development of your state, we believe it is necessary to align with the efforts of other states and the U.S. federal government and introduce an appropriate form of regulation that is not excessive.

FIRE EQUIPMENT MANUFACTURERS' ASSOCIATION

Saving Lives, Protecting Property.

January 28, 2025

Commissioner Melanie Loyzim Maine Department of Environmental Protection 17 State House Station 32 Blossom Lane Augusta, Maine 04333-0017

Submitted via email to: rulecomments.dep@maine.gov; PFASproducts@Maine.gov

Re: Chapter 90, Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

Dear Commissioner Loyzim,

On behalf of the Fire Equipment Manufacturers' Association (FEMA) and its members, we appreciate the opportunity to provide comments regarding the Chapter 90 draft rule related to products containing Perfluoroalkyl and Polyfluoroalkyl substances. As the Department considers implementation of the upcoming product sales prohibitions, and criteria for currently unavoidable use exemptions, we wish to reiterate the critical importance of portable fire extinguishers and fire suppression systems in protecting the public health and safety in Maine.

Last year, FEMA and member company, Amerex Corporation, submitted proposals to the Department for currently unavoidable use determination relative to fire suppression products utilizing F-gas extinguishing agents. Within these proposals, we outline the health and safety risks associated with a sales prohibition of fire extinguishing products and lack of available alternatives that necessitate an exemption.

In summary, F-gas fire extinguishing agents, as listed in the FEMA CUU Petition dated February 28, 2024, and filed with the Maine DEP, are critical for protecting essential infrastructure from fire and explosion hazards, including:

- Commercial and military aviation
- Maritime industry
- National defense systems and military combat vehicles
- Public transit systems
- Telecommunication systems, electrical equipment, data centers, and storage installations
- Petrochemical facilities and energy pipelines
- Explosion hazards
- Power generation, storage, transmission, and control

FIRE EQUIPMENT MANUFACTURERS' ASSOCIATION

Executive Director: THOMAS ASSOCIATES, INC.

It is crucial to note that these F-gas agents are NOT AFFF (Aqueous Film Forming Foam [Fluorinated]) firefighting foam agents which have generated persistence, bioaccumulation and toxicity (PBT) concerns.

F-gas extinguishing agents used in portable fire extinguishers and fire suppression systems pose minimal risk to human health as they are non-toxic when used as directed and readily evaporate into the air, thus are not bioaccumulating. These fire extinguishing agents have been declared acceptable for use by the US Environmental Protection Agency under the <u>EPA Significant New</u> <u>Alternatives Policy (SNAP) List for Fire Suppression and Explosion Protection</u>, as well as by the Federal Aviation Administration, the Department of Defense, and the US Coast Guard.

Moreover, the European Union is proposing a critical use exemption from its PFAS regulation for F-gas fire-suppressing agents "where current alternatives damage the assets to be protected or pose a risk to human health," noting that there is sufficiently strong evidence indicating the current unavailability of alternatives for some applications. (European Chemicals Agency (ECHA): <u>Annex XV Restriction Report-Proposal for a Restriction</u>, March 22, 2023, p. 126).

In addition to their safety role, portable fire extinguishers, including those using F-gas agents, have been shown to significantly reduce carbon emissions from building fires. A study by Jensen Hughes, <u>A Review of the Impact of Fire Extinguishers in Reducing the Carbon Footprint of</u> <u>Building Fires</u>, found that using portable fire extinguishers can reduce fire-related carbon emissions by 93.6%, beyond the reduction achieved by automatic fire sprinklers. When used together, the reduction is nearly 99%. The early application of fire extinguishing agents is key to minimizing these emissions, underscoring the importance of these tools in environmental protection.

As the Department continues to refine the PFAS in Products Program, we encourage you to consider the essential role of portable fire extinguishers and fire suppression systems in Maine. We strongly urge you to include an exemption or currently unavoidable use determination for F-gas fire suppression agents listed in the EPA's SNAP list for *Substitutes in Fire Suppression and Explosion Protection* within the new regulations. Thank you for your consideration of this important issue.

Respectfully submitted,

Fire Equipment Manufacturers' Association (FEMA) – Government Relations Committee <u>fema@femalifesafety.org</u> 216-241-733

About FEMA

Founded in 1930, FEMA is a trade association whose members employ thousands of American workers, dedicated to manufacturing commercial fire protection equipment to serve as the first line of defense against fire in its early stages. Members of FEMA formed the Government Relations Committee (GRC) in 2003 to address legislative and regulatory issues relating to portable fire extinguishers, pre-engineered systems, and other fire protection products. The Committee aims to educate officials and legislators about the importance of comprehensive fire

safety policies. By monitoring state fire code adoptions, as well as legislative and regulatory proposals at the state and federal levels, the GRC is able to engage in the conversation, providing both the industry's point of view and technical expertise in the debate on important public policy matters.

FREUDENBERG-NOK SEALING TECHNOLOGIES



Freudenberg-NOK Sealing Technologies 46790 East Anchor Ct. Plymouth, MI 48170

Plymouth, MI January 28th, 2025

RE: Comment on Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

Co	Sontent		
1.	Introduction	1	
2.	CUU Proposed Timeline	2	
3.	Duration of CUU Determination	2	
4.	Conclusion	2	

1. Introduction

Freudenberg Sealing Technologies (FST) is a leading supplier of advanced sealing products for customers in the automotive and general industry. In researching, developing, and introducing innovative product and process solutions, the company benefits from 175 years of engineering and materials experience. The focus has always been on the technological demands and requirements of our customers.

Since the development of the Simmerring® rotary shaft seal in 1929, FST has continuously expanded its portfolio of industrial seals and components, offering a large variety of technological solutions that address critical factors such as performance, durability, friction, emissions, and material compatibility. In addition to a wide range of in-house developed, high-quality, engineered sealing solutions, the company also works with its customers to design and validate their specific sealing systems.

With the world's largest range of seals, FST offers sealing products for everything from dental drills and filling lines to wind turbines, aircraft, and automotive transmissions. Seals are often small components, usually invisible but essential for the smooth functioning and long service life of the system in which they are installed. In all application areas and industries, the company's unique materials expertise and continuous innovation create the basis for continued customer satisfaction. The company operates at 60 locations worldwide with appr. 13,000 employees. Sales in 2023 amounted to 2.7 billion dollars. In North America, FST operates 18 sites with the contributions of 4,700 associates and in 2023 generated sales of 1.1 billion dollars.

FST fully supports all efforts to improve protection of human health and the environment from risks posed by chemicals. Preventive health care, environmental protection, occupational safety, the safety of machines, production lines and processes, and product safety as well as good corporate citizenship are of great importance at FST.

FST aims to continuously reduce its environmental impact throughout the entire value chain. While developing new products and technologies safe and environmentally sound manufacturing, utilization, and disposal practices are adopted. In addition to this, FST is constantly focusing its efforts on reducing the environmental impact by using natural resources more efficiently, lowering emissions, saving energy, water, and other operating materials, as well as optimizing transportation processes. Waste is handled in accordance with the

FREUDENBERG-NOK SEALING TECHNOLOGIES 46790 East Anchor Ct.

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FREUDENBERG-NCC

principle that prevention is better than recycling is better than disposal. Residual substances that can neither be avoided nor recycled are disposed of in a responsible manner and in accordance with national regulations. FST's management systems comply with internationally recognized standards.

2. CUU Proposed Timeline

FST is concerned about the restriction limiting CUU proposals to a maximum of 36 months before the product's sale prohibition takes effect. In many industries we serve, development and manufacturing timelines are extensive and often exceed the proposed three-year limit. Product development can begin years before the final sale date, factoring in formulation development, testing, and both customer and regulatory approval. Considering these extended timelines, FST respectfully requests that CUU proposals be permitted up to 60 months in advance of the product's sales prohibition.

3. Duration of CUU Determination

For the reasons stated above, FST also supports CUU determinations being valid for a period longer than five years, if justified. Given product development timelines and needs, extended CUU determinations would provide greater certainty. Given the limited duration of a CUU determination, having a streamlined renewal process would also be welcome, reducing the burden of the CUU determination process for manufacturers in scope.

4. Legal Obligation of Manufacturer to Report

Due to the nature and complexity of supply chains it is possible that the manufacturer, when selling its goods e.g. to its customers, service providers or distributors, does not have the required information on whether the delivered goods will be installed in a product or component that is currently exempted from the PFAS prohibition or not. That means the manufacturers, as suppliers further down the supply chain, cannot control the risk and thus be liable as they do not know to which customers, states and countries the distributors, importers and retailers are further selling its goods. With this in mind, FST requests additional consideration be given to manufacturers of products with multiple end uses, where the end use of the product is unknown to the manufacturer.

Thank you for your consideration of our comments. If there are any additional questions or discussion regarding FNSTs comments, please do not hesitate to reach out.



January 28, 2025

Maine Department of Environmental Protection 17 State House Station 32 Blossom Lane Augusta, Maine 04333-0017

Submitted by email to PFASProducts@Maine.gov

Re: Chapter 90 Posting Draft for PFAS in Products Rule

Disclaimer: Nothing in this submission relates to firefighting foams or the chemical agents used in firefighting foam.

The Halon Alternatives Research Corporation, Inc. (HARC) appreciates the opportunity to provide comments to the Maine Department of Environmental Protection (DEP) in response to the Chapter 90 posting draft for the PFAS in products rule. HARC is a non-profit trade association formed to promote the development and approval of halon alternatives that serves as an information clearinghouse and focal point for cooperation between government and industry on issues of importance to special hazard fire protection. HARC members encompass all levels of the fire protection industry including agent manufacturers, equipment manufacturers, distributors/installers, recyclers, and end-users.

On March 1, 2024, HARC submitted to DEP a Currently Unavoidable Use (CUU) proposal for halogenated clean agents used in fire suppression and explosion protection. The proposal contained information on important uses of halogenated clean agents for which non-PFAS alternatives do not exist and are not currently in development. As such we expect there to be continuing uses of halogenated clean agents well beyond January 1, 2032.

The exemptions for SNAP-approved refrigerants, foams and aerosol propellants should be extended to fire suppression and explosion protection agents

The amended law includes a later prohibition date of January 1, 2040, and an exemption for refrigerants, foams and aerosol propellants that are listed as acceptable, acceptable subject to use conditions, or acceptable subject to narrowed use limits under the EPA Significant New Alternatives Program (SNAP). HARC believes that DEP should extend this exemption to fire suppression and explosion protection agents that are listed as acceptable, acceptable subject to use conditions, or acceptable subject to narrowed use limits under SNAP. HARC is not aware of any justification for excluding these agents from the SNAP exemption as they are in some cases the same chemicals as those being used for exempted applications. Fire suppression agents are used in smaller quantities, have lower emission rates, and have much higher rates of recycling than most other SNAP application sectors. They are used to protect life safety and high value assets in applications that are critical to the functioning of society such as commercial aviation,

energy production, and information technology (data centers, cell phone sites). In addition, SNAP approved fire suppression and explosion protection agents are not sold to consumers as they are prohibited for residential use under SNAP.

HARC believes there was either an oversight that fire suppression and explosion protection agents were not specifically listed in the SNAP exemption, or there was confusion that their use is somehow related to firefighting foams. As noted above there is no relationship between the use of halogenated clean agents for fire suppression and explosion protection and the use of firefighting foams on class B fires. Firefighting foams are aqueous solutions with releases to ground, while halogenated clean agents are gaseous agents or volatile liquids that result in atmospheric emissions.

Proposals for currently unavoidable use determinations

The concept draft language proposes to limit the submission of CUU proposals to between 36 and 18 months before the date of the applicable sales prohibition. While we understand why DEP would not want to make a CUU determination too far in advance of the prohibition date to allow for the development of alternatives, HARC does not believe that 36 months provides enough lead time for the design of projects that may require the use of halogenated clean agents. The design of a commercial aircraft, energy production facility, or data center can occur years in advance of completion and typically includes specification of the fire suppression system. The development and approval times for new fire suppression agents and systems can take decades. HARC notes that during the January 16 public hearing on Chapter 90 at least two commenters, including the Maine Chamber of Commerce, supported allowing CUU submissions sooner than 36 months.

As noted in our CUU submission, the development of new substances has been aggressively pursued within this sector for more than 30 years with limited success. An expectation that new options not already considered in the past can be developed and brought to market in 5, 10, or 20 years is not supported by historical experience. Several important fire risk applications (for example, civil aviation and nuclear powerplants) still require halons even after pursuing alternatives for 30 years.

This history has led to a consensus within the fire protection community that it is highly unlikely new non-PFAS alternatives will suddenly be discovered. Below is a quote from the 2023 Progress Report of the United Nations Environment Program (UNEP) Technology and Economic Assessment Panel (TEAP) that sums up this consensus:

"Furthermore, all known candidate clean agent chemical groups have already been researched, such that discovering alternatives that are zero ODP, low GWP, and non-PFAS is highly unlikely. Based on these factors, there is little to no financial incentive for companies to invest in the research and development of potential new fire suppression agents. As there are no new candidate fire suppressants available for consideration that are not PFAS under these broad definitions, it is anticipated that the only options that will be available after the 12-year derogation are the same ones available today." HARC respectfully requests that DEP reply to our March 1, 2024, CUU submission and provide an opinion on whether as things stand now, DEP agrees that there are currently unavoidable uses of halogenated clean agents for fire suppression. We would also suggest that DEP consider widening the window for the submission of CUU proposals to 60 months before the applicable prohibition date.

Please let us know if you have any questions or would like to discuss these issues in further detail.

Respectfully submitted,

Thom los

Thomas Cortina Executive Director HARC 571-243-9918 cortinaec@comcast.net


January 3, 2025

Maine Department of Environmental Protection Kerri Malinowski Farris 17 State House Station Augusta, Maine 04333-0017 <u>pfasproducts.dep@Maine.gov</u>

RE: Maine Department of Environmental Protection, Ch. 90 Title 38, Section 1614 Amendments

Dear Maine Department of Environmental Protection,

Maine has been a leader in the country on the issue of banning harmful per- and polyfluoroalkyl substances (PFAS). Heating, Air-conditioning & Refrigeration Distributors International (HARDI) supports adopting Chapter 90 Title 38 Section 1614 Amendments as proposed with the exemptions for heating, ventilation, air conditioning, and refrigeration (HVACR) equipment until 2040. HARDI supports the unavoidable use exemption process outlined in the proposal; however, HARDI suggests that the Maine Department of Environmental Protection also adds an unavoidable use exemption when a separate state or federal regulation or code prohibits PFAS alternatives.

HARDI is a trade association comprised of over 800 member companies, more than 450 of which are U.S.–based wholesale distribution companies serving HVACR contractors and technicians in the state. Over 80 percent of HARDI's distributor members are classified as small businesses that collectively employ more than 60,000 U.S. workers, representing an estimated 75 percent of the U.S. wholesale distribution market of HVACR equipment, supplies, and controls.

Maine is justified in seeking to reduce the use of harmful PFAS. HARDI recognizes that not all PFAS should be considered dangerous to human health. According to a systematic review by the National Institutes of Health (NIH), the three factors that create a danger to long-term human health are "[*p*]ersistent, bioaccumulative, and toxic substances ... that can subsist for decades in human tissues and the environment."ⁱ According to REACH, the European Union regulation for protecting human health, hydrofluorocarbons (HFCs) refrigerants do not meet the *persistent*, *bioaccumulative*, or *toxicity* factors necessary to make them dangerous PFAS.ⁱⁱ HARDI appreciates the exemption granted in the legislation for the HVACR industry until 2040 and supports this language as drafted.

Moreover, HARDI suggests that the language used in the "unavoidable use" section should consider the potential overlap between future refrigerant regulations and the use of refrigerants containing PFAS. In the HVACR industry, multiple overlapping systems are in place to ensure that refrigerants are safe for the environment and human health.

The Environmental Protection Agency's (EPA) Significant New Alternatives Policy (SNAP) program mandates the approval of refrigerants as alternatives to existing ones, including those containing PFAS. Refrigerants without SNAP approval cannot be used. Furthermore, the EPA can impose use restrictions on these refrigerants based on safety considerations. For instance, the limit on the amount of propane used as a refrigerant in refrigeration products was recently increased.

However, equipment utilizing propane as a refrigerant must meet safety standards. These safety standards can prevent the utilization of non-PFAS refrigerants if there is no safe method for their use. As a result, propane, which is often suggested as an alternative to planned PFAS refrigerants, cannot be used in home air conditioning due to the lack of SNAP approval or safety standards. This indicates that PFAS has an unavoidable use due to separate state or federal regulations and codes.

HARDI recommends that the Department of Environmental Protection include state and federal regulations or codes as a valid unavoidable use category. This will ensure that if separate Maine or Federal regulations restrict alternative refrigerant options, the initially planned PFAS-containing refrigerant will qualify for the unavoidable use exemption. As mentioned, the PFAS within the HVACR system refrigerant poses fewer health risks than other PFAS sources. The legislation and the now-drafted regulation were designed to protect the public from the health hazards associated with severe PFAS exposure, a health risk not shared by fluorine-containing HVACR refrigerants. HARDI supports adding language for an unavoidable use exemption for the PFAS to be permitted when a separate regulation prohibits the alternative substance.

HARDI supports Chapter 90 Title 38 Section 1614 Amendments as presented and asks the Maine Department of Environmental Protection to update the draft language with this change when the regulation is proposed.

Sincerely,

All fare

Todd Titus Director of State and Public Affairs Heating, Air-conditioning, & Refrigeration Distributors International

• 445 Hutchinson Avenue, Suite 550, Columbus, OH 43235

¹ Fernández-Martínez, N. F., Ching-López, A., Olry de Labry Lima, A., Salamanca-Fernández, E., Pérez-Gómez, B., Jiménez-Moleón, J. J., Sánchez, M. J., & Rodríguez-Barranco, M. (2020). Relationship between exposure to mixtures of persistent, bioaccumulative, and toxic chemicals and cancer risk: A systematic review. Environmental research, 188, 109787. https://doi.org/10.1016/j.envres.2020.109787

ⁱⁱ REACH Online, Annex XIII: Criteria for The Identification of Persistent, Bioaccumulative and Toxic Substances, and Very Persistent and Very Bioaccumulative Substances, https://reachonline.eu/reach/en/annex-xiii.html



January 28, 2025 Kerri Malinowski Farris 17 State House Station Augusta, ME 04333 (207) 215-1894 pfasproducts.dep@Maine.gov

Re: PFAS in Products Program: Posting Draft Language to Implement Title 38, Section 1614

381

Dear Ms. Farris,

On behalf of the Household & Commercial Products Association¹ (HCPA) and its members, we want to convey our comments on the Posting Draft for Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substance. The Household & Commercial Products Association (HCPA) appreciates the opportunity to comment to the Maine Department of Environmental Protection (DEP or the Department) on the new posting draft language² to implement the recently amended Title 38, section 1614. HCPA thanks the Department for providing this opportunity during an informal outreach process that will help inform formal rulemaking.

HCPA appreciates the efforts of the Department to date and the continued opportunity to provide additional comments to refine the regulation. HCPA has previously submitted letters expressing concerns about the Concept Draft for determining currently unavoidable uses (CUU) of perfluoroalkyl and polyfluoroalkyl substances (PFAS) in products and the concerns raised previously about the criteria for and responsible parties of CUU applications and clarity of confidentiality claims of submissions are incorporated by reference.

I. HCPA Comments on Definitions

HCPA appreciates the Department's removal of the Note for the term "cleaning products," thereby removing some of the ambiguity as to whether industrial cleaning products are not included within the scope. It may be useful to explicitly note that industrial cleaning products are not in the scope of the regulation.

HCPA notes that the definition of "general cleaning product" was removed from the

¹ HCPA is the premier trade association representing the interests of companies engaged in the manufacture, formulation, distribution and sale of more than \$180 billion annually in the U.S. of familiar consumer products that help household and institutional customers create cleaner and healthier environments. HCPA member companies employ hundreds of thousands of people globally. HCPA represents products including disinfectants that kill germs in homes, hospitals and restaurants; air fresheners, room deodorizers, and candles that eliminate odors; pest management products for pets, home, lawn, and garden; cleaning products and polishes for use throughout the home and institutions; products used to protect and improve the performance and appearance of automobiles; aerosol products and a host of other products used every day.

² Available at <u>https://www.maine.gov/dep/rules/#13139124</u>

current proposal and recommends that it be included in the regulation.

HCPA is concerned that the definition of "commercially available analytical method" may lead to incorrect testing methods for particular PFAS or inconsistent results. We also note that PFAS analysis is a rapidly developing area and that commercially available analytical methods, unmodified or modified, may not be suitable for testing certain PFAS. HCPA strongly encourages the inclusion of science-based criteria for appropriate regulatory testing methods and approaches while distinguishing between screening approaches and rigorous analytical techniques.

HCPA notes that "complex product" does not appear to be defined, as indicated within the Note under Section 6. HCPA encourages the inclusion of a definition or clarifying language to differentiate between a product, product component, or complex products.

II. HCPA Requests Additional Detail Regarding Manufacturer Responsibility and Fee Amount

HCPA appreciates that the Department is allowed to establish by rule and assess a fee payable by a manufacturer required to comply with the law's notification requirements. This will help identify who the party responsible for reporting should be. The term "manufacturer" includes the entities that manufacture a product or whose brand name is legally affixed to the product. However, there are numerous circumstances when two different entities meet that definition: one may manufacture the product, and the other may legally affix its name to the product. In such circumstances, it is unclear who the "manufacturer" is and, therefore, which entity has the reporting requirement. HCPA recommends additional guidance to assist manufacturers and the Department in determining responsibility.

HCPA welcomes the reduced amount of \$1,500, but it would be helpful to understand better the justification for this amount and how it would cover the department's reasonable costs in administering and implementing Maine's PFAS in Products Program. HCPA requests clear and transparent documentation so stakeholders can better understand how this amount was determined.

III. HCPA Comments on Certificate of Compliance

HCPA reiterated the request for more information on certificates of compliance. Specifically, as manufacturers have 30 days to fill out forms provided by the Department that have not yet been shared, it remains challenging to indicate whether 30 days is sufficient time. For instance, if a manufacturer does not intentionally add PFAS to a product but must test a raw material to confirm compliance, that analytical testing may take more than the proposed 30 days. We would appreciate it if the Department could provide detailed information and/or the actual Certificates of Compliance before the formal rulemaking so stakeholders can provide more informed feedback on their utility.

IV. HCPA Comments on the Criteria for a Currently Unavoidable Use Proposal

HCPA thanks the Department for including criteria for a proposal for a Currently Unavoidable Use (CUU) determination. HCPA is concerned that the Department has not finalized any rules that would provide detail on what is considered "essential for health, safety or the functioning of society" or how to determine if "alternatives are not reasonably available." HCPA strongly recommends that, before requesting and making determinations on CUU proposals, the Department first finalize a rule that clearly defines the terms "alternative," "essential for health, safety or the functioning of society," and "reasonably available" to provide clarity to stakeholders.

HCPA further encourages the development of guidance relevant to pesticide products that address public health pests containing an active ingredient considered a PFAS under Maine law and regulated in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to provide additional clarity on whether these products will be exempted via Federal preemption or whether a company would need to seek a CUU determination. Further, it is unclear if this would apply to a pesticide product addressing public health pests containing an inert ingredient considered a PFAS under Maine law and regulated under FIFRA and how it would relate to CUU determination.

HCPA notes that the Posting Draft provides an option for individual *or* collective CUU determination; however, the listed criteria are tailored to an individual manufacturer's request. If the department is allowing submissions to be made at an industry level via a trade association, the criteria would seem to need to be adjusted to reflect that the submitter is an organization rather than an individual company. HCPA encourages the inclusion of additional language for separate processes to account for collective submissions.

HCPA can also envision additional scenarios, such as protective packaging or the use of PFAS in the manufacturing process, that would likely need to be considered. HCPA believes specific criteria are needed to define the parameters companies should use to structure their CUU proposals. This would minimize the likelihood that an application is considered insufficient and not granted, and it would also create a more transparent process for evaluating CUUs.

V. HCPA Requests Clarification on Claims of Confidentiality Related to Currently Unavoidable Use Proposals

HCPA recognizes that the Department's rulemaking process includes approval by the Board of Environmental Protection in a public meeting and response to public comments. Thus, we understand the Department's strong recommendation that proposals for currently unavoidable use determinations do not contain claims of confidentiality.

However, some requirements may trigger proposers to request confidentiality within the criteria. For example, the assessment of the cost difference between obtaining PFAS for use in a product and without is likely something a proposer would want to keep confidential.

Indeed, there can be other examples of manufacturers wanting to keep certain details confidential, as many markets are highly competitive. Therefore, HCPA believes that the Department needs to be able to claim certain information as confidential within the process and justify a rulemaking on the portions of what can be public information.

VI. HCPA Requests Clarification of the Responsible Part to Report to the Department

As previously mentioned, HCPA appreciates that the new concept draft language contains criteria for a proposal for a CUU determination. As proposals can be submitted by manufacturers individually or collectively, HCPA assumes that trade associations can submit proposals on behalf of their members and that consortiums of manufacturers can be formed to submit a proposal. HCPA would appreciate confirmation of this assumption.

VII. HCPA Comments on the Timeline to Submit Proposals for Currently **Unavoidable Use Determinations**

HCPA is concerned with the timeline for which requesters must submit CUU proposals. By requiring proposers to submit their submissions 18 months before the applicable sales prohibition, products subject to a sales prohibition starting January 1, 2026, would not be allowed to be submitted. HCPA believes there needs to be a process for which products subject to the January 1, 2026 sales prohibition can be reviewed.

Further, while HCPA hopes and thinks that those needing to submit proposals for later sale prohibitions (2029, 2032, and 2040) should have sufficient time to provide proposals no later than 18 months prior, HCPA believes the department needs to provide flexibility in terms of the timeline to submit proposals for those products. This rigid timeline may prove ineffective, and HCPA believes the Department should allow submissions earlier to avoid undue delays. If possible, we recommend that the DEP consider applications for CUU proposals earlier than 36 months before the enforcement ban for products subject to the 2029, 2032, and 2040 sales prohibitions. Allowing a submission earlier than the proposed time frame of 18/36 months would provide industry and end-users with certainty in the market and minimize the disruption of a sales prohibition upon Maine businesses and consumers. HCPA also believes the additional time will allow the Department to allocate resources for the CUU determinations better.

HCPA looks forward to working with DEP and other stakeholders to ensure that Maine residents continue to have access to products that improve their daily lives. Please do not hesitate to contact HCPA if you have questions about our comments.

Sincerely,

Steven Bennett, Ph.D. Executive Vice President, Scientific & Regulatory Affairs

384

Proposed Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substance under Maine's Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution, 38 M.R.S. § 1614

Comments of the Hitachi Energy North America

Hitachi Energy appreciates the opportunity to provide these comments in response to Maine's Department of Environmental Protection's (DEP) proposed rule for notification requirements, sales prohibitions and currently unavoidable use determinations for products containing intentionally added PFAS under Maine's Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances [PFAS] Pollution (the "Proposed Rule"). Hitachi Energy and grid technology providers will likely be adversely affected by the proposed changes being considered.

Hitachi Energy is a global technology leader that is advancing a sustainable energy future for all. With our North American headquarters in Raleigh, North Carolina, the company employs more than 6,300 in both manufacturing and office locations throughout the region, serving customers in the utility, industry and infrastructure sectors with innovative solutions and services across the value chain. Together with customers and partners, we pioneer technologies and enable the digital transformation required to accelerate the energy transition toward a carbon-neutral future. Hitachi Energy is proud to have proven track record and unparalleled grid technology installed base in more than 140 countries.

We request a modification of the exemption to include **power grid technologies** alongside the current definition, *"Nonconsumer electronics, nonconsumer power grid equipment, and nonconsumer laboratory equipment not ordinarily used for personal, family or household purposes."*

Without this inclusion or clarification that power grid technologies apply in the exemption there is a **potential impact to grid technology providers ability to deliver the equipment needed to ensure a reliable and resilient grid**.

The following bullets are some of the key points on power grid equipment which need to be considered in the regulation process.

Power Grids Are Essential for the Functioning of Society:

• Power grid products are critical for the reliable and efficient transmission and distribution of electricity, which is fundamental to the functioning of modern society.

• Imposing restrictions on PFAS in power grid products could undermine reliability of critical products and lead to significant disruptions in the power supply, affecting both residential and industrial consumers.

• Power grid products support essential services such as healthcare, emergency services, as well as everyday conveniences like lighting, heating, and communication.

Lack of Viable Alternatives:

• Non-consumer power grid infrastructure must meet international safety requirements due to extreme operation conditions (e.g., high voltage, high current, extreme temperatures, adverse weather conditions, etc.). PFAS materials are used in non-

consumer power grid infrastructure due to the unique properties of these materials, such as high thermal stability, chemical resistance, and electrical insulation, which are crucial for the safe operation of electrical infrastructure.

• Currently, viable PFAS-free alternatives that can match the safety, performance, and reliability, standards required for non-consumer power grid infrastructure are extremely limited despite ongoing R&D programs, it is very likely that for some applications no suitable alternatives can be identified.

Trained Professionals and Safety Protocols:

• The maintenance and operation of power grid products are carried out by highly trained professionals who follow stringent safety and environmental protocols. This ensures overall efficacy and reliability of the grid.

• The useful life of equipment and components is very long, often exceeding 40 years with appropriate maintenance. This contrasts with single-use and/or limited-life consumer goods, which reach their end-of-life sooner.

Support for Renewable Energy Transition:

• Non-consumer power grid infrastructure plays a crucial role in integrating renewable energy sources into the grid.

• To utilize any renewable energy technology, it must be connected to the electrical network through non-consumer power grid infrastructure. Any legislation or regulation impacting non-consumer power grid sector will greatly impact the availability and accessibility of renewable energy.

• Our ecofriendly circuit breakers utilize 3.5% of C4-FN, a **PFAS not classified as toxic**, by using this small amount of PFAS gas to replace SF6, the global warming impact is reduced by 99% compared to the only other commercially available high voltage transmission switchgear system on the market.

We stand ready to partner with you in the implementation of this critical legislation, to provide further information on the current technology available for power grid technologies, and other discussions on advanced research to support development of new viable alternatives.

We would welcome the opportunity to meet with DEP staff to address our comments, provide additional technical information on our products to ensure transparency, and to assist in refining the Proposed Rule prior its finalization.



Kerri Malinowski Farris Maine Department of Environmental Protection 17 State House Station Augusta, Maine 04333-0017

Re: <u>Maine Department of Environmental Protection (MDEP) Proposed PFAS In Products Rule; Chapter 90:</u> <u>Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances</u>

Dear Ms. Kerri Malinowski Farris,

Honeywell appreciates the opportunity to comment on the PFAS In Products Rule; Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances ("proposal" or "proposed rule"), which provides for the implementation of "Act to Amend the Laws Relating to the Prevention of Perfluoroalkyl and Polyfluoroalkyl Substances Pollution and to Provide Additional Funding" (LD 1537).

Honeywell is an integrated operating company serving a broad range of industries and geographies around the world. Honeywell manufactures various fluorinated gases, including hydrofluorocarbons ("HFC"), hydrochlorofluoro-olefins ("HCFO"), hydrofluoroolefins ("HFO") fluorocarbons and their mixtures ("Blends"). These fluorinated gases are used in refrigeration, heating, ventilation and air conditioning ("RHVAC"), mobile air conditioning ("MAC"), thermal management systems ("TMS") in electric vehicles ("EV"), propellants in metered dose inhalers ("MDI") and insulation foam blowing agent applications. Honeywell also produces a fluoropolymer - polychlorotrifluoroethylene ("PCTFE") - used in the primary and secondary packaging of medicinal products, medical devices, and over-the-counter ("OTC") medications.

Honeywell submits the following summary remarks in response to Maine DEP's proposal and solicitation for feedback, which are discussed further in the subsequent pages:

- 1. Honeywell is seeking definitional clarity on: reasonably available, manufacturer and unit
- 2. Maine DEP should establish clear reporting ranges for PFAS testing to ensure accurate identification and quantification of these compounds
- 3. Honeywell supports maintaining internal testing capabilities to support the data required for compliance using Commercially Available Analytical Methods
- 4. DEP should accept Currently Unavoidable Use (CUU) applications for 2040 ban categories earlier than 36 months prior to sales prohibition and make initial CUU determinations as soon as possible ahead of the prohibition
- 5. The DEP CUU determination program should align with existing federal and international policies to ensure coherence and avoid duplication of efforts
- 6. The DEP should enable confidential information in the review of CUU determinations and ensure information protection to allow comprehensive reviews

Should you have any questions regarding our submission please don't hesitate to get in touch with us.

Sincerely, W we Atashi Bell, PhD Senior Director, Global Government Relations, Atashi.Bell@Honeywell.com

387

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1. Honeywell is seeking definitional clarity on: reasonably available, manufacturer and unit

a. Reasonably available

The proposed definition for "reasonably available" should include considerations such as safety, energy efficiency, toxicity, flammability, and supply chain considerations. Honeywell suggests that the definition and interpretation of reasonably available should consider not only the comparative cost of PFAS alternatives to the existing PFAS on a per-volume basis, but also the costs related to the manufacturing process and the necessary equipment modifications required to implement these new PFAS alternatives. This would account for the potential consequences of less energy efficient equipment, including the energy cost differential and the demand on the energy grid should a reasonable alternative, as per the Maine definition, be readily available.

Honeywell recommends increasing the scope of costs within the definition of "reasonably available." When considering costs, DEP should account for increased costs in the manufacturing process, to small businesses, and to end-users. High costs create barriers to adoption and may severely impact end users and consumers with limited financial resources. Evaluating costs will allow DEP to assess the economic feasibility, or reasonableness, of transitioning to alternative substances and will ensure that feasible alternatives are identified where needed. For example, most of the foam blowing insulation contractors, such as spray foam contractors, reliant on HFOs based insulation are characterized as small businesses. These enterprises often operate on a local or regional scale, providing insulation services to residential, commercial, and industrial clients. Due to the specialized nature of their work, these contractors typically have limited resources and may face challenges in transitioning to alternative blowing agents.

Finally, DEP should consider establishing a transparent and well-defined framework in making its determination of the reasonable availability of alternatives. Subsection (i) of the American Innovation and Manufacturing Act of 2020 (AIM Act)¹, entitled "Technology Transitions," may serve as a useful example of criteria that an alternative must meet prior to establishing restrictions on the use of a substance being substituted. Under this provision, the Environmental Protection Agency (EPA) is required to consider "the availability of substitutes for use taking into account technological achievability, commercial demands, affordability for residential and small business consumers, safety, consumer costs, building codes, appliance efficiency standards, contractor training costs, and other relevant factors..."² Honeywell urges the Maine DEP to consider adopting a similar approach in assessing substitutes to PFAS and identifying the key criteria for reasonably available alternatives as the AIM Act. Maine DEP could consider bridging approvals from the AIM act program for their alternative solutions or adopting a similar framework. ³

a. Manufacturer

Further clarification on the term "manufacturer" will help identify which party is responsible for reporting. The term "manufacturer" includes the entities that manufacture a product or whose brand name is legally affixed to the product. However, there are numerous circumstances when two different entities meet that definition: one may manufacture the product and the other may legally affix their name to the product. In such circumstances, it

¹ https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section7675(a)&num=0&edition=prelim

² https://www.govinfo.gov/content/pkg/USCODE-2020-title42/html/USCODE-2020-title42-chap85-subchapVII.htm

³ https://www.govinfo.gov/content/pkg/USCODE-2020-title42/html/USCODE-2020-title42-chap85-subchapVII.htm

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is not clear who the "manufacturer" is and therefore which entity has the reporting requirement. Therefore, the proposed regulation should include a clarifying note and examples of other situations where multiple entities can be the manufacturer to avoid reporting the same materials multiple times.

d. Unit

The meaning of a "unit" should be clarified for chemical producers (Section 3A(1)(b)). The proposed regulation should clarify the meaning of "unit" within the description of the requirement for direct manufacturers to report the total number of units sold annually in the State of Maine or nationally. Honeywell recommends that "unit" for chemical producers be total volume by weight sold. Total number of units sold annually can have a variety of meanings depending on the product or product component—for chemical producers, for example, product is typically sold through cylinders and containers of different sizes. The fluorocarbon is then used in an end-product where it is counted again as a unit. Therefore, it would be important to clarify this for manufacturers to ensure consistency across reports.

2. Maine DEP should establish clear reporting ranges for PFAS testing to ensure accurate identification and quantification of these compounds

Maine DEP should outline the standards and goals that the PFAS testing is intended to address. There are many commercial PFAS compounds that are proprietary chemicals, for which there are no commercially available analytical methods. Without analytical standards to test for these proprietary chemicals, commercial laboratories may not be able to sufficiently quantify the PFAS ranges in their products, and unintentional omissions may occur. Determining exact PFAS concentrations for complex articles in robust supply chains like automotive or aerospace which are often wholly dependent on full material supplier disclosure and product knowledge. There could be instances where suppliers do not disclose certain information and unintentional omissions may occur. To ensure these manufacturers comply with the reporting requirements, the department should establish clear methods, standards, and approved reporting ranges for known PFAS compounds where identification and quantification is possible.

3. Honeywell supports maintaining internal testing capabilities to support the data required for compliance using Commercially Available Analytical Methods

In order to meet the obligations under this rule and facilitate compliance, Honeywell recommends DEP allow for both in-house and external testing. First, external testing can result in the following issues: samples may become contaminated in transit, there may be delays in data turnaround time, and there is limited visibility when assessing errors. To ensure quality control and reliable results, Honeywell prioritizes robust internal testing capabilities and industry standard certifications to ensure that any data reported is repeatable, reproducible and well documented. As such, Honeywell recommends retaining internal testing as an acceptable path to compliance within the proposed rule.

Further, Honeywell's internal laboratory facilities maintain widely recognized quality standards of ISO 90001 and, for products entering the automotive market, IATF 16949. These facilities have the testing capabilities to utilize any commercially available analytical methods identified to assess the required PFAS requirements as outlined in the proposed rule. Honeywell's testing facilities have the equipment capabilities to address the reporting

requirements outlined in section (3)(A)(e) of the proposed rule. For example, gas chromatography equipped with various detectors, such as flame ionization, thermal conductivity or mass spectrometry, is used for impurity analysis of products and all calibration of gasses are connected to the National Institute of Standards and Technology (NIST) standards. To further showcase the sophistication of testing and method development capabilities, Honeywell has developed commercially available analytical methods that exceed industry standards when it is noted that industry standard methods are not incorporating the best currently available science. These methods and our quality programs, when appropriate, are audited by non-governmental agencies to ensure appropriate rigor and accuracy.

390

For these reasons, Honeywell supports allowing for the flexibility of internal and external testing.

4. DEP should accept CUU applications for 2040 ban categories earlier than 36 months prior to sales prohibition and make initial CUU determinations as soon as possible ahead of the prohibition

Accepting applications earlier than the proposed timeframe will provide greater certainty to the market. An unfavorable CUU determination and sales prohibition could disrupt the market and impact Maine businesses and consumers. Allowing more lead time for CUU determinations will enable industry to ensure the continued availability of critical solutions, while providing ample time to develop new, non-regrettable substitutions that can be readily adopted by the consumer. Significant time is needed to transition to alternative chemistries, with some applications needing several decades, as evidenced by the industry transition from Halon-Based applications.

Industry Example: Halon-Based Applications

Halons are an industry application example of ozone-depleting substances with an essential use exemption under the Montreal Protocol. Despite decades of innovation efforts by the Aerospace and Defense (A&D) industry to replace them, the only resultant solution, Halon 1211, would be deemed a 'regrettable substitution' based on Maine's definition of PFAS, thus making the 'new' solutions non-viable. The A&D industry successfully substituted Halon 1211 in portable (handheld) and lavatory receptacle extinguishers used in commercial aircrafts and is working to substitute halons in commercial aircraft fire suppression systems. Without the new Halon 1211 substitutes, this industry would be left without an effective solution to fire safety as innovation for new solutions could take an indeterminate amount of time.

This example underscores the critical need for extended lead times when transitioning from established essential solutions. Accepting CUU applications earlier than 36 months prior to the applicable sales prohibition will give industries sufficient time to develop and implement new, non-regrettable substitutions while maintaining the availability of critical solutions.

5. The DEP CUU determination program should align with existing federal and international policies

Coordination with other domestic programs, such as those established by federal agencies like the EPA, is recommended to ensure coherence in regulatory frameworks and prevent duplication of efforts. Other PFAS essential use determinations that can be relied on by the DEP include the EPA's Significant New Alternatives Policy (SNAP) Program, EPA's new chemical review program under Section 5 of the Toxic Substances Control Act

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(TSCA), the Federal Food, Drug, and Cosmetic Act (FFDCA), and other federal programs whereby either the PFAS, or products containing them have been deemed acceptable for their intended use through risk assessments by federal agencies. PFAS-containing products that are subject to, or necessary for, meeting federal specifications (e.g., military specifications, United States Federal Aviation Administration (FAA) standards, or NASA requirements) should also be considered currently unavoidable use. Such an approach will help Maine DEP concentrate its efforts on non-essential uses within consumer products. This approach also provides fairness and market stability for businesses that have successfully completed federal reviews for their PFAS-containing products that must meet military, technical, or similar government specifications.

EPA SNAP Program

Maine DEP could consider modelling or bridging their determination approach to the EPA's SNAP program, which operates as a regulatory framework aimed at identifying and promoting the use of environmentally preferable alternatives to ozone-depleting substances (ODS) and high-global warming potential (GWP) substances in various sectors. SNAP is designed to ensure the adoption of the best refrigerants across viable sectors:

- Identification of Alternatives: SNAP assesses potential substitutes for ODS and high-GWP substances used in refrigeration, air conditioning, and other applications. It evaluates the environmental impact, safety, and efficacy of these alternatives to determine their suitability for specific sectors.
- Regulatory Determination: Based on its evaluation, SNAP issues regulatory determinations that categorize alternatives as acceptable, unacceptable, or acceptable subject to use conditions. Acceptable alternatives are those deemed environmentally preferable and safe for use, while unacceptable alternatives are prohibited.
- Sector-Specific Guidelines: SNAP develops sector-specific guidelines and regulations to guide the use of acceptable alternatives in various applications. These guidelines may include usage restrictions, performance standards, and reporting requirements to ensure proper implementation and monitoring.
- Stakeholder Engagement: The SNAP program engages stakeholders, including industry representatives, environmental advocates, and scientific experts, throughout the decision-making process. This collaboration helps to gather input, address concerns, and foster consensus on the adoption of alternative refrigerants.
- Technology Assessment and Innovation: SNAP encourages ongoing research and development of new refrigeration technologies and alternative substances with lower environmental impact. By promoting innovation, the program seeks to continually improve the availability and performance of environmentally friendly refrigerants across different sectors.
- Compliance Monitoring and Enforcement: SNAP monitors compliance with its regulations and guidelines through inspections, data reporting requirements, and enforcement actions against violators. This helps to ensure that the best refrigerants are used in every viable sector while deterring the illegal use of prohibited substances.

Harmonization with existing criteria is crucial to maintain consistency in regulations, promote efficiency, and avoid conflicting requirements that could hinder effective environmental protection efforts such as ozone layer protection.

5

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6. The DEP should enable confidential information in the review of CUU determinations and ensure information protection to allow comprehensive reviews

Much of the data needed to analyze a CUU determination will be trade secret and otherwise business confidential. Honeywell recognizes the difficulty Maine DEP faces in its effort to develop and implement unavoidable use criteria through public rulemaking. The agency must find a balance between protection of the environment and burden to industry while staying consistent with existing confidentiality statutes. Maine Title 10, §1542 trade secret is defined as "information, including, but not limited to, a formula, pattern, compilation, program, device, method, technique or process, that: A. Derives independent economic value, actual or potential, from not being generally known to and not being readily ascertainable by proper means by other persons who can obtain economic value from its disclosure or use;" Maine DEP should apply this standard and pre-identify within the rule categories of information provided under the Maine Statute as trade secret and not publicly available. Maine should outline a methodology which allows for proprietary information to be shared in confidence with the state without being made public during the rulemaking process, so that a comprehensive review can be conducted.

Conclusion

Honeywell appreciates the opportunity to submit comments to the Maine Department of Environmental Protection. We hope that the CUU criteria are adequately protective while also fostering innovation and promoting economic opportunity within the state. Honeywell appreciates DEP's consideration of these suggestions and would be glad to participate in further discussions about these comments and we look forward to reviewing and commenting on the proposed rule.



January 28, 2025

Kerri Malinowski Farris Safer Chemicals Program Manager Maine Department of Environmental Protection Office of the Commissioner 17 State House Station Augusta, ME 04333 Via <u>rulecomments.dep@maine.gov</u>

Re: Comments on MDEP Concept Draft Language for the Proposed Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances Rule

Dear Ms. Farris,

The International Safety Equipment Association (ISEA) submits these comments for the Maine Department of Environmental Protection's (MDEP) proposed PFAS in Products Rule. ISEA is the association for companies that design, test, manufacture and supply a wide range of personal protective equipment (PPE) and safety equipment, including high visibility safety apparel, work gloves, head protection and more.

In Maine, PPE and safety equipment protect 512,200 workers across a number of industries, including 47,000 who are public sector workers¹. In the State, this industry sector employs nearly 1,400 individuals and pays \$67.8 million in wages. Companies in this sector also contribute \$30 million in state taxes and add \$213.5 million to Maine's overall economic activity². Nationwide, the industry protects over 125 million workers in the U.S.

Structure of our comments

First, ISEA asks MDEP to include products required to meet standards or requirements of the Occupational Safety and Health Administration (OSHA) as a separate Exemption in Sec. 4. Second, while the definition of "textile article" already appears to exclude them, ISEA asks that MDEP explicitly exempt textile articles that are components of PPE and safety equipment, including in the "textile article" section of Sec.5(C)(7).

Exemptions Request: OSHA and MRSA Title 26³ Should Be Added to the List of Exempt Agencies

ISEA urges that the U.S. Occupational Safety and Health Administration⁴ (OSHA) be separately listed as a federal agency for which items needed for compliance are exempted.

¹ https://safetyequipment.org/industry-impact/

² https://safetyequipment.org/industry-impact/

³ <u>https://legislature.maine.gov/statutes/26/title26ch6.pdf</u> (MRSA Title 26)

⁴ 29 CFR 1910

The proposed *Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances* rule exempts items "regulated by or under the jurisdiction of" the U.S. Food and Drug Administration (FDA) as well as items "…required to meet standards or requirements of the FAA, the National Aeronautics and Space Administration (NASA), the United States Department of Defense (DOD) or the United States Department of Homeland Security (DHS)."

PPE and safety equipment required to be used to be compliant with OSHA regulations are equally important and must also be included in the Exemptions section. OSHA's workplace safety regulations cover private sector workers in the state, while Maine's regulations in MRSA Title 26 cover public sector workers. ISEA believes this recommendation is on firm ground because **such items are essential for keeping the State's workforce safe from occupational hazards**. PPE and safety equipment are "essential for health, safety or the functioning of society⁵." In fact, workplace fatalities in Maine are steadily increasing. In 2023, Maine saw 27 workplace fatalities⁶, up from 23 workplace fatalities in 2022, which was higher than both 2021 and 2020⁷.

Request: Explicitly Exempt Textile Components of PPE and Safety Equipment

ISEA asks that MDEP explicitly exempt textile articles that are components of PPE and safety equipment **by adding PPE and safety equipment to the other exclusions listed in the "textile article" section of Sec.5(C)(7)**. This would create a new subparagraph (c). PPE and safety equipment are required for legal and regulatory compliance and selected to protect workers against specific hazards in the workplace. Such PPE and safety equipment includes high visibility safety apparel needed to keep workers safe from being struck by moving vehicles; garments that are specially designed to keep workers cool when working in conditions above 80°F; head protection, which includes textile suspension system; and more. While the definition of "textile article" already appears to exclude non-consumer textile articles like those used in industrial and fire services PPE, an explicit exception would align with laws in other states.

Other states exempt PPE from their laws to ban PFAS in various products, including Rhode Island, California, New York and Colorado.⁸

RI's PFAS legislation, signed into law in June 2024, exempts PPE in its "clothing" definition:

"Clothing items intended for regular wear or formal occasions <u>does not</u> include personal protective equipment."⁹ (emphasis added).

⁵ While this phrase is used to define "currently unavoidable use," it also recognizes the importance of keeping workers safe as they conduct important jobs that keep the state moving forward.

⁶ https://www.bls.gov/charts/census-of-fatal-occupational-injuries/state-fatal-work-injuries-map.htm

⁷ https://www.bls.gov/iif/state-data/fatal-occupational-injuries-in-maine-2020.htm

⁸ PPE exemption text in Colorado's PFAS bill, HB 22-1345 is found in the definition of textiles: "Textile" does not include textiles used in medical, professional, or industrial settings."

⁹ RI bill 2024 – S 2152; Ch. 18.18, Sec. 23-18.18-3.Definitions (link to RI PFAS bill)

A California law that went into effect earlier this year also exempts PPE,¹⁰ and a recent New York law addressing PFAS in apparel exempts "professional uniforms that are worn to protect the wearer from health or environmental hazards, including personal protective equipment."¹¹

ISEA recommends Maine base its definition of PPE on RI's established definition of PPE to align the proposed new Sec. 5(C)(7)(c) exemption:

Personal Protective Equipment means equipment used to minimize exposure to hazards that cause serious workplace injuries and illnesses that may result from contact with chemical, radiological, physical, biological, electrical, mechanical, or other workplace or professional hazards.

ISEA recommends the following definition of safety equipment:

Safety Equipment means "equipment used or intended to identify, evaluate, or provide alerts to hazardous atmospheres."

Both of ISEA's recommendations would make certain workers in Maine will not be without critical protective items, while PPE manufacturers work with their suppliers to understand where PFAS may be present and work to identify and implement alternatives where feasible.

In Maine, approximately 1,800 individuals are employed directly in Maine's logging industry.¹² These 1,800 workers support another 3,800, who support the logging industry. This industry is well known to be among the most hazardous¹³. Loggers use a wide range of PPE and safety equipment, from high visibility shirts and vests, to hearing protection, gloves, chaps and protective footwear. A 2021 study "showed the industry facing mounting challenges including rampant inflation, worker shortages, declining profits and more."¹⁴ An abrupt change in the PPE these workers use would add an unwelcome burden to a critical industry already facing economic stress. In addition, Maine's proposed rule is a medium-range phase-out, during which PPE and safety equipment manufacturers will have time to evaluate where PFAS may be present in their products and work to identify feasible alternatives, as noted above.

Maine's agricultural economy is also facing high production costs, including labor and other inputs.¹⁵ Similarly, an abrupt change to the PPE and safety equipment that keeps Maine's agriculture workforce safe from occupational hazards would be an unnecessary additional stressor.

¹⁰ California Code, Health and Safety Code - HSC § 108970 (a)(1) and (f).

¹¹ NY Environmental Conservation (ENV) CHAPTER 43-B, ARTICLE 37, TITLE 1, § 37-0121 (4)(b)(i).

¹² Professional Logging Contractors; "Economic impact study...," March, 2023

¹³ "Logging is hazardous work" BLS; Compensation and Working Conditions Winter 1998,

¹⁴ Professional Logging Contractors: "Logging and Trucking in Maine- 2021 Economic Contribution," 2023

¹⁵ Maine Agricultural Overview, Sept. 2023. (<u>link</u>)

In Appendix I, ISEA includes examples of PPE and other safety equipment required by OSHA and the Federal Highway Administration to keep workers safe from occupational hazards.

In conclusion, ISEA believes exemptions for PPE and safety equipment make sense. These exemptions will allow the State's workers to remain protected from workplace hazards without abrupt changes to supply.

Thank you for your attention to these comments. I can be reached at <u>cmackey@safetyequipment.org</u> if you or your colleagues have any questions or would like additional information.

Sincerely,

Cam Mackey President & CEO International Safety Equipment Association

Appendix I

Examples of PPE required to be provided to employees as per OSHA regulations:

Hand protection 29 CFR 1910.132 Safety eyewear 29 CFR 1910.133 Fall protection. 29 CFR 1910.140 Head protection 29 CFR 1910.135 Respiratory protection 29 CFR 1910.134 Portable gas detection 29 CFR 1910.146 Firefighter PPE 29 CFR 1910.156

Respiratory Protection (29 FR 1910.134) covers: Filtering Facepiece respirators Elastomeric Half-Mask Respirators Full facepiece respirators Powered air purifying respirators Tight fitting Loose fitting Self-contained breathing apparatus Industrial 29 CFR 1910.156 Firefighting 29 CFR 1910.156

NOTE - OSHA requires all respirators used at work to be certified by the National Institute for Occupational Safety and Health (NIOSH)

Examples of PPE required to be provided to employees as per Federal Highway Administration regulations include:

High visibility safety apparel meeting ANSI/ISEA107-2015 and ANSI/ISEA 107-2020 are required by Federal Highway Administration's Manual of Uniform Control Devices:

Sec. 6C.05 – requires compliance with ANSI/ISEA107-2015

Sec. 7D.05- requires compliance with ANSI/ISEA107-2020



January 28, 2025

Kerri Malinowski Farris Program Manager for Maine's Safer Chemicals Program Maine Department of Environmental Protection 17 State House Station 32 Blossom Lane Augusta, Maine

JP4EE comments to MDEP CONCEPT DRAFT LANGUAGE FOR PFAS IN PRODUCTS RULE POSTING DRAFT under Maine law 38 M.R.S. §1614

https://www.maine.gov/dep/rules/index.html#13139124

Name of the associations which make this input:

The Japanese electrical and electronic industrial associations:

- JEITA (Japan Electronics and Information Technology Industries Association)
- CIAJ (Communications and Information Network Association of Japan)
- JBMIA (Japan Business Machine and Information System Industries Association)

JEMA (Japan Electrical Manufacturers' Association)

The four Japanese electrical and electronic industrial associations – JEITA, CIAJ, JBMIA and JEMA (hereinafter JP4EE) – hereby express gratitude to the Maine Department of Environmental Protection (DEP)'s for years of efforts to preserve, improve and prevent diminution of the natural environment of the State. We conduct our businesses in the US and all over the world and are firmly committed to protecting human health and the environment and to complying with chemical substance legislations as defined by the countries and regions where we operate. Also, we support active prevention or minimizing chemical pollution by hazardous PFAS. In this spirit, we have carefully and conscientiously examined the MDEP CONCEPT DRAFT LANGUAGE FOR PFAS IN PRODUCTS RULE POSTING DRAFT and confirmed some of our comments to the concept draft submitted in August 2024 have been reflected. We would appreciate that MDEP accepted industry's concerns and recommendations which make the regulation feasible. However, since there are still concerns remained in the posting draft, we would like to submit our comments and recommendations here.

We submitted our general comments on the Maine PFAS law at Submission Requirements on Currently Unavoidable Uses (CUUs) conducted in December 2023 and Comment submission to the MDEP CONCEPT DRAFT LANGUAGE FOR

JP4EE comments to MDEP CONCEPT DRAFT LANGUAGE FOR PFAS IN PRODUCTS RULE POSTING DRAFT

PFAS IN PRODUCTS RULE in August 2024. Nevertheless, we would also like to submit them again in attachment 1 to 3 since our basic position is still unchanged and valid.

Also, we would like to submit our comments to each section on the posting draft language published in this time as follows.

JP4EE comments to each section

1. Definition

(i) The definition of "Article" should be newly added to Subsection 1.

"Article" is solid state products and the chemicals in the articles are designed to be kept in the products in many cases. Especially for the longer life products such as electrical and electronic equipment, the performance and safety must be kept during their expected useful life, therefore the users are seldom exposed to chemicals in products in use phase.

In considering such features of the articles, most of chemical laws including the U.S. TSCA set different requirements for them from the chemical products. For example, TSCA PFAS reporting (Section 8(a)(7))has set special conditions for the imported articles in order to make the reporting feasible for the importers. We consider that Maine regulations should align with the U.S. and global handling of the articles in order to smooth distribution of daily-use products.

Our proposal to Subsection 1 A. 10 : We consider the definition of "Article" same as TSCA defined at 40 CFR 704.3 and others. The U.S. EPA proposed this definition also to Section 751.1 of PART 751 "REGULATION OF CERTAIN CHEMICAL SUBSTANCES AND MIXTURES UNDER SECTION 6 OF THE TOXIC SUBSTANCES CONTROL ACT" in May 8th 2024.

https://www.govinfo.gov/content/pkg/FR-2024-05-08/pdf/2024-09606.pdf

Article means a manufactured item

(1) which is formed to a specific shape or design during manufacture,

(2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.

(ii) A. 10. Cookware product.

The scope of "cookware products" should be clarified as non-electric cookware products including those exampled in A-10 such as pot, pan and bowl. The definition of "electronics" proposed by this posting draft language may also be applicable to electric cookware products, because they have electrical, digital, magnetic

or similar capabilities.

In current posting draft language, "Cookware product" is defined as follows;

"Cookware product" as defined at 38 M.R.S. § 1614(1)(A-10) is limited to houseware intended to be in direct contact with food or beverage.

However, in this definition it is unclear whether "houseware" includes electric cookware products.

Electric cookware may have some parts which may be in direct contact with food but is composed of many electronic parts which are non-contact with foods and considered to be currently unavoidable uses (CUU), as other consumer electronics (see our comments in Subsection 4 and 9(iii) below). Please note that our proposal for CUU has included many electric cookware such as Microwave Ovens (GPC 10001952). The currently proposed wording in the posting draft creates a legal uncertainty, that is, if an electric cookware has food-contact-parts and electronic parts which would be considered as CUU, how to treat such cookware under this definition? For example, EU REACH Regulation or RoHS Directive set detailed exemptions within a product, but such operation creates so heavy burden both on the authorities and the industry. MDEP has considered CUU to be set for each product category as a whole which is identifiable by GPC, etc.. On the other hand, MRSA §1614(4) has set the exemptions by broader categories than GPC. We support the ways of setting CUU or exemptions not for the parts or applications in a product level but for the whole product level (i.e. broader categories than GPC).

Following case might be happened for example. If the "cookware products" would include electric cookware, Maine people would not be able to buy any Microwave Ovens on and after January 1st, 2026.

About PFAS in electronic products, we consider as follows:

Firstly, electric products (complex articles) contain very small amount of PFAS if used in the first place. Secondly, exposure of chemical substances from electric products (complex articles) are negligible in normal use since they are designed to be durable so that chemical substances in the article are not exposed to ensure functionality during their long lifetime.

We consider that these are also applicable to electric cookware.

Therefore, as electric cookware poses little risk to human and the environment compared to non-electric cookware, we request that the definition be revised as follows.

Our proposal to Subsection 1 A. 10:

"Cookware product" as defined at 38 M.R.S. § 1614(1)(A-10) is limited to houseware intended to be in direct contact with food or beverage.

"houseware" does not include electric cookware products, such as microwave ovens, are classified as electronic equipment.

3. Notification

(i) Subsection 3. A indicates as follows.

... this prohibition is effective immediately for all covered products, including those already in the stream of commerce. ...

Normally, manufacturers don't have ownership for stocks distributed in the market (i.e. products already in the stream of commerce) after selling their products to distributors and cannot control sales of such stocks. From the perspective of the distributers in Maine, the products which they had already and legally purchased will suddenly become incompliant after the date of prohibition. In such cases, they will be forced to dispose them and owe the cost for it. This might cause confusion in the distribution of consumer electronic products in the State of Maine. In order to make the requirements feasible and manageable for manufacturers of the products and to avoid the possible confusion, we would propose that the prohibition applies to products manufactured after the date of prohibition. This measure will make all the products compliant before they are sold to Maine, and the distributers will be able to keep their business in peace.

Our proposal to Subsection 3. A:

Upon the applicable effective date listed in Section 5 a product containing intentionally added PFAS <u>and</u> <u>manufactured on or after the date</u> is prohibited from being sold, offered for sale, or distributed for in the State of Maine, including any products to which a currently unavoidable use determination may apply...

(ii) Subsection 3A(1)(b) should be more flexible for the imported products and should include consideration of the confidentiality.

Section 3A(1)(b) requests manufacturers to submit an estimate of the "total number of units" sold annually in the State of Maine or nationally. The appropriate unit for such estimation depends on the form or type of the product. Even under TSCA PFAS reporting, which only requires reporting about the past record, allows to select appropriate unit of measurement for reporting of the imported products <u>under § 705.18 "Article importer and R&D substance reporting options"</u>.

In addition, we assume this consists of sales that were made in the past calendar year prior to the notification submission date, but detailed sales plan or estimation generally belongs to each company's confidential business information. Therefore, this item of the individual notification should not be published if the submitter of the notification states that it is confidential.

Our proposal to Section 3A(1)(b):

(b) An estimate of the total number of units sold annually in the State of Maine or nationally. <u>For the products</u> <u>imported from the outside of the United States, such estimation may be reported by using any of the following</u> <u>unit of measurement provided that such unit used in the reporting is clearly specified by using following code</u>:

<u>Code</u>	Unit of measurement	
LB	Pounds.	

JP4EE comments to MDEP CONCEPT DRAFT LANGUAGE FOR PFAS IN PRODUCTS RULE POSTING DRAFT

<u>TN</u>	Tons.
<u> </u>	Quantity of imported products.
<u>0</u>	Other (must specify).

<u>The Department must not publish this part of each notification when the submitter of the notification clearly</u> <u>states that such estimation belongs to business confidential information of the submitter. The data aggregated</u> <u>from the notifications may be published.</u>

(iii) Subsection 3.A.(1)(d) :About the identification of PFAS:

For PFAS substances in which the specific CASRN is unknown, DEP would still require IUPAC chemical name in Section 3A(1)(d)(i) and (ii). However, upstream suppliers may not be able to disclose any more information than that the substances are PFAS due to trade secret (confidentiality) reasons. Especially for many of the article importers, they only purchase the articles and cannot obtain the detailed information on chemical contents in the articles because almost all the global chemical regulations including TSCA do not require Chemical Data Reporting or Safety Data Sheet (SDS) for the articles (Normally, SDS is not created for articles). In that case, we will not be able to obtain such chemical name information and therefore would like DEP to approve a submission that simply indicates the "use of PFAS". More concretely, an option similar to TSCA §705.18 (a) (2) (ii) should be allowed.

Our proposal: Following subparagraph (iii) should be added after the Section 3A(1)(d)(ii):

(iii) If the specific chemical identity of the PFAS imported in a product (an article) is not known to or reasonably ascertainable to the submitter of the notification (e.g. if the chemical identity is claimed as confidential business information by the submitter's supplier, or if the submitter knows they have a PFAS but is unable to ascertain its specific chemical identity), the submitter may provide a generic name or description of the PFAS.

(iv) Subsection 3.A.(1)(e): About the amount of each of the PFAS in the product or any product component:

Section 3A (1) (d) (i) to (iii) requires that the amount of each of the PFAS in the product be determined by analysis or, if this is not possible, the total organic fluorine be reported and, if this is neither possible, the amount shall be reported based on information provided by a supplier or "as falling within a Department-approved range", which seems to be indicated in the online notification system. We would like to ask MDEP for clearly mentioning the range, more concretely, options similar to those under TSCA §705.18 (a) (2) (viii) should be allowed.

The amount of individual PFAS in complex articles cannot be measured by analysis (no commercially available analytical method for PFAS in complex articles), and the analytical method of the total organic fluorine cannot be practically conducted for such articles due to the difficulty of sample preparation. Upstream suppliers may not be able to provide information on PFAS content due to trade secret reason. Even if not, the article purchasers cannot obtain the detailed information on chemical contents in the articles because almost all the global chemical regulations including TSCA do not require Chemical Data Reporting or Safety Data Sheet for the articles as mentioned above.

Our proposal to Subsection 3.A.(1)(e) :

(iii) based on information provided by a supplier or as falling within a range approved by the Department.

For amount of PFAS in the imported products (articles), submitters of the notification may select from among the ranges of concentrations listed in the following table.

TABLE — CODES FOR REPORTING MAXIMUM CONCENTRATION OF PFAS IN AN IMPORTED PRODUCT(ATRICLE)

<u>Code</u>	Concentration range (% weight)		
<u>AM1</u>	Less than 0.1% by weight.		
<u>AM2</u>	At least 0.1% but less than 1% by weight.		
<u>AM3</u>	At least 1% but less than 10% by weight.		
<u>AM4</u>	At least 10% but less than 30% by weight.		
<u>AM5</u>	At least 30% by weight.		

4. Exemptions.

Currently, 38 MRSA §1614(4) and this posting draft exempt only non-consumer electronics regarding electronics products as follows:

- (11) A semiconductor, including semiconductors incorporated into electronic equipment, and equipment and materials used in the manufacture of semiconductors;
- (12) Non-consumer electronics and non-consumer laboratory equipment not ordinarily used for personal, family or household purposes; and

(13) Equipment directly used in the manufacture or development of products described in subsections 5 through 12, above.

We understand that this Subsection is based on 38 MRSA §1614(4) but would like to explain here again that the unfeasibility of the ban of consumer electronics containing PFAS. And we would like to highlight that consumer electronics should be also exempted in addition to exemptions listed in the Subsection 4.

Our proposal to Subsection 4: Following exemption should be added to the Subsection 4 as follows:

(14) Consumer electronics

Detailed explanation on our proposal:

It is important to understand that the technology used in both consumer and non-consumer electronics is nearly identical. As consumer products increasingly require advanced functionality and digitalization, the need for PFAS becomes unavoidable. Current Subsection 4(11) exempts semiconductors, but currently unavoidable uses of PFAS in consumer electronics are not limited to the semiconductor units.

PFAS plays an essential role in modern consumer electronics, providing critical functionalities that cannot be achieved with other materials. Its unique ability to deliver multiple high-level functions simultaneously is the

main reason for its use. These functions include:

- 1. Optical function
- 2. High-speed communication/transmission function
- 3. Piezoelectric function
- 4. Sliding function in mechanical section
- 5. Display function (Liquid crystal)
- 6. Safety and safety functions
- 7. Functional surface
- 8. Semiconductor Note: Exempted by 38 MRSA §1614(4)(K)
- 9. Thin film device production process Note: Exempted by 38 MRSA §1614(4)(M)
- 10. Energy supply (Battery, Fuel cells, Solar cells)
- 11. Refrigeration, Air-conditioning and heat pump sector RACHP (Refrigerant)
- 12. Passive electronic components and manufacturing process Note: Exempted by 38 MRSA §1614(4)(M)

These functionalities are not abstract or generalized; they are the foundation of modern, high-performance consumer electronics. We would like to illustrate this point using mobile phones as an example.

Mobile phones, which are considered to be classified as consumer electronics, are not covered by the exemptions permitted for non-consumer electronics under proposed Subsection 4. In modern mobile phones, PFAS are needed for many purposes, including semiconductors that handle processing power, displays with high power consumption efficiency, high-speed communication that achieves excellent electrical performance, and coatings for durability and protection. Unlike older analog phones, which could be manufactured without PFAS, today's mobile phones cannot be produced without it.

PFAS uses which are currently unavoidable in a mobile phone



If consumer electronics are not exempted, Maine residents may face significant challenges in accessing essential devices like mobile phones, televisions, personal computers, and refrigerators.

We understand that 38 MRSA §1614 and the posting draft provide other measure to cope with this issue, that is, applying "Currently-Unavoidable-Use (CUU)" derogations. However, these technological issues are common to the whole industry and the product categories needing CUU are extremely large in number, as we provided the list before. In addition, many other complicated articles in EEE have been already exempted from 38 MRSA §1614 but only the consumer electronics remain to be regulated. In such situation, we believe that setting a new exemption should be better for both MDEP and the industry, from the viewpoint of avoiding administrative burden, than getting huge number of applications from the industries in many countries and regions.

The use of PFAS in consumer electronics is not arbitrary—it is a necessity. When substituting chemicals in EEE, the performance of the finished products must be guaranteed. This performance requirement persists even when potential alternatives with similar uses exist. PFAS's multifunctionality is unmatched, and its use is restricted to situations where no viable alternatives exist.

Accordingly, if a product model does not require such high performance, it would not be necessary to use PFAS.

JP4EE comments to MDEP CONCEPT DRAFT LANGUAGE FOR PFAS IN PRODUCTS RULE POSTING DRAFT

However, other similar but "high-grade" models may demand higher performance and therefore require PFAS. For example, fixed analog phones could be manufactured without PFAS but current mobile phones cannot be, and the residents in the state of Maine will not be able to purchase the mobile phones within the State if consumer electronics is not exempted nor granted as CUU at least. The situation would be the same for other consumer electronics today such as televisions, personal computers, refrigerators, etc. We are concerned about not only obliging the Maine citizens inconvenience, but also adverse impact to the economy in the state caused by this PFAS prohibition.

Importantly, the necessity of PFAS cannot be distinguished solely by the product category as classified under the Global Product Classification (GPC) system. Moreover, PFAS-based materials are significantly more expensive, often costing several to over ten times more than non-PFAS materials. For this reason, PFAS is only used in applications where its multifunctionality is indispensable and essential to meeting the performance requirements of the product.

In addition to their selective use based on performance requirements, PFAS used in electronics products, whether in consumer or non-consumer applications, have a very low vapor pressure, meaning they do not volatilize at room temperature. These substances are designed to ensure that they remain in the place where they are applied, even under harsh environmental conditions, so that their performance can be demonstrated. As a result, we believe it is highly unlikely that PFASs will be released into the environment from these products during the use phase.

It is also important to note that, according to the European Chemicals Agency (ECHA), the electronics and semiconductor sectors account for less than 1% of PFAS use and emissions. We believe a similar situation exists in Maine. This demonstrates that the environmental impact of PFAS use in electronics is minimal compared to other industries.

Finally, durable, high-performance electrical and electronic equipment is vital for modern society. Without PFAS, it would be nearly impossible to meet the performance demands of modern electronics. Before introducing strict regulations, it is essential to conduct a thorough socio-economic assessment. Such an assessment would ensure that regulations are both feasible and enforceable, avoiding unintended consequences for consumers and businesses alike.

5. Prohibition on Sale of Products Containing Intentionally Added PFAS

Under Subsection 5.H, prohibition provision applies to a retailer who sells, offers for sale or distributes for sale after receiving a notification pursuant Section 8(2). However, for example, it is possible that a company voluntarily notifies a retailer that certain products are subject to prohibition after 2026. Nevertheless, if the retailer continues to sell the PFAS-containing products despite the company's notification, we believe the retailer will be solely liable for violating the prohibition. The rule should specify who is responsible for violations in such

a case.

9. Currently Unavoidable Use.

We would welcome that the DEP clearly specifies the renewal of CUU in the concept draft. In order to ensure the CUU scheme made feasible, we would like DEP to further consider the following issues to be solved.

(i) About the timing of submitting the currently unavoidable use proposals:

In 9.A, the text indicates as follows.

... For initial currently unavoidable use proposals, the requester shall submit the information in this Section no later than 18 months prior to the applicable sales prohibition. The Department will not consider any proposals for an initial currently unavoidable use determination prior to 36 months in advance of the applicable sales prohibition ...

We are concerned that the CUU proposal submitted within the period will not be determined until just before the date of prohibition or even after the date of prohibition. Also, we are seriously concerned that there is a possibility of causing disruption of the supply chain because of not immediately completing substitution of components containing PFAS in target products and/or inconvenience for the Maine citizens because of not providing necessary products if the CUU proposal would not be granted just before / even after the date of prohibition. A manufacturer who submitted the CUU proposal believes the proposal is to be granted and can continuously distribute the products containing PFAS. He submits the CUU proposal because substitution is impossible. While he must continuously study and examine substitution of PFAS, it cannot be immediately achieved. If the proposal would be rejected, he cannot immediately substitute the PFAS.

As a precedent of prohibiting substances in complex articles, EU RoHS Directive, which is now recognized as defacto standard for the restriction of hazardous substances in EEE, has an exemption clause for certain uses. RoHS Directive requires to submit renewal application by 18 months before the end of validity period, but the exemption is kept valid even after the validity period during the period of examination of the application. Furthermore, even if the application is not granted, the restriction is not immediately applied but the maximum of 18-month transition period will be given from the decision. In reality, many of the renewal applications which were submitted before January 2018 because July 2020 was the end of validity period are not determined whether the renewal is granted even now (i.e. more than 6 years are passed from their submission).

We recognize that PFAS have more than 10,000 substances and are used in various essential uses. While we cannot estimate how many CUU proposals will be submitted, in order to minimize such confusion, we would like to propose that, at least, followings are clearly indicated in the text.

- 1. CUU is tentatively granted during examination of the CUU proposal by MDEP
- 2. Appropriate transition period is given in case of not granting the CUU proposal

10

JP4EE comments to MDEP CONCEPT DRAFT LANGUAGE FOR PFAS IN PRODUCTS RULE POSTING DRAFT

Furthermore, proposed timeframe for submission of CUU proposals is quite concerning since the uses of PFAS and PFAS alternatives are still being studied. There should be enough time between DEP's decision and the prohibition date to allow manufacturers to amend the CUU proposal as necessary, or to prepare for the upcoming prohibition. We would request DEP to initiate an examination for CUU proposals which we submitted in February 2024 without waiting until 36-month before.

(ii) About the scope of the CUU proposals: Broader scope should be accepted especially for the complicated manufactured items such as electronics.

MDEP proposed Subsection 3(c) as follows:

C. A manufacturer may submit a single notification to the Department for multiple products if all of the products are covered by the same currently unavoidable use determination found in section 9(B).

To minimize the burden in MDEP and the industries, we would like the CUU proposals can be submitted more broadly, and should not be based on HTS/GPC and NAICS combinations. Due to the ubiquitous nature of PFAS, we would like proposals to be based on industry sector instead (e.g. electronics sector). In most cases, the reasons of PFAS use are almost the same in many EEE categories and it is also very common to EEE that very small amounts of PFAS contained is unlikely exposed outside EEE because of the necessity to maintain the required quality and functionality over the long period of use. Therefore, if CUU is determined for each HTS/GPC code, huge number of CUU applications would be necessary despite the same uses, and DEP would have to verify the approval of CUU for all those applications . Furthermore, importers of consumer electronics in the state of Maine would result to have to owe heavier application cost.

In order to solve this problem, it is desirable to allow CUU determination proposal at a higher level which is similar to the scope of the exemptions. As described in the attachment, PFAS is used in electronics to provide other functions which are essential to the operation of the electronics in addition to low refractive index and heat resistance, and almost all the electronics will be subject to CUU. Therefore, we believe that it is desirable to grant CUU for the consumer electronics field as a whole.

(iii) Our proposal for CUU has already been submitted in February 2024.

As mentioned above, we understand that the comments submitted in the request for comments on CUU in February 2024 are the "proposal for CUU determination by manufacturers" described in section 9A of this Concept Draft, and we request that the CUU be determined based on this proposal. If it is necessary for manufacturers to propose CUU in addition to this, the impact on manufacturers, who need to bear enormous application work and fees, will be immense.

After submission of our comments on CUU above, MRSA §1614 (4) is revised and following items are added to exemptions:

K. A semiconductor, including semiconductors incorporated in electronic equipment, and equipment and

materials used in the manufacture of semiconductors;

L. Nonconsumer electronics and nonconsumer laboratory equipment not ordinarily used for personal, family or household purposes; and

M. Equipment directly used in the manufacture or development of the products described in paragraphs E to L.

As we explained in our comments to Subsection 4, CUUs of PFAS in electronics are not limited to the semiconductors. Though these technological issues are common to the whole industry and many other complicated articles have been already exempted from 38 MRSA §1614 but only the consumer electronics remain to be regulated. In such situation, we believe that setting a new exemption should be better for both MDEP and the industry, from the viewpoint of avoiding administrative burden, than getting huge number of applications from the industries in many countries and regions.

However, if it is not possible to set a new exemption in Subsection 4, the setting a CUU to all the consumer electronics would be indispensable as the second-best measure.

Therefore, we would like to highlight that the CUU entries we have submitted in February 2024 will hardly be reduced by the revision of MRSA §1614 (4).

(iv) CUU which is submitted by an individual company or group and granted by the DEP should be able to be used by all other entities using the granted uses. We would request to clearly stipulate it in this rulemaking.

We understand that CUU granted will be listed in Section 9(B) and a person other than the submitter can utilize the CUU as long as the same combination of industry sector and product category. We would like to request MDEP to clearly indicate it in the Rule.

For complex articles like EEE, if intentionally added PFAS is contained to a part, such PFAS is most likely not added by the manufacturer of the final product but an actor in far upstream supply chain. A PFAS used in a certain use in a certain product category by a manufacturer is most likely used in the same use in other product categories by other manufacturers. Also, the reason not being able to substitute the PFAS in the use is not basically different. It is simply increasing workload for both industries and the DEP if it needs CUU application each and it needs to examine each application. Therefore, in order for balancing between achievement of policy objectives and effective implementation, it is desirable to apply the use of PFAS granted as CUU to all those who utilize the use in addition to enable CUU application in as high level as possible mentioned above.

EU RoHS Directive, de facto standard of the restriction of certain hazardous substance in EEE, also has the exemption clause. Even under EU RoHS, an exemption granted can apply to all entities using the exemption.

Conclusion:

We hope our input would provide substantive information to ensure the smooth and practical implementation of PFAS management to realize a healthy environment and a sustainable economy for the present and future generation in the State of Maine.

We wish to work together with the MDEP to make the Act and the Rule feasible for implementation. Should you have any questions, please do not hesitate to contact the JEITA secretariat.

Sincerely yours,

Koji Ueno

Koji Ueno Senior Manager for Green Innovation Business Strategy Division Japan Electronics and Information Technology Industries Association (JEITA) Ote Center Bldg.,1-1-3, Otemachi, Chiyoda-ku, Tokyo 100-0004, Japan TEL +81-70-3297-8599 <u>koji.ueno@jeita.or.jp</u>

About Japanese electrical and electronic (E&E) industrial associations:

About JEITA

The objective of the Japan Electronics and Information Technology Industries Association (JEITA) is to promote the healthy manufacturing, international trade and consumption of electronics products and components in order to contribute to the overall development of the electronics and information technology (IT) industries, and thereby further Japan's economic development and cultural prosperity.

About CIAJ

Mission of Communications and Information network Association of Japan (CIAJ). With the cooperation of member companies, CIAJ is committed to the healthy development of info-communication network industries through the promotion of info-communication technologies (ICT), and contributes to the realization of more enriched lives in Japan as well as the global community by supporting widespread and advanced uses of information in socio-economic and cultural activities.

About JBMIA

Japan Business Machine and Information System Industries Association (JBMIA) is the industry organization which aims to contribute the development of the Japanese economy and the improvement of the office environment through the comprehensive development of the Japanese business machine and information system industries and rationalization thereof.

About JEMA

The Japan Electrical Manufacturers' Association (JEMA) The Japan Electrical Manufacturers' Association (JEMA) consists of major Japanese companies in the electrical industry including: power & industrial systems, home appliances and related industries. The products handled by JEMA cover a wide spectrum; from boilers and turbines for power generation to home electrical appliances. Membership of 291 companies, http://www.jema-net.or.jp/English/

PFAS in Electrical and Electronic Equipment (EEE)

Four Electrical and Electronic Industry Associations in Japan (JP4EE)



1. PFAS in Electrical and Electronic Equipment (EEE)

The Japanese EEE industry

has consistently supported actions to reduce risks from hazardous substances, and

 has taken practical measures in a serious and diligent manner to meet the requirements of global chemical legislation such as EU REACH Regulation.
e.g.: Establishing and utilising <u>chemSHERPA</u> for smooth and effective communication of chemical information between companies throughout the supply chain.

> The use of PFAS remains unavoidable in a wide variety of EEE

- Due to the high cost of PFAS-based parts and materials, we only use them only where the **multi-functionality** of PFAS is required to meet the performance requirements of EEE, making it extremely challenging to find alternatives for current applications.
- When substituting chemicals in EEE, the performance of the finished product must be warranted. Performance matters, even when there are potential alternatives with similar uses.

The electronics and semiconductor sectors account for less than 1% of PFAS uses and emissions.

Durable, high-performance EEE is essential to modern society and requires close consideration from a socio-economic perspective, feasible and enforceable.

2. Multi-functionality of PFAS₁₄ (Not satisfied with a blend of alternative materials)



- e.g. Printed Circuit Board in a Mobile Phone System The component needs
- Low dielectric constant
- Heat resistance
- Flame retardancy

There may be alternative materials that satisfy each specific property, but... - Formulating a functional blend of alternative materials is in most cases, extremely challenging in practice.

Depending on the property, it is the worst property from the constituent materials that determines the final properties of the blend.

	Material A (e.g. PPE)	Material B (e.g. PI)	Material C (e.g. Br-based material)	blend of Material A/B/C	Fluorinated material
Low dielectric constant	0	\bigtriangleup	×	$\triangle \sim \times$	\bigcirc
Heat resistance	\bigtriangleup	\bigcirc	—	$ riangle \sim imes$	0
Flame retardancy	×	×	\bigcirc	\bigcirc	\bigcirc

 \bigcirc =Excellent; \bigcirc =good; \triangle =not good; \times =bad
3. Complexity of the Supply Chain of EEE and Related Sectors

EEE consists of many components & parts, and each component or part has its own complex supply chain as shown below.



C. Electrical & Electronic Equipment Manufacturers

4. Wide Variety of EEE

A wide variety of EEE (both B2C and B2B) with different applications exist, many of which require the use of PFAS to achieve their essential functions. A "One fits all" prohibition of EEE is not feasible.

416



1.Large household appliances



2.Small household appliances



3. IT and telecommunications equipment



4. Consumer equipment



5. Lighting equipment



6. Electrical and electronic tools



7. Toys, leisure and sports equipment



8. Medical devices (exempted from 38 MRSA \S 1614)





10. Automatic dispensers







11. Other EEE not covered by any other categories

9. Monitoring and control instruments Industry uses (exempted from 38 MRSA $\ \S$ 1614)

5. Functions of PFAS required in EEE

PFAS's **multi-functionality** is the most important reason for their use in EEE and cannot be achieved by othe<u>r potential alternatives</u> in most cases.

1. Safety and safety functions



- 3. Sliding function in mechanical section
- 4. Piezoelectric function
- 5. Display function (Liquid crystal)
- 6. Optical function
- 7. Functional surface
- 8. Semiconductor Exempted from 38 MRSA §1614
- 9. Thin film device production process Exempted from 38 MRSA §1614

Pressure Sensor

(Smart watch)

security camera

- 10. Energy supply (Battery, Fuel cells, Solar cells) Industry uses are exempted from 38 MRSA §1614
- 11. Refrigeration, Air-conditioning and heat pump sector RACHP (Refrigerant)
- 12. Passive electronic components and manufacturing process-Exempted from 38 MRSA §1614









6. Many uses of PFAS are currently unavoidable

Mobile phones contain a wide range of electronic parts. Many of those parts contain PFAS as listed below.

Antennas 2. High speed communication **Optical Lens. Actuator** Liquid crystal panel and transmission function Image sensor, LEDs etc. or OLED 1. Optical function 5. Display function 3. Piezoelectric function 8. Semiconductor Touch screen Printed Circuit Board, 3. Piezoelectric function Cable 2. High speed communication Enclosure and transmission function 6. Safety and 6. Safety and safety functions safety functions 8. Semiconductor 12. Passive electronic components Coating of and manufacturing process smartphone surfaces **Coating of Electric** Components 7. Functional surface 7. Functional surface **Touch Sensor** Flexible substrate Fingerprint sensor 2. High speed communication Gyroscope and transmission function etc. 9. Thin-film device manufacturing process Speaker, Microphone Batterv 3. Piezoelectric function 10. Energy supply Vibrator motor Sealing material 4. Sliding function in mechanical section Lubricant. 6. Safety and safety functions Sealing material (SIM/SD tray)

The numbers are linked to the essential functions in "Functions

of PFAS required for EEE" in our

comment.

4. Sliding function in mechanical section

7. PFAS Contribute to Safety and safety functions

Insulating and anti-dripping materials need the multi-functionality of PFAS.

Required functions/properties of EEE: Electric insulation, drip-prevention, heat resistance, durability **Required functions for materials:** Low dielectric constant, flame retardancy, chemical resistance, etc.



8. PFAS Contribute to High-speed Communication/Transmission Functions

PFAS are the only compounds that provide multi-functionality required by electronic parts for high-frequency applications as shown below:

Required functions and properties of EEE : Low dielectric constant at high frequencies and low transmission loss

Low dielectric

constant

Low

transmission

loss

╋

Water and oil repellency

Flame retardancy

Required functions for materials : Water and oil repellency, flame retardancy, etc.

Examples of parts which need the use of PFAS:



9. PFAS Contribute to the Sliding Eunction in Mechanical Sections

PFAS are the only compounds that can simultaneously provide multiple functions necessary for EEE as well as manufacturing equipment of components for such EEE **to properly work under various environments**.

Required functions and properties: Lubricity, abrasion resistance, machineability (elasticity) **Required functions for materials:** Low water absorption, low moisture permeability, etc.



10. Why cannot blend of materials achieve the necessary specifications that multi-functional PFAS has?

(1) It is difficult to blend the different materials.

(2) Even if blending is successful, material with poor properties makes the mixture property impossible to achieve the desired properties. (Blend of materials shows not the best of the property of each original material has but the worst of each.)

For example;

Heat resistance Light/weather resistance

Chemical resistance

(The material with **poorest property** will decompose first, making the blend unsatisfied the specification)

Low refractive index
 Low dielectric constant / low dielectric tangent
 Oil repellency
 (Blended materials will lower its property)

Cleanliness
 (Blend will leach additives, fluoropolymers don't need additive)

11. Difference of blended material vs fluorinated material

Blended material



The material with the worst property deteriorates, and the blended material (overall product) no longer meets the specifications.

Fluorinated material



No change



28th January, 2025

To: Ms. Kerri Malinowski Farris Maine Department of Environmental Protection (DEP) 17 State House Station Augusta, Maine 04333 (Submitted via email to: pfasproducts.dep@Maine.gov)

JRAIA's Request to Maine Department of Environmental Protection (DEP) regarding Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS)

The Japan Refrigeration and Air Conditioning Industry Association (JRAIA) representing manufacturers of refrigeration and air conditioning equipment in Japan, and its member companies are committed to maintaining and improving living standards by providing environmentally sustainable refrigeration and air conditioning products/services for human comfort and industrial processes.

We would like to comment regarding the Maine Department of Environmental Protection's (DEP) posting draft "Ch. 90 Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances" in compliance with amended The Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution (38 M.R.S. §1614).

HVACR and water heating equipment provides critical services to society by providing life-saving climate control and ventilation in most buildings, notably homes, hospitals, schools, and elder care facilities. The cold chains for both food and medicines, such as vaccines, depends on transportation and storage provided by transport and commercial refrigeration equipment manufactured by our members.

JRAIA members greatly appreciate DEP's response to feedback on the proposed regulations. We thank DEP for exempting a critical electrical component (semiconductors) and for exempting product components incorporated within complex products from the notification requirement. JRAIA continues to note the practical challenge of complex product manufacturers complying with the proposed regulations.

Merely identifying the use of chemicals in supply chains is an exceptionally challenging and often unsuccessful task for manufacturers of complex systems, due to the general lack of transparency around component composition and the number of chemicals (approximately 9,000) included in the overly broad definition of PFAS the State of Maine continues to use as the basis for this regulation. This is exacerbated by confidentiality claims by component manufacturers and suppliers and the lack of clarity on whether this regulation will impact chemicals embedded in the polymer matrix of equipment components.

JRAIA urges Maine to focus its efforts on the regulation of PBT chemicals in high-exposure products.

Although the key focus of Maine's legislation is persistent, bioaccumulative, and toxic (PBT) PFAS that pose a risk to human health and the environment, Maine's definition of PFAS implicates a much broader group of chemicals that do not all share these three critical properties. For example, the low global warming refrigerants used in HVACR and water heating systems are not persistent or bioaccumulative, and they have low levels of toxicity. Moreover, HVACR and water heating products are hermetically sealed and tend to have a useful life over 15 years. Refrigerants and HVACR and water heating technology provide lifesaving heating and cooling and is integral to the cold chain for both food and medicine. These technologies are also vital to the decarbonization of our society. Additionally, certain polymers that meet Maine's definition of PFAS (i.e., fluoropolymers such as polytetrafluoroethylene (PTFE)) are used in a wide variety of products with unlikely potential for human or environmental release or exposure during use of the product, therefore, presenting minimal risk associated with the actual product itself.

Maine's broad definition of PFAS includes approximately 9,000 known chemicals. Even for industries with strong knowledge of the chemical make-up of components, it is extremely difficult to ensure an accurate dataset of chemicals within their supply chains. The HVACR and water heating industry must request, accumulate and summarize chemicals in components to even determine if their final products contain PFAS



to fully understand the effects of these draft regulations. Focusing the legislation on the non-polymer PBT PFAS will ensure Maine is able to protect human health and the environment from PFAS pollution, without putting unnecessary and ineffective burden on industries whose products may contain low-exposure PFAS that are not persistent, bioaccumulative, or toxic.

JRAIA would like to thank Maine for excluding new equipment use refrigerants and servicing-use refrigerants of HVACR equipment. JRAIA also thanks Maine for excluding refrigerants subject to acceptable use conditions pursuant to the U.S. Environmental Protection Agency's (EPA) Significant New Alternatives Program (SNAP). This will allow Maine consumers continued access to the newest generations of low global warming potential refrigerants and refrigeration equipment.

JRAIA urges DEP to clarify the definition of "Cooling, heating, ventilation, air conditioning or refrigeration equipment."

While we appreciate Maine's creation of a category of "Cooling, heating, ventilation, air conditioning or refrigeration equipment," this wording creates regulatory ambiguity for the HVACR and water heating industry. This category does not specify that water heating, water cooling, dehumidifiers, air cleaners, and all other space conditioning equipment are also included in the scope of the category. JRAIA requests the DEP to clarify if the scope of "cooling, heating, ventilation, air conditioning or refrigeration equipment" includes all equipment used to improve the indoor air environment or if it has a narrower scope.

JRAIA notes that some HVACR and water heating applications are not regulated under EPA's SNAP and would request that DEP provide a compliance pathway for product which utilize these refrigerants that are not covered under EPA's SNAP.

JRAIA urges DEP to amend its language regarding the effective date of the regulation.

JRAIA is concerned with language in the draft regulation stating DEP's intent to make the prohibition of products containing intentionally added PFAS effective immediately for all covered products, including those already in the stream of commerce. JRAIA strongly recommends DEP amend the prohibition to be effective on products containing intentionally added PFAS entering the stream of commerce at a date no earlier than one year from the publication of the final rule based on the manufacture date of the product. This kind of advanced notice would allow affected parties to contact suppliers and gather the most accurate data available to report to DEP. Additionally, without this lead time, inventory can become stranded causing a shortage of equipment and increasing costs to consumers in Maine. This additional time will also allow DEP to effectively staff and train the personnel who will manage reporting and certification requirements. JRAIA notes this is a common practice for chemical reporting. EPA finalized a one-year information

collection period following the effective date of Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, which was then followed by a six-month reporting period. Thus, reporting forms were to be due a total of 18 months following the effective date of EPA's rule.

JRAIA requests DEP to clarify the exclusion of embedded components in the regulation.

AHRI's Directory of Certified Product Performance lists over 4 million unique products with over 9 million new products sold and installed annually in homes and businesses. Members must parse through tens of thousands of stock-keeping units (SKUs), each having hundreds of associated components and spare parts, to better understand whether their products will be affected by this draft regulation.

Collectively, this introduces hundreds of millions of potential chances for any given component to contain one of the thousands of PFAS included in Maine's PFAS definition. JRAIA's members have discovered in previous chemical reporting that frequently, component suppliers are unable to disclose the chemical composition of their components to their manufacturer customers, as the chemical composition is confidential intellectual property. While the draft regulations provide a process by which suppliers may substantiate these claims, JRAIA believes compliance challenges will inevitably complicate and delay the implementation of this regulation.

Chemicals in HVACR components are not disposed of in waterways, nor do they result in exposure through drinking water. The burden for this type of regulation would be impossible or nearly impossible for



manufacturers to comply with. JRAIA notes that components used in HVACR are not generally accessed by the public.

JRAIA requests DEP to clarify the definition of "complex product" in the regulation.

JRAIA also notes that DEP does not define "complex product" in this regulation. JRAIA requests DEP consider clarifying the definition of "complex product" to align with Directive 98/71/EC OF THE European Parliament and of the Council (Directive - 98/71). Directive - 98/71 defines "complex product" as a product which is composed of multiple components which can be replaced permitting disassembly and reassembly of the product. It is important to address the definition of complex products to remove any ambiguity as to the reporting requirements.

Products or components containing de minimis levels, less than 0.1% by weight, of any PFAS should be exempt from the regulation.

PFAS in electrical and other components are difficult for manufacturers to track. Manufacturers have limited visibility and control over complex, multi-tiered, global electronics supply chains. Manufacturers must rely on the accuracy of reporting from every supplier throughout their entire supply chain on trace amounts of a chemical, even those that are present unintentionally. JRAIA notes there are common components in use by the HVACR and water heating industries that could be manufactured at the same facilities producing components for industries that can contain PFAS. This could result in unintentional cross-contamination and the continued presence of de minimis quantities of PFAS in components used in HVACR and water heating equipment. We continue to urge DEP to exempt articles that contain only de minimis quantities of PBT or non-PBT PFAS of 0.1% by weight or less, which will allow for a practicable regulation that is reasonably implementable. Not having a de minimis exemption puts an unreasonable burden on manufacturers, and therefore, DEP should provide permanent regulatory relief.

Conclusion

JRAIA thanks DEP for incorporating our previous feedback to acknowledge the complexity of HVACR and water heating products and the critical role they serve in the functioning of modern society.

JRAIA thanks DEP for the opportunity to comment on the Posting Draft for the Maine PFAS in Products Program and requests a discussion regarding ways to protect public health and the environment while considering the practical challenges to compliance with this concept draft.

We would be happy to provide any further information you may require.

Best Regards,

their late.

Koji Hatano Deputy General Manager, International Affairs Department The Japan Refrigeration and Air Conditioning Industry Association (JRAIA) Email: <u>iraia-global@jraia.or.jp</u>

About JRAIA

The Japan Refrigeration and Air Conditioning Industry Association (JRAIA) was originally established in February 1949 as the Japan Refrigerating Machine Manufacturers Association which was thereafter reorganized in February 1969 to become an incorporated association and renamed as it is at present.

JRAIA is the industry association representing over 160 manufacturers of refrigeration and air conditioning equipment in Japan. We, the members of JRAIA, have so far been dedicated to offering quality products to the global markets including the U.S. JRAIA aims to promote and improve production, distribution and consumption of refrigeration and air conditioning equipment and their applied products, as well as auxiliary devices and components, automatic controls and accessories and thereby contribute to the steady development of Japanese industry and the improvement in people's standard of living.

For more information, please see JRAIA's website: <u>www.jraia.or.jp</u> Email: jraia-global@jraia.or.jp From: Judith Gonzalez <Judith.Gonzalez@yageo.com>
Sent: Thursday, January 23, 2025 3:37 PM
To: DEP Rule Comments <RuleComments.DEP@maine.gov>
Subject: Comment on Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

EXTERNAL: This email originated from outside of the State of Maine Mail System. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Subject: Comment on PFAS Regulations - Definition of "Electronics" and "Semiconductors"

Dear Maine Department of Environmental Protection,

We appreciate the opportunity to provide input on the proposed PFAS regulations published on December 20, 2024. We have reviewed the definitions included in the proposal and would like to seek clarification on the following points:

- Definition of "Electronics": We noticed that "electronics" is included in the definitions, however the definition is very broad. We would like to understand whether this definition is intended to capture passive electronic components, such as our primary product line of capacitors. If the definition of "electronics" is not intended to capture passive electronic components, we would further request confirmation of whether the definition of "semiconductor" is intended to capture passive electronic components.
- 2. Scope of Exemptions: We are seeking confirmation of whether our capacitor products are within the scope of the Exemptions described in the proposed Chapter 90 Rule. Capacitors are passive electronic components used for the purpose of electrical energy storage. Capacitors are ubiquitous to all electronics industries, including automotive, computer, telecommunications, green energy, defense, consumer, industrial, medical, aerospace, and more. Given the critical role of capacitors in all electronics applications, we believe it is important to ensure that they are appropriately classified.

We respectfully request that the Department consider providing more detailed guidance on these definitions to avoid any ambiguity. Additionally, we suggest that capacitors be explicitly mentioned in the exemptions if they meet the criteria for Currently Unavoidable Use (CUU).

Thank you for your attention to this matter. We look forward to your response and are available for any further discussions or clarifications.

Best Regards,

Karina Judith Gonzalez Director – Environmental Compliance and CSE KEMET T: 864-963-6698 (USA) | 81 8329-7955 ext. 6698 (MX) Judith.Gonzalez@yageo.com kemet.com



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If you have received this e-mail and it was not intended for you, please let us know, and then delete it.

We thank you for treating our confidential information in a courteous and professional manner.



MEMORANDUM

TO:	Maine Board of Environmental Protection
FROM:	Cathy Breen, Director of Government Affairs
DATE:	January 28, 2025
RE:	Comments on Draft Rule on Public Law 2021, c. 477, (LD 1503, 130th Legislature)

Thank you for taking the time to read these comments regarding the draft rules related to Maine's recent PFAS legislation.

- Under the definition for "Commercially available analytical method" the Department states that "Commercially available analytical methods do not need to be performed at a third-party laboratory." Unfortunately, the chemical industry has a poor track record of policing itself on whether or not their products cause harm. As a result, the state's interest in public health and safety requires a third-party laboratory in this section.
- 2. Regarding section A(4)(e) "A comparison of the known risks to human health and the environment between PFAS and the materials identified in Subsection a," this draft rule is not consistent with the intent of the legislation. The legislature understood that there are harms caused by these chemicals, and that's why it voted to eliminate them to the greatest extent possible in Maine. It did not enact a "risk-based" framework but rather an "essential use-based" framework. A "risk-based" framework opens the door to unnecessary and unintended CUU designations, and that is not what the law intended. The rules need to stick with the "essential use" framework.
- 3. Under the definition of "cookware," it should not exempt products used to prepare food outside of household settings. "Cookware" should apply to foods prepared in commercial and/or industrial settings. This is consistent with the intent of the legislation.

January 28, 2025



Melanie Loyzim Commissioner, Maine Department of Environmental Protection 17 State House Station Augusta, ME 04333

Re: Comments on Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances and Currently Unavoidable Use Determinations

Dear Commissioner Loyzim,

On behalf of the Maine Organic Farmers and Gardeners Association (MOFGA), I am pleased to submit these comments on Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances and specifically, on provisions relating to "Currently Unavoidable Use" determinations. In general, MOFGA supports the draft, which is part of a long-overdue implementation of Maine laws intended to "turn off the PFAS tap" and eliminate future PFAS contamination at the source. We do have several suggestions to clarify the rule and ensure that the regulations reflect the language and intent of the underlying enabling statutes.

About MOFGA.

A broad-based community, MOFGA is transforming our food system by supporting farmers, empowering people to feed their communities, and advocating for an organic future. MOFGA certifies 537 organic farms and processing operations representing roughly \$120 million in sales. We're working hard to create opportunities for Maine's next generation of farmers. Each of these farmers is a Maine businessperson for whom economic health and environmental health are interdependent.

MOFGA'S interest in the rulemaking.

MOFGA has a strong interest in this rulemaking. Unfortunately, adhering to organic practices provides no guarantee that PFAS contamination won't impact an organic farm business. Whether organic or conventional, farms can produce contaminated crops and animal products, and farm families are vulnerable to health problems, if using drinking and irrigation water contaminated with PFAS, contaminated feed, or growing crops on soils once spread with PFAS-contaminated sludge. Since 2016, when PFAS was first found to have contaminated water, milk and soils at a Maine dairy farm, MOFGA has been on the front lines working with farmers experiencing PFAS contamination of farmland.

According to Maine Department of Environmental Protection (DEP or the Department) reports, of October 30, 2024, 82 farms, both conventional and organic, have been affected by PFAS contamination, with 5 going out of business as a result, and 3 more with substantially diminished



businesses. 66 farms exceeded the Maine Department of Agriculture, Conservation and Forestry (DACF) soil screening level, and 35 farms exceeded Maine's interim drinking water standard.¹ Both conventional and organic farms have been affected. Farm families have been tested and found to have unimaginably high levels of PFAS in their blood.

PFAS contamination has been costly. Maine's investigation of PFAS contamination is ongoing, and additional farms are likely to be found to be contaminated as the Department continues its investigatory work through 2025 and subsequent years. Since July 1, 2018 through the end of 2024, DEP spent close to \$20 million investigating contamination from land-based sewage sludge and septage applications and paying for drinking water filtration systems for residential wells contaminated with PFAS from sludge or septage spreading.²

Annual costs for DEP's PFAS investigation and drinking water remediation are expected to rise substantially as additional contamination is discovered and as stricter federal drinking water standards are enforced. The Department's recent status report determined that it would cost the state over \$1.3 billion to furnish every private well owner in Maine with a whole-home filtration system, and annual maintenance and monitoring costs for these systems could amount to almost \$1.9 billion annually.³ This figure doesn't include the costs to community drinking water systems, many of which are also contaminated with PFAS. Whether the cost is paid by the State with taxpayer funds, or locally through property taxes, or by individual households, Maine is paying a high price for PFAS contamination of drinking water caused by PFAS in products which ends up contaminating sewage sludge, landfill leachate, and ground and surface waters.

These eye-popping figures don't include the costs of addressing agricultural impacts. As of March 2024, more than \$2,657,000 has been provided by DACF for financial assistance to farmers impacted by PFAS contamination. This funding includes \$1,413,000 to 10 farms for income replacement; \$884,000 to 11 farms to support farm viability and infrastructure (including funding for clean feed, new equipment, greenhouses, water delivery, fencing); and \$96,000 for 5 water filtration systems.⁴ Ongoing, Maine has established a PFAS Fund to assist farmers,⁵ with initial funding of \$65 million (60M from state funds, 5M from the U.S. Department of Agriculture).⁶

This costly PFAS burden has directly impacted MOFGA as an organization. MOFGA has expended significant staff time and financial resources helping farmers deal with the devastating consequences of PFAS contamination, including by fundraising and administering with the Maine Farmland Trust an emergency relief fund as a bridge to the State's efforts to stand up publicly funded assistance.⁷ Through this fund, financial assistance has been provided to more than 100 Maine farmers to investigate PFAS contamination risks, and to help farmers and farm workers cope with stress related

¹ Legislative briefing January 22, 2025 and Maine Department of Environmental Protection, "Status of Maine's PFAS Soil and Groundwater Investigation at Sludge and Septage Land Application Sites" (January 15, 2015), p.19,

https://www.maine.gov/tools/whatsnew/attach.php?id=13144983&an=1

² Status of Maine's PFAS Soil and Groundwater Investigation, p.39

³ Status of Maine's PFAS Soil and Groundwater Investigation, p.48

⁴ Maine Department of Agriculture, Conservation and Forestry Update, January 31, 2024, https://legislature.maine.gov/doc/10699 ⁵ https://legislature.maine.gov/legis/statutes/7/title7sec320-K.html

⁶ Maine PFAS Fund Plan (2023), <u>https://www.maine.gov/dacf/ag/pfas/docs/pfasfund/admin-plan-pfas-fund-final.pdf</u>

⁷ https://www.mofga.org/pfas/pfas-emergency-relief-fund/

to contamination. It is anticipated that at least \$80 million will be needed to address just the agriculture-related costs of PFAS.

MOFGA's Comments.

Given the economic, health and environmental havoc already caused by widespread PFAS contamination of soils, water, food, people and the natural environment, further regulation is needed – not only to investigate and clean up past PFAS pollution, but to prevent future harm caused by this ubiquitous and persistent family of chemicals. For this reason, MOFGA supports Chapter 90, which is aimed at eliminating PFAS at the source. We do, however, recommend some changes in the posting draft to more closely align with legislative intent and ensure the rule doesn't create loopholes.

Comments on definitions.

<u>"Chemically formulated</u>." This definition is never used in the body of this rule, although it is used (but not defined) in PL 2023, c. 630, which the rule is intended to implement. In the statute, it is used in the context of "air care products" and "automotive maintenance products." Without context, it is hard to comment on the appropriateness of this definition within the rule.

<u>"Clothing item.</u>" This definition excludes footwear, scarves and other clothing that is worn on or about the human body. This definition is narrower than, and inconsistent with, the legislation this rule is supposed to implement. PL 2023, c. 630 bans "textile articles" as of January 1, 2026, and shoes and other articles of clothing excluded in DEP's draft rule are not excluded from the definition of "textile articles" in the law, which also does not include a separate definition of "clothing." The only apparel exclusion in the law for textile articles is for "outdoor apparel for severe weather conditions." [38 M.R.S. §(1)B-1(7)(a)] This definition should be revised to be consistent with the law, which covers any item of clothing except for some outdoor apparel, for which separate criteria apply.

"<u>Commercially available analytic method</u>. "This definition, when cross-referenced with the notification provisions of the rule, §3.A(1)(e), would allow manufacturers to self-test for the amount of each of the PFAS in the product or any product component. This testing would determine whether the product is covered by Maine's law or not – a test showing no PFAS would bypass requirements in the law to manufacture the product with alternatives – as well as various notification provisions when the amount of PFAS in a product changes. This testing should be conducted by an independent, third-party laboratory, which the proposed rule doesn't require.

"*<u>Consumer products.</u>"* This definition isn't in the law and isn't used elsewhere in the proposed Rule 90. What is the purpose of this definition? It appears to be surplusage and should be deleted.

"<u>Cookware product</u>." This definition is inconsistent with the law, which did not carve out an exemption for commercial cookware, see 38 M.R.S. §1614(1)A10. What would be the justification for this distinction, given the potential exposure of the public, as well as restaurant and food service workers? What about school kitchens? The law specifically focuses on the need for enhanced protections for children from products designed for their use. There is nothing in the law that indicates that the Legislature did not intend to regulate commercial cookware.

"*<u>Cosolvent</u>."* This definition isn't in the law and isn't used elsewhere in the proposed Rule 90. What is the purpose of this definition? It appears to be surplusage and should be deleted. If there is a reason

for it, then it should be revised to delete "in small amounts" so that it reads: "Cosolvent" means substances added to a primary solvent to increase the solubility of a poorly soluble compound." Otherwise, it unnecessarily limits the application of the definition.

<u>"Fluorinated container</u>." The law includes a prohibition on the sale of "products listed in subparagraphs (1) to (9) that do not contain intentionally added PFAS but that are sold, offered for sale or distributed for sale in a fluorinated container or in a container that otherwise contains intentionally added PFAS." 38 M.R.S. §1614(5)B-1. The proposed rule limits the prohibition to fluorinated containers where the container has been treated with fluorine atoms "to create a permanent barrier." There may be other reasons to treat a container with fluorine, and the law does not include this limiting phrase, which should be deleted from the proposed rule. This provision is of particular importance to MOFGA, since fluorinated containers used in agricultural settings have been found to leach PFAS into liquids stored in those containers.

"*Product."* "Product" is defined at 38 M.R.S. §1614(1)(G) – not paragraph (H).

"*Reasonably available*." The concept of an alternative being "reasonably available" is linked to the definition of "alternative" and "essential for health, safety or the functioning of society" in PL 2023, c. 630, which this rule implements.⁸ Neither of these definitions mention cost as a factor in determining if alternatives are available. In fact, under the definition of "essential for health, safety or the functioning of society" a product must be "unavailable" to trigger the analysis of its essentiality.⁹ This is a high bar to meet; the manufacturer must show that the cost of modifying the product or process is so high that the manufacturer would not make the product at all and it would become "unavailable."

The provision in the draft rule that an alternative to a PFAS product is considered "reasonably available" only at a "comparable cost" would potentially allow manufacturers to avoid reformulating their products or processes even where alternatives do in fact exist at a cost that is financially viable for the company. There is a long history of environmental regulations spurring research and development and technological change, where affected manufacturers claimed -- as it turned out, incorrectly -- that high costs would prevent compliance. Indeed, innovation in response to regulatory requirements can lead to "innovation compensation" – that is, profit – that exceeds the cost of complying with regulations.¹⁰

⁸ " 'Alternative' means a substance or chemical that, if used in place of a PFAS in a product, would result in a functionally equivalent product and would reduce the potential for harm to human health or the environment or that has not been shown to pose the same or greater potential harm to human health or the environment as the PFAS. "Alternative" includes: (1) A reformulated version of a product in which the intentionally added PFAS in the product has been removed; and (2) Changes to a product's manufacturing process that result in the removal of the PFAS from the product." PL 2023, c. 630, §1. A-5.

⁹ " 'Essential for health, safety or the functioning of society' means a use of a PFAS in a product when the function provided by the PFAS is necessary for the product to perform as intended, such that the unavailability of the PFAS for use in the product would cause the product to be unavailable, which would result in: (1) A significant increase in negative health outcomes; (2) An inability to mitigate significant risks to human health or the environment; or (3) A significant disruption of the daily functions on which society relies." PL 2023, c. 630, §1. B-1.

¹⁰ Ma L, Ma S, Tang Q, Sun M, Yan H, Yuan X, Tian W, Chen Y. Environmental regulation effect on the different technology innovation-based the empirical analysis. PLoS One, Jan 5, 2024, <u>https://pmc.ncbi.nlm.nih.gov/articles/PMC10769098/</u>

The definition also includes a performance standard that isn't in the law and should be removed. The law requires only that an alternative be "functionally equivalent product." 38 M.R.S. §1614(1)A-5.

"<u>Semiconductor</u>." This is a health and safety-based regulation. The Department should make every effort to narrowly construe exemptions; the definition of "semiconductor" in the draft rule includes the vague phrase "intended to perform electronic and other related functions." The National Institute of Standards and Technology (NIST) glossary for semiconductors defines the function as "material that can act either as a conductor or an insulator of electricity, depending on small changes in voltage."¹¹

"<u>Significant change</u>." We recommend revising this standard to match the Department's PFAS reporting ranges. A "significant change" would be the addition of PFAS in an amount that causes the total amount of PFAS to move from one range to another. This is simpler than the approach in the draft rule and helpful from an enforcement perspective. We agree with the provision in the draft rule that a change in the "responsible official or contact information" should also trigger the notification requirement.

Comments on information requirements and criteria for determining "currently unavoidable use."

The lynchpin of the regulatory framework of PL 2023, c. 630 is the requirement that manufacturers of PFAS-containing products must demonstrate that the PFAS-containing product is "essential for health, safety or the functioning of society" in order to remain on the market. 38 M.R.S. §1614(1)B-1. Significantly, even though the 2023 legislation amended the earlier 2021 PFAS law to modify various compliance deadlines and provide for additional exemptions, it simultaneously narrowed and clarified the definition of "essential for health, safety or the functioning of society" to make clear that this is not a routine claim, but a specific finding that an "unavailable" product would result in "(1) A significant increase in negative health outcomes; (2) An inability to mitigate significant risks to human health or the environment; or (3) A significant disruption of the daily functions on which society relies."

It follows that the rule must include clear requirements for information to be submitted by manufacturers seeking an exemption from the law. To reiterate, the burden is on the manufacturer to establish the scientific and health basis for any exemption. The rule should detail what information and analysis meets this standard. The draft rule is too vague in this regard.

Some of the language in in Section 9.A.(7), Currently Unavoidable Use, is inappropriate and potentially confusing in suggesting scenarios that might justify a manufacturer's claim that even though it is complying with a similar PFAS prohibition in another jurisdiction, it should be exempt in Maine.

• Paragraph (7)(a) suggests a manufacturer could claim that suppliers can't meet its need due to increased demand for PFAS alternatives. The second sentence of (7)(a) should be struck out, so that this paragraph reads in its entirety: "A justification explaining how products available in compliance with other similar sales prohibitions are not reasonably available alternatives for the product subject to the proposed CUU in the State of Maine."

¹¹ https://www.nist.gov/semiconductors/semiconductor-glossary

 Similarly, Paragraph (7)(b) suggests a claim that Maine's climate renders alternatives ineffective. Again, this is unnecessary language which almost suggests an additional exemption for weather. Paragraph (7)(b) should read in its entirety: "Documentation that products containing PFAS alternatives in other jurisdictions would not perform as intended in the State of Maine."

To the extent that the Department believes explanatory language of this nature is important and helpful, it should only be included in an interpretive note, not as part of the rule text.

Proprietary information.

We appreciate the note in Section 9 on Currently Unavoidable Use discouraging claims of confidentiality in CUU proposals. In addition, in Section 10, Proprietary Information, the Department should make clear that information on health or environmental impacts must never be classified as confidential.

Conclusion

Thank you for the opportunity to submit these comments. MOFGA strongly supports removing PFAS from products sold in the State of Maine, which has been the source of significant contamination of our environment and farm soils and water. Exclusions should be narrowly construed, and the evidentiary bar high for establishing that an exception is applicable.

Respectfully submitted,

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Heather Spalding Deputy Director Maine Organic Farmers and Gardeners Association





January 28, 2025

Maine Department of Environmental Protection 17 State House Station Augusta, ME 04333 Submitted via email: <u>rulecomments.dep@maine.gov</u>

Re: Chapter 90, Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

The Maine State Chamber of Commerce appreciates the opportunity to provide comments on the Department of Environmental Protection's proposed rule, Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances, to implement 38 MRSA § 1614. As Maine's largest business association, representing a network of over 5,000 businesses, we are committed to supporting policies that strike a balance between protecting the environment and public health without imposing undue burden on businesses or hindering Maine's economic growth and competitiveness.

We appreciate the Department's willingness to partner with the Chamber and various stakeholders to amend Maine's PFAS in Products law during the 131st Legislative session; we believe these changes that were made strike a much better balance than was what originally passed by the Legislature in 2021. While this rule follows much of the framework of P.L. 2024, c. 630, the Chamber is advocating for a few changes that would ensure greater clarity and predictability for Maine businesses.

Definitions

The Chamber believes the definition of "Commercially available analytic method" could be enhanced in a way that enables testing methods that reflect the current analytical methods available and the unique properties of PFAS compounds. Ultimately, testing methods should be allowed that result in the most reliably available data. Specifically, it is important to recognize that many commercial PFAS compounds are proprietary chemicals. As a result, there is currently a void of commercially available analytical methods. Setting analytical standards can help laboratories develop reliable testing methodologies. We ask the definition of "commercially available analytic method" be amended to:

"any test methodology that provides quality control parameters, required frequency, and performance criteria that must be met to satisfy method objectives and assure data quality that is used by a laboratory that performs analysis or tests for third parties to determine the concentration of PFAS in a product. Commercially available analytical methods do not need to be performed at a third-party laboratory as long as the method is under the laboratory's scope of accreditation. The laboratory performing the testing should have ISO/IEC 17025 Testing and Calibration Laboratories certification or be accredited through the National Environmental Laboratories Accreditation Conference (NELAC) whose standards are based on ISO requirements."

The Chamber would also ask that the Department add "including technologies to help control the environment" to the definition of "Environmental Control Technology".

Under the definition of "Intentionally added PFAS", there is a note stating:

"NOTE: Intentionally added PFAS includes degradation by-products serving a functional purpose or technical effect within the product or its components. Products containing intentionally added PFAS include products that consist solely of PFAS. Intentionally added PFAS does not include PFAS that is present in the final product as a contaminant or PFAS used in the manufacturing process or comes into contact with the product during the manufacturing process but is not present in the final product."

The Department should consider developing a focused definition of "contaminant" to address those that are not intended to be present in the final product. The low levels currently sought need to consider that detectable background PFAS levels can be present from sample collection and lab contamination. There should be a clear direction to differentiate between a contaminant and a true result. The assessment of contaminants should be based on multiple factors including process knowledge, the level and identify of the PFAS.

Recognizing that semiconductors are manufactured in Maine and across the globe, we greatly appreciate the Department amending the definition of "Semiconductor" to that which was suggested by the semiconductor industry. This definition creates alignment with the "semiconductor chip product" definition in 17 U.S.C. § 901(a)(1). To ensure Maine is not an outlier, we ask that you keep the definition as is currently defined in the rule.

Fees

As has been stated in the Chamber's written comments on the concept draft and in public testimony, the Chamber continues to urge the Department to determine a limit on the total amount of fees that can be assessed on businesses. Individual notification fees for businesses requiring a Currently Unavoidable Use (CUU) determination could impose a significant financial burden, particularly for small and medium-sized businesses who may lack the resources to absorb such costs. Large businesses with a diverse product line could also experience financial burden because of an individual product notification fee.

Currently Unavoidable Use Process

The current language of the proposed rule does not allow businesses to submit a CUU proposal prior to 36 months in advance of the product's sales prohibition. The Chamber believes this window is insufficient given the extended timelines often required to bring a product to

market. The journey from research and development to manufacturing, regulatory approvals, and ultimately, market introduction, can span several years, particularly for complex products in highly regulated industries. The complex and often unpredictable nature of these processes means that a 36-month window will likely not provide the necessary foresight for businesses to adequately prepare. In light of these considerations, the Chamber respectfully requests that the timeline for submitting CUU proposals be extended to five years.

Being able to submit a CUU proposal up to five-years in advance of a sales prohibition would also provide sufficient time for the regulatory process to unfold and allow the Department to review and assess CUU proposals with greater clarity and consideration.

Finally, we believe that given CUU determinations are valid for five years, aligning the submission window with the duration of the determination further strengthens the rationale for a five-year timeline. Extending the timeline for submitting CUU proposals to five years would provide businesses with the foresight needed to navigate the complexities of product development and market introduction while ensuring that regulatory decisions are based on the most current and accurate information. It would also mitigate the risk of unnecessary market disruptions if a CUU were not granted.

For those seeking an additional CUU determination upon the expiration date, the Chamber believes that a streamlined renewal process focusing only on new information since the previous determination would be less burdensome for applicants and Department staff. Doing so in this way will eliminate the need to submit and review known details, allowing for a greater focus on new and relevant information.

Proprietary Information

Information included in a CUU proposal will include proprietary information. We appreciate that the Department recognizes the importance of keeping this information confidential and will handle it accordingly.

Conclusion

Thank you again for the opportunity to provide comments on the proposed Chapter 90 rule. The Maine State Chamber of Commerce appreciates your consideration of the suggested changes.

Sincerely,

Ashley Luszczki Government Relations Specialist Maine State Chamber of Commerce January 28, 2025

Submitted via Email to: Melanie Loyzim, Commissioner Maine Department of Environmental Protection 17 State House Station Augusta, ME 04333

Subject: Comment on Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

NEMA Comments on:

Proposed Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substance under Maine's Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution, 38 M.R.S. § 1614

To Maine Department of Environmental Protection:

The National Electrical Manufacturers Association (NEMA) represents over 300 electrical equipment and medical imaging manufacturers that make safe, reliable, and efficient products and systems. Together, our members contribute 1% of U.S. GDP and directly provide nearly 460,000 American jobs, contributing more than \$240 billion to the U.S. economy.

NEMA appreciates the opportunity to submit comments to Maine's Department of Environmental Protection (DEP) proposed rule for products containing PFAS substances and would like to propose modifications to the rule for improving legal certainty for electrical manufacturers.

Electrical products are essential for the functioning of the society; they are used in the generation, transmission, distribution, and safe and efficient use of electricity. PFAS are used to make a diverse array of these products, many of which are critical contributors to meeting our nation's goals relating to electrification, energy security, and sustainability. These products include electronic components found in pacemakers, electronic sensors, industrial automation relays and soft starters, circuit boards, solar panels, batteries and semiconductors.^{1 2} PTFE, which is included in broad PFAS definitions, is used as an electrical insulator for ultra-high performance insulated wire, which is used in transformers, electrical vehicles, wind turbines, and assorted motor applications where failure cannot be tolerated. PTFE also provides an essential insulating function in high voltage circuit breakers.

¹ <u>https://www.atsdr.cdc.gov/pfas/</u>

² <u>https://fluoropolymerpartnership.com/</u>

Other PFAS, such as C4-Fluronitrile and C5-Fluroketone gases, are important alternatives to SF6, which has a high global warming potential. In grid decarbonization strategies throughout the country, C4-Fluronitrile, and C5-Fluroketone can replace Sulfur Hexafluoride (SF6) in providing insulation for different power grid equipment like medium- and high-voltage switchgear and circuit breakers, at a much lower climate impact.

Definitions - Electronics

NEMA is concerned that the definition of "electronics" as proposed in the rule is subject to interpretation and does not provide legal certainty. To ensure there is a common understanding among all actors in the electrical value chain, and to provide legal certainty for electrical manufacturers and its suppliers and customers, we propose to add examples of electrical equipment in Section 2:

2. Definitions

Electronics. "Electronics" means technology having electrical, digital, magnetic, wireless, optical, electromagnetic, or similar capabilities, including electrical equipment such as, but not limited to, power grid equipment, motors and generators, arc welding, batteries, electrical conduits, fuses, enclosures, connectors, wiring devices, low voltage distribution equipment, power electronics, residential & commercial controls, wires & cables, industrial automation controls, commercial and industrial lighting equipment, residential light fixtures (luminaires), electric vehicle and transportation management equipment.

Moreover, further clarity could be provided by also including examples in Section 4. We propose that Section 4(12) reads as follows:

4. Exemptions.

A. The following are exempt from the requirements of this Chapter: . . .

(12) Non-consumer electronics, non-consumer laboratory equipment not ordinarily used for personal, family or household purposes, <u>power grid equipment and other</u> <u>electrical equipment</u>; and

NEMA appreciates this opportunity to provide comments to DEP on the proposed rule and as well would like to express our support for the comments submitted by the Chemical Users Coalition and the Complex Products Manufacturers Coalition.

Thank you for your consideration.

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Board of Environmental Protection Department of Environmental Protection 17 State House Station 28 Tyson Drive Augusta, ME 04333-0017

January 28, 2025

Written Comments on Rulemaking for Chapter 583: Nutrient Criteria for Class AA, A, B, and C Fresh Surface Waters

Dear Members of the Board of Environmental Protection,

On November 21, 2024, the Board of Environmental Protection was introduced to the proposed Chapter 583 rules by staff from the Department of Environmental Protection (DEP), and the Board voted to post the rule changes for public comment and public hearing. The public hearing was held on January 16, 2025. I attended both meetings and provided testimony in support of the proposed rule changes at the public hearing. I am now providing follow-up written comments regarding the information I presented at the public hearing.

Reasons We Support Chapter 583 Rulemaking Overall

As populations within Maine continue to grow and more development pressure is placed on watersheds across the state, more waterbodies will be at risk of eutrophication if adequate management actions are not taken. Currently, there is a concerning trend of increasing cyanobacteria blooms in inland lakes and macroalgae blooms in coastal waters in Maine. Although these rules only apply to freshwater rivers and streams, these moving waterbodies are the primary vehicles by which nutrients enter our lakes and coastal waters. By establishing a framework to determine if freshwater rivers and streams are impaired for nutrients using a combination of total phosphorus (TP) concentrations and response indicators (e.g., nuisance algal cover, chlorophyll-*a* concentrations, and sewage fungus), these rules will allow DEP staff to designate waterbodies experiencing eutrophication as impaired for nutrients. This designation will open the door for federal funding and other resources that can be used to develop and implement management strategies to reduce nutrients and improve water quality across the state.

These rules have been developed with sound scientific justification, extensive stakeholder engagement, and close coordination with the Environmental Protection Agency. Although these rules reflect a big step in the positive direction for the protection of surface waters from nutrients, they would not trigger a substantial change in the number of waterbodies that are currently listed as impaired due to the similarities between the response indicators used in the rule and the current process that DEP uses to evaluate attainment of aquatic life use standards through biomonitoring (i.e., a lot of the waterbodies that would now be considered impaired under this rule are already impaired for aquatic life use or other reasons). This positive but relatively modest change to the number of waterbodies listed as impaired within the state will allow the waterbodies that need comprehensive nutrient management to receive funding to perform that management without overwhelming department staff with an influx of new impaired waterbodies or threatening to divert funding away from other waterbodies with important water quality impairments other than nutrients.



Other downstream positives impacts that this rule will have on water quality in Maine include:

- Encouraging more TP and chlorophyll-*a* data to be collected across the state as municipalities, watershed associations, and other interested parties evaluate whether their waterbodies of interest are attaining the criteria.
- Enabling the early detection of eutrophication issues by establishing a framework where TP concentrations can be compared to an established threshold before that threshold is surpassed and broader impacts to the ecosystem are observed (i.e., response indicators).

Technical Questions

We have a few technical questions about the specific methods used to develop the TP concentrations displayed in Table 1 and the reasoning behind the changes to the proposed TP and chlorophyll-*a* concentrations in prior drafts of the nutrient criteria compared to the current TP and chlorophyll-*a* concentrations in the proposed rules today.

These questions are as follows:

- 1. What is the Department's reasoning behind using the regression equations of TP and chlorophyll-*a* concentrations and the changepoint analysis of percent nuisance algal cover and TP concentrations for the determination of the TP criteria for Class C waters and not in the determination of the criteria for Class AA & A and Class B? Were these additional analyses used for Class C waters because there were an insufficient number of samples to compute the probability of low gradient sites attaining at least Class C standards?
- 2. What is the Department's reasoning for adjusting the methodology and subsequently the proposed values for the TP and chlorophyll-*a* concentrations from prior drafts of the nutrient criteria to the proposed values in the rules today?

Recommendations to Improve the Rules

To improve clarity and flexibility in the rules, we propose the following recommendations:

- Consider allowing Department staff to conduct a study to develop a site-specific TP value for Case C in the decision framework (Figure 1) like Case B. Case C is the situation where TP concentrations are below the criteria but one or more of the response variables is in nonattainment. In the current rules, the Department can conduct a study to develop a site-specific value for a nutrient other than TP, but not TP. Due to the heterogeneity in nutrient conditions across waterbodies, it is possible that some waterbodies have a lower TP threshold than others, which could warrant the development of a lower criteria similar to how higher criteria can be developed in Case B.
- Recommend adjusting the table on page one of the rules that outlines which waterbodies are covered by Chapter 583 so that it is clearer, particularly as it pertains to impoundments. The applicability of the rules to impoundments is clear from the Definitions section, but the size restrictions attached to the impoundments in table on page one introduces confusion.



Thank you for the opportunity to provide input on this rulemaking; we appreciate the Department's consideration of these comments. Please feel free to contact me if you have any questions or need additional information.

Sincerely,

Lal

Luke Frankel

Woods, Waters, & Wildlife Director and Staff Scientist Natural Resources Council of Maine 3 Wade Street Augusta, ME 04330 Phone: (207) 430-0116 Email: <u>lfrankel@nrcm.org</u>



January 28, 2025

Maine Department of Environmental Protection 17 State House Station Augusta, ME 04333

Re: Comments on the Concept Draft for PFAS in Products Program

Dear Board of Environmental Protection,

Thank you for the opportunity to provide comments on the draft rules for Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances. Below you will find the Natural Resources Defense Council's comments on the draft rule. We appreciate the work that the Department has done to draft this language. We do, however, have concerns with some of the language in the draft.

The idea of essential use was first introduced in the Montreal Protocol, which addresses environmental harms caused by ozone-depleting substances by setting a timetable for phasing them out, with time-limited exemptions for essential uses.¹

Since then, the concept has been proposed for broader use and further developed by experts in chemical regulation and PFAS as a way to systematically, efficiently, and transparently reduce unnecessary uses of chemicals of concern, including PFAS - a task that is urgently needed in response to the PFAS crisis.² Most recently, Bălan et al., 2023, published a paper intended to

² Cousins, Ian T., Gretta Goldenman, Dorte Herzke, Rainer Lohmann, Mark Miller, Carla A. Ng, Sharyle Patton, et al. "The Concept of Essential Use for Determining When Uses of PFASs Can Be Phased Out." *Environmental Science: Processes & Impacts* 21, no. 11 (November 13, 2019): 1803–15.

https://doi.org/10.1039/C9EM00163H; Glüge, Juliane, Rachel London, Ian T. Cousins, Jamie DeWitt, Gretta Goldenman, Dorte Herzke, Rainer Lohmann, et al. "Information Requirements under the Essential-Use Concept: PFAS Case Studies." *Environmental Science & Technology* 56, no. 10 (May 17, 2022): 6232–42. <u>https://doi.org/10.1021/acs.est.1c03732</u>; Cousins, Ian T., Jamie C. De Witt, Juliane Glüge, Gretta Goldenman, Dorte Herzke, Rainer Lohmann, Mark Miller, et al. "Finding Essentiality Feasible: Common Questions and Misinterpretations Concerning the 'Essential-Use' Concept." *Environmental Science. Processes & Impacts* 23, no. 8 (August 1, 2021): 1079–87. <u>https://doi.org/10.1039/d1em00180a</u>.

¹ Ozone Secretariat. "Handbook for the Montreal Protocol on Substances That Deplete the Ozone Layer." United Nations Environment Programme, May 1991. <u>https://p2infohouse.org/ref/17/16875.pdf</u>; D'Souza, Sheila. "The Montreal Protocol and Essential Use Exemptions." *Journal of Aerosol Medicine* 8, no. s1 (January 1995): S-13. <u>https://doi.org/10.1089/jam.1995.8.Suppl_1.S-13</u>.

describe the optimal implementation of this concept in the US and Canada.³ We have summarized this in an issue brief that provides concrete examples of the essential use concept.⁴

Furthermore, in 2020, the European Union released its Chemicals Strategy for Sustainability, calling for phasing out use of the most harmful chemicals such as PFAS and endocrine disruptors, except for uses that are determined to be essential for society.⁵ The EU Commission followed this call with the publication of "Guiding Criteria and Principles for the Essential Use Concept in EU Legislation Dealing with Chemicals" in 2024.⁶ The main principles and criteria for implementing this concept generally align between all of the scientific papers, commentaries, and authoritative bodies in the EU. Unfortunately, these well-reasoned and peer reviewed principles and criteria are not reflected in Maine's draft regulations.

In practice the concept is straightforward, and is addressed by answering the following three questions when applied to PFAS use: 1) Are there no safer alternatives to PFAS that are reasonably available? (2) Is the function provided by PFAS in the product necessary for the product to work?⁷ (3) Is the use of PFAS in the product critical for health, safety, or the functioning of society? The answer to all three questions must be yes in order to justify continued use of a class of chemicals as concerning as PFAS (receive a "currently unavoidable use" or CUU exemption).⁸

Maine's draft regulations, however, conflates several concepts, risks confusion as to what qualifies for a CUU exemption, and creates unnecessary burdens for both regulated entities and the agency. We recommend the following changes to address these issues:

1) The criteria for making a CUU determination should be clearly stated and align with current thinking on the essential use concept.

content/EN/TXT/PDF/?uri=CELEX:52024XC02894.

³ Bălan, Simona A., David Q. Andrews, Arlene Blum, Miriam L. Diamond, Seth Rojello Fernández, Elizabeth Harriman, Andrew B. Lindstrom, et al. "Optimizing Chemicals Management in the United States and Canada through the Essential-Use Approach." *Environmental Science & Technology*, January 19, 2023. <u>https://doi.org/10.1021/acs.est.2c05932</u>.

⁴ Reade, Anna. "The Essential-Use Approach: A Policy Tool for Reducing Exposures to Toxic Chemicals." NRDC, January 31, 2023. <u>https://www.nrdc.org/resources/essential-use-approach-policy-tool-reducing-exposures-toxic-chemicals</u>.

⁵ Scholz, Stefan, Werner Brack, Beate I. Escher, Jörg Hackermüller, Matthias Liess, Martin von Bergen, Lukas Y. Wick, Ana C. Zenclussen, and Rolf Altenburger. "The EU Chemicals Strategy for Sustainability: An Opportunity to Develop New Approaches for Hazard and Risk Assessment." *Archives of Toxicology* 96, no. 8 (August 1, 2022): 2381–86. <u>https://doi.org/10.1007/s00204-022-03313-2</u>.

⁶ EU Commission. "Guiding Criteria and Principles for the Essential Use Concept in EU Legislation Dealing with Chemicals," 2024. <u>https://eur-lex.europa.eu/legal-</u>

⁷ As the EU Commission points out, "Technical functions of most harmful substances that only impart properties relating to convenience, leisure, decoration or luxury to the user of the final product should normally not be deemed necessary for health or safety or critical for the functioning of society."

⁸ In the EU guiding criteria and principles, the three questions they recommend considering are laid out in Figure 1 on page 9 (two of the questions are articulated in Step 1 and the other question is in Step 2) and accompanying discussion thereafter.

- 2) The information being requested in the draft rule should align with the criteria for CUU decision making and should not introduce extraneous considerations.
- 3) The definition of "reasonably available" undermines the essential use concept and should be changed to better reflect the statue.
- 1) CUU Criteria Should be Clearly Identified in One place

We recommend that the Department align its criteria for determining CUU with established scientific literature and the guidance prepared by the EU Commission. In short, the use of PFAS in a product category is a CUU only if all the following criteria are met: (1) There are no safer alternatives to PFAS that are reasonably available. (2) The function provided by PFAS in the product is necessary for the product to work. (3) The use of PFAS in the product is critical for health, safety, or the functioning of society.

Recommended change (in red strikeout and underline):

Insert a new Subsection 9.A with CUU criteria:

9. Currently Unavoidable Use.

<u>A. A use of PFAS is a currently unavoidable use only if all of the following criteria are</u> met: (1) There are no safer alternatives to PFAS that are reasonably available. (2) The function provided by PFAS in the product is necessary for the product to work. (3) The use of PFAS in the product is critical for health, safety, or the functioning of society.

A B. Proposal for Currently Unavoidable Use Determinations.

2) Only Information Relevant to the CUU Criteria Should be Required from Manufacturers

It is troubling to see risk-based information and analysis requested from manufacturers in the Department's draft rules. As is implied by the name, the essential-use approach is designed to aid policymakers in discontinuing any non-essential uses of chemicals of concern in products or processes where they are not critical for health, safety, or the function of society. The idea of the essential-use approach is not to perform analysis of levels of exposure or risk from particular uses of a chemical or chemicals of concern. Instead, it proposes that chemicals whose use poses a hazard to human health and the environment should only be used when absolutely necessary. The Maine legislature has already determined that any use of PFAS, especially when considering their lifecycle, is of serious concern and should be avoided whenever possible. Thus the essential use concept - using the clear, established criteria we outline above - is the only relevant approach here. The essential use concept should not be tied to risk-based

decision making or tack on additional analysis of exposures, which would only serve to undermine the concept and create unnecessary reporting, analysis and review.

Recommended changes:

Delete all risk and exposure information required and anything else not related to the CUU criteria and align information request to CUU criteria.

B.A Proposal for Currently Unavoidable Use Determinations.

Proposals for currently unavoidable use ("CUU") determinations may be submitted by manufacturers individually or collectively. A separate proposal must be submitted for each individual combination of product category and the associated industrial sector. The Department requests that manufacturers submit their proposals to PFASProducts@maine.gov with a subject line of "CUU Proposal for [GPC/HTC] in [NAICS] sector by [Proposal Submitter's Name or Organization]".

For initial currently unavoidable use proposals, the requester shall submit the information in this section no later than 18 months prior to the applicable sales prohibition. The Department will not consider any proposals for an initial currently unavoidable use determination prior to 36 months in advance of the applicable sales prohibition; any proposals received prior to this date will need to be updated and resubmitted between 36 and 18 months before the effective date of the applicable sales prohibition (with the exception of CUU proposals for sales prohibitions taking effect 2026, which must be submitted no later than June 1, 2025). Proposals received after the 18 months prior to the sales prohibition effective date may be evaluated for inclusion in a subsequent rulemaking. Proposals received after the sales prohibition is in effect will be evaluated for inclusion in a subsequent Department CUU rulemaking.

A proposal must, at a minimum, contain:

(1) A brief description of the type of product to which PFAS is intentionally added including:

(a) A brief narrative of the product; its physical structure and appearance; how it functions; and if applicable its place in larger items, systems, or processes;(b) If applicable, the Global Product Classification (GPC) brick category and code, or if GPC is not applicable then the Harmonized Tariff System (HTS) code; and

(c) The North American Industry Classification System (NAICS) code for the sector

or sectors in which the products containing intentionally added PFAS will be utilized.

(2) An explanation of why the availability use of PFAS in the specific product identified in subsection 1 is essential for health, safety or the functioning of society. This may include or take the form of a description of the negative impact that would be caused by the unavailability of PFAS for use in the product and the subsequent unavailability

or unsatisfactory performance of the product; [Note: The recommended deletion of "unsatisfactory performance" is related to the comments provided further below that criteria such as this insert extra-statutory considerations into the analysis of reasonable availability of alternatives. In addition, for consistency with subsection (3) below and with the recommended criteria above, we recommend modifying the language to reference "use of PFAS" instead of availability.]

(3) A description of how the specific use of PFAS in the product is essential to the function of the product. Including:

(a) If this use of PFAS is required by federal or state law or regulation, provide citations to that requirement. For the purposes of this subsection, "required" means the applicable statute or regulation specifically states that PFAS or a specific PFAS is required to be present in the product, not that the proposer's understanding or experience of PFAS is necessary to meet a performance standard; such performance standards may be addressed in subsection b, below;

and

NOTE: Products required to meet certain federal standards or regulated under certain federal programs are exempt from this Chapter. See section 4 for more information.

(b) The required specific characteristic or combination of characteristics that necessitate the use of PFAS chemicals. The function provided by PFAS in the product and why it is necessary for the product to work, i.e., required for the product to perform its primary function.

(4) Evidence that demonstrates that there no safer alternatives to the use of PFAS that are reasonably available, inclusive of materials, processes, designs, products, or chemicals, and that are sufficient for achieving the primary function provided by the product. A description of whether there are alternatives for this specific use of PFAS which are

reasonably available including:

(a) Identification of specific compounds, classes of materials, or combinations of materials identified as potential alternatives including the removal of PFAS without substitution;

(b) An assessment of how the materials in subsection a, above, meet or fail to meet the criteria identified in 3(b);

(c) An assessment if materials identified in subsection a, above, are anticipated to be available in sufficient quantities to meet production needs without regard to cost;

(d) An assessment of the anticipated cost difference between obtaining PFAS for use in a product and obtaining the material identified in (a), for the same purpose;

(e) A comparison of the known risks to human health and the environment between PFAS and the materials identified in (a); and

(f) An assessment of whether there are feasible changes to the manufacturing process of the product that would eliminate the need for PFAS.

(5) A list of federal regulations, other State of Maine rules, and regulations of other states which the product described in subsection 1 is subject to by reason of containing

intentionally added 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.

(6) If, in another jurisdiction the product is 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;

(a) A justification explaining how products available in compliance with other similar sales prohibitions are not reasonably available alternatives for the product subject to the proposed CUU 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; or

(b) 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;

(8) Contact information for the submitter of the proposal. The contact person or persons should be familiar with the contents of the proposal and, if necessary, be able to answer Department questions or provide additional requested information.; and (9) Any information known or reasonably ascertainable by the manufacturer regarding the impacts on human health or the environment of PFAS in 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 a

sewage or septage system, and (iii)The recycling rate of the product.

Information submitted to the Department must contain sufficient detail or supporting documentation to satisfy the requirements of the currently unavoidable use as essential for health, safety or the functioning of society for which alternatives are not reasonably available.

If any of the information above is omitted from the proposal, the requestor must explain why this information is omitted.

3) The definition of "reasonably available" should be changed to better reflect the statute

In the draft rules, the Department proposed to define "reasonably available" with respect to alternatives as:

"Reasonably available" means a PFAS alternative which is readily available in sufficient quantity and at a comparable cost to the PFAS, to include changes to the manufacturing process, it is intended to replace and performs as well as or better than PFAS in a specific application of PFAS in a product or product component

The definition includes two problematic components.

<u>First, the criterion of "performs as well or better than PFAS in a specific application of PFAS"</u> has no connection to the concept of a "reasonably available" alternative since it does not relate to availability. It's not clear why this criterion is being added to the consideration of the reasonable availability of alternatives. Performing as well or better than PFAS is not necessary for an alternative to work and could unintentionally eliminate the ability to consider alternative materials, designs or processes (leaving only chemical drop-in replacements for consideration). For example, a safer alternative to stain resistant sprays for avoiding stains on upholstery could be the use of detergents or the use of fibers that are inherently stain resistant. These are completely different alternatives or approaches to the product and not just an alternative to the specific application of PFAS.

Furthermore, the Maine statute includes a broad definition of alternative that is focused on the functional equivalence of the *product (not just PFAS)*, and that is inclusive of other materials, designs, or processes. The definition expressly contemplates the removal of PFAS as an alternative, i.e., even if the alternative (no PFAS) does not perform as well or better than PFAS, as long, as the *product* still serves an equivalent function:

"Alternative" means a substance or chemical that, if used in place of a PFAS in a product, would result in a <u>functionally equivalent product</u> and would reduce the potential for harm to human health or the environment or that has not been shown to pose the
same or greater potential harm to human health or the environment as the PFAS. "Alternative" includes: (1) A reformulated version of a product in which the intentionally added PFAS in the product has been removed; and (2) Changes to a product's manufacturing process that result in the removal of the PFAS from the product. (emphasis added)

The functionally sufficiency of an alternative is more appropriate to consider, especially in the context of implementing the essential use concept. "Functional substitution" is a method for identifying and evaluating alternatives to a substance that focuses on the function of the product and encourages a broader consideration of how this function can be achieved. For example, if focusing on the end use function of shopping receipts, harmful bisphenols in thermal paper could be eliminated by redesigning the paper itself or providing electronic receipts. Multiple papers and reports have described this important concept, including the European Chemicals Agency in its "Strategy to promote substitution to safer chemicals through innovation."⁹ Additionally, in the EU's guiding criteria and principles for the essential use concept it states that,

"Acceptable alternatives must be capable to provide the function and the level of performance that society can accept as sufficiently delivering the expected service and be safer ... the assessment should not only consider possible alternatives with the same level of performance but also any alternative with a function and a level of performance that society can accept as sufficiently delivering the expected service. Therefore, the possible alternatives that need to be considered are:

— products in the market in the same product category that do not use the most harmful substance;

— the alternatives that have a lower performance, provided it is acceptable from the societal point of view (10);

— those alternatives that provide a similar technical function and a similar level of performance to those provided by or with the most harmful substance"

A product without PFAS need not perform as well or better than a PFAS-laden product in order to achieve the required function. For instance, Maine has previously phased out PFAS-containing firefighting foams for liquid fires even though those foams may act marginally more

⁹ Tickner, Joel A., Jessica N. Schifano, Ann Blake, Catherine Rudisill, and Martin J. Mulvihill. "Advancing Safer Alternatives Through Functional Substitution." *Environmental Science & Technology* 49, no. 2 (January 20, 2015): 742–49. <u>https://doi.org/10.1021/es503328m</u>.

Roy, Monika A., Ian Cousins, Elizabeth Harriman, Martin Scheringer, Joel A. Tickner, and Zhanyun Wang. "Combined Application of the Essential-Use and Functional Substitution Concepts: Accelerating Safer Alternatives." *Environmental Science & Technology* 56, no. 14 (July 19, 2022): 9842–46. <u>https://doi.org/10.1021/acs.est.2c03819</u>.

Cousins, Ian T., Jamie C. De Witt, Juliane Glüge, Gretta Goldenman, Dorte Herzke, Rainer Lohmann, Mark Miller, et al. "Finding Essentiality Feasible: Common Questions and Misinterpretations Concerning the 'Essential-Use' Concept." *Environmental Science: Processes & Impacts* 23, no. 8 (2021): 1079–87. https://doi.org/10.1039/D1EM00180A.

European Chemicals Agency. *Strategy to Promote Substitution to Safer Chemicals through Innovation: January 2018.* LU: Publications Office, 2018. <u>https://data.europa.eu/doi/10.2823/99862</u>.

quickly to put out fires than PFAS-free alternative foams; however, the alternatives are just as successful at putting out fires, and that is the key function.

<u>Second, a cost threshold is not appropriate in this context,</u> because the cost implications can vary dramatically from product to product. Rather the focus should be on assessing what is "reasonably available." We believe that inquiry could involve considerations of adequate supply of the alternatives and potentially the cost to the public. Costs to manufacturers are variable and subject to market pressures, including the Department's actions. An alternative may initially start out significantly more expensive than the PFAS it is intended to replace, but as demand increases, the cost can fall rapidly, and a mandated switch away from PFAS could be the catalyst for demand for the alternative to increase. This is why it is important for cost considerations to not be determinative (and to have determinations of "currently unavoidable use" be time bound, as the availability of alternatives can change over time).

The need for any consideration of costs to be more focused on the impact to the public rather than the manufacturer is reinforced by the nature of alternatives that should be covered. As we propose above, the Department should adopt definitions that make clear that alternatives can include materials, processes, designs, products, or chemicals that achieve the desired result. In the example above where detergents are a viable alternative to PFAS treated upholstery, there would be little to no direct costs to the public, but there might be economic impacts for the manufacturer of the PFAS treated upholstery. Thus, the cost to the manufacturer should not be the relevant cost for the Department's analysis.

Furthermore, while there should be some consideration of the significance of additional cost to the public, minor costs should not influence the analysis. Even when considering costs to the public, a set threshold in absolute dollars should not be used as product categories may vary significantly in scale of cost. Nor is a percentage-based threshold appropriate because the significance of a certain percentage cost difference depends on the context–a high percentage could still amount to mere cents. In addition, any cost should be considered alongside societal costs of PFAS exposure and clean up.

We note that the statute makes no mention of cost.

Recommended changes:

Modify the definition of "reasonably available" to remove extraneous and extra-statutory considerations.

"Reasonably available" means an PFAS alternative to the use of PFAS or to the product containing PFAS which is readily available in sufficient quantity or can become readily available in sufficient quantify in the relevant timeframe. and at a comparable cost to the PFAS, to include changes to the manufacturing process, it is intended to replace and performs as well as or better than PFAS in a specific application of PFAS in a product or product component

Please refer to our comments to the Minnesota Pollution Control Agency that detail our recommendations on how to develop regulations on the CUU concept that are in line with the many years of science and policy work spent developing this concept by experts in the field.¹⁰

Sincerely,

Anna Reade, PhD Senior Scientist & Director PFAS Advocacy

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Avi Kar Senior Attorney & Senior Director, Toxics

Katie Pelch

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¹⁰ Kar, Avi, Anna Reade, and Katherine E Pelch. "Re: Request for Comments: Planned New Rules Governing Currently Unavoidable Use Determinations about Products Containing Per-and Polyfluoroalkyl Substances (PFAS), Revisor's ID Number R-4837," February 29, 2024. <u>https://www.nrdc.org/sites/default/files/2024-03/currently-unavoidable-use-determinations-</u> 20240209.pdf. Personal Care Products Council Committed to Safety, Quality & Innovation

January 27, 2025

Commissioner Melanie Loyzim Maine Department of Environmental Protection State of Maine 17 State House Station Augusta, Maine 04333

Sent Via Electronic Mail: PFASProducts@Maine.gov

Re: Comments to DEP's Proposed Rule to Implement Maine's PFAS in Products Program

The Personal Care Products Council (PCPC)¹ respectfully submits the following comments on the Maine Department of Environmental Protection (DEP) for the proposed rule, **Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances.**

PCPC and its member companies have long been supportive of commonsense laws and policies that protect both the consumer and the environment. For this reason, we have supported laws in other states that prohibit certain intentionally added PFAS from use in cosmetics. We have appreciated the opportunity to weigh in on earlier versions of this proposed rule, and we further appreciate this opportunity for feedback. The concerns addressed in our prior submissions remain critical to our industry, and we emphasize the following recommendations.

§2. DEFINITIONS

We appreciate efforts to increase specificity in this section. We continue to request further clarification, particularly on the following points:

• *Commercially available analytical method*: The proposed definition for this term is challenging for industry because today's commercially available methods are inadequate

454

¹ Based in Washington, D.C., the Personal Care Products Council (PCPC) is the leading national trade association representing global cosmetics and personal care products companies. Founded in 1894, PCPC's approximately 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the U.S. As the makers of a diverse range of products millions of consumers rely on and trust every day – from sunscreens, toothpaste, and shampoo to moisturizer, lipstick, and fragrance – personal care products companies are global leaders committed to product safety, quality, and innovation.

to detect specific PFAS in the complex matrices that exist for the wide range of products in the market today. There are several reasons for this:

- PFAS are a highly complex chemical classes of compounds with diverse functional groups attached to the fluoroalkyl moiety (e.g., Perfluoroalkyl acids, Polyfluoroalkyl acids, PFAA precursors, etc.). This could represent hundreds of targets that "commercial methods" will need to be able to target. The referenced EPA methods² generally test for PFAS *in soil and water* and are <u>not</u> specific to finished products or packaging. While there are available test methods that measure PFAS in consumer products/cosmetics, they are not necessarily considered "commercial methods" as defined.
- Even established testing methods used for cosmetics products will need to be validated/verified for the corresponding product matrixes meaning they will require modifications which is not something that is permitted under the proposed definition.
- The lack of adequate commercially available test methods makes DEP approved "ranges" even more important. PCPC again asks that DEP provide additional clarity on how it will establish such approved ranges.
- Fluorinated Container: 38 MRSA Section 1614(4)(B)) provides that the provision
 "...does not apply to the package of a product prohibited from sale, offer for sale or
 distribution for sale pursuant to subsection 5, paragraph B, B-1, D or E if that package is
 a fluorinated container." (*emphasis added*). We request that DEP engage with
 stakeholders to define the term "fluorinated container" and to further specify what
 processes or packaging types qualify as fluorinated.

In sum, PCPC continues to strongly urge DEP to build in greater flexibility on the test methodology/ies used to measure PFAS in finished products and to establish DEP-approved ranges as soon as possible.

² EPA PFAS Methods: (1) ASTM D7968: Standard Test Method for Determination of Perfluorinated Compounds in Soil by Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS) (PDF)(17 pp, 175 K) [ASTM may charge a fee for this document.] (2) <u>ASTM D7979: Standard Test Method for</u> Determination of Perfluorinated Compounds in Water, Sludge, Influent, Effluent and Wastewater by Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS) (PDF)(18 pp, 181 K) [ASTM may charge a fee for this document.]

§3: NOTIFICATION

PCPC also continues to oppose the proposed language that would provide confidentiality protections under the Maine Freedom of Information Act rather than the Uniform Trade Secrets Act. As written, this protection neglects the relevant interests of the business community impacted by the regulation. The Uniform Trade Secrets Act was designed as a legal framework to provide uniform definitions and protections for trade secrets throughout the country, whereas the Maine Freedom of Information Act exists to govern public records disclosure within the state. The Uniform Trade Secrets Act is thus a much more appropriate means of governing the protection of confidential business information in a manner that enables companies to comply with this new requirement without fear of compromising proprietary material.

§4: EXEMPTIONS.

The elimination of the previous exemption for cosmetic packaging, particularly as written, creates significant frustration and confusion across our industry. While overall packaging remains exempt, certain types of fluorinated packaging have now been brought back into the scope of this regulation without appropriate explanation of what processes or packaging types technically qualify. Fluorination is a broad term that encompasses a diverse subset of post-treatment process categories, which can occur at different stages of production, depending on the type of application and method used. Significant clarification is needed on this point.

§8: CERTIFICATE OF COMPLIANCE.

PCPC also continues to request that DEP establish a provision to allow for a window of opportunity to correct, such that a manufacturer notified about a violation of this policy has a reasonable period of time, for instance 30 or 60 days, to bring all relevant products into compliance prior to suffering consequences.

§9: CURRENTLY UNAVOIDABLE USE.

PCPC requests a Currently Unavoidable Use (CUU) determination for fluorinated containers.

Thank you for the continued opportunity to engage in this process and provide comments on the proposed draft. Should you have any questions or wish to discuss any of the above points with us, please do not hesitate to contact me.

Sincerely,

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Emily Manoso Executive Vice President, Legal and Regulatory Affairs & General Counsel, PCPC



January 28, 2025

From: Jay West Executive Director Performance Fluoropolymer Partnership

To: Maine Department of Environmental Protection

Re: Chapter 90: Product Containing Perfluoroalkyl and Polyfluoroalkyl Substances (December 20, 2024)

Submitted via email to rulecomments.dep@maine.gov

Thank you for the opportunity to submit comments to the Maine Department of Environmental Protection (hereafter "the Department") on the proposed rule to implement 38 MRSA § 1614 (hereafter "proposed rule"¹) on behalf of the American Chemistry Council's Performance Fluoropolymer Partnership.² The Partnership's members are some of the world's leading manufacturers, processors, and users of fluoropolymers, including fluoroelastomers, and polymeric perfluoropolyethers. The Partnership's mission is to promote the responsible production, use, and management of fluoropolymers, while also advocating for a sound scienceand risk-based approach to their regulation.

Our comments are organized below according to the appearance of text in the proposed rule.

2. Definitions.

Alternative. It is our understanding that the phrase "functionally equivalent product" in the statutory definition of "alternative" encompasses a performance dimension such that products with shorter service lives or diminished reliability are not "functionally equivalent." Products using or formulated with "alternatives" that have shorter service lives or diminished reliability may also have undesirable consequences in terms of greater rates of material use and waste generation, as well as less resiliency, reliability, and safety. We recommend that the Department include an interpretive note stating that the concept of "functionally equivalent product" includes duration of a product's or product component's service life and reliability of performance under foreseeable conditions of use.

We are also concerned that the phrase "has not been shown" in the statutory definition could be interpreted in such a way that a substance could be deemed an acceptable "alternative" despite the absence of any data regarding the potential health and/or environmental effects of that substance, which, in our opinion, is unacceptable in the evaluation

¹ <u>https://www.maine.gov/tools/whatsnew/attach.php?id=13139124&an=2</u>

² <u>https://fluoropolymerpartnership.com/</u>

of potential alternatives, since such an interpretation could be an inadvertent invitation to a regrettable substitution. We therefore request that the Department include an interpretive note explaining that, in the Department's consideration of alternatives, evidence or substantiation of *not* posing "the same or greater potential harm to human health or the environment as the PFAS" is required.

We also request that the Department provide additional detail regarding the information and methodology suitable to verify the reduction of "potential for harm to human health or the environment" and for finding that an alternative has "not been shown to pose the same or greater potential for harm to human health or the environment as that PFAS." The bases for such determinations must be consistent, fair, transparent, and well-defined.

Chemically-formulated. It is our understanding that the Department is defining this term because it appears without definition in the statute in the definitions of "Air care product" and "Automotive maintenance product" If the Department is defining "chemically-formulated" for any other purpose, we request clarification.

Clothing item. It is our understanding that the Department is defining this term because it appears without definition in the statute in the definition of "Outdoor apparel for severe wet conditions." If the Department is defining "clothing item" for any other purpose, we request clarification.

Commercially available analytical method. We appreciate the Department's attempt to define this term, which the legislature left undefined in the statute, but we continue to disagree with the Department's approach. As we explained in comments submitted to the Department on July 18, 2022, and August 30, 2024, the proposed definition is too generic ("any method") and contains no language that contemplates whether a method has been validated, which is essential to help assure data quality and reliability. To create an even playing field and to help assure that its regulatory decisions are based on sound data the Department must elaborate its intention regarding baseline criteria or performance standards for "any test methodology" and the laboratories providing data to the Department.

Regarding the in-house use of commercially available methods, the Department should recognize that, practically speaking, some modifications or use of a proprietary in-house method may be needed where no commercially available methods exist (due to the matrix to be sampled or other consideration related to a formulated product's chemistry, the lack of commercially available analytical standards for proprietary PFAS chemicals, or other similar issues). If a manufacturer can provide the Department with information concerning the accuracy, precision, specificity, detection limit, and quantification limit of the method, modifications and in-house methods should be accepted.

We suggest that the Department modify the definition to set a minimum expectation and acknowledge the potential need for flexibility by adding the following language:

"Commercially available analytical method" means any test methodology used by a laboratory that performs analyses or tests for third parties to determine the concentration of PFAS in a product. <u>Commercially available analytical methods</u> <u>must have been independently validated and must include quality control</u> <u>parameters and performance criteria that satisfy method objectives and assure</u> <u>data quality.</u> Commercially available analytical methods do not need to be performed at a third-party laboratory; however, the method must remain unmodified when not performed by a third-party laboratory; however, the method <u>must remain unmodified when not performed by a third-party laboratory, unless</u> <u>modifications are approved by the Department. Any laboratory used by a</u> <u>manufacturer to determine the concentration of PFAS in a product must be</u> <u>certified to the most current version of ISO/IEC 17025 or the Organization for</u> <u>Economic Cooperation and Development's Principles of Good Laboratory</u> <u>Practice.</u>

ISO/IEC 17025³ is an international standard that sets a minimum threshold for the competence, impartiality, and consistency of laboratories, and therefore the accuracy and reliability of their testing. It is recognized globally as the core requirement for laboratory competency. The Organization for Economic Cooperation and Development's Principles of Good Laboratory Practice (GLP)⁴ "is a quality system concerned with the organisational [*sic*] process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported."

Also, we highlight the very practical matter that, depending on the number of currently unavoidable use (CUU) determinations, there is likely insufficient third-party laboratory capacity to handle all the testing that compliance with the program described in the proposed rule would require. Therefore, manufacturers acting in good faith should not be precluded from using documented in-house methods or penalized for otherwise being delayed in their reporting due to third-party laboratory capacity constraints. The Department must make accommodation for such circumstances.

Consumer products. We support the proposed definition of "consumer products" in the proposed rule.

Cookware product. It is our understanding that the definition of "cookware product" includes small articles and utensils but includes neither large appliances, such as refrigerators and ranges, nor small appliances, like coffee makers and toasters.

Cosolvent. The term "cosolvent" does not appear elsewhere in the proposed rule, and it is not in the statute. If the Department is defining this term for any purpose relative to the implementation of the statute, we request clarification.

³ ISO/IEC 17025. General requirements for the competence of testing and calibration laboratories. (2017; reaffirmed 2023).

⁴ Organization for Cooperation and Development. 2005. Good Laboratory Practice: OECD principles and guidance for compliance monitoring. OECD Publishing, Paris, <u>https://doi.org/10.1787/9789264012837-en</u>.

Distribute for sale. We disagree with the proposed definition of "distribute for sale." It could be interpreted to include the United States Postal Service and other transportation companies, since they "transport a product with the … understanding that it will be sold or offered for sale by a receiving party." The Department should clarify that such entities (i.e., those that are not product or product component distribution companies) will not be considered a "manufacturer."

Electronics. It is our understanding that the Department is defining this term because it appears without definition in the statute. If the Department is defining "electronics" for any other purpose, we request clarification.

Environmental control technology. It is our understanding that the Department is defining this term because it appears without definition in the statute in the definition of "textile article." If the Department is defining "environmental control technology" for any other purpose, we request clarification.

Essential for health, safety, or the functioning of society. We appreciate that the legislature has taken steps to clarify the phrase "essential for health, safety, or the functioning of society." However, the statutory definition, which includes the phrase "the unavailability of PFAS for use in the product would cause the product to be unavailable," could be interpreted in a manner that results in Maine residents being deprived of products essential to their health or safety because similar products made without PFAS are available on the market, even if the performance of those nominally similar products is inadequate to protect health or safety.⁵Therefore, we urge the Department to include an interpretive note explaining that the use of PFAS in a product will be considered essential for health, safety or the functioning of society if the unavailability of PFAS for use in that product would result in adverse health or safety outcomes or significant disruptions of the daily functions on which society relies.

Also, it is our understanding that the phrase "function provided by the PFAS" in the statutory definition of encompasses a temporal dimension such that duration and reliability during the service life of a product or product component are part of the "function provided by the PFAS."

Finished product. It is our understanding that the Department is defining this term because it appears without definition in the statute in the definition of "cleaning product." If the Department is defining "finished product" for any other purpose, we request clarification.

Fully fluorinated carbon atom. It is our understanding that the Department is defining this term because it appears without definition in the statute in the definition of "perfluoroalkyl and polyfluoroalkyl substances" or "PFAS." If the Department is defining "fully fluorinated carbon atom" for any other purpose, we request clarification.

⁵ For example, fluoropolymer-coated electrical wire provides superior insulating performance in high temperature and high physical stress environments. Even though other types of coated wire are available, they provide inferior protection in high stress environments, which can lead to adverse health and/or safety outcomes.

Furthermore, it is our understanding that the Department is suggesting that (a) any substance with at least one perfluorinated methyl group $(-CF_3)$ or a perfluorinated methylene group $(-CF_2-)$ is a PFAS, and (b) a substance with a -CFR'R'', where R' and R'' are neither fluorine nor hydrogen, is not a PFAS. We request that the Department elaborate in more detail the implications of the definition of "fully fluorinated carbon atom" for the identification of substances that would be considered PFAS under the statute.

Functionally equivalent. We support the proposed definition of "functionally equivalent" in the proposed regulation and recommend that the Department include an interpretive note stating that the concept of "functionally equivalent product" includes duration of a product's or product component's service life.

Intentionally added PFAS. We agree with the interpretation of "intentionally added PFAS" provided in the note accompanying the definition.

Intrinsic to the design or construction of a building. It is our understanding that the Department is defining this term because it appears without definition in the statute in the definition of "architectural fabric structure." If the Department is defining "intrinsic to the design or construction of a building" for any other purpose, we request clarification.

Laboratory equipment. It is our understanding that the Department is defining this term because it appears without definition in the statute. If the Department is defining "laboratory equipment" for any other purpose, we request clarification.

We are concerned that the definition focuses on "analysis" when, in reality, laboratory equipment may be used for additional purposes. We recommend that the Department modify the definition in the proposed rule as shown here:

"Laboratory equipment" means any analytical <u>or monitoring</u> instrument or <u>other</u> support equipment that is <u>usedrequired</u> to <u>conduct research or generate</u> the results of an analysis. Laboratory equipment includes, but is not limited to, any tool, <u>apparatus</u>, gear, or appliance that is intended to be used in the creation, <u>separation</u>, <u>sampling</u>, <u>or monitoring</u> of a substance, <u>a mixture of substances</u>, <u>a process</u>, <u>or electromagnetic phenomena</u>, such as <u>incubators</u>, <u>fume hoods</u>, <u>laboratory water equipment</u>, reaction vessels, gas generators, <u>sensors</u>, <u>or preparatory or purifying equipment</u>.

Reasonably available. We support the proposed definition of "reasonably available" in the proposed regulation.

Significant change. As noted in previous public comments submitted to the Department (November 10, 2022, and August 30, 2024), a 10% deviation is likely to be very common due to variability in testing methods and the low levels of PFAS likely to be reported. A "significant change" should be at least 50% to eliminate this type of analytical and reporting variability. Also, the text in the final rule should include the phrase "intentionally added" as shown here:

"Significant change" means a change in the composition of a product which results in the addition of a specific, <u>intentionally added</u> PFAS; a change in the amount of <u>intentionally added</u> PFAS of more than <u>50%</u> increase or decrease, above the method variability etc.

3. Notification.

Section A. The proposed rule reflects the statute's provision that the notification requirements apply only to manufacturers "with greater than 100 employees." It is our understanding that "100 employees" refers to (a) full-time employees (FTEs) or the equivalent and (b) the entire company and not the number of employees physically located in Maine. If the Department's interpretation is different, the Department should make its interpretation explicit in the final regulation. Also, we appreciate and support the extension of the known or reasonably ascertainable standard to the notification process.

Also, to minimize the burden on the Department and companies doing business in Maine, the Department should consider consolidating the product notification process under Section 3 with the process for obtaining a CUU determination from the Department under Section 9. In other words, the Department should allow manufacturers to report the product information required under Section 3 of the proposed rule as part of their request for a CUU determination, rather than requiring preparation and review of two separate submissions.

Section A(1)(a)(iii). The Department proposes that notifications include "The general type of the product". How is "general type of the product" materially different than the GPC brick category or the HTS descriptor and code? This request for "general type" appears redundant and open to broad interpretation, making comparison difficult. It should not appear in the final rule.

Sections A(1)(c), (d), and (e). These sections can be clarified with the addition of the phrase "intentionally added" in front of each occurrence of "PFAS."

Section A(1)(d)(ii). We note that the Department has added "the chemical name following the nomenclature of the international union of pure and applied chemistry (IUPAC)" as an alternative to a chemical abstract service (CAS) registry number. This is a modification from the Departments August 2024 concept draft which included "a description approved by the Department." We do not support the Department's proposal to use IUPAC names as an alternative to CAS numbers. IUPAC names present the same concerns and infirmities as CAS numbers: most importantly, suppliers are often unwilling to provide downstream product manufacturers with either CAS numbers or IUPAC names because this information is frequently considered to be confidential business information and is often actively protected against disclosure under Federal law.

To account for this marketplace and regulatory reality, the Department should allow reporting of U.S. EPA-assigned Accession numbers. PMN numbers or LVE numbers as an alternative to reporting CAS numbers. Virtually all chemicals in commerce with confidential chemical identities should have been assigned one of these unique identifiers by U.S. EPA prior to, or upon, commercialization. Since these identifiers, unlike CAS numbers, are not themselves confidential, they are more readily obtained from suppliers. They can also be cross-referenced to EPA health and safety databases.

Section (A)(1)(e). The Department is requiring the amount of each of the PFAS in the product or any product component by selecting an approach that is appropriate. We suggest that the manufacturer chooses one of the identified approaches and request that the Department adds the word "or" at the end of items (i), (ii), and (iii).

Section (A)(1)(e)(ii). We do not support the use of total organic fluorine (TOF) measurements as a proxy or surrogate for the amount of PFAS in a product or product component, and TOF data should not be used to make conclusive statements about the type, source, or concentration of any specific PFAS or group of PFAS substances. TOF should only be used as a screening method, as it is prone to identifying inorganic fluorides or other organofluorine substances that do not meet Maine's definition of PFAS. In fact, U.S. EPA, in its recently updated draft guidance on PFAS disposal and destruction offers the following caution:

TOF analysis is an ongoing research area: data users must recognize the benefits of receiving general screening data for a wide array of potentially present PFAS, while also recognizing the limitations and uncertainties inherent in not knowing which PFAS or class of PFAS is present in the sample, including uncertainties associated with potential health risk. In addition, to minimize the risk of PFAS false positives, techniques within a validated method or methods must be developed that demonstrate effective separation and removal of inorganic fluorine from organic fluorine (Koch et al., 2020). TOF is not specific to PFAS, and any fluorine-containing compounds (e.g., pesticides, pharmaceuticals) that are retained during extraction would be included in the organic fluorine measurement.⁶

The Department should also review TOF protocols used by manufacturers for the extraction and accounting for inorganic fluorine according to standardized, validated protocols. In cases where any other method identified in Section (A)(1)(e) can be used, the Department should require manufacturers to use it.

Section A(1)(e)(iii). The proposed rule states that notifications and fees for products with affirmative CUU determinations must be received by the Department prior to the effective date of the applicable prohibition in Section 5. We suggest collection of fees as part of the consolidated submission discussed above, coupled with (i) a refund process and (ii) a rejection of the product notification submission for CUU requests that are not granted by the Department.

⁶ U.S. Environmental Protection Agency. Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances—Version 2 (2024). April 8, 2024. Page 58. <u>https://www.epa.gov/system/files/documents/2024-04/2024-interim-guidance-on-pfas-destruction-and-disposal.pdf</u>.

Also, Section 3(a)(1)(e)(iii) contemplates a "Department-approved range, implemented in the Department's online notification system." We request clarification of whether Department-approved ranges for products or categories of products will be communicated to manufacturers in advance of seeing them in the online notification system. Asked differently, will preparing a notification be the first time a manufacturer will see and become aware of Department-approved ranges? To design and execute a robust compliance strategy, manufacturers must understand the reporting system, including any Department-approved ranges, far in advance of the notification deadline.

Section A(1)(e)(iv). We request that the Department clarify how it will use "the total weight of the product" to estimate the amount of intentionally added PFAS in the product that is not entirely a PFAS as defined by statute. For respondents that utilize this option, the Department should consider requesting an estimate of the percentage PFAS content.

Section A(1)(f). The Department should clarify that notifications submitted under the statute *as revised* (i.e., after April 16, 2024), but prior to the availability of the digital reporting system, must be resubmitted within 90 days of the digital database becoming available. For example, notifications submitted to the Department in 2023, pursuant to the statute as originally enacted, will not need to be resubmitted to the Department unless the covered products receive a CUU determination and are placed in commerce in Maine.

Section A(2)(a)(iv). We request that the Department clarify the requirement in this section. For example, is it reasonable to expect that a publicly available source of substantially equivalent information not controlled or administered by the Department would be updated in response to requests by the Department as required at Section D? It seems more practical to require a reporting manufacturer to update substantially equivalent information in response to a request from the Department, rather than requiring that the source itself be updated.

Section D(1). We suggest the following modifications to differentiate between manufacturers who are also formulators and manufacturers who are not and are therefore likely to rely on information from a formulator (what may be several steps removed in the value chain):

(c) Prior to the start of sales of a product with a new formulationor when there that is a significant change in the amount or type of PFAS present in the product.

(d) Within 60 days of when it is known that there is a significant change in the amount or type of intentionally added PFAS present in the product.

Section F. The phrase "evidence sufficient to demonstrate" is vague. Without a clear understanding of the Department's expectations, reporting manufacturers may not be able to respond to a request from the Department in a timely and complete manner. We also request clarification of what is considered a timely response and suggest modifying the text as follows:

A manufacturer shall provide maintain records documenting the basis for the information contained in the notification and, upon request by the Department,

evidence sufficient to demonstrate the accuracy of the information reported in subsection Aprovide such records to the Department within 60 days.

4. Exemptions.

Section A. The proposed rule does not consider the ongoing need for replacement parts for complex products and other equipment under section 4(A). For example, while the proposed rule includes an exemption for watercraft and seaplanes, the Department does not also consider the need for replacement parts for exempt watercraft and seaplanes. If replacement parts that are or incorporate intentionally added PFAS are not available, it may not be possible to repair watercraft and seaplanes currently in use. Not acknowledging the very real and unavoidable need for replacement parts will significantly burden Maine businesses, government institutions, medical centers, the Maine National Guard, and consumers and may lead to premature disposal, creating unnecessary waste, unnecessarily occupying landfill space, and unnecessarily consuming virgin resources. Acknowledging the need for an exemption for replacement parts will significantly reduce the overall burden of the rule on the types of entities mentioned previously and the Department itself.

We offer the following additional provision to address replacement parts:

(14) Replacement parts for products described in Subsections 5 through 13, above.

Section A(1). We support the use of the word "governs" in this section. We continue to emphasize that manufacturers of products or product components subject to export administration regulations of the Department of Commerce's Bureau of Industry and Security or otherwise controlled for export by the State Department, Treasury Department, U.S. Nuclear Regulatory Commission, Department of Energy, Patent and Trademark Office, Department of Defense may be prohibited by such governance instruments from revealing information about formulation. In such cases, applying for a CUU determination and submitting a notification and fee may be impossible.

Section A(4)(10). There is a typo. The corrected version is as follows:

"A watercraft as defined in 32 M.R.S. § 13001(28), or a seaplane, expectexcept that the exemption . . ."

5. Prohibition on Sale of Products Containing Intentionally Added PFAS.

General. The definition of "Offered for sale" in the proposed rule is "to make a product available for purchase, including through online sales platforms that deliver into the State of Maine." Does the Department expect that on-line retail sales platforms reject purchases that will be shipped to a Maine address? The Department needs to provide more detail on how online retail sales will be affected by the proposed rule. The Department should also confirm that a transaction will not be considered a "sale" or "offer for sale" in the State of Maine unless, as a result of the transaction, the item being purchased would be physically present in Maine. For

example, a vendor may sell PFAS-containing products or equipment to ABC Company for use or sale outside the state of Maine. The transaction should not be considered a "sale in Maine" just because ABC Company (the purchaser) is headquartered in Maine.

6. Fees.

Section A. The statute authorizes the Department to assess a fee for notifications "to cover the department's reasonable costs in administering the requirements of this section." The Department has provided no analysis showing that a \$1,500 fee per notification would cover "reasonable costs." Without a more detailed forecast of the Department's costs, it is challenging to evaluate the proposed fee in the proposed rule or any other potential approaches to fees. The Department should also cap fees, either as an annual amount or per manufacturer.

The rationale for setting fees should be transparent about revenue generated by fees and how the fees will be used to manage the program. Fees should be calibrated appropriately such that the Department does not collect more in fees than what is needed to administer the program, and the Department should give itself flexibility to alter fee amounts depending on the changing needs of the program.

We request that the Department make available with the final rule a robust economic analysis of anticipated program costs and the estimated number of notifications (including product category notifications). We also request that the Department make publicly available an annual audit of fees collected and its program administration costs.

In addition, it is our reading that the contemplated fee is a one-time fee for the notification of either an individual product or a group of products that fall within a specific GPC brick (or HTS code if a GPC code does not apply). We request the Department's confirmation.

Also, the draft regulation states, "No fee is required for information updates to an existing notification or changes to inactive status." It is our reading of the draft regulation that "updates" covers all types of updates described in 3D (in "Notifications"). Furthermore, it is our reading that, if a manufacturer sells, offers for sale, or distributes in Maine a new product that falls within an existing category that has an affirmative CUU designation, the manufacturer would not be required to pay an additional fee, since the product already fits into a category for which a fee has been paid. We request the Department's confirmation.

Section A interpretive note. The first sentence of the note is clear. However, the second sentence says, "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." The Department should provide a definition of "complex product." Neither the proposed rule nor the statute contain a definition.

Also, the draft regulation states, "No fee is required for information updates to an existing notification or changes to inactive status." It is our reading of the draft regulation that "updates" covers all of the types of information required under 3(A)(1) (in "Notifications"). Furthermore, it is

our reading that, if a manufacturer sells, offers for sale, or distributes in Maine a new product that falls within an existing category that has an affirmative CUU designation, the manufacturer would not be required to pay an additional fee, since the product already fits into a category for which a fee has been paid. We request the Department's confirmation.

8. Certificate of Compliance.

Section A. The language at A(1) gives a manufacturer 30 days to respond with certified forms to an inquiry from the Department concerning the presence of intentionally added PFAS in a product. We anticipate that 30 days is insufficient should (a) testing be needed to prepare an adequate response to the Department or (b) the recipient of the inquiry requires more time to demonstrate that it took steps to reasonably ascertain whether the product or product component contains intentionally added PFAS. The Department should establish a limit of 120 days in both cases.

9. Currently Unavoidable Uses.

We request that the Department exclude fluoropolymers and fluoropolymer-based products from the scope of the proposed regulations. Fluoropolymers are large, stable molecules that have been demonstrated^{7,8} to meet criteria for identifying "polymers of low concern" for potential impacts on humans and the environment.^{9,10} As demonstrated in the cited works, fluoropolymers are insoluble substances and therefore do not present concerns about mobility in the environment, in contrast to certain highly water soluble PFAS substances. In addition, fluoropolymers are neither bioavailable nor bioaccumulative, are not long-chain non-polymer PFAS, such as PFOA and PFOS, and do not transform into non-polymer PFAS in the environment. Furthermore, because of their chemical and heat resistance as well as their dielectric properties, fluoropolymers are often used in components such as gaskets, tubing, electrical wiring, and printed circuit boards, that are found in tens of thousands of different products. Administering the envisioned program will be exponentially less complex and burdensome if fluoropolymers are excluded.

 ⁷ Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J. and Hernandez, O. (2018), A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integr Environ Assess Manag, 14: 316-334, https://doi.org/10.1002/ieam.4035.
⁸ Korzeniowski, S.H., Buck, R.C., Newkold, R.M., El kassmi, A., Laganis, E., Matsuoka, Y., Dinelli, B., Beauchet, S., Adamsky, F., Weilandt, K., Soni, V.K., Kapoor, D., Gunasekar, P., Malvasi, M., Brinati, G. and Musio, S. (2022), A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. Integr Environ Assess Manag, https://doi.org/10.1002/ieam.4646.

⁹ Organisation for Economic Co-operation and Development. 2009. Data analysis of the identification of correlations between polymer characteristics and potential for health or ecotoxicological concern. Document ENV/JM/MONO(2009)1. Paris (FR).

¹⁰ BIO by Deloitte. (2014). Technical assistance related to the review of REACH with regard to the registration requirements on polymers – Final report prepared for the European Commission (DG ENV), in collaboration with PIEP.

Section A. The Department states in the proposed regulation that it will not consider CUU proposals prior to 36 months in advance of the applicable sales prohibition. **This proposal is unacceptable.** Instead, manufacturers should be permitted to submit CUU proposals to the Department as soon as the regulations are finalized. To assure that final CUU determinations are based on current information, manufacturers that submit a CUU proposal more than 36 months prior to the applicable sales prohibition should be required to certify, within that 36-month period, that there are no material changes to the information that was included in the original CUU proposal.

468

The PFAS in products regulation has created significant market uncertainty regarding the availability of fluoropolymer products and product components required for many uses that are not exempt by statute. Regarding the January 1, 2032, prohibitions in particular, putting manufacturers and their entire supply chains on hold and in regulatory limbo will have significant disruptive consequences to the availability of fluoropolymers in many use categories the reliability and safety on which Maine's citizens, businesses, and institutions rely, including, but certainly not limited to, the following:

- Safety and critical functioning of manufacturing, including the storage, movement, and in-process containment of hazardous, corrosive, or explosive substances;
- Energy exploration, conservation, research and harvesting including hydrogen, solar, wind, oil, hydroelectric, and gas;
- Uses to support the safety and critical functioning of transport vehicles such as trains, planes, automotive, ocean-going vessels, and other passenger and cargo transport vehicles;
- Communications (e.g. 5G) and navigation systems;
- Municipal, industrial, and agricultural water and wastewater treatment systems;
- Multiple military and national defense uses¹¹;
- Lubrication systems and sealing systems operating under harsh conditions; and
- Uses that help to reduce the impacts of climate change, conservation of natural resources and the realization of the United Nations sustainable development goals, which include reducing global warming, energy conservation, protection of biological diversity.¹²

If the Department does not begin to consider CUU proposals immediately, there could be significant disruptive consequences, particularly where uses critical to Maine's economy and infrastructure are concerned.

In addition to the uncertainty the PFAS in products law creates, we also believe the Department must act expeditiously to avoid costly, last-minute product recalls. The statute is clear that a product cannot be sold or offered for sale after the prohibition date. A manufacturer

¹¹ See Department of Defense. Critical Per- and Polyfluoroalkyl substances Pursuant to Section 347 of the James M Inhofe National Defense Authorization Action for Fiscal Year 2023 (Public Law 117-263). August 2023. <u>https://www.acq.osd.mil/eie/eer/ecc/pfas/docs/reports/Report-on-Critical-PFAS-Substance-Uses.pdf</u>.

¹² <u>https://sdgs.un.org/goals</u>.

should not be put in a position of not being able to submit a CUU proposal until 36 months before the potential prohibition date and then having to wait until the finalization of a CUU rule to understand its obligations. The 36-month start time, combined with an unknowable number of months for the completion of a rulemaking process, could foreseeably lead to immediate and likely impossible (in terms of time) product recalls that will affect Maine businesses and consumers and have potentially significant solid waste implications for Maine's counties and municipalities.

We strongly recommend that the Department accept and begin to process CUU proposals immediately after the PFAS in products rule is finalized. We would appreciate clarity from DEP on the amount of time it anticipates to complete a CUU rule-making process. Furthermore, in the event that a CUU application has been submitted within the prescribed timeframe and the Department fails to render a final regulatory determination prior to the statutory ban date, the ban will not go into effect until three months after the Department completes the CUU rule-making process.

We also request that the Department create an appeals mechanism such that any manufacturer that can demonstrate that it will be aggrieved by the Department's denial of a CUU application. CUU determinations will involve the careful consideration of detailed economic, scientific, and engineering information. It is reasonable to assume that a manufacturer applying for a CUU determination may not be able to anticipate all of the Department's or the Board's questions in advance of or during a rule-making process, and it is therefore necessary to instate an appeals process that allows a manufacturer to bring forth new information and have the Department's decision reconsidered. The Rules of the Department of Environmental Protection describe an appeal procedure for a licensing decision made by the Department¹³ that could serve as a model for an appeals process for CUU determinations.

We are also unclear about what constitutes a "separate proposal." The proposed rule states that "A separate proposal must be submitted for each individual combination of product category and the associated industrial sector." This sentence is unclear and requires clarification. Take for example a fluoropolymer gasket might be assigned to a single product category but is used in multiple industrial sectors (e.g., heavy construction equipment, snowmobiles, riding lawn mowers). Is the single category and all of the associated use industries a single submission, or is a separate submission required for each user industry, even though the gasket is used for the same function (e.g., in the fuel line) in each industry? The Department should allow a single product that serves multiple industries for the same function to be covered under one CUU determination (and notification and fee for affirmative CUU determinations).

¹³ State of Maine. Rules of the Department of Environmental Protection. 06-096 Chapter 2: Processing of Applications and Other Administrative Matters, Section 23: Appeals to the Board of Commissioner License Decisions.

https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.maine.gov%2Fsos%2Fcec%2 Frules%2F06%2F096%2F096c002.docx&wdOrigin=BROWSELINK

Regarding the proposed "must at a minimum" elements of a CUU proposal, we do not agree with the Department's presumption that every manufacture of any size in any supply chain that might wish to submit a CUU proposal possesses perfect and complete information (or nearly so) to meet the "must at a minimum" standard. To the contrary, the proposed level of information required will be particularly challenging for manufacturers who are further down the value chain from the manufacturing or processing of the intentionally added PFAS substance in the product in question. For example, at Section 9(A)(1)(c), the Department proposes that a CUU proposal must contain "The North American Industry Classification System (NAICS) code for the sector or sectors in which the products containing intentionally added PFAS will be utilized." It is our understanding that manufacturers of product components may not know all sectors that use their products.

It is precisely for this reason that the standard "known or reasonably ascertainable by" exists. In the proposed regulation, the Department applies the "known or reasonably ascertainable by" standard to item 9. We believe it is reasonable and practical to extend it to *all elements* in the list. Proposal submitters will be required to report known elements and to demonstrate efforts to reasonably ascertain information they do not know. We therefore recommend that the phrase immediately preceding the list of elements be modified as follows:

A proposal must <u>at a minimum contain the following information to the degree it</u> is known or reasonably ascertainable:

The Department should allow a compliance extension of up to 18 months in cases where the Department, for any reason, does not or is otherwise unable to make a CUU determination before the statutory sale ban goes into effect. For example, if a manufacturer develops a product in mid-2030 or 2031, that manufacturer should be able to submit a CUU proposal, even though the product did not exist 18 months prior to the January 1, 2032, date.

Lastly, the Department should also address the renewal of CUU determinations by providing more detail on conditions and procedures for renewal. We suggest that to expedite the process, the Department could implement a certification program whereby a manufacturer can update some information from its previous CUU application but can also certify the accuracy of information if there has been no change.

Section A(2). We interpret the language at this section would require manufacturers to explain "why the availability of PFAS in the specific product" is "essential for health, safety or the functioning of society." It is our interpretation that "why the availability" includes considerations for performance and safety. We do not see an alternative interpretation that would allow the Department to make the determination required by statute that "that unavailability of the PFAS for use in the product would cause the product to be unavailable, which would result in:

- (1) A significant increase in negative health outcomes;
- (2) An inability to mitigate significant risks to human health or the environment; or
- (3) A significant disruption of the daily functions on which society relies."¹⁴

¹⁴ 38 MRSA §1614(1)(B-1)

If the Department is interpreting the proposed language at Section (A)(2) differently, that interpretation should be articulated clearly in the final regulation.

Sentence above interpretive note following 9(e)(iii). We appreciate that the Department proposes to give a manufacturer the opportunity to explain why any of the information detailed in this section is not included in a CUU proposal.

Interpretive note following 9(e)(iii). We note the Department's recommendation to avoid inclusion of proprietary information in CUU proposals. Those proposals will require the Department to consider information about product formulations, manufacturing processes or costs, and substance identities that may be commercially sensitive. The assertion of proprietary information cannot be an automatic basis for deeming incomplete or rejecting CUU proposals at any point in the regulatory process. There are many examples of regulatory processes subject to public comment (e.g. Title V permits under the Clean Air Act) that have procedures allowing for the protection of proprietary information. The Department must develop procedures to conduct CUU-related regulatory determinations while protecting legitimate, substantiated claims of proprietary information.

Section A, final paragraph. It is our reading that the Department is placing no limitation on the number of CUU renewals a manufacturer can request. Also, it appears that the Department envisions a 12-month period between making a determination on a CUU renewal and the expiration of a CUU designation. It is highly unlikely that a manufacturer can switch to a Department-mandated alternative (by virtue of denying a CUU renewal) in 12 months. Therefore, we request the following, more realistic, change:

The Department will consider all subsequent proposals no sooner than 24-36 months prior to and no later than 12-24 months prior to the expiration date of the determination in effect.

10. Proprietary Information.

We appreciate that the legislature has directed DEP to protect proprietary information in the administration of the program.

Thank you again for the opportunity to provide these comments on the proposed regulation. We would be happy to meet with the Department to discuss any of our questions, concerns, and suggestions in more detail.

Jay West Executive Director Performance Fluoropolymer Partnership



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January 27, 2025

Submitted via email to rulecomments.dep@maine.gov

Melanie Loyzim Commissioner, Maine Department of Environmental Protection (DEP) 17 State House Station Augusta, ME 04333

Re: <u>Comments on Proposed Chapter 90 Rule for Products Containing</u> <u>Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS)</u>

Dear Commissioner Loyzim:

The PFAS Pharmaceutical Working Group¹ (PPWG) is a group of manufacturers and distributors of drugs, biologics, animal drugs, and medical devices. PPWG appreciates the opportunity to provide comments on DEP's proposed Chapter 90 rule concerning PFAS in products (the Rule), implementing 38 M.R.S. § 1614. In April 2024, the Maine legislature – with the input of DEP and other stakeholders – passed L.D. 1537 which amended 38 M.R.S. § 1614 to make the law more workable for DEP to implement and for the regulated community to comply with. PPWG urges DEP to take a similar pragmatic approach with the Rule to avoid a situation where DEP struggles to execute a regulatory program in excess of what the legislature intended. A pragmatic approach to this rulemaking will also help ensure that the regulated community is able to comply, thereby facilitating a transition away from PFAS in products to a feasible extent and on a timeline that is appropriate.

L.D. 1537 added several exemptions to all of 38 M.R.S. § 1614's provisions, including for drugs and devices, veterinary products, nonconsumer laboratory equipment, and for equipment directly used in the manufacture or development of exempted products. Notwithstanding these exemptions, PPWG still has serious concerns with how the law's material restrictions, as implemented in the Rule, may impact products in medical, pharmaceutical, and animal health product supply chains to the extent these products are not covered by an exemption.

For example, if the statute's restrictions apply to certain products used by upstream suppliers (e.g., if these upstream products are not directly used in the manufacture or development of a drug or device) or to non-exempted products used in the industry (such as in research and development (R&D) or distribution of a drug or device), that may negatively affect the production and availability of the industry's exempted products or the ability to continue manufacturing these products within the specifications or marketing authorizations granted by the U.S. Food and Drug Administration (FDA). This situation would contribute to uncertainty over whether certain critical medical,

¹ PPWG's member companies, which include their subsidiaries and affiliates, are Amgen Inc.; Bristol Myers Squibb Company; GSK; Merck & Co., Inc.; Pfizer, Inc.; and Roche.

pharmaceutical, and animal health products can remain on the market in Maine, contravening the legislature's intent to ensure Mainers' continued access to these lifesaving and life-enhancing products.

38 M.R.S. § 1614 restricts intentionally added PFAS in products starting in 2032 (and on other dates for some specific products) except for currently unavoidable uses (CUU) of PFAS. "Currently unavoidable use" is defined in the statute as "a use of PFAS that the department has determined by rule under this section to be essential for health, safety or the functioning of society and for which alternatives are not reasonably available." Manufacturers of products covered by CUU determinations must also submit a notification to DEP, or else those products are subject to the 2032 restriction. In line with PPWG's concerns described above, narrow application of the statute's CUU standard paired with other provisions in the Rule that are unworkable could risk impacts on the availability of products that the Maine legislature has specified are exempt from the law's provisions.

PPWG requests that DEP avoid this result in the Rule. Specifically, DEP should:

- Implement criteria that account for how a restriction on a particular PFAS in a product may impact other products and processes up and down supply chains. Specifically, the criteria for assessing what is "essential for health, safety, or the functioning of society" should consider societal impacts that may be broader than direct use of the end product itself. In addition, direct and indirect supply chain costs and risks should be considered in determining whether alternatives are "reasonably available."
- Provide a longer runway to submit CUU determination proposals, timely respond to such proposals, and include a presumption in favor of CUU determination renewals. These provisions will help ensure that the CUU determination process is fair and efficient. For instance, DEP should be required to review and act on proposals submitted as soon as the Rule is finalized, rather than having companies wait until 36 months before the applicable sales prohibition to submit proposals. This longer runway is crucial given the years-long processes involved with adjusting product lines in the industry and to prevent a bottleneck scenario where DEP must review all submitted proposals shortly before the relevant sales prohibition takes effect.
- Where appropriate, make CUU determinations for broad categories of products rather than on a product-by-product basis. For many types of products, making CUU determinations for individual products would almost certainly omit some products that are critical to health, safety, or the functioning of society. Applying CUU determinations to groups of products or categories of products intended for specified uses would be more efficient, would promote consistent treatment across related products, and would accomplish statutory objectives.
- Prioritize review of CUU determination proposals for products used in medical, pharmaceutical, and animal health product supply chains. Given that DEP should expect a very large number of proposals for CUU determinations to be submitted, this prioritization will aid in making sure proposals relevant to the industry (and therefore to products exempted from the statute) do not get lost in the queue.

- <u>Limit the Rule's scope to a finite list of PFAS with CAS Numbers</u>. Without a specified list of chemical names with CAS Numbers, tracking a class of tens of thousands of chemicals through complex supply chains, such as those that exist in this industry, is virtually impossible.
- Include a de minimis threshold in the Rule for PFAS below 0.1% by weight in the product. A 0.1% by weight threshold provides a rational, reasonable level consistent with de minimis chemical levels applied by other regulators, and would help mitigate the due diligence burden on supply chains.
- Incorporate robust protections in the Rule for confidential business information (CBI). DEP's note in the proposed Rule that CUU determinations should not contain CBI claims could have a chilling effect of deterring companies from submitting CUU determination proposals. DEP should therefore implement a process to permit such CBI claims in CUU determination proposals. Relatedly, DEP should be required to include in the reporting portal a mechanism for claiming CBI in notifications.
- I. The CUU Determination Process Should Reflect the Impacts a PFAS Restriction May Have Up and Down Supply Chains.

PPWG recommends that DEP include the following provision in section 9 of the Rule:

In any subsequent Department CUU rulemaking, the Department shall grant a CUU determination for PFAS applications or end products, and for the supply chain, research, development, and production activities required to produce such PFAS applications or end products, when the Department has evidence, or when a manufacturer, organization, or other entity has submitted evidence, that an application, product, or category of products provides benefits related to health, safety, or the functioning of society and that there are no reasonably available alternatives for that use.

A product shall be deemed to provide benefits to health, safety, or the functioning of society where the Department has evidence, or the manufacturer, organization, or other entity has submitted evidence, that the product supports:

- (a) For health physical or emotional health or wellness;
- (b) For safety the safety or security of the public from danger, injury, or property damage;
- (c) For the functioning of society identified consumer, commercial, or industrial demands for the product; or
- (d) The manufacture, distribution, or research and development of any product subject to an exemption in 38 M.R.S. § 1614(12)(D-M).

This provision would accomplish a number of important objectives. First, section 9 of the Rule as proposed currently does not impose any requirements on DEP for reviewing CUU determination proposals (aside from stating that such an evaluation will occur in a subsequent rulemaking), and this provision would add critical language to provide companies with an understanding of how proposals will be evaluated. Second, this provision helps avoid arbitrary and subjective determinations by stating that DEP "shall" grant the requested determination if the manufacturer

has submitted qualifying evidence meeting the statutory criteria. Relatedly, this provision clarifies that DEP should grant a CUU determination *sua sponte* when the agency has sufficient evidence to do so, since 38 M.R.S. § 1614 does not require that CUU determinations be made only upon manufacturer request. Third, this provision specifies that the determination should apply not only to the end product itself, but to products and processes in the supply chain that are necessary to produce that product; without this, a CUU determination could be substantially undermined, or even rendered meaningless, given that it is not possible to produce end products without upstream activities.

Fourth, this provision appropriately explains what information demonstrates that a PFAS use is essential for health, safety, or the functioning of society. Health, safety, and societal benefits should be described expansively to capture the naturally broad scope of these terms. Moreover, the fact that a PFAS use supports the manufacture, distribution, or R&D of a product subject to an exemption in 38 M.R.S. § 1614(12)(D-M) is sufficient to demonstrate that the PFAS use is essential for health, safety, or the functioning of society, since the Maine legislature exempted these products presumably due to their critical roles in society that could be unduly impacted by the law's PFAS restriction.

PPWG also recommends the following definition of "reasonably available alternative":

"Reasonably available alternative" means a substance, material, technology, process, or otherwise that is currently available at commercial scale and that, when used in place of intentionally added PFAS, does not result in:

- (a) A decrease in availability, performance, life expectancy, quality, or durability of the product or of any upstream or downstream manufacturing, distribution, or research and development activities associated with that product;
- (b) A significant increase in manufacturing, design, testing, capital investment, or other costs for the product or for any upstream or downstream manufacturing, distribution, or research and development activities associated with that product; or
- (c) Risks to human health or the environment that would not be present, or present in lesser degrees, with use of the intentionally added PFAS, including but not limited to risks from toxicity, energy consumption, product safety, product unavailability, and disposal.

The Rule as currently proposed would define this term as "a PFAS alternative which is readily available in sufficient quantity and at a comparable cost to the PFAS, to include changes to the manufacturing process, it is intended to replace and performs as well or better than PFAS in a specific application of PFAS in a product or product component." This proposed definition lacks the needed clarity that PPWG's recommended definition provides. Like with PPWG's requested provision on essentiality, this recommended definition recognizes that the evaluation of any potential alternative must involve an assessment of how the alternative may affect other parts of the supply chain, particularly to avoid unintended impacts on other products such as those covered by an exemption in 38 M.R.S. § 1614(12).

Likewise, PPWG's recommended definition accounts for how the evaluation of an alternative must consider the real, commercial availability of the alternative. The evaluation must consider not just the direct cost of switching to an alternative in a product, but also the costs of the whole process for designing and implementing the alternative – including the costs that may be borne by other companies in the product's supply chain. Lastly, the risks associated with an alternative can have substantial impacts on the alternative's availability. PPWG's recommended definition reflects how these risks could stem not only from the toxicological profile of the alternative itself, but also from risks across the product's lifecycle. These risks could include, but are not limited to, sustainability considerations (energy consumption, climate impacts, etc.), manufacturing product safety, end product safety and efficacy (e.g., flammability, shelf life, stability), end product unavailability (e.g., health risks of skipping doses or delaying treatment because of unavailability), and disposal.

II. Ensure the CUU Determination Process is Efficient and Fair Through Submission and Review Timelines, and Through Renewals.

DEP should remove the language in section 9(A) of the proposed Rule providing that DEP will not consider any CUU determination proposals submitted prior to 36 months in advance of the applicable sales prohibition. Instead, DEP should review and act on proposals that are submitted starting on the date the Rule is finalized.

It can take several years for companies in the medical, pharmaceutical, and animal health product industry to effectuate product reformulations and redesigns in part because these modifications often require thorough regulatory approvals by the FDA and other bodies and because any such changes need to be extensively vetted for their impact on the health of patients and others that use this industry's products. Moreover, the capital expenditure and other financial planning needed to upgrade equipment, modify production lines, and make other investments in preparation for a change in the composition of a product can take many years to implement. These modification processes cannot go from start to finish within the 36-month period that DEP has proposed, especially given that DEP's decision on a CUU determination proposal would be made even closer than 36 months from the date of the relevant sales prohibition. In other words, it is foreseeable that PFAS applications in the medical, pharmaceutical, and animal health product industry in use as of the date the Rule is finalized may still be unavoidable in 2032, and therefore these PFAS uses constitute *current* unavoidable uses both when the Rule is finalized and in 2032.

While many of this industry's products are covered by exemptions in 38 M.R.S. § 1614(4), as mentioned above, there could be scenarios where the production or availability of these exempted products may be negatively impacted by the law's restrictions. The timeline for when DEP begins accepting and evaluating CUU determination proposals should therefore account for the fact that a decision on a proposal has the potential to impact a large swath of products up and down supply chains that can require several years – and not just 36 months – to effectuate changes to and which are imposed by a new material restriction. Further, DEP should expect a very large number of CUU determination proposals to be submitted. If all companies must submit proposals within the same 36-month period before the applicable sales prohibition, there is a very real possibility of a bottleneck scenario where DEP would be overloaded with proposal reviews and would not be able to come to decisions on all submitted proposals by the applicable compliance date. DEP should prevent this from happening in the Rule.

In addition, PPWG recommends that the following provisions regarding CUU determination proposal review timelines be included in section 9 of the Rule:

In the event that the Department fails to, by the applicable sales prohibition, either (1) finalize a rule implementing a timely submitted CUU proposal or (2) decline to issue such a rule, the requested CUU determination shall be automatically approved and remain valid until six months after the Department issues a decision on the proposal.

If a proposal for a renewed CUU determination is timely submitted, the Department shall grant that renewal unless the Department determines that there is significant evidence that alternatives to the relevant PFAS use have become reasonably available or that the PFAS use is no longer essential to health, safety or the functioning of society.

If a proposal for a renewed CUU determination is denied by the Department, the relevant sales prohibition as applied to the products covered by the previously issued CUU determination shall not go into effect until one year after the expiration of that previously issued CUU determination.

While the Rule as proposed includes timelines for when companies must submit CUU determination proposals, no such timelines are included for when DEP must act on such proposals. The Rule should require DEP to timely act on CUU determination proposals in advance of the applicable compliance deadline, and if DEP fails to timely respond that should function as an automatically approved CUU determination for at least six months from when DEP issues a decision. This process would be in line with exemption procedures under other chemical regulatory programs, such as under Article 5 of the European Union's Restriction on Hazardous Substances Directive (RoHS) through which an existing exemption to RoHS's restrictions remains valid until the European Commission has decided on a renewal application. PPWG's requested six-month delay for when the sales prohibition would take effect in this situation is necessary to provide a sell-through buffer in the event that DEP denies the proposal after the relevant compliance deadline provided in the statute.

Likewise, DEP should include a presumption in the Rule in favor of CUU determination renewals. Specifically, as mentioned in PPWG's recommended provisions above, DEP should grant renewals unless there is significant evidence that alternatives have become reasonably available or that the use of PFAS is no longer essential for health, safety, or the functioning of society. Moreover, if a proposal for a renewed CUU determination is denied by DEP, there should be a grace period of at least one year for manufacturers to transition to alternatives. These procedures will act as safeguards to ensure that impacted stakeholders from across supply chains are able to properly plan for and then rely on CUU determinations.

III. Where Appropriate, CUU Determinations Should Be Made For Broad Product Categories Rather Than Product-By-Product.

Section 9(A) of the Rule as proposed states that "a separate [CUU] proposal must be submitted for each individual combination of product category and the associated industrial sector." PPWG supports a process where DEP will make CUU determinations for broad categories of products where appropriate, rather than on a product-by-product basis. 38 M.R.S. § 1614 does not require that CUU determinations be made only for individual products, and this process would waste both

public and private resources as manufacturers will likely end up preparing and submitting several proposals for like products, and DEP will need to carefully compare proposals to assess potential duplication. Moreover, product-by-product determinations would almost certainly omit some products that should be covered by a CUU determination but are not because of arbitrary line drawing in the scope of the determination.

DEP should consider making CUU determinations in line with the broad product categories employed by the U.S. Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA) PFAS reporting rule, 40 C.F.R. Part 705. Under that rule, manufacturers are to report PFAS in their products through use of broad consumer and commercial product category codes found in table 5 to 40 C.F.R. § 705.15(c)(4). These codes were taken from EPA's TSCA Chemical Data Reporting program, which were in turn based on Organisation for Economic Co-operation and development harmonized codes.²

Relatedly, DEP should remove the requirement in section 9(A)(1)(b) for CUU determination proposals to include the GPC brick category and code (or, if GPC is not applicable then the HTS code). The imposition of a requirement to provide GPC- and HTS-level information does not fit with the type of broad categorical CUU determinations that will need to be granted by DEP. These codes are typically used for specific product classifications that are more suited for detailed trade and inventory purposes rather than broad regulatory determinations such as for CUUs of PFAS. Additionally, it is not practical to expect manufacturers to gather this information to include in proposals, as it requires significant effort and resources to accurately classify products at this granular level. Assessing GPC- and HTS-level information in proposals would also place an undue burden on DEP and potentially lead to some relevant codes being left out of the CUU determination process inadvertently.

IV. Prioritize Review of CUU Determinations for Products Used in Medical, Pharmaceutical, and Animal Health Product Supply Chains.

The Maine legislature recognized the importance of protecting Mainers' access to lifesaving and life-enhancing medical, pharmaceutical, and animal health products through the exemptions for these products in 38 M.R.S. § 11614(12). In addition, states are largely preempted from regulating these products because these items are already heavily regulated by the FDA. Therefore, the exemptions for medical, pharmaceutical, and animal health products in the statute also avoid disputes about the scope of federal preemption as applied to 38 M.R.S. § 1614.

To avoid undermining these exemptions and their critical functions, DEP should prioritize requests for CUU determinations concerning products used in medical, pharmaceutical, and animal health product R&D, manufacturing, distribution, and supply chains. Such prioritization could include, for example, flagging such requests for expedited review outside of a normal, first-come, first-served queue. This prioritization would help protect the integrity of medical, pharmaceutical, and animal health manufacturing, distribution, R&D, and supply chains in the event of a backlog of CUU determination requests.

² EPA, Instructions for Reporting PFAS under TSCA Section 8(a)(7), Appendix D (Nov. 2024), https://www.epa.gov/system/files/documents/2024-12/tsca-8a7-reporting-instructions_11-25-24.pdf.

V. Limit the Rule's Scope to a Finite List of PFAS with CAS Numbers.

DEP should limit the scope of the Rule to a finite list of PFAS with CAS Numbers. Without such a list, tracking the vast family of PFAS, which includes tens of thousands of chemicals, through intricate supply chains that exist in the industry becomes nearly impossible.

Limiting the Rule to a finite list of PFAS with CAS Numbers is also consistent with PFAS in products regulatory schemes in other jurisdictions. For example, Environment and Climate Change Canada (ECCC) released PFAS reporting requirements in July 2024 that are limited to 312 specific PFAS, each of which carry a CAS Number or Confidential Accession Number (for when the specific chemical identity is confidential).³ This list of 312 PFAS was chosen because these specific PFAS are known or anticipated to be in Canadian commerce and have not recently been surveyed, as opposed to a larger universe of PFAS without a nexus to commerce.⁴ DEP should follow ECCC's direction in the Rule.

VI. Include a De Minimis Threshold in the Rule.

DEP should specify that the Rule's requirements do not apply to products containing less than 0.1% by weight of PFAS. 38 M.R.S. § 1614 only applies to intentionally added PFAS, and PFAS below PPWG's requested de minimis level is very likely to be unintentionally present. Further, this de minimis level aligns with similar thresholds employed in several other chemical reporting and restriction programs, such as EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), which includes a 0.1% by weight reporting threshold for substances of very high concern.⁵ Similarly, EU RoHS limits the presence of certain substances to a 0.1% concentration threshold.⁶ EPA has also recently incorporated 0.1% concentration thresholds into chemical restrictions under several TSCA rules, including in the agency's restrictions for phenol, isopropylated phosphate (3:1) (PIP (3:1)) and decabromodiphenyl ether (decaBDE),⁷ as well as in risk management rules for methylene chloride, trichloroethylene, and perchloroethylene.⁸

A 0.1% de minimis threshold in the Rule is rational and reasonable, and it would help avoid imposing excessive due diligence burdens on companies to detect trace chemical amounts throughout global supply chains. This de minimis threshold would also alleviate administrative burdens on DEP by reducing the number of notifications for items containing only trace amounts of PFAS. We therefore recommend that DEP include the following provision in the Rule:

This Chapter does not apply to the sale, offer for sale, or distribution for sale in the State of Maine of products containing less than 0.1% by weight of any PFAS.

³ Canada Gazette, Part I, Volume 158, Number 30: Supplement, Notice with respect to certain per- and polyfluoroalkyl substances (July 27, 2024).

⁴ ECCC, Guidance manual for responding to the: Notice with respect to certain PFAS, at page 5 (July 2024), https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/pfas-s71-guidance-manual.html.

⁵ EU REACH, Art. 7(2) (this threshold is calculated by reference to the weight of an article).

⁶ EU RoHS, Annex II (this threshold is calculated by reference to the wright of a homogenous material).

⁷ 89 Fed. Reg. 91486 (November 19, 2024).

⁸ 89 Fed. Reg. 39254 (May 8, 2024); 89 Fed. Reg. 102568 (Dec. 17, 2024); 89 Fed. Reg. 103560 (Dec. 18, 2024).

VII. Incorporate Robust Protections for CBI into the Rule.

DEP's note on page 20 of the proposed Rule explains that, while 38 M.R.S. § 1614(12) and section 10 of the proposed Rule provide a mechanism for protecting CBI, CUU determinations are subject to the notice-and-comment rulemaking process and therefore DEP "strongly recommends that all proposals for currently unavoidable use determinations do not contain claims of confidentiality." This statement is concerning given that the type of information DEP will require to be included in CUU proposals (such as chemical identities and functions of these chemicals) will undoubtedly contain CBI.

The medical, pharmaceutical, and animal health product industry treats the chemical composition of materials as proprietary information that is carefully protected and of significant commercial value. This proprietary information includes not just PFAS identities, but also the purpose of the PFAS in the product, research being done on potential PFAS alternatives, and related information that may need to be included in CUU proposals. Accordingly, DEP should consider ways in which companies can protect CBI included in CUU proposals, such as by allowing companies to submit unredacted and CBI-redacted versions of requests. DEP could also implement in-camera reviews where DEP assesses unredacted proposals and then summarizes key points and findings for the public while excluding proprietary details. Relatedly, the portal that DEP will use for notifications under the Rule must contain a well-defined CBI framework that permits reporters to claim any and all notification elements as CBI.

VIII. Conclusion.

PPWG thanks DEP for considering its comments on the proposed Rule. If you have any questions, please feel free to contact me.

Sincerely

Ryan J. Carra

Counsel for PFAS Pharmaceutical Working Group Beveridge & Diamond, PC 1900 N Street NW, Suite 100 Washington, DC 20036 (202) 789-6059 rcarra@bdlaw.com



Lori K. Gramlich Assistant House Majority Leader (207) 287-1430 Lori.Gramlich@legislature.maine.gov HOUSE OF REPRESENTATIVES 2 STATE HOUSE STATION AUGUSTA, MAINE 04333-0002 (207) 287-1400 TTY: Maine Relay 711

January 16, 2025

Public Comment on Proposed Routine Technical Rule – Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

Good morning, I am Lori Gramlich, Assistant House Majority Leader and State Representative serving the lovely seaside community of Old Orchard Beach. Thank you for the opportunity to comment on the proposed Chapter 90 rule regarding products containing PFAS.

During my time in the Legislature, I have worked to address the increasingly alarming concerns around PFAS contamination and the way these chemicals affect our lands and our health. I have personally sponsored several proposals to protect Mainers from the health risks posed by PFAS exposure, including LD 1503 in the 130th Legislature, which created the landmark law to phase out avoidable uses of intentionally added PFAS. As House Chair of the Environment and Natural Resources Committee during the 131st Legislature, I worked closely with my colleagues and stakeholders on LD 1537, which amended that critically important law to allow for greater success in its implementation.

I am deeply grateful for the Department staff, environmental and public health advocates, and industry stakeholders who have informed the work we are providing feedback on today. The draft rule is well done, and while I have feedback to draw your attention to today, I am pleased to support it overall and offer the following suggestions to further strengthen it before final adoption by the Department.

First, I ask that the Department increase the specificity of the definitions in the proposed rule. For example:

- "Commercially available analytical method" testing does not need to be done by a third-party lab. Industry shouldn't be allowed to test their own materials. There is vague language about not altering third-party lab protocols. The definition should also be more specific. In theory, a lab could use any test methodology that they want for a third-party.
- "Chemically formulated" is defined as "a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources." What about instances where it does not chemically "change" the natural substance, but it is still added to the substance?

• Cosolvent: It is not clear to me why "in small amounts" is in the definition. Cosolvents can be used in a wide range of concentrations.

Second, I believe additional language is needed in Section 9 to accomplish the following:

- Require manufacturers to clearly articulate the characteristics in question are necessary for the relevant product's function in health, safety or the functioning of society; and,
- Provide specific criteria to guide industry when comparing the known risks of PFAS with any such risks posed by alternative materials.

Finally, I respectfully urge you to ensure that this draft rule is not weakened in any way before final adoption. Current law is the result of extensive work between the Legislature, executive branch and various advocacy groups to compromise. It allows a number of exemptions requested by industry and aligns our timeline with that of other states, providing uniformity. Where delays or exceptions may have been helpful or necessary, we have already made them. Now is the time to move forward.

I am so proud of the nation-leading work we have done here in Maine to not only recognize the threat that PFAS chemicals pose but to also take thoughtful, meaningful action. The bottom line is that we need to ensure these rules serve to further strengthen our protections against unnecessary PFAS contamination and exposure.

Thank you for your consideration.





January 28, 2025

Submitted via email to rulecomments.dep@maine.gov

Melanie Loyzim Commissioner Maine Department of Environmental Protection 17 State House Station Augusta, Maine 04333-0017

Re: Comments from SEMI and SIA in Response to the DEP Proposed Rule for PFAS in Products

Dear Commissioner Loyzim:

On behalf of SEMI¹ and the Semiconductor Industry Association (SIA),² we write to offer comments in response to the Maine Department of Environmental Protection's (DEP) proposed Chapter 90 rule (the Proposed Rule) to implement 38 M.R.S. § 1614. That statute restricts intentionally added PFAS in all products starting in 2032 (and on other dates for specified products), unless a product is determined by DEP to be a currently unavoidable use (CUU) of PFAS. The law also requires manufacturers of products covered by CUU determinations to report certain information to DEP. However, certain products are exempt from all of the law's provisions, including semiconductors and equipment and materials used in the manufacture of semiconductors.

These comments discuss the definition that DEP has put forward for "semiconductor" in the Proposed Rule, and serve as a follow-on to comments jointly submitted by SEMI and SIA on August 30, 2024 regarding DEP's Concept Draft. SEMI and SIA appreciate DEP's efforts on the Proposed Rule and look forward to future engagement as it relates to the semiconductor supply chain.

¹ SEMI[®] represents more than 3,000 member companies to advance the technology and business of electronics manufacturing. SEMI members are responsible for the innovations in materials, design, equipment, software, devices, and services that enable smarter, faster, more powerful, and more affordable electronic products. Electronic System Design Alliance (ESD Alliance), FlexTech, the Fab Owners Alliance (FOA) and the MEMS & Sensors Industry Group (MSIG) are SEMI Strategic Association Partners, defined communities within SEMI focused on specific technologies. Since 1970, SEMI has built connections that have helped its members prosper, create new markets, and address common industry challenges together. SEMI maintains offices in Bangalore, Berlin, Brussels, Hsinchu, Seoul, Shanghai, Silicon Valley (Milpitas, Calif.), Singapore, Tokyo, and Washington, D.C. For more information, visit <u>www.semi.org</u>.

² SIA has been the voice of the semiconductor industry for over 45 years, representing 99 percent of the U.S. semiconductor industry by revenue and nearly two-thirds of non-U.S. chip firms. Semiconductors are one of America's top export industries and a key driver of America's economic strength, national security, and global competitiveness. The semiconductor industry directly employs over 300,000 workers in the United States, and U.S. semiconductor company sales totaled \$264 billion in 2023. Through this coalition, SIA seeks to strengthen leadership of semiconductor manufacturing, design, and research by working with Congress, the Administration, and key industry stakeholders around the world to encourage policies that fuel innovation, propel business, and drive international competition. Additional information is available at <u>www.semiconductors.org</u>.

I. Comments Regarding Definitions (Section 2)

a. Definition of Semiconductor

SEMI and SIA appreciate that DEP adopted in the Proposed Rule the semiconductor definition recommended in the comments submitted jointly by SEMI and SIA in August 2024. This new definition is better aligned with the broad exemption for semiconductors that the Maine Legislature included in 38 M.R.S. § 1614(4)(K) as amended through L.D. 1537.

As previously noted, this definition that is now included in the Proposed Rule reflects the semiconductor chip product definition used at the federal level in 17 U.S.C. § 901(a)(1). This harmonization of DEP's future rule with federal law is crucial given that our industry operates across the country and globally, meaning that inconsistencies between how jurisdictions define semiconductor must be avoided to ensure regulatory consistency. In addition, the use of the phrase "discrete functional object" ensures the inclusion of the assembled, packaged semiconductor devices that are in fact the products being sold. Finally, the additional changes from the Concept Draft to the Proposed Rule concerning the exclusionary portion of the semiconductor definition more accurately reflect the various components, such as printed circuit boards and auxiliary items, that do or do not comprise a semiconductor.

After further assessment of the definition, SEMI and SIA would like to propose one more change to the "semiconductor" definition, which is to remove the word "related" as follows:

"Semiconductor. "Semiconductor" means material having conductivity characteristics intermediate between conductors and insulators, as well as a discrete functional object having two or more layers of metallic, insulating, or semiconductor material, deposited or otherwise placed on, or etched away or otherwise removed from, a piece of semiconductor material in accordance with a predetermined micron or sub-micron pattern and intended to perform electronic and other related functions. Semiconductors do not include commonly associated materials such as printed circuit boards (PCB), PCB mounting solder, PCB mounting flux, external wires, PCB screen printing ink, connectors and sockets, or PCB conformal coatings."

Microelectromechanical systems (MEMS), including MEMS that are only micromechanical systems (e.g., grids, nozzles, trays, screens) and which do not have an electronic element, are nonetheless manufactured using semiconductor processes, but might not be recognized as having functions "related" to electronic functions. Deleting the ambiguous term "related" helps ensure legal certainty.

b. Note following Definition of Semiconductor

The note following DEP's semiconductor definition in the Proposed Rule states that "[a] product must meet the definition of a semiconductor product will not be considered a semiconductor solely because other products that serve the same or similar purpose are semiconductors." The note contains a grammatical error that makes its meaning unclear. Further, the note references "the definition of semiconductor product" even though that term is not proposed to be defined. There is only a definition of "semiconductor". SEMI and SIA believe that the purpose of this note is to make clear that a "semiconductor" is not just a material but also a type of product subject to the semiconductor exemption in section 4.A.(11) of the Proposed Rule. To address these issues, SEMI and SIA suggest the following revised note instead:

"NOTE: semiconductor means both a material and a type of product that is a discrete functional object as described in the definition. Semiconductor products (discrete functional objects) include, but are not limited to, integrated circuits, micro electromechanical systems, solar cells, patterned flat panel display substrates, light emitting diodes, sensors/detectors, and other products."

II. Comments Regarding Exemptions (Section 4)

a. Note following Subsection 11 of Section 4(A)

Section 4(A) of the Proposed Rule outlines and provides clarifying notes on the products exempt from DEP's future rule pursuant to 38 M.R.S. § 1614(4) as amended through L.D. 1537. The note under Subsection 11 of Section 4(A) in the Proposed Rule explains in part that "[w]hile semiconductors incorporated into electronic equipment are exempted from this Chapter, electronic equipment in their entirety is not." This is the same note DEP included in the Concept Draft. As explained in the SEMI-SIA comments from August 2024, this statement is unclear, and potentially inaccurate, given that the law's exemption for semiconductors at 38 M.R.S. § 1614(4)(K) covers "equipment . . . used in the manufacture of semiconductors." Such exempted semiconductor manufacturing equipment could be electronic equipment. Moreover, 38 M.R.S. § 1614(4)(L) and (M) exempt, respectively, non-consumer electronics and equipment directly used in the manufacture or development of products described in paragraphs E to L.

SEMI and SIA therefore reiterate our recommendation that the note under Subsection 11 of Section 4(A) in the Proposed Rule be edited to clarify that electronic equipment used in the manufacture of semiconductors is also exempt. Rewritten, this note should read as follows:

NOTE: While semiconductors incorporated into electronic equipment are exempted from this Chapter, electronic equipment in their entirety is not exempt unless otherwise specified in this Chapter (for example, the electronic equipment is used in the manufacture of semiconductors, is considered a non-consumer electronic product under Subsection 12, or (as described in Subsection 13) is otherwise considered equipment directly used in the manufacture or development of products described in Subsections 5 through 12).

b. Note Following Subsection 13 of Section 4(A)

As mentioned above, 38 M.R.S. § 1614(4)(M) exempts "[e]quipment directly used in the manufacture or development of the products described in paragraphs E to L." SEMI and SIA reiterate our recommendation, originally included in our SEMI-SIA submission from August 2024, that DEP include a note following Subsection 13 of Section 4(A) in the rule to clarify the meaning of "directly used" in this context, in line with the fact that the Maine Legislature included this exemption in the statute as a means to broadly protect supply chains on which exempted products such as semiconductors rely:

NOTE: Equipment "directly used" in the manufacture or development of products described in Subsections 5 through 12 includes equipment and related materials used for the servicing, maintenance, operation and upgrading of products described in Subsections 5 through 12.

III. Conclusion

SEMI and SIA are committed to the need for environmental protection and the sustainability of semiconductor manufacturing operations, which is a complex challenge. SEMI and SIA are grateful for the opportunity to engage on this matter and on DEP's planned rulemaking efforts and are available to meet at your convenience to further elaborate on the issues discussed in these comments. If you have any questions or would like to discuss our positions, please do not hesitate to contact Ben Kallen, Senior Manager for Public Policy and Advocacy at SEMI (bkallen@semi.org) and Alex Gordon, Manager of Government Affairs at SIA (agordon@semiconductors.org).


THE MAINE SENATE 132nd Legislature

3 State House Station Augusta, Maine 04333

Henry L. Ingwersen Senator, District 32

January 27, 2025

Board of Environmental Protection 17 State House Station Augusta, Maine 04333

Dear Board of Environmental Protection,

Thank you for the opportunity to make some comments on the draft rules for LD 1537, An Act to Amend the Laws Relating to the Prevention of Perfluoroalkyl and Polyfluoroalkyl Substances Pollution and to Provide Additional Funding. The following comments are divided up into the sections of the draft they refer to.

Definitions

1. The draft rule defines chemically formulated as "a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources". However, there are times when PFAS is added to the substance and doesn't chemically "change" the natural substance. This definition needs to take into account instances when that occurs.

2. The definition of clothing in the draft rule states "Clothing item" means an article of wearing apparel designed to be worn on or about the human body. The definition does not include clothing items that are accessories or special clothing, such as jewelry, watches, purses, handkerchiefs, scarves, ties, headbands, belts, or shoes. While the law doesn't specifically define clothing, this definition excludes all of the above-mentioned items that could be considered "clothing items". The definition needs to be clearer.

3. Under the definition for "Commercially available analytical method" the Department states that "Commercially available analytical methods do not need to be performed at a third-party laboratory". I disagree, because industry, in deference to fairness and transparency, should not be allowed to test their own materials. Experience has shown the public that industry has not always been trustworthy and transparent when it comes to the health impacts of PFAS or the use of PFAS in certain products. I believe that industry should be required to use a third party to test to prove that the information is correct and valid.

4. Under the definition of "cookware" the draft states "NOTE: The definition of cookware is limited to houseware. Cookware does not encompass items intended for use in and market exclusively for use in commercial, industrial, or institutional settings." By limiting cookware to "houseware" this definition does not encompass the intent of the statute. LD 1537 in section A-10, states that the definition of cookware "Cookware product" means a durable houseware product intended to be used to prepare, dispense or store food, foodstuffs or beverages, including, but not limited to, a pot, pan, skillet, grill, baking sheet, baking mold, tray, bowl and cooking utensil." In the statute there is no exemption for industrial or commercial cookware.

5. Fluorinated Container. The draft defines a fluorinated container as "any container which has been treated with fluorine atoms to create a permanent barrier." The statute makes no exceptions for the purpose for which containers are fluorinated. To narrow the scope of the definition based on a single purpose, "to create a permanent barrier" is contrary to statute. Fluorinated containers should be covered regardless of purpose for the fluorine treatment, which may be different than "to create a permanent barrier". The agency does not have the authority to narrow the definition of a statutory term. Instead, the definition should read "any container which has been treated with fluorine atoms".

6. For the definition of semiconductor, part of the definition states "intended to perform electronic and other related functions". Since this will be an exemption from the law, this definition needs to be clear and detailed, specifying the purpose of semiconductors to avoid an unnecessarily broad definition.



Henry L. Ingwersen Senator, District 32 3 State House Station Augusta, Maine 04333

8. Reasonably available: The draft definition states that a PFAS alternative is "reasonably available" if "readily available in sufficient quantity and at a comparable cost to PFAS." Comparable cost should not be included in this definition. The concept of a "comparable" cost is too vague, given that the costs can vary dramatically from product to product. In fact, an alternative product may drop in price as it is found to be an available alternative to the use of PFAS. The definition also includes "intended to replace and perform as well as or better than PFAS in a specific application of PFAS in a product or product component". Performance is irrelevant to the concept of "reasonably available" and should be removed.

Currently Unavoidable Use

1. In the currently unavoidable use section A(3)(b) the draft states "The required specific characteristic or combination of characteristics that necessitate the use of PFAS chemicals." Industry should have to provide additional information as to why this characteristic(s) is necessary for the products' function in health, safety, or the functioning of society. A justification for the need for PFAS for the function of the product alone should not be sufficient for a Currently Unavoidable Use (CUU) exemption.

I would recommend that the State establish clear criteria for making CUU decisions so that the required information being requested clearly connects to the corresponding criteria. This clear correspondence between criteria and information requests which will be used to make CUU decisions serves two purposes: it weeds out unnecessary questions and makes the entire process easier to understand for all parties. Finally, the criteria should line up with international scientific work on this, which is also reflected in the European Union guiding principles and criteria for the essential use concept. As it currently is, the draft does not make clear what criteria will be used to determine CUU designation and how the information requested aligns to the criteria, so that a justified decision can be made.

2. Under section A(4)(e) "A comparison of the known risks to human health and the environment between PFAS and the materials identified in Subsection A". It makes no sense to require risk based criteria to get a currently unavoidable risk designation. When the law was passed, it was passed because there is agreement that the use of any PFAS is a problem and that we need to stop all uses that we can. It is settled science that PFAS, in almost any amount, is a risk to human health. This is the essential use concept. This statute was not intended to set up a risk-based framework, and goes against the intent of the law that *any use of PFAS must be necessary for the "health, safety, and functioning of society"*.

I appreciate the work you are undertaking in regards to this very important statute. Thank you for your deliberation.

Respectfully submitted,

Senator Henry Ingwersen Senate District 32 *Arundel, Biddeford, Dayton, Hollis and Lyman*

Chair, Health and Human Services Committee * Agriculture, Conservation, and Forestry Committee State House (207) 287-1515 * Fax (207) 287-1585 * Toll Free 1-800-423-6900 * TTY 711 Henry.Ingwersen@legislature.maine.gov * legislature.maine.gov/senate Proudly representing Senate District 32: Arundel, Biddeford, Dayton, Hollis, Lyman

From:	Graham, Tom
То:	DEP, PFASProducts
Subject:	FW: Comment on Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances
Date:	Thursday, January 23, 2025 9:27:45 AM

From: BParris@seweurodrive.com <BParris@seweurodrive.com>
Sent: Thursday, January 23, 2025 8:55 AM
To: DEP Rule Comments <RuleComments.DEP@maine.gov>
Cc: caecilia.benzin@sew-eurodrive.de; Creece@seweurodrive.com
Subject: Comment on Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

EXTERNAL: This email originated from outside of the State of Maine Mail System. Do not click links or open attachments unless you recognize the sender and know the content is safe.

To Whom it may Concern,

<u>SEW-Eurodrive, Inc.</u> is a global manufacturer of industrial power transmission products - primarily enclosed gearing, electric motors, and electronic motor controls. We do not sell products in the consumer market and our products generally are not reaching consumers. Instead, these products are used in machinery and equipment in manufacturing, logistics and other such industrial environments.

The exemptions enumerated in the draft rulemaking of Chapter 90 Section 4A seem to focus concern primarily on consumer exposure to PFAS. Of interest to our company are points (12) and (13) of section 4A where non-consumer electronics and laboratory equipment as well as items used in the manufacture of other exempted items are themselves exempted. This provides an exemption for a large portion of our product. There is a concern with larger products in our portfolio that, while not necessarily used to manufacture exempted items and not by definition electronic nonetheless pose no greater risk to consumers than our smaller products that are exempt. We would like clarification as to the intention of the rule in regards to such products and whether we can consider all of our products exempt on the basis that they all exist and operate in similar environments isolated from common exposure by the general public.

Best regards, Billy Parris Corporate Engineering Manager



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Slingshot 53 Exchange Street, #200 Portland, ME 04101 **slingshot,org**

Testimony on Chapter 90 Rulemaking

Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

Board of Environmental Protection

Dana Colihan, Co-Executive Director | January 24th, 2025

Dear Chair Lessard and members of the Board of Environmental Protection,

Slingshot is submitting comments in support of the draft Chapter 90 rules and we urge the BEP to avoid weakening any of the requirements.

Whether your community is facing polluted water from sludge spreading, an AFFF spill, or a leaking landfill, you deserve to know the facts, make your voice heard, and create the changes you want to see. Slingshot is an environmental health and justice organization, working alongside communities most impacted by environmental threats to take aim at polluters and build community power.

We are currently facing one of the largest contamination crises of our time-with communities around the country discovering daily that their water is polluted with per and polyfluoroalkyl substances or PFAS. PFAS are a toxic, man-made class of chemicals, commonly known as "forever chemicals," which were created by chemical companies for things like non-stick coating or fire fighting foam. However, PFAS have been linked to serious health impacts like kidney cancer, reduced immune system function, thyroid disease, liver damage, and more.

We co-facilitate the National PFAS Contamination Coalition, which is composed of 42 community groups from across the country, including Maine, that are directly impacted by PFAS. The coalition is fighting for a world where people are not exposed to any PFAS, where there is justice for the victims of PFAS exposure, and where laws and regulations prevent contamination disasters like this from happening again. From this work, we have witnessed the harm PFAS have on our bodies, families, and environment.

We need to do everything in our power to stop PFAS exposure and turn off the tap of contamination. We shouldn't have PFAS in our products, we shouldn't have PFAS in our water, and we shouldn't have PFAS in our bodies.

In many ways, Maine has been a leader in taking steps to tackle the PFAS contamination crisis. Maintaining strong requirements for "currently unavoidable use(s)" is critical to ensuring that we do everything in our power to prevent exposure to PFAS.

491

For decades, companies like 3M and Dupont knew about the serious dangers of these chemicals, but covered up the health impacts from the public, regulators, and even their own employees. We are now collectively paying the price.

We need to ensure that industry doesn't shirk responsibility or weaken these rules, because there is a real human cost to negligence. It is time to put people over profit and stop preventable exposure.

This is why we are asking the BEP to ensure the strengthening or tightening of language in a few key areas:

- In the currently unavoidable use section [A(3)(b)] "the required specific characteristic or combination of characteristics that necessitate the use of PFAS chemicals" – it is critical to go beyond just asking industry for the characteristics that necessitate the use of PFAS. The intent of the law is to ensure that these chemicals are used only when absolutely essential, given their danger to human health and their propensity to accumulate over time. Thus, we need to require industry to provide clear information as to <u>why</u> this characteristic is necessary for the products' function for the health, safety, or functioning of society.
- Under section A(4)(e) ("comparison of the known risks to human health and the environment between PFAS and the materials identified in Subsection a".) - There needs to be clear criteria laid out for completing such an assessment, or we will only see information or studies presenting an industry slant.
- 3. We need tighter and clearer definitions for certain terms, including:
 - a. **Reasonably available**. The draft definition states that a PFAS alternative is "reasonably available" if *"readily available in sufficient quantity and at a* comparable cost to PFAS." This definition creates a significant loophole, and fails to create the kind of imperative necessary to change corporate behavior. The root of the PFAS contamination crisis is that companies have been allowed to externalize the massive cost to society of these products: costs to the health care of people sickened by exposure; costs to farmers whose land is contaminated by PFAS-containing sludge; costs to water providers to filter out and attempt to destroy and dispose of PFAS; and costs to homeowners whose well water is no longer safe to drink, not to mention costs to taxpayers. Where there is a firm imperative, science and business will come together to find alternatives. Without a firm imperative, polluters will continue to choose chemicals that are the lowest cost to them, ignoring the cost to their neighbors' and consumers' health and financial well being. A tight definition of "reasonably available" - that does not focus on the cost or 'comparable' cost – is essential to creating a firm imperative for companies to use safer alternatives.

493

- **b. Commercially available analytical method.** Industry should not be allowed to test their own materials. They should be required to use a third party laboratory.
- **c. Chemically-formulated.** We need to more clearly include or account for instances where substances are formulated or manufactured by adding PFAS even if it does not *chemically* change the natural substance. For example, covering a carpet with stain-resistant PFAS does not change the chemical composition of the carpet itself, but it absolutely introduces PFAS chemicals into people's homes where children play.
- **d. Cosolvent.** "In small amounts" does not need to be specified in the definition. Cosolvents can be used in a wide range of concentrations.

We appreciate the hard work that has gone into the drafting of these rules, we support the draft, and urge the BEP to avoid weakening any of the requirements – especially related to the requirements for the currently unavoidable use. Thank you for taking our recommendations into consideration and taking action to protect Mainers and the environment.





SUSTAINABLE PFAS ACTION NETWORK

Kerri Malinowski Farris Maine Department of Environmental Protection 17 State House Station Augusta, Maine 04333-0017

FILED VIA rulecomments.dep@maine.gov

RE: Proposed Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substance under Maine's Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution, 38 M.R.S. § 1614

Dear Ms. Farris:

SPAN is writing to provide these comments in response to the Department of Environmental Protection's ("DEP" or "Department") proposed rule for notification requirements, sales prohibitions, and currently unavoidable use determinations for products containing intentionally added PFAS under Maine's Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances [PFAS] Pollution (the "Proposed Rule").

SPAN appreciates DEP's willingness to confer with SPAN previously and to consider these new comments on the Proposed Rule. As you know, SPAN is a coalition of PFAS users and producers committed to sustainable, risk-based PFAS management. Our members advocate for responsible policies grounded in science that provide assurance of long-term human health and environmental protection while recognizing the critical need for certain PFAS materials for U.S. economic growth and global competitiveness. SPAN was formed with the objectives of ensuring legislators and regulatory agencies are aware of the essentiality of products generated by our members while simultaneously supporting practical regulatory programs focused on protecting human health and the environment and maintaining America's global economic edge.

SPAN has commented on previous versions of the Proposed Rule, so rather than repeating our previous comments, we now offer the following limited, supplemental comments that highlight specific critical issues.

Definitions

• "Commercially available analytical method" is defined as:

"any test methodology used by a laboratory that performs analyses or tests for third parties to determine the concentration of PFAS in a product. Commercially available analytical methods do not need to be performed at a third-party laboratory."

SPAN recommends that the acceptable analytical methods should either be based on established EPA methods or reliable methods recognized by another equally rigorous regulatory standard-setting body. Similarly, if a product is being tested in a third-party lab, that third- party lab should be a third-party certified lab or one which documents the use of testing methods and internal procedures meeting Good Manufacturing Practice or Good Laboratory Practice standards. Grounding the scientific testing methodologies use with widely accepted methods and well understood testing standards will ensure scientific and regulatory credibility of the results. SPAN notes that methods focused solely on identifying the presence of fluorine in the material tested are not suitable for these purposes as the results are often misinterpreted as representing the presence of PFAS.

• "Reasonably available" is defined as:

"a PFAS alternative which is readily available in sufficient quantity and at a comparable cost to the PFAS, to include changes to the manufacturing process, it is intended to replace and performs as well as or better than PFAS in a specific application of PFAS in a product or product component."

In addition to the criteria mentioned in the definition, SPAN suggests that the definition also include as a factor whether use of the alternative imposes increased costs to small business and end users, such as potential consequences of less energy efficient equipment, including the energy cost differential.

Furthermore, DEP should establish a transparent and well-defined framework in making its determination of the reasonable availability of alternatives. Subsection (i) of the federal American Innovation and Manufacturing (AIM) Act of 2020 (42USC 7675) could serve as a model for criteria for alternatives.

• "Manufacturer" is defined (via reference to the statutory definition) as:

"the person that manufactures a product or whose brand name is affixed to the product. In the case of a product imported into the United States, "manufacturer" includes the importer or first domestic distributor of the product if the person that manufactured or assembled the product or whose brand name is affixed to the product does not have a presence in the United States."

As defined, "manufacturer" includes both the entities that manufacture a product or whose brand name is legally affixed to the product. However, there are numerous circumstances when two different entities meet that definition: one may manufacture the product and the other may legally affix their name to the product. SPAN requests that DEP explicitly identify the exact entity in such circumstances that is subject to the reporting requirements. DEP should provide real-life examples in the form of guidance based on input it should solicit from the manufacturing community. • "Semiconductor" is defined as:

"material having conductivity characteristics intermediate between conductors and insulators, as well as a discrete functional object having two or more layers of metallic, insulating, or semiconductor material, deposited or otherwise placed on, or etched away or otherwise removed from, a piece of semiconductor material in accordance with a predetermined micron or sub-micron pattern and intended to perform electronic and other related functions. Semiconductors do not include commonly associated materials such as printed circuit boards (PCB), PCB mounting solder, PCB mounting flux, external wires, PCB screen printing ink, connectors and sockets, or PCB conformal coatings."

SPAN appreciates that DEP has revised this definition to reflect the Department's awareness of the semiconductor chip product definition used at the federal level in 17 U.S.C. § 901(a)(1).

SPAN requests that the text appearing in the final sentence of the proposed semiconductor definition which describes materials that semiconductors "do not include" be omitted and modified to better reflect the intent of the statutory exemption at 38 M.R.S. § 1614(4)(K) and industry practice. Specifically, SPAN suggests the final sentence in the proposed definition be updated to read, "Semiconductor means both a semiconductor material and a type of product that is a discrete assembled functional object which is capable of being incorporated into electronic equipment." Such changes will ensure the final rule makes clear that a semiconductor is not just an etched and layered material, but also a type of assembled functional product described in the semiconductor exemption in section 4.A.(11) of the Proposed Rule, and capable of being "incorporated into electronic equipment".

SPAN also requests that the "NOTE" appearing immediately below the semiconductor definition on page 7 of the Proposed Rule be omitted entirely as it is poorly phrased and serves no clear purpose and could create significant confusion in the regulated community and DEP's enforcement personnel.

Notification and Reporting Provisions

• The Proposed Rule is unclear as to whether product components are subject to the law. While "components" was removed from the "Applicability" section in the Proposed Rule, there are multiple references to obligations concerning components in numerous defined terms, various "notes," as well as other sections. DEP needs to ensure that the removal of the term "components," a change that SPAN fully supports, is addressed consistently throughout the rule.

- Even assuming components are not covered, suppliers often are reluctant or unable to provide information on composition of the materials in components they supply due to confidentiality concerns. Even if there are no confidentiality concerns from the suppliers, it is often impossible or technically unfeasible to provide detailed information on PFAS composition in the products due to limited analytical methods (standardized or not), instrumentation, and an inability to accurately characterize unknown PFAS. Current standardized PFAS testing methods cover fewer than 50 PFAS molecules. The Department should provide further guidance and flexibility on reporting PFAS in manufactured products – especially at the CAS number and chemical identity and specific content levels.
- The contents of the notification to be required for materials subject to Currently Unavoidable Use (CUU) determinations can and should be minimized given the extent of information that will already be in DEP's possession as a result of the CUU application process and the materials concerning the product's contents provided in the application.
- The proposed rule requires entities that manufacture or distribute exempt items, such as military equipment (e.g., aircraft, weapon systems, vessels) and motor vehicles or watercraft that are required to meet FAA, NASA, DOD or DHS requirements, to submit notifications for "textiles" and "refrigerants" that are included or present as components of such products. DEP should provide a rationale as to why notifications are needed for these particular components and what purpose such reporting would serve.
- Furthermore, DEP needs to provide clarification as to how and when notifications are to be submitted for these textile and refrigerant parts of otherwise exempt items. SPAN recommends such textiles and refrigerants should be exempted when present in such items to avoid confusion and reduce the complexity of the regulations and to simplify the administrative burden on Maine DEP.

Sales Prohibitions

- SPAN requests that DEP include an "existing stocks" exclusion for PFAScontaining products that were manufactured and released into commerce (e.g., from manufacturers to distributors and retailers) prior to the final rule's effective date for the various prohibitions on non-exempt items. Such previously manufactured items should be excluded from the prohibitions and permitted to continue to move freely in commerce. This will ensure simplicity and reduce the risk of unintentional non-compliance on the part of all parties subject to the regulation.
- SPAN supports the Proposed Rule's terms that the sales prohibitions do not apply to used products. SPAN recommends that an exemption also should be

provided for replacement parts that are needed for routine repair and maintenance of existing (and used) products throughout their projected lifecycle. This is especially critical for complex and durable goods (such as consumer use appliances) which (if properly maintained) can have a lengthier period of use and reduce waste that would be generated through the unnecessary and premature disposal of such goods.

 Article manufacturers work within complex, often global, supply chains composed potentially of thousands of suppliers. We anticipate that upstream suppliers will need sufficient time and resources to become aware of and inform their downstream customers/manufacturers of the presence of PFAS. Consequently, even with due diligence, end-product manufacturers may only be notified concerning the presence of PFAS in their products after the restriction deadline has passed. SPAN therefore requests that DEP add a provision that explicitly states that manufacturers will not be penalized in such cases provided the manufacturers have made a good-faith effort to reasonably ascertain from their suppliers the presence of PFAS prior to selling the finished product in the state after the effective date of a specific prohibition.

Currently Unavoidable Use Process

- The Proposed Rule states that a CUU Proposed Rule must contain a significant amount of information on alternatives to the PFAS currently in use and information on the human and environmental effects of the PFAS used in a product. For complex product manufacturers, there is a strong likelihood that they will not possess such information. While the Proposed Rule states that the applicant is to provide "known or reasonably ascertainable" information, clarification is needed as to the actual level of due diligence required (and the consequences of not being able to supply such information) to determine how practical and/or burdensome this requirement will be.
- SPAN believes that the timeframes for submitting CUU applications are too rigid. DEP should allow for additional time for manufacturers to submit CUU applications in advance of the dates of a specific prohibition. Moreover, more time should be provided for DEP to review applications. Additional time for DEP's consideration of applications would prove critical in the event there is a need for dialogue with an applicant or supplemental information needed.
- SPAN requests that deadlines for DEP action on CUU Proposed Rules should be included and articulated in the regulation; provisions should be added for an applicant to supply additional information if needed through interactions with the DEP reviewers.

Proprietary Information

- The Proposed Rule states DEP's position that, because CUUs must be determined through a rulemaking, CUU determinations will not be issued for submissions that contain confidential information. This is simply untenable and impracticable for numerous reasons. For example, the composition of a product is very likely to be considered by the applicant to be confidential for the protection of highly-important trade secrets. If DEP will not allow such confidential information to be submitted (or will deny a CUU application on the basis of it containing confidential content), the CUU exemption process will be unusable for many product manufacturers, who will then be prohibited from selling their products in Maine. DEP's position also is completely unworkable for products that may have uses that are critical to national security and are subject to a variety of secrecy requirements (which often may extend to numerous products that go beyond those specific items that are exempt due to DOD, NASA, or FAA specifications requirements).
- The provision which DEP cites in the Proposed Rule concerning the Department's ability to protect confidential information is not specifically applicable to the underlying PFAS-in-products law (38 M.R.S. § 1614). DEP must explain how confidentiality will be guaranteed under the Proposed Regulations and cite the statutory authority for this interpretation.

Conclusion

SPAN requests that DEP carefully consider these comments and those submitted by other stakeholders. SPAN stresses that failure to implement some of the requested changes will adversely affect the availability of certain products and materials in Maine that are of critical importance. As always, SPAN welcomes the opportunity to meet with DEP staff to discuss and clarify our comments as DEP continues with the rule promulgation process.



Maine Department of Environmental Protection Syensqo Response to Proposed Rulemaking on PFAS in Products January 28, 2025

On behalf of Solvay Specialty Polymers USA, LLC, member of the Syensqo group ("Syensqo"), we appreciate the opportunity to submit comments to the Maine Department of Environmental Protection concerning the amended proposed rule, <u>Chapter 90</u>, to establish criteria for currently unavoidable uses of intentionally added PFAS in products and to implement the sales prohibitions and notification requirements for products containing intentionally added PFAS but determined to be a currently unavoidable use pursuant to the amended 38 M.R.S. 1614.

Syensqo is a global leader in advanced materials and specialty chemicals. Our tailor-made range of products and constantly evolving research offers everyday sustainable market-based solutions for next-generation transportation, resource efficiency, consumer goods, healthcare, and industrial production to accommodate United States (U.S.) consumers' needs. Syensqo, through its predecessors, has been connecting people and scientific minds for 160 years. Innovation is at our core and part of our DNA. In the U.S., Syensqo employs nearly 5,000 people working in 43 sites across 20 states. While Syensqo does not directly operate any facilities in Maine, our customers use our products that are essential to the economy of Maine, including many key downstream applications not covered by Maine's proposed exemptions to the currently unavoidable use paradigm.

We are a science company with a remarkable past, aiming to reinvent the future with our technologies, particularly in the emerging clean energy markets. In that vein, in October 2022, Solvay Specialty Polymers, LLC (a subsidiary of Syensqo) was awarded a \$178M grant from the Department of Energy (DOE) as part of an Infrastructure Investment and Jobs Act battery material funding program to produce a PVDF fluoropolymer production facility in Augusta, GA.¹ This facility has the potential to provide enough PVDF fluoropolymer to supply more than 5 million EV batteries per year at full capacity, and the project is expected to create more than 500 local construction jobs and 100 highly-skilled jobs. Once fully operational, our project is an American investment that will fill a significant domestic supply gap with all major feedstocks, including fluorspar (a designated critical mineral), coming from North America. Our PVDF also is stationary energy storage applications, and are key to ensuring low cost and reliable storage are available to developers. Both of these applications are necessary for Maine to achieve the state's statutory goal of net-zero GHG emissions by 2045. Moreover, PVDF is used in semiconductor manufacturing, chemical processing, and aerospace and defense and medical device applications.

^{&#}x27;See https://www.energy.gov/sites/default/files/2022-10/DOE%20BIL%20Battery%20FOA-2678%20Selectee%20Fact%20Sheets%20-%201_2.pdf



While we appreciate Maine's step to remove the onerous "general notification requirement" that was previously scheduled to take effect Jan. 1, 2025, we continue to strongly oppose a "currently unavoidable use" construct being applied to the entire class of PFAS chemistry for the reasons outlined below. Further, the enclosed appendix outlines Syensqo's detailed analysis of the key downstream uses of our fluorinated products that have a critical and irreplaceable impact on society. As such, Syensqo respectfully requests that these products are specifically deemed "currently avoidable" and a full exemption for fluoropolymers manufactured without fluorosurfactant process aids.

I. <u>This type of restriction is incompatible with complex critical supply chains and</u> <u>economies of scale.</u>

Manufacturers of fluoropolymers (and other polymeric PFAS substances) need sufficient sales and volume to justify the immense capital and operation costs of an advanced chemical facility and remain cost competitive in a truly global market (that exists for advanced polymer chemistries). For example, if only fluoropolymer coatings for architectural applications are deemed "currently unavoidable," but these coatings that are used in a variety of industrial applications are not approved, the loss of overall demand would be significant to the manufacturer. Syensqo's facilities service a multitude of different industries for different applications. In many cases, we are multiple tiers removed from our products' end use as a material supplier. This dynamic extends across our entire portfolio of fluorinated products. Allowing only "currently unavoidable uses" in specific downstream sectors – rather than analyzing the risk profiles of specific PFAS chemistries – would severely endanger the supply of materials for the approved uses by the state. The demand of PFAS products from these small sub-sectors cannot support the weight of the entire industry nor support the economies of scale that we need to compete with non-domestic manufacturers, particularly those based in China.

The US Department of Defense specifically highlights this problem as a key national defense vulnerability in their recent, "Report on Critical Per- and Polyfluoroalkyl Substance Uses."

"PFAS are critical to DoD mission success and readiness and to many national sectors of critical infrastructure, including information technology, critical manufacturing, health care, renewable energy, and transportation...

Emerging environmental regulations focused on PFAS are broad, unpredictable, lack the specificity of individual PFAS risk relative to their use, and in certain cases will have unintended impacts on market dynamics and the supply chain, resulting in the loss of access to mission critical uses of PFAS. These market responses will impact many sectors of U.S. critical infrastructure, including but not limited to the defense industrial base. Collectively, international and U.S. regulatory actions to manage PFAS'



environmental impacts and identify and eliminate PFAS from the market, and the resulting market changes, pose risks to DoD operations and the defense industrial base supply chain. In addition, impacts to the global PFAS supply chain will present risks to the DoD Foreign Military Sales program and to North Atlantic Treaty Organization interoperability."²

Ultimately, the market will adapt, and the supply of these critical materials will be available from foreign manufacturers who do not have the same environmental, labor, climate, and safety controls as U.S. suppliers. Moreover, it is highly likely that these critical supply chains will relocate to geopolitical adversaries and further disrupt domestic security for key manufacturing inputs.

II. <u>This regulation does not follow the science and fails to recognize key differences in</u> <u>PFAS chemistries</u>

Syensqo actively promotes the continued responsible and safe manufacture, use, and placement of products which are essential to U.S. industry and to the decarbonization of the global economy. We take the subject of PFAS very seriously, and health and safety are our top priorities.

The regulation currently does not recognize the distinct differences in PFAS chemistries, particularly with respect to fluoropolymers which present low hazards to human health and the environment. These chemistries are vital to the critical industries that are the foundation of our sustainable future, including hydrogen-based energy, semiconductor manufacturing, EV batteries, and aerospace and defense applications.

Specifically, fluoropolymers are molecules that are inert, relatively large and have "documented safety profiles; are thermally, biologically, and chemically stable, negligibly soluble in water, nonmobile, nonbioavailable, nonbioaccumulative, and nontoxic."³ Moreover, some of these fluorinated substances are even completely insoluble, including FKM (a fluoroelastomer) and PFPE lubricants.

III. <u>Alternative assessments should recognize the responsible manufacturing of certain</u> <u>PFAS chemistries.</u>

Concerns about fluorochemistry have focused on the use of fluorosurfactant process aids used in the production of polymers.

² See <u>https://www.acq.osd.mil/eie/eer/ecc/pfas/docs/reports/Report-on-Critical-PFAS-Substance-Uses.pdf</u>

³ See Korzeniowski, S.H.; Buck, R.C.; Newkold, R.M.; El Kassmi, A.; Laganis, E.; Matsuoka, Y.; Dinelli, B.; Beauchet, S.; Adamsky, F.; Weilandt, K.; et al. A Critical Review of the Application of Polymer of Low Concern Regulatory Criteria to Fluoropolymers II: Fluoroplastics and Fluoroelastomers. Integr. Environ. Assess. Manag. 2023, 19, 326–354.



"The objective of this analysis is to evaluate the evidence regarding the environmental and human health impacts of fluoropolymers throughout their life cycle(s). Production of some fluoropolymers is intimately linked to the use and emissions of legacy and novel PFAS as polymer processing aids. There are serious concerns regarding the toxicity and adverse effects of fluorinated processing aids on humans and the environment." ⁴

Over the last several years, we have invested millions of dollars to advance our technology where we now produce all of our fluoropolymers in the U.S. without the use of fluorosurfactants. Fluorosurfactants are non-polymeric process aids that help ingredients work together in manufacturing some fluoropolymers and historically included PFOA and PFOS, that are among the PFAS substances under the most intense spotlight. We were able to develop a next generation, more sustainable range of specialized fluoropolymers without the use of fluorosurfactants while keeping the unique properties of these products, as required for special applications.⁵

A recent November 2023 scientific review specifically analyzed how the industry has responded to these claims amid new regulatory actions globally on "essential use"/"currently unavoidable use"/etc.,

"Because they are concerned about the negative aspects of the fluorinated polymerization aids (FPAs or surfactants) currently used to replace PFOA, FP [fluoropolymer] manufacturers have been overcoming the great challenge to produce FPs free from FPAs...*FPs produced without any FPAs should be exempt for all* uses across all industries including consumer applications as they raise no risk to the environment or to mammal and human health, in addition to the fact that FPs also match the PLC [polymer of low concern] criteria."⁶ (Emphasis added.)

The supply of fluoropolymers for critical product supply chains is currently a delicate balance between market demand and regulation. A full exemption for fluoropolymers that are responsibly manufactured for industrial uses represents a path forward to address environmental, national security and economic competitiveness priorities.

Alternatively, should the Maine DEP continue with the "currently unavoidable use" construct that solely focuses on downstream uses, we request that additional categories

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⁴ See Lohmann, Rainer, Ian T. Cousins, Jamie C. DeWitt, Juliane Glüge, Gretta Goldenman, Dorte Herzke, Andrew B. Lindstrom, et al. 2020. "Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS?" Environmental Science & Technology 54 (20): 12820–28. <u>https://doi.org/10.1021/acs.est.0c03244</u>.

⁵ See <u>https://www.syensqo.com/en/innovation/science-solutions/pfas</u>

⁶ See Améduri B. Fluoropolymers as Unique and Irreplaceable Materials: Challenges and Future Trends in These Specific Per or Poly-Fluoroalkyl Substances. Molecules. 2023 Nov 13;28(22):7564. doi: 10.3390/molecules28227564. PMID: 38005292; PMCID: PMC10675016.



be created for more critical industries that are not covered under the proposed regulations' exemption categories.

As mentioned in the section above, our enclosed annex outlines Syensqo's detailed analysis of the key downstream uses of our fluoromaterial products that have a critical and irreplaceable impact on society, and we request that Maine DEP consider all categories listed for an exemption. Below are a list key industrial applications and products that we request Maine DEP consider for additional exemptions:

- Automotive Within the automotive sector, fluoropolymers find application in several key technical components, such as gaskets, hoses, joints, O-rings, seals, cords, cables, or sleeves. Additionally, they are applied in articles that constitute part of components used in automotive, such as membrane in the fuel cell or bearing shafts in air conditioner compressors. Fluoropolymers are used in the transport sector primarily due to their resilience, broad thermal and chemical resistance and low friction properties, as well as due to their resistance to swelling and permeability. Without an exemption, nearly every automobile currently manufactured would not be able to be sold in Maine.
- Aeronautics Fluorpolymers and Perfluoropolyethers are widely used in the aerospace industry for their general ability to withstand harsh conditions, with some sub-uses and end-applications similar to the ones described for the automotive sector. Indeed, in the aeronautic sector FPs are widely used as gaskets, hoses, joints, O-rings, seals, cords, cables, or sleeves inside the aircraft. The current proposed Chapter 90 "Products Containing PFAS" draft language exempts "A product required to meet standards or requirements of the FAA, the National Aeronautics and Space Administration (NASA), the United States Department of Defense (DOD) or the United States Department of Homeland Security (DHS)." However, this exemption would not cover specific products that are used in the aerospace and defense industry, but are not explicitly certified by each of these federal agencies. Syensgo and its customers manufacture numerous upstream fluoropolymer products that are used in defense and aerospace applications such as fighter jets, or engine and structural parts for civilian and commercial aircraft. With the proposed "currently unavoidable use" construct, airports and airfields in Maine will find many of their necessary service and spare parts unavailable due to the lack of a specific FAA certification on many aerospace products containing fluoropolymers.
- **Batteries and E-mobility** Batteries are essential for powering a wide range of applications, from smartphones and power tools to mission-critical assets like data centers and nuclear power plants. They are critical enablers of the growth of electric vehicles, e-bikes, and e-scooters, contributing to economic development and job creation. Additionally, batteries play a vital role in powering machines such as drones, rockets, and satellites, as well as providing energy storage for electrical grids. Without an exemption from Maine DEP, critical fluoropolymer products will be banned from usage in high density batteries, which would force manufacturers to switch back to



inefficient, less advanced chemistry batteries. As consumers continue to demand higher range EVs and longer lasting consumer batteries, an exemption for batteries is necessary to ensure strong demand to continue to electrify our economy.

- Renewable Energy Nearly every innovative clean energy generation source, from solar, wind, nuclear, geothermal, hydropower, energy storage, and carbon capture all rely on fluoropolymers in their products for protective coatings, sealing, and lubrication to ensure efficient and safe operation. Without an exemption for the energy industry, developers and utilities in Maine would find nearly all of their necessary clean technologies banned. Meanwhile emerging technologies such as green hydrogen use fluoropolymers in membranes used in electrolysis as well as in hydrogen storage and transport applications, such as valves, sealing and pipes. Green hydrogen is a key future technology for decarbonization, especially for hard-to-abate industrial applications that require heat generation. Hamstringing Maine utilities and developers would only increase demand for price-volatile and GHG-heavy energy sources like natural gas and petroleum and would ultimately reduce grid reliability and hurt Maine ratepayers.
- Industrial application (e.g., lubricants, sealant) Sealing devices and materials serve a crucial role in the safe containment of fluids in several markets, including but not limited to automotive, aerospace, pharmaceuticals, industrial and mineral extraction. Industrial sealings are used to contain media inside hardware and the seal materials must withstand the environmental conditions of the application. Using a lower performing lubricant would result in a shorter lifetime, higher costs due to the more frequent replacements and in some cases an increase of the safety-risk. Without an exemption, Maine companies who rely heavily on many of these industrial products would find many of their industrial equipment banned.
- **Electronics** While semiconductors and its manufacturing equipment are exempted, many key parts that impact the waterproofing and performance of consumer electronics would not be covered by the exemption categories. Other fluoropolymer uses in electronics include the treatment medium for touchscreen glass, which protects the touch screen glass from fingerprints and degradation from skin oils. A lack of an exemption would drastically reduce the quality and longevity of many electronic products, which would likely result in the products ending up in the waste stream.

While the currently exempted product categories do give some manufacturers of critical products regulatory certainty, the exemptions do not recognize the reality that fluoromaterials are used in industrial applications. Maine needs to proactively exempt the currently non-exempted critical product supply chains and industry categories listed above to ensure consumers and industry have access to the critical products that they need. Lastly, we respectfully request that Maine DEP recognizes that many key products, like the ones we listed above, have no viable alternative and thus should not potentially have their exemption revoked in the future. Having regulatory certainty is crucial for further domestic investment in these critical product supply chains.



Maine's goal to eliminate GHG emissions by 2045 is both ambitious and achievable if, and only if, the energy industry is allowed to continue the use of fluoropolymers. Within the current proposed rule, no exemptions exist for energy generation and storage systems. Much of our current and future renewable energy systems rely heavily on fluoropolymers in the manufacturing process and finished products. Hydrophobic coatings on solar glass and weatherproof backsheets, PVDF in EV batteries and stationary energy storage systems, and components within onshore and offshore wind turbines would all be banned under the "currently unavoidable use" construct.⁷ For many of these products, like PVDF separators in EV battery and energy storage products, continued innovation will require greater usage of fluoropolymers, not less, to achieve the efficiency and safety standards demanded by customers and consumers.⁸

As written, the current proposed language does not create any carve outs for renewable energy systems, and energy developers and utilities would find themselves cut off from accessing necessary renewable energy solutions. Without these key technologies, Maine would not be able to decarbonize its grid and roads to meet its statutory requirements, and would continue its reliance on liquefied natural gas and other fossil energy. Furthermore, with New England continuing to close current and prevent future natural gas infrastructure, ratepayers in Maine will continue to see increased costs for basic utility functions without renewable resources bridging the gap.

We encourage the Maine DEP to take all measures to implement this statute while maintaining regulatory certainty and U.S. competitiveness in critical product supply chains. It is vital that non-problematic fluoromaterials are not only allowed in commerce, but have sufficient demand and the regulatory certainty to maintain cost-competitiveness. Thank you for your consideration of our comments.

Very truly yours,

Dalale

David A. Cetola Vice President, Global Government Affairs Syensqo Group <u>dave.cetola@syensqo.com</u>

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https://www.americanchemistry.com/chemistry-in-america/chemistries/fluorotechnology-per-and-polyfluoroalkyl-substances-pfas/pfas-critical-to-renewable-energy

⁸ See https://www.uschamber.com/assets/documents/Essential-Chemistries_-Providing-Benefits-Across-the-U.S.-Economy.pdf



<u>ANNEX</u>

Introduction

Fluoropolymers (FPs) and Perfluoropolyethers (PFPEs) are known to have an extremely high thermal, oxidative and chemical stability. Most of the technical knowledge about the stability of FPs and PFPEs is related to test conditions which simulate their use (often by accelerated tests); conditions that are in general harsher than the environmental conditions that a FP can experience if released into the environment (e.g. landfill). FPs are thermally, biologically, and chemically stable, barely soluble in water, immobile and insoluble in organic solvents.

FPs are the only materials that simultaneously possess heat resistance, weather resistance, chemical resistance, water repellency, lubricity, and unique optical/electrical properties, and they have become indispensable materials in many fields, including the energy field (fuel cells and lithium-ion batteries), semiconductor field (clean members, etching gas), electrical and electronic communications field (wire cladding and liquid crystal materials), transportation field (cars, airplanes, railroads), oil & gas industry field and medical field (catheters, protective clothing).

Many sectors of use of FPs – such as aerospace and transportation, construction, medical devices, electronics, food processing, and water and wastewater treatment – are regulated by strict standards to ensure the highest level of safety and performance. Other industrial sectors require a high level of protection for both the workplace and the environment. For instance, in the chemical processing sectors, it is necessary to prevent any leakage of hazardous chemicals from pipelines, vessels, pumps and valves. FPs coatings and sealings are often considered the only suitable option to reach the highest level of safety in this application field.

FPs find application in medicine and biomedical fields, where biocompatibility and inertness are key properties. FPs are also applied in medical diagnosis and cure, from nuclear magnetic imaging (due to high F content and short Tl and long T2 relaxation time), drug delivery, and tissue engineering. FPs are also used to enhance the effectiveness of PDT (Photo Dynamic Therapy). Moreover, an important application of FPs is in the development of membranes for blood separation, or as the base polymer matrix for implantable devices. Other examples of essential medical equipment include cables with FP insulation are suitable for very high frequency signals, which is essential for transmitting huge amounts of data generated by MRI, PET, and CT scans. Additionally, FPs are biocompatible according to ISO 10993, which means that they can be placed in physical contact with patients' skin. Most potential alternatives have not been certified as biocompatible.

Additionally, due to their molecular weights with controlled viscosities along with very high purity levels, these materials are an excellent choice for membranes covering a broad range



of porosity and shapes. Indeed, FPs find application in water purification/filtration for drinking water and for wastewater treatment. Syensqo's FPs are used to make microfiltration and ultrafiltration flat sheet and hollow fiber membranes for a wide range of bioprocessing and medical filtration applications. For instance, PVDF (Solef®), ECTFE (Halar®), PTFE (Algoflon®) and PFSA (Aquivion®) are applied under different forms (e.g. pellet, powder, membranes or dispersions) in membranes and filtration systems.

The fluoropolymers mainly used for lubrication purposes are Polymist and Algoflon[®], used as friction and wear additive or grease thickener, and PFPE oils (Fomblin[®]), used on its own or as base oil in grease formulation or in combination with PFAS-based solvent as carrier/deposition. Due to its compatibility/solubility in PFPE lubricants, functionalized PFPEs, Fomblin[®] PFPE and Fluorolink[®] PFPE, can be used as additives in PFPE oil, PFPE based grease/paste or in combination with PFAS-based solvents to impart corrosion protection to metallic part such as, no limited to, rolling bearings. PFPE based lubricants are used in a broad range of applications in which the harsh condition makes it impossible for other materials to reach the desired performance and the safety requirements. PFPE-based lubricants combine the low coefficient of friction with excellent resistance to chemicals and extreme temperatures (-80°C to over 270°C), while at the same time being non-flammable, allowing for extended durability in use. In addition, PFPE-based lubricants being non-toxic, odorless, dielectric, offering excellent compatibility with materials (plastics, elastomers) and resistance to high pressure oxygen (liquid & gas) provide safety in use in multiple sectors.

Overall, FPs and PFPEs are a versatile group of substances used in a very broad range of applications. For most of the applications and sectors they represent the state-of-the-art materials thanks to their unique combination of properties. Their performance together with their extreme durability has made these products ubiquitous in many industrial sectors.

As detailed in our separate submissions accompanying this one, the analysis of alternatives concludes that these currently remain the sole suitable materials for applications requiring resilience to extreme temperatures, adverse chemical agents, mechanical stress, and resistance to oil and water, or a low coefficient of friction.

The relevant product family names and HTS codes are listed below. However, these are only representative of our products which are considered raw materials to finished articles and not the finished articles themselves that downstream users produce.

ALGOFLON®/POLYMIST® PTFE (Polymers of tetrafluoroethylene) - HTS 3904610090 HYLAR®/SOLEF® PVDF (Homo- and co-polymers of vinylidene fluoride) - HTS 3904695000, 3911902500 TECNOFLON® Fluoroelastomers (Copolymers of vinylidene fluoride/hexafluoropropylene/others) - HTS 3904691000 AQUIVION® PFSA (Copolymer of tetrafluoroethylene and perfluorosulfonylvinylether) - HTS 3904695000



HALAR® ECTFE (Copolymers of ethylene and chlorotrifluoroethylene) - HTS 3904695000 GALDEN®, FLUOROLINK®, FOMBLIN® Perfluoropolyethers - HTS 3907290000

There are other product HTS codes that contain PTFE and/or other PFAS that are an integral part of the composition. Due to the short time period for response this list may not be exhaustive: 391190250, 3908907000, 3208900000, 3907300000, 3910000000, 3911902500, 3911904500, 3921904090, 6815120000, 6815130000, 7019120080, 7019519090, 7019694021 and 7019901100.

Batteries and E-mobility

Batteries are essential for powering a wide range of applications, from smartphones and power tools to mission-critical assets like data centers and nuclear power plants. They are critical enablers of the growth of electric vehicles, e-bikes, and e-scooters, contributing to economic development and job creation. Additionally, batteries play a vital role in powering machines such as drones, rockets, and satellites, as well as providing energy storage for electrical grids.

FPs are largely used in the energy sector, covering a wide field of applications, including conventional energy generation and renewables technologies. Specifically, they find extensive application in the production process of Li-ion batteries, where FPs constitute essential components.

Batteries consist of two electrodes, a separator and an electrolyte. Each electrode consists of an active material mass which is coated onto a current collector. As chemical resistance and tolerance to a high range of working temperatures are crucial for batteries, PFAS, and in particular FPs, are used in key components for all high performance and lithium battery technologies, mainly in active material masses, electrolytes, valves, gaskets, washers, membranes, and coatings.

As reported by RECHARGE⁹ batteries are a main enabler for the transition towards low-emission mobility, decarbonised energy generation and digitalisation and contribute to generate significant economic growth and provide jobs for millions of people. Due to their unique properties, both polytetrafluoroethylene (PTFE) and polyvinylidene difluoride (PVDF – both homopolymer and copolymer) are used as binder materials in the active material masses in electrodes in a wide range of battery technologies.

PVDF binders have several roles inside the battery, they help to disperse the active material and the conductive additive in the solvent during the fabrication process; they hold the active material and the conductive additive together and connect them to the current collector, ensuring the mechanical integrity of the solid electrode without significantly impacting electronic or ionic conductivity; they act as an interface between the composite electrode

⁹ Europe's industry association for advanced rechargeable and lithium batteries



and the electrolyte. As mechanical degradation of electrodes is believed to be one of the key mechanisms that limits battery life, binders with excellent properties are a key component to maximizing battery life. PVDF has several unique enabling properties, such as chemical and electrochemical stability which are essential properties to enable the binder to function for long periods and over numerous cycles without degradation of the battery. PVDF is the only proven material that can sustain a large voltage range from 0 to 5V at industrial scale for various battery designs and high-capacity cells. This stability guarantees its safe use in the electrochemical environment of the lithium cell. The insolubility of PVDF in the liquid electrolyte is advantageous for lithium-ion batteries because it provides stability and prevents the binder material from leaching into the electrolyte, which could negatively impact the performance and safety of the battery. Additionally, PVDF enhances mechanical properties, including stiffness, toughness and hardness as well as good adhesion to the active material, the conductive additive, and the current collector. PVDF ensures the flexibility of electrodes. The positive electrode binder must be able to withstand the forces that result from the expansion and contraction of active materials during charge/discharge cycles; thermal stability is also important, both for the high temperatures commonly used for electrode fabrication and also for operation of the battery at various temperatures; good dispersive capabilities are important to help distribute the slurry evenly over the current collector during fabrication. PVDF binders, due to the C-F bond properties, offer higher stability due to their resistance to oxidation compared to non-fluorinated binders. They can also prevent self-discharge by inhibiting some electrochemical reactions and thus improve the energy density as well as lifespan of the battery. PVDF stability avoids degradation of the polymer during the use stage, and potential emissions to the environment. Internal studies conducted at Syensqo demonstrated that no changes in PVDF structure were observed after recycling end-of-life PVDF compared to virgin PVDF. Recycling of lithium-ion batteries is a rapidly growing industry, which is vital to address the increasing demand for metals, and to achieve a sustainable circular economy. Currently, relatively little information is known about the environmental risks posed by LIB recycling. Many other binder materials have been evaluated as replacements for PVDF. However - based on the current status of development - all other materials have been found to oxidize at the high voltage at the positive electrode. Syensgo's batteries solutions portfolio consists of products such as PVDF (Solef[®]) for binders and separator coatings. Syensqo also provides high-performance polymers, such as PTFE (Hyflon[®]), for cell gaskets and battery modules to reduce weight and improve battery safety.

The relevant product family names and HTS codes are listed below. However, these are only representative of our products which are considered raw materials to finished articles and not the finished articles themselves that downstream users produce.

ALGOFLON®/POLYMIST® PTFE (Polymers of tetrafluoroethylene) - HTS 3904610090 HYLAR®/SOLEF® PVDF (Homo- and co-polymers of vinylidene fluoride) - HTS 3904695000, 3911902500



TECNOFLON® Fluoroelastomers (Copolymers of vinylidene fluoride/hexafluoropropylene/others) - HTS 3904691000

Availability of alternatives

The only type of rechargeable battery which does not use PFAS is lead-acid batteries. However, it must be pointed out that lead-acid batteries have low energy density and cannot serve the various and technologically complex sectors that currently use PFAS in batteries. Indeed, PFAS-based batteries serve applications where a variety of performances are required, amongst which are high energy, high power, very long life, superior reliability, ability to withstand extreme temperatures. Lead-acid batteries have limited capacity in these respects and cannot be considered as suitable alternatives.

Additionally, it is deemed that for the following uses, as of today, there are no available alternatives:

- PVDF as the binder of the active material masses
- PTFE as the binder of the active material masses
- Use of PFAS as electrolytes
- PTFE & FEP in gaskets & washers in chemically aggressive environments
- PFA, VDF, HFP, FKM in gaskets in high performance batteries which require very thin high-performance gaskets
- PTFE in oxygen permeable membranes in Zinc air batteries
- PTFE / PVDF in solid electrolyte/ gel polymer in solid-state batteries

Hydrogen

The emerging hydrogen technologies rely heavily on FPs, including membranes used in electrolysis (proton exchange membranes – PEM, alkaline electrolysers – AEL, anionic exchange membrane electrolysers – AEMEL), compressors used in biomass gasification and biogas or methane reforming, as well as in hydrogen storage and transport applications (valves, sealing and pipes).

Electrolysers are a crucial technology for green hydrogen production using electricity from renewable sources. It is a new technology which is projected to grow rapidly worldwide in the coming years.

In the hydrogen industry, electrolysers and fuel cell applications are fundamental technologies that rely on FPs as key materials for their production. Other demanding complementary industrial processes are also essential for the development of the hydrogen economy. Ultimately, fuel cells, electrolysers and those industrial processes are heavily reliant on the use of FPs. As mentioned, the hydrogen industry has great potential to provide a decarbonization pathway for energy-intensive industries, such as the steel industry, acting both as feedstock and fuel source.



Syensqo's offer to the hydrogen industry includes high-performance FPs including Aquivion[®], which find use from the core to the stack, to the plant. Common applications include membranes, electrode binders, hydrogen gaskets, diaphragms, enclosures, hydrogen cell frames and end plates, in addition to uses in thermal management and air systems. FPs are also key materials in Carbon Capture, Utilisation and Storage (CCUS) technologies and hydrogen end use applications, spanning from mobility uses to industrial off-takers, such as ammonia or steel production.

The relevant product family names and HTS codes are listed below. However, these are only representative of our products which are considered raw materials to finished articles and not the finished articles themselves that downstream users produce.

AQUIVION® PFSA (Copolymer of tetrafluoroethylene and perfluorosulfonylvinylether) - HTS 3904695000 HYLAR®/SOLEF® PVDF (Homo- and co-polymers of vinylidene fluoride) - HTS 3904695000, 3911902500 TECNOFLON® Fluoroelastomers (Copolymers of vinylidene fluoride/hexafluoropropylene/others) - HTS 3904691000 HALAR® ECTFE (Copolymers of ethylene and chlorotrifluoroethylene) - HTS 3904695000

Availability of alternatives

Electrolysers and fuel cell applications represent pivotal technologies for the hydrogen industry, strongly reliant on the use of FPs. Due to the high specialized material technologies, the industry has thus far not identified any alternative materials that could substitute FPs in the current applications. No alternative is foreseen today or in the near future for the substitution of FPs in the key application of hydrogen technology, thus making the use of FPs crucial for a transition towards climate neutrality. As reported by Chi Hoon Park et al¹⁰, there have on sulfonated hydrocarbon membranes been researches ongoing for medium-temperature and low-humidity PEM fuel cells (PEMFCs) as potential alternatives to fluorinated materials. However, as concluded by the authors of the study, although properties and performance of these materials may be seen as promising, their durability is generally regarded as poor, due to the oxidation by oxygen radicals. Additionally, at the current development stage, the technology is not mature enough to be considered for industrial application.

Although certain indicators of performance of non-PFSA membranes can suggest their relevance from an alternative standpoint, these non-PFSA membranes (such as hydrocarbon) in electrolyser applications have failed to demonstrate a pathway to commercial lifetimes (>50,000h for electrolyser applications) or at relevant temperature (>79°C). The timeframe required for developing and implementing an alternative must as

¹⁰ <u>Sulfonated hydrocarbon membranes for medium-temperature and low-humidity proton exchange membrane fuel cells (PEMFCs) -</u> <u>ScienceDirect</u>



well be closely considered: as reported by Hydrogen Europe¹¹, suitable chemistry would need to be found to accommodate for this major barrier. If, and only if, suitable chemistry (with overall reduction of risk through lifecycle) was to be identified one day, deployment cycles are in 10-year timeframes, with a minimum of 5-year demonstration period with reasonable scale, i.e. adding another 15 years on top of the time required to find the substance.

513

<u>Automotive</u>

Within the automotive sector, FPs find application in several key technical components, such as gaskets, hoses, joints, O-rings, seals, cords, cables, or sleeves. Additionally, they are applied in articles that constitute part of components used in automotive, such as membrane in the fuel cell or bearing shafts in air conditioner compressors.

The automotive industry's International Material Data System (IMDS), taken in Q1, 2022, provide a clear overview on the impact and utilization of PFAS and PFAS-based articles in the automotive industry:

- Nearly 8 million automotive parts contain PFAS substances.
- Over 5 million of these parts contain FPs and fluoroelastomers.
- The largest reported PFAS is PTFE, which is used in nearly 4 million automotive parts.
- PTFE counts for nearly 50% of the total reported PFAS in automotive parts and more than 70% of fluoropolymer uses.
- Fluoropolymer use impacts hundreds of automotive applications, which will need to be evaluated.

FPs are used in the transport sector primarily due to their resilience, broad thermal and chemical resistance and low friction properties, as well as due to their resistance to swelling and permeability. It is important to remark that many components based on FPs are in fact instrumental to the vehicle emission control (CO2 and NOx) and to the reduction of the fuel consumption. In conclusion, due to their physicochemical properties, FPs reduce evaporative emissions contributing to a cleaner environment.

The number of applications of FPs and PFPEs in the automotive sector is very extensive, a non-exhaustive list of applications is provided here:

- Components of electrical vehicles, such as electric motors, cables for electrical gears and Li-ion batteries
- In every Li-Ion battery, PVDF is used as binder in the cathode and separator coating and often even as key material for the separators and FKM gaskets are largely used as well
- Wires and cables for energy and data distribution (for communication and systems' control) in land vehicles

¹¹ European association of the Hydrogen Industry



- Cables in land vehicle catalysts and NOx, oxygen and lambda sensors which monitor the vehicles emissions and carbon footprint, contributing to emission control.
- Land vehicle wheel bearing seals and in general seals protecting automotive bearings.
- FKM seals in combustion engines, water and oil filters, shock absorbers, cooling systems, turbochargers, gearboxes and transmissions, E-axles, crankshafts, clutches.
- Low permeability FKM layers in the Fuel hoses and filler neck hoses, air Ducts (Turbo chargers) and Exhaust gas recirculation hoses used for the engine efficiency and the emission reduction. Both systems need FKM as the inner layer.
- Perfluorinated ionomers are used as membrane and electrode binder materials in fuel cell catalyst coated membranes (CCMs) and membrane electrode assemblies (MEAs) which are components in fuel cell stacks in fuel cell engines-in automotive.
- Sensors (pedal, battery, oil, radar, rain-light, ABS NOx, Oxygen, Temperature)
- Ionomers, specialized FPs with ionic properties, are used in ion exchange membranes (IEMs) that provide mechanical and chemical stability while delivering high proton conductivity. IEMs are critical components in fuel cells, while other FPs find use in batteries, sensors and circuits that are enabling the evolution of the transportation industry.
- Lubrication of sintered metal bearings in A/C electric fan, rolling bearing, electrical contacts & switches, fuel tank sensors, throttle valves, EGR - Exhaust Gas Recirculation valves, sunroof sealing, electronic window motors, spark plug boots, HVAC plastic gear boxes, ABS systems, weatherstripping.
- Lubrication of plastics & elastomers for Aid assembly during the manufacturing of the car.

PFPEs are widely used in the automotive sector as lubricants since combining a unique set of properties in a wide temperature range (low & high) and offering safety (non flammable, no failure due to stress cracking in contact with plastics & elastomers). Moreover, PFPEs are used in the automotive sector as "lifetime" lubricants and the use of alternative lubricants may bring a reduction in sustainability. PFPEs have peculiar properties (such as, among other low friction properties, durability, hydrophobicity, temperature/heat resistance, chemical stability) that make them irreplaceable in specific lubrication applications.

PFPEs lubricants are essential for the automotive industry since they take on different functionalities in different parts of the vehicle, e.g. low friction, heat/temperature resistance, durability, chemical stability, long lasting functionality. These functionalities of the PFPEs are in many cases simultaneously needed and no alternative lubricant can take over all this in once. As the PFPEs with those functionalities are relatively expensive they are only used in very specific cases, e.g. in harsh conditions where no other alternatives can be used (high temperature differences, a product/part cannot be replaced easily and in case several of above-mentioned functionalities must be fulfilled simultaneously). In addition, non PFPE based lubricants would lead to higher costs for the customer due to increasing maintenance frequency (regreasing/relubrication).



Syensqo portfolio of high-performance materials used in the automotive sector features Tecnoflon® FKM, used in the production Engine seals, transmissions, Exhaust Gas recirculation systems, sensors, Turbo systems, brakes , and Fomblin® PFPE which is used in the production of brake systems and transmission.

The relevant product family names and HTS codes are listed below. However, these are only representative of our products which are considered raw materials to finished articles and not the finished articles themselves that downstream users produce.

TECNOFLON® Fluoroelastomers (Copolymers of vinylidene fluoride/hexafluoropropylene/others) - HTS 3904691000

FOMBLIN® Perfluoropolyethers - HTS 3907290000

HYLAR[®]/SOLEF[®] PVDF (Homo- and co-polymers of vinylidene fluoride) - HTS 3904695000, 3911902500

ALGOFLON®/POLYMIST® PTFE (Polymers of tetrafluoroethylene) - HTS 3904610090

AQUIVION[®] PFSA (Copolymer of tetrafluoroethylene and perfluorosulfonylvinylether) - HTS 3904695000

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Availability of alternatives

It has been widely commented by various stakeholders in the automotive sectors (e.g. ACEA, Ford, Tesla, KAMA, JAMA, FPG etc) that there is no actual viable alternative for several FPs applications. In particular, it has been noted that no viable alternatives exist for the dynamic seals in the gearbox. Lubricating fluids used in gearboxes (ATF) do contain special additive packages for the reduction of wear, increasing service intervals, increasing resistance to micro-pitting and they are all chemically aggressive for the non-fluorinated candidate sealing materials, such as AEM, ACM, HNBR or NBR. Immersion tests at 130°C and 150°C for a period of 1000h in gearbox fluids show that only FKM seals can maintain the sealing properties and ensure the safety and the warranty of the automotive transmissions.

While the alternatives maturity is not fully clear to the actual automotive manufacturers, the wide variety of applications described above suggest that to achieve the same properties granted by the use of FPs this substitution could affect the very design of these applications making their validation and implementation much more complex. As an example, the substitution of the air conditioning gasses would need to redesign the entirety of the mobile air conditioning system, and with it the entirety of the vehicle.

Regarding PFPEs, currently no substances are available taking over the whole bundle/package of functionalities of PFPE in lubricants. Additionally, it is not possible to estimate any costs for alternatives as no alternatives are available on the market to



substitute PFPE in lubricants in our products which takes over all the functionalities mentioned prior. Therefore no cost comparison is possible.

<u>Aeronautics</u>

FPs and PFPEs are widely used in the aerospace industry for their general ability to withstand harsh conditions, with some sub-uses and end-applications similar to the ones described for the automotive sector. Indeed, in the aeronautic sector FPs are widely used as gaskets, hoses, joints, O-rings, seals, cords, cables, or sleeves inside the aircraft.

Other uses within the aerospace industry include:

- Safety wires used in aircraft engines in high temperature areas. In addition, conventional manual flight controls have been replaced by an electronic system which has as primary benefit weight reduction. PTFE as insulation provides excellent electrical resistance combined with fire resistance and low smoke.
- FPs are widely used in commercial and military airplanes, due to their excellent thermal stability that helps insulate the cables that run through the aircraft, their superior resistance to aging, radiation and fire and their chemical compatibility, which allows the safe and durable flow of fuel and other aircraft fluids.
- Components such as seals, hoses and wiring needed to withstand extreme temperatures and aggressive chemicals in aircraft. Aircraft equipment must be resistant to many chemicals including jet fuel, engine lubrication oils, hydraulic fluids, rocket propellants and oxidizers. They must be able to do so at extreme (both very high and very low) temperatures. Fluoroelastomers seals allow all the equipment to withstand these aggressive substances increasing their lifetime, resulting in lower emissions and higher safety standards.

Aircraft interiors may also be coated with FP film, to facilitate safety, cleaning and anti-fouling over a long-life span. The FP coating also offers fire-retardant properties. FP parts in the aircraft must be able to withstand exposure to harsh chemicals, such as oils and fuels, including biofuels which may contain high levels of alcohol (methanol, ethanol) and environmental conditions (humidity, soil / dirt). Their high chemical compatibility ensures the right level of performance and safety of all the critical parts (engine, fuel systems, emission control systems, thermal management, transmissions).

The space community has come to rely on PFPE-based lubricants, whose characteristics (low outgassing, low temperature performance, outstanding stability in the presence of oxygen) offer long-life lubrication for equipment functioning in space for years unattended with no opportunity to relubricate. Some applications include:

- Lubrication of the Space Shuttle: wing flap and tail rudder/speed brake actuators, hydraulic system, cargo bay doors/bay lift arm, crew seat adjustments gears and the oxygen system.
- Lubrication of Space Suit: breathing pack and arm/leg joints bearings.



- Lubrication of Hubble Space Telescope: optical adjustment bearings and gears.
- Lubrication of Space Station: oxygen system, docking hardware, treadmill, instrument bearings, valves and switches.

PFPEs are also widely used as lubricants and coating materials in the aerospace industry.

Regarding Syensqo's product portfolio, we offer various solutions that support the aerospace industry and aircraft OEMs with a range of beneficial performance and process capabilities. Among others, our products include a selection of specialty polymers indicated for aerospace propulsion solutions, such as:

- Ajedium[®] film (made from Halar[®] ECTFE) offers excellent adhesion to composite substrates and superior aesthetic surfaces. It is used as protective layer on the engine acoustic ring panel against the aggression of the harsh environment typical of the entrance of an aircraft engine;
- Tecnoflon[®] Fluoroelastomers (FKM) and Perfluorelastomers (FFKM) These highly resilient synthetic rubbers retain critical properties in chemically aggressive environments at extreme temperatures. Tecnoflon[®] FKM and FFKM are also highly resistant to UV light and ozone and perform best in O-rings and seals for hydraulic systems.
- Composite Materials are used in aerospace, security and defense products.

The relevant product family names and HTS codes are listed below. However, these are only representative of our products which are considered raw materials to finished articles and not the finished articles themselves that downstream users produce.

TECNOFLON® Fluoroelastomers (Copolymers of vinylidene fluoride/hexafluoropropylene/others) - HTS 3904691000

HALAR® ECTFE (Copolymers of ethylene and chlorotrifluoroethylene) - HTS 3904695000 There are other product HTS codes that contain PTFE and/or other PFAS that are an integral part of the composition. Due to the short time period for response this list may not be exhaustive: 391190250, 3908907000, 3208900000, 3907300000, 3910000000, 3911902500, 3911904500, 3921904090, 6815120000, 6815130000, 7019120080, 7019519090, 7019694021 and 7019901100.

Availability of alternatives

The situation on alternatives for the aeronautics sector is mostly similar to that of the automotive sector – where no alternatives to FPs and PFPEs are currently viable. Moreover, in the Aerospace sector, the implementation of new alternatives would need much more time. Indeed, in this particularly high-tech and heavily regulated environment, finding and deploying safe alternatives to FPs will take much longer. With no known suitable replacements for PTFE as insulating material, and given the number of critical implications it covers, it is fair to conclude that phasing out those substances may take a similar amount of time, if not longer.



The Aerospace, Security and Defence Industries Association of Europe (ASD) has provided¹² a precise description of all the uses that are relevant for the Aerospace industry and for which no alternatives are available.

Semiconductors

The semiconductor industry serves several end-use markets including automotive electronics, computing & data storage, consumer electronics, industrial electronics, wired communications and wireless communications. Semiconductor devices are essential components of electronic devices and are at the center of technological advancements and an enabling technology for a number of key applications that make a significant contribution to society.

FPs possess a unique set of characteristics that are required for many of the critical articles and the use is often required by safety and insurance guidelines. FPs are also required to prevent particle generation which is detrimental to semiconductor production yield.

Semiconductor devices (also known as "chips", or "integrated circuits") are essential components of electronic devices. Semiconductor devices are extremely complex to manufacture. This requires the utilization of process chemicals, manufacturing equipment, and manufacturing facility infrastructure which may contain PFAS substances. PFAS, and specifically FPs, provide specific and unique capabilities within semiconductor process chemistries, semiconductor manufacturing equipment and facilities, as well as the electronic products they drive. Without PFAS, the ability to produce semiconductors and the facilities and equipment related to and supporting semiconductor manufacturing would be put at risk. FPs are essential components for the electronics and semiconductor sectors, having several applications because of their durability in a broad spectrum of extreme conditions (temperature, pressure, chemicals, mechanical stress, high energy plasma, high vacuum). They are considered essential by most manufactures of electronic equipment, as alternative materials cannot meet the necessary specifications and could have higher risks compared to FPs.

FPs are broadly used in cables and wires, as they are the only materials that can withstand very high temperatures, exposure to chemicals, as well as mechanical stress. Their very good flexibility is another factor contributing to the popularity of FPs as cable jacketing.

Additionally, FPs resins and coatings grant speed and low latency to communication equipment used in the recently developed 5G technology.

FPs and PFPEs are used in the semiconductors sector in the following forms:

• Articles (FP pipes, ducts, fittings, valves, parts, seals) used in semiconductors manufacturing plants infrastructure, for ultrapure water systems, exhausts, chemical

¹² ASD submission to 2nd Stakeholder Consultation on EU REACH PFAS Restriction



delivery systems where a high degree of cleanliness and precision is required, while ensuring long lasting and safe operation.

- Heat transfer fluids (PFPE) used in chillers for their wide temperature range of operation, electric properties minimizing process interferences, non toxicity, non flammability, and non contaminant impact on the chips.
- Test fluids (PFPE) used in test equipment for immersion testing, thermal shock testing and thermal cycling thanks to their wide temperature of operation, electric properties and outstanding material compatibility.
- Lubrication fluids (PFPE) and grease component (PFPE/PTFE paste) used in vacuum pumps for bearings and gear box lubrication for harsh condition processes (high temperature, harsh gasses and chemicals, high vacuum) thanks to their low outgassing, wide temperature range of operation, non toxicity, non flammability, and non contaminant impact on the chips.
- O-rings, seals, flanges (FP) used in processing tools for sealing applications thanks to their low outgassing properties, resistance to chemicals and high energy plasmas, wide temperature range of operation
- As formative / protective coating on electronic parts and semiconductors to protect from harsh conditions. Printed circuit boards are an example, with numerous extensions, of where such a coating can be applied.
- FP components in hard disk drives can also extend the life of those parts that need a high dielectric strength.
- In vapor phase soldering equipment where PFPEs fluids bring precise temperature control, thus increasing yield and also enabling replacing lead-based technologies.
- In sealing that can protect sensitive electronic components from external agents, such as moisture, acids or alkalis. This use also includes gaskets, O-rings and other sealing equipment or lining of tubing / pipes and other fluid-handling equipment, e.g., in *in vitro* diagnostic devices or cooled / refrigerated devices, to prevent leakage that could impair the function of the electronic component.
- As insulation and jacketing of cables used in devices, allowing these to operate at higher temperatures and harsher conditions for longer.

Many Syensqo products play a pivotal role in the semiconductors industry including ECTFE (Halar[®]), PTFE (Polymist[®]), PVDF (Solef[®]), amorphous FPs (Hyflon[®]) and PFPE (Fomblin[®] and Galden[®]).

<u>Halar® ECTFE</u>

Halar[®] lightweight, semi-crystalline, and melt-processable fluoropolymer offers complete chemical resistance to the full range of semiconductor chemicals and solvents. Halar[®] ECTFE exhibits a unique structure that enables an unparalleled combination of physical and mechanical benefits, in addition to abrasion, temperature, and fire resistance. With ultra-pure grades and a broad range of melt viscosities, Halar[®] ECTFE is an exceptional solution in many semiconductor processing applications, such as duct coatings and structural parts for wet cleaning equipment.



<u>Galden® - PFPE</u>

These inert, dielectric and high-performance heat transfer fluids offer low evaporation rates and low viscosity with boiling points ranging from 55°C to 270°C and an end-use temperature of up to 290°C. Because Galden® HT PFPE excels in a wide range of temperatures, specifically as heat transfer fluid with high boiling temperature for chillers, these solutions contribute to semiconductor devices that withstand highly aggressive operating conditions. Galden® HT PFPE products feature extremely low surface tension, low evaporation losses, and enhanced compatibility with a range of materials for effective wetting in almost all conventional sealing and gasket materials.

Fomblin[®] PFPE

The Fomblin® PFPE family of inert fluids offer low evaporation weight loss, excellent chemical inertness, and high-temperature resistance for semiconductor applications that require the highest-quality vacuum. These fluids exhibit excellent lubrication properties, outstanding compatibility with a broad range of materials, no flash or fire point, exceptional radiation stability, and high dielectric properties. Fomblin® PFPE achieves superior performance with low molecular weight variation, controlled viscosity, and extremely low vapor pressure in essential applications like lubrication for vacuum pumps.

Solef® PVDF

Solef[®] is a pure, non-reactive thermoplastic specially designed for semiconductor components and has been the go-to piping material for ultra-pure water systems in semiconductor fabs since the 1980s because of its high purity and low leachable. Solef[®] PVDF offers intrinsic chemical stability and fire and oxidation resistance to withstand some of the most aggressive environments without degradation.

Tecnoflon® FFKM

This family of fluoroelastomers is specifically designed for demanding applications, like seals and O-rings, in semiconductor processing. Tecnoflon® FFKM grades exhibit extremely high thermal resistance up to 340°C and are resistant to nearly all semiconductor chemicals. Additionally, these fluoroelastomers are formulated with superior strength, high purity, and good plasma resistance for excellent performance in long service life applications.

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HALAR® ECTFE (Copolymers of ethylene and chlorotrifluoroethylene) - HTS 3904695000 GALDEN®, FOMBLIN® Perfluoropolyethers - HTS 3907290000 HYLAR®/SOLEF® PVDF (Homo- and co-polymers of vinylidene fluoride) - HTS 3904695000, 3911902500



TECNOFLON® Fluoroelastomers (Copolymers of vinylidene fluoride/hexafluoropropylene/others) - HTS 3904691000

Availability of alternatives

Data on alternatives for the application of FPs in the semiconductors sector do not find consensus among various stakeholders. While some alternatives could be already available on the market, it is worth mentioning that, for semiconductors, no drop-in substitution is feasible. Every use and application has to be re-engineered in order to evaluate if the new material will fulfill the specific requirements.

The European Semiconductor Industry Association (ESIA) has reported¹³ that the semiconductor industry has been researching PFAS-free alternatives for 25 years. There may be some instances where substitution is possible. However, in most applications, no alternatives to FPs have thus far been identified. For instance, in most photolithography applications, PFAS-free materials have been found to be not technically feasible or ineffective. For many applications in the semiconductor industry it would be necessary to reinvent potential PFAS-free alternatives. Identifying and implementing is a lengthy process that involves academic research, material supplier research, development (validation), scale-up, and subsequent efforts by the semiconductor manufacturer for demonstration (verification), integration, implementation, and scale-up to high-volume manufacturing. Even though all PFAS uses have their specific challenges and timelines for development, it will take 15 to more than 20 years to develop PFAS-free alternatives for most of the photolithography uses.

Regarding the use of fluoroelastomers (FKM) and perfluoroelastomers (FFKM) as sealing agents during semiconductor manufacturing process, SEMI (global industry association representing electronic manufacturing and design supply chain) has evaluated¹⁴ various PFAS-free alternatives, namely ethylene propylene diene monomer (EPDM), silicone rubbers, aryl ketone polymer (PEEK) and hydrocarbon elastomers. None of the alternatives assessed were able to meet all functionalities assessed, i.e. wafer contamination, chemical compatibility, safety/environmental protection and impact on the manufacturing process – showing how PFAS-free alternative to FKM and FFKM in the uses above outline is currently not available.

There are no known viable alternatives to lubricants used in the semiconductor production process as well as used in the photolithography process.

¹³ ESIA submission to Stakeholder Consultation on EU REACH PFAS Restriction

¹⁴ SEMI Assessment of Proposed Alternative Fluoroelastomers for Sealing



Industrial application (e.g., lubricants, sealant)

Sealing devices and materials serve a crucial role in the safe containment of fluids in several markets, including but not limited to automotive, aerospace, pharmaceuticals, industrial and mineral extraction. Industrial sealings are used to contain media inside hardware and the seal materials must withstand the environmental conditions of the application.

FPs and PFPEs are ubiquitous in every industrial plant. FPs are typically used in sealants, coatings on valves and piping, gaskets, personal protective equipment/ clothing, refrigerants, membranes, filter materials and membranes, foams, greases/ lubricants, mold release, conveyor belts, O-rings, columns/ internals, diaphragms, processing aids, etc. Without these materials and pieces of equipment, industrial plants can no longer operate. PFPEs lubricants are used in lubricant applications across various sectors, where they provide a low coefficient of friction that is important for the machineries and for all other equipment to function as required. The FPs mainly used for lubrication purposes are PFPE oils and PTFE micropowders. PFPEs are used as lubricating oil on its own, or in formulation with functionalized PFPEs for example to enhance corrosion resistance of the lubricated metal parts. In addition, PFPE-based lubricants are resistant to chemicals and to high pressure oxygen (liquid & gas) providing safety in use in oxygen equipment such as valves, pumps and compressors for the chemical industry. PFPE-based grease offer high temperature (> 200°C) and corrosion resistance in several bearing applications such as, not limited to, corrugator paper machines. The unmatched high temperature resistance of PFPE-based grease makes it the lubricant of choice for the tire mold lubrication, adequate lubrication of the segments during the tire manufacturing / vulcanization step, reducing downtime and maintenance. PTFE micropowders are used as additives in lubricating greases and coatings. They are used when a low friction coefficient (-75°C to over 270°C) is needed in a broad range of temperature. They can also be used in inks for various applications and in various coatings and paints, where abrasion resistance is required. As such FP lubricants are used across a broad range of applications, including the chemical sector, automotive and transportation in general, industrial machinery and the semiconductor industry, especially where high temperatures are expected, due to the high heat resistance of FPs. They can also be used as additives in waxes, inks, paintings, thermoplastics, elastomers, synthetic oils, and greases. The family of high-performance lubricants, Fomblin® PFPE offers unmatched performance in several industrial applications. These inert FPs are a material of choice for lubricants for industrial electronics, as they are engineered specifically for applications where heat, chemicals, solvents, corrosion, flammability and service life pose notable lubrication challenges. Sealants FPs are widely used in industrial settings as molded sealing components to prevent leakage of hazardous or infectious agents in industrial processes, FPs sealants are used to meet extreme operating conditions (heat, corrosion, pressure, etc.) without which equipment could not guarantee the safety and reliability of industrial infrastructures. It is worth mentioning that many of the sectors where FPs based sealings are used are heavily regulated so any change to the materials used would need many years to be accepted and regulated. Sealants play a role in increasing the efficiency of energy and industrial


infrastructures, as well as preventing methane and CO2 leakages. Sealing devices are also critical to green technologies such as CCUS and Hydrogen. Our portfolio of diverse materials for industrial coatings and sealings includes industry-proven solutions to guarantee enhanced quality, protection and durability. Our portfolio of trusted specialty polymer solutions feature brands such as Hylar[®] PVDF, Polymist[®] and Algoflon[®] L PTFE Micronized Powders and Halar[®] ECTFE.

The relevant product family names and HTS codes are listed below. However, these are only representative of our products which are considered raw materials to finished articles and not the finished articles themselves that downstream users produce.

FOMBLIN® Perfluoropolyethers - HTS 3907290000 HYLAR®/SOLEF® PVDF (Homo- and co-polymers of vinylidene fluoride) - HTS 3904695000, 3911902500 ALGOFLON®/POLYMIST® PTFE (Polymers of tetrafluoroethylene) - HTS 3904610090 HALAR® ECTFE (Copolymers of ethylene and chlorotrifluoroethylene) - HTS 3904695000 TECNOFLON® Fluoroelastomers (Copolymers of vinylidene fluoride/hexafluoropropylene/others) - HTS 3904691000

Availability of alternatives

Finding an alternative that has similar properties to FPs lubricants and PFPEs lubricants is challenging for many applications. In general, using a lower performing lubricant would result in a shorter lifetime, higher costs due to the more frequent replacements and in some cases an increase of the safety-risk. None of the alternatives that have been suggested would be able to fit all the functionalities achieved by using FP and PFPEs lubricants. Moreover, it has to be noted that many of the proposed alternatives could pose a more severe risk to human health and to the environment than the FPs and PFPEs that they would substitute.

Oil and Gas

FPs are widely used in the oil and gas industry, which involves the transfer of aggressive chemical agents, such as oils, acids and petroleum and gas products, and is also exposed to harsh environmental conditions.

Oil and gas drilling requires the use of "downhole" fluids that contain aggressive additives. In addition, the pumped liquids contain a broad mix of compounds that can degrade piping and pumping equipment. The drilling equipment can also be exposed to high temperatures and pressures.

FPs are used in the sealings for pipes, valves and joints and as inner liners and coatings for piping and high-pressure hoses, due to their high chemical and heat resistance. Other examples of equipment using FPs includes exploration seals, on/off and control valves for fluids, pumps, actuators and control accessories.



Similarly, FPs low permeation rate also makes FPs an ideal material for seals, valves and pumps for gas transfer and storage equipment, as they minimize leakage.

They are also used as insulation and jacketing of cables used in drilling as well as in surface and downhole cables and subsea cables for offshore installations. Use of FPs in cables allows for the cables' downsizing, making them more suitable for downhole applications (e.g., data logging, trace heating and ESP power cables).

Syensqo's Fomblin PFPEs products have a temperature resistance up to 290 °C, significantly above the usual operational temperatures in Oil&Gas applications, making them the products of choice for this particular sector.

The relevant product family names and HTS codes are listed below. However, these are only representative of our products which are considered raw materials to finished articles and not the finished articles themselves that downstream users produce.

HYLAR[®]/SOLEF[®] PVDF (Homo- and co-polymers of vinylidene fluoride) - HTS 3904695000, 3911902500

TECNOFLON® Fluoroelastomers (Copolymers of vinylidene fluoride/hexafluoropropylene/others) - HTS 3904691000

Availability of alternatives

Several downstream users have reported that, for what concerns the O&G sector, no feasible alternative to FPs based gasket and O-rings exist on the market, so a very long period of time would be needed to allow the implementation of an alternative inside the oil&gas industry. The use of less safe materials for both the downhole liquids and sealing equipment /gaskets and O-rings) would result in higher risk of leakages and environmental spills.



January 27, 2025

Kerri Malinowski Farris Maine Department of Environmental Protection 17 State House Station Augusta, ME 04333

RE: Comments on Chapter 90 Posting Draft Dated December 20, 2024

Dear Ms. Farris:

Taconic is submitting these comments in response to the Public Notice of the Posting Draft of Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances dated December 20, 2024.

As stated in Section 4(A) of the Posting Draft, several products or product categories, described in subsections 1-13, are exempt from the requirements of this Chapter. Based on Section 4(A) subsection 13, the list of exempt products includes "Equipment directly used in the manufacture or development of products described in subsections 5 through 12, above." Taconic requests that Maine DEP consider expanding subsection 13 to include all equipment directly used in the manufacture or development of products when the equipment is not incorporated into the product.

For instance, industrial conveyor belts with intentionally added fluoropolymers are frequently used in manufacturing processes that require flexibility, heat resistance, and non-stick properties provided by the fluoropolymer coating. As currently written in the Posting Draft, certain fluoropolymer belts will be exempt based only on the products or product categories carried on the belts, and not on the form, function, or risks inherent in the use of the fluoropolymer belt. Fluoropolymer belts used in the manufacturing of non-consumer electronics would be exempt, but the same belt used in the manufacture of consumer electronics would be prohibited.

As another example, fluoropolymer coated tapes are typically used as a release material in industrial composite molding, like for custom-built watercraft hulls. As currently written in the Posting Draft, fluoropolymer tapes used in composite molding exempt product categories, such as watercraft hulls, would be exempt, while fluoropolymer tapes used for composite molding a non-exempt product category like wind-turbine blades would be prohibited even though the masking tape and molding process may be otherwise identical for both exempt and non-exempt product categories.

Taconic request Maine DEP consider the expansion of the exempt categories to include equipment/products that contain intentionally added PFAS used in manufacturing of other products where the PFAS-containing equipment/product is not incorporated into the final products.

Taconic appreciates the opportunity to provide input in the rulemaking process. Please contact me if you have any questions at (518) 658-3202, x-205.

Sincerely,

Rachel Farnum

Rachel Farnum, PE Environmental Specialist Tonoga, Inc, dba Taconic

cc: Jeff Mirarchi, Taconic Lori Mason, Taconic



Trelleborg Sealing Solutions feedback to the POSTING DRAFT of Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances (Draft date December 20, 2024)

In general:

To begin we would like to thank the Maine Department of Environmental Protection for the opportunity to provide comments and concerns to POSTING DRAFT of Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances (Draft date December 20, 2024)! Trelleborg Sealing Solutions as a downstream user, produces seals and polymer bearings for machines and equipment for an unimaginable segment of the entire society. These segments are both industrial as well as professional.

Fluoropolymers and fluoroelastomers are critical and essential contribution to all of society include:

> Human and environmental health and safety e.g.

- Defense
- Avoidance of major accidents
- Chemical industry
- Nuclear powerplants
- Avoid catastrophes
- Supply of for instance
 - Energy
 - o Food,
 - Drinking water
 - Raw materials
- > Healthcare e.g.
 - Pharmaceuticals
 - Medical devices

Minimized energy consumption and prolonged maintenance cycles of a vast range of equipment and installations

In general, customer requirements determine the nature of the materials used for the seals and bearings we manufacture. In cases of demanding conditions, ranging from very to extremely, of use by our customers fluoropolymers and fluoroelastomers represent the only choice. Fluoroelastomers and fluoropolymers possess unique properties. Properties such as: low coefficient of friction, chemical compatibility, wide temperature range for use (low to high), mechanical properties allowing high surface speeds, practically non-ageing, and compatibility regarding electron and gamma radiation. It is these unique properties that represent absolute prerequisites for many specific segment requirements. It is only when these unique properties are extremely essential, that fluoroelastomers and



fluoropolymers are utilized. The high price of fluoroelastomers and fluoropolymers alone ensures that use of these materials is minimized. This fact drastically reduces the use of fluoroelastomers and fluoropolymers as well as human exposure and emissions to the environment. Additionally, the fluoroelastomers and fluoropolymers used in our products, meet OECD-criteria of "polymers of low concern." They are neither bioavailable, watersoluble, or toxic. In essence, fluoropolymers and fluoroelastomers are safe for their intended uses.

Along with the previously mentioned, fluoropolymers and fluoroelastomers are in general, critical for innovation and for sustainability! Aims of many strategic initiatives of the United States of America like the Carbon Reduction Program, the Chips and Science Act and the Digital Government Strategy are simply impossible without the use of fluoropolymers and fluoroelastomers. For these reasons we strongly advocate for a time unlimited exemption from any regulatory action for all fluoroelastomers and all fluoropolymers. This time unlimited exemption to be added to section 4 of Chapter 90 should include all monomers and processing aids needed for manufacturing of fluoropolymers and fluoropolymers. This exemption of safe fluoroelastomers and fluoropolymers would be much clearer compared to the current approach focusing on products and uses. It would contribute in a more than reasonable manner to limit the proposed restriction of PFAS and assure the sustainable standard and quality of living as well as future opportunities of the entire society.

Alternatives for fluoroelastomers and fluoropolymers do not exist! Consequences of a total ban of fluoroelastomers and fluoropolymers for uses of manufacturing of seals, bearings and many other products would be dramatic! This ban will greatly affect the standard and quality of living. Future opportunities of the entire society will be lost! A restriction or even ban of fluoroelastomers and fluoropolymers as irreplaceable materials would catapult us all back into the Middle Ages!

In detail

2. Definitions.

"Perfluoroalkyl and polyfluoroalkyl substances (PFAS). "Perfluoroalkyl and polyfluoroalkyl substances" or "PFAS" is defined at 38 M.R.S. §1614(1) (F)." (page 6)

The scope of this definition for PFAS is by far too broad and inappropriate. There exists an extremely urgent need for differentiation between various PFAS. Detailed comprehensive lifecycle assessments are proving that fluoropolymers and fluoroelastomers are safe! Due to lack of relevant risks for human health and for the environment fluoropolymers and fluoroelastomers as well including monomers and processing aids for manufacturing of these must be granted a time-unlimited exemption of this intention!

From our view, the current inappropriate definition of the scope of this draft forces us and many others to "guess" if and how specific activities/products are affected. Comprehensive information obligations for "intentionally added" PFAS as well as standardized analytical



methods for PFAS do not exist. Companies and authorities have no chance to evaluate the status of compliance of products and processes by paperwork nor by laboratory tests! The establishment of a comprehensive information obligation for "intentionally added" PFAS for at least five years prior to a comprehensive PFAS restriction represents the only reasonable approach. This will allow companies to become aware of PFAS probably contained in for instance raw materials or processing aids. In the meantime, standardized analytical methods for relevant PFAS could be developed.

We as a downstream user, produce seals and polymer bearings for machines and equipment for an unimaginable segment of the entire society. To provide an exhaustive list of all sectors and uses of relevance of all our activities is not possible. To allow all sectors and companies a legally secure assessment of their affectedness, the scope of the restriction must be communicated in a clear and transparent manner. A list of relevant substances containing IUPAC names and CAS numbers is required for the analysis of affectedness along global supply chains. The establishment of a comprehensive information obligation for "intentionally added" PFAS for at least five years prior to a comprehensive PFAS restriction represents, from our view, a suitable approach to control PFAS emissions and to prepare a more targeted regulation. This would also enable companies and authorities to define reasonable targeted risk minimization measures.

4. Exemptions. (starting page 11)

We appreciate that the current posting draft of Chapter 90 contains several exemptions for specific products but would like to mention that from our perspective this approach does not represent the best option. As the existing list of exemptions must be regarded as not exhaustive and not appropriate, we propose a time-unlimited exemption of fluoroelastomers and of fluoropolymers including all raw materials for instance monomers and processing aids needed for manufacturing of these. This exemption to be added to section 4 of Chapter 90 would be much clearer compared to the current approach focusing on products and uses. Trelleborg Sealing Solutions as a downstream user, produces seals and polymer bearings for machines and equipment for an unimaginable segment of the entire society. To provide an exhaustive list of all sectors and uses of relevance of all our activities is not possible as even many of our customers are manufacturers of equipment and parts for customers of many segments. An exemption of fluoroelastomers and of fluoropolymers would contribute in a more than reasonable manner to limit the proposed restriction of PFAS and assure the sustainable standard and quality of living and future opportunities of the entire society.

Reason:

Fluoropolymers and fluoroelastomers

- have documented safety profiles
- are thermally, biologically, and chemically stable
- are negligibly soluble in water
- are nonmobile, nonbioavailable, nonbioaccumulative, and nontoxic



Therefore, they meet the criteria of the OECD for "polymers of low concern". Although fluoropolymers and fluorelastomers fit the PFAS structural definition, they have very different physical, chemical, environmental, and toxicological properties when compared with other PFAS. For sure fluoroelastomers and fluoropolymers are persistent, however, they do not pose a relevant risk for human health or for the environment leaving no reason to restrict or even ban these.

The manufacture of fluoroelastomers and fluoropolymers takes place only at a very small number of sites under strictly controlled conditions. Specifically, the handling of monomers as intermediates is kept rigorously contained permitting a very low risk for health of humans and the environment. In addition to monomers as intermediates, processing aids are needed for manufacturing of fluoroelastomers and fluoropolymers. In the past fluorosurfactants have been widely used as processing aids for manufacturing of fluoroelastomers and fluoropolymers. These in contrast, to monomers are not consumed during manufacturing, leading to a specific content of fluorosurfactants in the final polymer/elastomer. This does pose a risk to the health of humans and the environment. For good reason several fluorosurfactants have been restricted/banned in the past. In general, we observe that all manufacturers of fluoropolymers have changed their manufacturing processes to become fluorosurfactant-free or are in the process to do so. We expect that over the short-term all processes for manufacturing of fluoroelastomers and fluoropolymers will be changed to fluorosurfactant-free whenever feasible leading to the entire manufacturing process of fluoroelastomers and fluoropolymers may be regarded as of extremely low risk.

We are a downstream user of fluoropolymers and fluoroelastomers and to our best knowledge all polymers relevant to our activities are meeting the OECD-criteria of "polymers of low concern". Tests performed by an external accredited laboratory using LC-MS showed e.g., for engineered plastics like Ethene-1,1,2,2-tetrafluoro-homopolymer (PTFE) or Tetrafluoroethylene-propylene copolymer (TFE/P) that no measurable low-molecular PFAS was detected with a detection limit of 10 ppb (10 μ g/kg). In general, we observe that all manufacturer of fluoropolymers have changed their manufacturing processes to become fluorosurfactant-free or are in the process to do so. We expect that over the short to medium term tests results of all fluoropolymers and fluoroelastomers will show no detected measurable low-molecular PFAS.

As it is common sense that fluoroelastomers are regarded as persistent we assume that these do not pose a risk for human health and for the environment during their lifecycle. Additionally, during use products are installed leading to no exposure to people as well as to the environment. Our view is substantially supported by a detailed comprehensive lifecycle assessment executed by Gujarat Fluorochemicals GmbH in collaboration with Ramboll we are referring to as this assessment proves that fluoropolymers and fluoroelastomers are safe! Unfortunately, we are not able to provide the original report on this assessment as we have no access to it but expect the results will be published in a scientific journal over the short term.



Unfortunately, today there is no established system for industrial scale recovery of materials like fluoroelastomers and fluoropolymers. It's our opinion that an open consortium of industrial and professional stakeholders would be the most meaningful setup to materialize recycling systems as mentioned above. Today incineration and landfilling represent the main ways to treat waste of products made of fluoroelastomers and fluoropolymers. As shown above our products made of fluoroelastomers and fluoropolymers don't pose a risk to human health and for the environment this is assumed to be valid also for landfilling. Regarding incineration we would like to refer to a study by Conversio in 2022 (German based consultant) prepared for Pro-K (Fluoropolymer Downstream User Association) and Gujarat Fluorochemicals GmbH. This study has shown that at its end-of-life approximately 85% of all fluoropolymers and fluoroelastomers end up in waste-to-energy recovery incinerators. A recent project initiated and commissioned by Gujarat Fluorochemicals, executed by the Karlsruhe Institute of Technology (KIT) in cooperation with Société Générale de Surveillance (SGS), was conducted to assess that fluoropolymers and fluoroelastomers get fully incinerated without any formation of short chain or long chain PFAS. The study clearly demonstrated that fluoropolymers and fluoropolymers are converted to inorganic fluorides and carbon dioxide. The inorganic fluorides detected were hydrogen fluoride. A large majority of samples indicated that longchain PFAS were below levels of 1 ng/m³ (>99% of samples associated with 860°C condition and >98% of samples associated with 1100°C condition). There were no short chain PFAS detected post incineration. TFA was non-detectable in all samples with a reporting limit of 14 µg/m³. The results confirm that fluoropolymers and fluoroelastomers at their end of life when incinerated under representative municipal incinerators conditions do not generate any measurable levels of PFAS emissions and therefore pose no risk to human health and the environment. The study provides strong evidence that incinerating a mixture of fluoropolymers and fluoroelastomers under representative municipal waste combustion conditions leads to complete mineralization of the C-F bonds, no significant emissions of long-chain PFAS, and no significant emissions of TFA or light fluorocarbons such as CF_4 or C_2F_6 .

As mentioned above there do not exist relevant risks due to landfilling or incineration of seals made of fluoroelastomers and fluoropolymers. We work intensively on the research and development for technologies and processes for recovery of the materials of end-of-life products made of fluoroelastomers and fluoropolymers. We regard these activities as part of our activities for sustainability as well as to contribute to enhance resource efficiency.



Trelleborg Sealing Solutions as a downstream user, produces seals and polymer bearings for machines and equipment for an unimaginable segment of the entire society. The fluoropolymers and fluoroelastomers we use are listed in the table on the next page:

Chemical name	CAS No.
Ethylene-tetrafluoroethylene copolymer (ETFE)	25038-71-5
Tetrafluoroethylene-perfluoropropylene copolymer (FEP)	25067-11-2
Tetrafluoroethylene-propylene copolymer (FEPM)	-
Perfluoroelastomer (FFKM)	-
Fluoroelastomer (FKM)	9011-17-0 64706-30-5
Fluorosilicone Rubber (FVMQ)	-
Polychlorotrifluoroethylene (PCTFE)	9002-83-9
Perfluoroalkoxy polymer (PFA)	26655-00-5
Ethene, 1,1,2,2-tetrafluoro-, homopolymer (PTFE)	9002-84-0
Polyvinylidene difluoride (PVDF)	24937-79-9
Tetrafluoroethylene-propylene copolymer (TFE/P)	-
Modified Ethene, 1,1,2,2-tetrafluoro-, homopolymer (TFM)	9002-84-0

To provide an exhaustive list of all sectors and uses of relevance of all our activities is not possible. To allow all sectors and companies a legally secure assessment of their affectedness, the scope of the restriction must be communicated in a clear and transparent manner. A list of relevant substances containing IUPAC names and CAS numbers is required for the analysis of affectedness along global supply chains. The establishment of a comprehensive information obligation for "intentionally added" PFAS for at least five years prior to a comprehensive PFAS restriction represents, from our view, a suitable approach to control PFAS emissions and to prepare a more targeted regulation. This would also enable companies and authorities to define reasonable targeted risk minimization measures.

In general, customer requirements determine the nature of the materials used for the seals and bearings we manufacture. In cases of demanding conditions, ranging from very to extremely, of use by our customers fluoropolymers and fluoroelastomers represent the only choice. Fluoroelastomers and fluoropolymers possess unique properties. Properties such as: low coefficient of friction, chemical compatibility, wide temperature range for use (low to high), mechanical properties allowing high surface speeds, practically non-ageing, and compatibility regarding electron and gamma radiation. It is these unique properties that represent absolute prerequisites for many specific segment requirements. It is only when these unique properties are extremely essential, that fluoroelastomers and fluoropolymers are utilized. The high price of fluoroelastomers and fluoropolymers alone



ensures that use of these materials is minimized. This fact drastically reduces the use of fluoroelastomers and fluoropolymers as well as human exposure and emissions to the environment. Additionally, the fluoroelastomers and fluoropolymers used in our products, meet OECD-criteria of "polymers of low concern." They are neither bioavailable, water-soluble, or toxic. In essence, fluoropolymers and fluoroelastomers are safe for their intended uses. Seals and polymer bearings made of or containing fluoroelastomers and fluoropolymers we produce are used for manufacturing, installation, operation, and maintenance of equipment of for instance:

- Aerospace
- Defense
- Energy sector
- Chemical Industry
- Pharmaceutical Industry
- Medical devices
- Agriculture equipment
- Food Industry
- Refrigeration
- Air conditioning and heat pumps
- Trains
- Ships
- Transportation
- Semiconductors
- Electronics Industry
- Machine manufacturing
- Equipment manufacturing
- Processing equipment
- Recycling Industry
- Fluid Power
- Machine tools
- Marine
- Presses
- Robotics
- Sanitation
- Insulating gas in electrical equipment
- Construction products
- Petroleum and mining
- Textile & leather Industry



The seals and polymer bearings made of or containing fluoropolymers and fluoroelastomers are critical and essential contribution to all of society include:

> Human and environmental health and safety e.g.

- o Defense
- Avoidance of major accidents
- Chemical industry
- Nuclear powerplants
- Avoid catastrophes
- Supply of for instance
 - Energy
 - o Food,
 - o Drinking water
 - o Raw materials
- > Healthcare e.g.
 - Pharmaceuticals
 - Medical devices
- Minimized energy consumption and prolonged maintenance cycles of a vast range of equipment and installations

Alternatives for fluoroelastomers and fluoropolymers do not exist! Consequences of a total ban of fluoroelastomers and fluoropolymers for uses of manufacturing of seals, bearings and many other products would be dramatic! This ban will greatly affect the standard and quality of living. Future opportunities of the entire society will be lost! A restriction or even ban of fluoroelastomers and fluoropolymers as irreplaceable materials would catapult us all back into the Middle Ages!

Contact information for this submission.

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January 28, 2025

Submitted via email to rulecomments.dep@maine.gov

Melanie Loyzim Kerri Malinowski Farris Maine Department of Environmental Protection 17 State House Station Augusta, ME 04333

Re: Comments of Valmet, Inc. and Valmet Flow Control Inc. Proposed Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances; to establish criteria for currently unavoidable uses of intentionally added PFAS

Dear Commissioner Loyzim and Ms. Farris:

On behalf of Valmet, Inc. and Valmet Flow Control Inc. (collectively, "Valmet" or the "Company") we appreciate the opportunity to comment on the possible Chapter 90 Draft Rule, Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances: to establish criteria for currently unavoidable uses of intentionally added PFAS. Valmet is aware that effective January 1, 2032, any product containing intentionally added PFAS may not be sold in Maine unless the use of PFAS in the product is specifically designated as a Currently Unavoidable Use (CUU) by the Maine Department of Environmental Protection.

Valmet is a leading global developer and supplier of process technologies, automation and services for the pulp, paper, tissue, energy, and other process industries. A number of Valmet's technology use fluoropolymer containing components, which are critical for a wide range of industrial applications. Therefore, Valmet sees the need for balanced and pragmatic approaches to managing PFAS, without compromising critical functions of industry and society continue or adversely impacting businesses, communities, and public health.

To determine the currently unavoidable uses, Valmet submitted a preliminary list of its current products and spare parts that contain intentionally added PFAS and comments on considerations for the proposed rules relating to exemptions to the state of Maine on March 1, 2024. In addition, Valmet submitted its informal comments on the Concept Draft Language for the PFAS in Products Rule to implement Title 38, section 1614 on August 30, 2024. Valmet now supplements these earlier submittals by providing the information below in response to the latest request for public comments.

GENERAL STATEMENT OF POSITION

Valmet maintains that the Maine Department of Environmental Protection should grant Currently Unavoidable Use (CUU) status to fluoropolymers in industrial use, thereby exempting them from the ban.

Fluoropolymers are a group of polymers that fall within the definition of per- and polyfluoroalkyl substances (PFAS). Fluoropolymers exhibit low reactivity, low water solubility, and a high average molecular weight. Fluoropolymers also have a high molecular weight (over 100,000

Da), and therefore cannot cross the cell membrane, and thus are not bioavailable or bioaccumulate. Due to these characteristics, fluoropolymers have low human and environmental toxicity concerns.¹

With the benefit of its strong industrial background, Valmet respectfully submits that fluoropolymers serve an indispensable role in modern industry. Such chemicals are widely used by numerous businesses. Among other things, they serve to ensure industrial health and safety and resource-efficient operations in harsh industrial environments.

Viable one-to-one alternatives for the vast majority of fluoropolymers do not yet exist. Therefore, sweeping prohibitions on the distribution and use of such products, as contemplated by the Maine Assembly and DEP, will have a disruptive effect not just on critical industrial operations but also on the availability of everyday commodities such as tissue, paper, and paperboard. Such disruptions are also likely to frustrate efforts to meet sustainability goals, as fluoropolymers are an integral part of many technologies used to achieve carbon dioxide-free goals and in the production and storage of hydrogen.

Given these realities, Valmet strongly believes that fluoropolymer-containing products in industrial use should be categorized as "currently unavoidable uses" of PFAS and, therefore, exempted from future prohibitions on intrastate sale or distribution.

Specific comments to the Maine Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances, criteria for currently unavoidable uses of intentionally added PFAS in products.

- With respect to Section 3(A)(1)(e)(iii), Valmet supports the Department's proposed approach of a range-based approach to PFAS reporting. Such an approach is expedient, especially where standardized characterization methods are not provided. It will reduce the burden to industry.
- With respect to Section 9(A) (generally), the specified timeframe for gathering all the information necessary for a CUU application is too short. The application deadline is between January 2029 to June 2030. This leaves only 4 to 5.5 years to identify, test, validate and certify the alternatives and solutions. Considering also the broad variety of products across the multiple industries Valmet serves, this timeframe is in no way sufficient relative to the amount of work required with expected material characterization, multiple testing, potential redesign of components and technologies, standardization and recertifying the machinery. The speed of the certification process is also determined by the capacity of the auditing bodies. Therefore, Valmet urges a longer transition period, 25 years at minimum.
- With respect to Section 9(A)(3) and (4) (generally), Valmet maintains that many aspects of the proposed rule will be challenging for manufacturers, as they depend on information provided by their suppliers. It is Valmet's experience that suppliers often do not readily know the function of the PFAS in the materials that they supply with specificity. Nor do they know or provide whether viable alternatives exist. Insisting on the provision of all of this information will functionally negate the procedure of obtain a CUU Determination. CCU applicants should be permitted to present their case in a more general manner, relying on things such as literature searches and publicly

¹ Améduri, B., Fluoropolymers as Unique and Irreplaceable Materials: Challenges and Future Trends in These Specific Per or Poly-Fluoroalkyl Substances,

available information regarding the overall presence and role of PFAS in various categories of products.

537

- With respect to Section 9(A)(4)(a), Valmet notes that the "identification of specific compounds, classes of materials, or combinations of materials identified as potential alternatives including the removal of PFAS without substitution" is in many cases not currently feasible within the industries Valmet serves. Therefore, insistence upon this criterion will deprive the industry as a whole of CUU determinations for many products. The proposed rule should be revised to offer a pathway for companies, such as Valmet.
- With respect to Section 9(A)(4)(c) and (d), the tasks contemplated under these subsections are feasible only after those contemplated by subsections 4(a) and 4(b) have been completed. Therefore, Valmet urges a longer timeframe along the lines of our comment above pertinent to Section 9(A) (generally).
- With respect to Section 9(a)(4)(e), there is currently a dearth of standardized test methods available to evaluate the health and safety impacts of most of these substances on humans or the environment. Without more specific guidelines, it will be difficult for the authority to make decisions based on varying data. Therefore, Valmet recommends that standard test methods be specified in the final rule.

Thank you for the opportunity to comment and we look forward to further engagement on this important topic. Please contact the undersigned if you would like more information from us.

Respectfully,

hut LTm to

Rob Turner Director, Legal Counsel, North America 3720 Davinci Court, Suite 300 | Norcross, GA 30092 rob.turner@valmet.com



Environmental Affairs and Sustainability

28 January 2025

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VDMA feedback to the Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances Draft Rule (Draft date December 20, 2024)

In General

To begin with we would like to thank the Maine Department of Environmental Protection for the opportunity to provide comments and concerns to MDEP Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances Draft Rule (Draft date December 20, 2024)!

The VDMA represents more than 3,600 German and European mechanical and plant engineering companies. The USA is a significant market for VDMA members.

PFAS and PFAS-containing materials are needed in **the machinery and equipment manufacturing industry** whenever **extreme conditions** (high or low temperatures, high frictional resistance, aggressive/corrosive/toxic chemical conditions, or a combination of these) prevail. Therefore, most existing industrial uses (e. g. fluoropolymers in seals, valves, pipes, gaskets) as well as future technologies (e. g. fuel cell, water electrolysis, heat pump, solar system, batteries) **often do not have equivalent alternatives** to the expensive PFAS.

Clarifications are needed

We welcome the specific exemptions to the prohibitions for non-consumer electronics, offhighway vehicles, all-terrain vehicles, side-by-side vehicles, farm equipment, and equipment directly used in the manufacture or development of products described in subsections 5 through 12, as added to Public Law 2023, c. 630.

With regards to **non-consumer electronics** what remains uncertain is whether the mechanical and plant engineering (e.g., production machines, logistics and intralogistics applications) are excluded? Additionally, what is the status of gearboxes or other 'partly completed machinery'? According to the EU Machinery Directive 2006/42/EC, 'partly completed machinery' is defined as an assembly that almost forms a machine but cannot independently perform a specific application. This type of machinery is intended to be incorporated into or assembled with other machines or partly completed machinery to form a complete machine that complies with the directive. While some of these 'partly completed

machinery' may eventually be powered by electric drives, this is not universally the case. If a complete system encompasses more than just electrical devices, should it still be classified as 'electronics,' or should all 'mechanical' components be considered within the scope?

The exemption for non-consumer electronics shows that the primary focus should be on products that pose a risk and are more likely to impact a larger number of end-users and the environment. Industrial applications, such as the use of fluoropolymers for a seal in a mechanical and plant engineering application, do not pose a risk during their use. Otherwise there would be unnecessary regulatory burdens on this sector.

Examples of VDMA members' products

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PFAS use in machinery and equipment manufacturing industry (examples, non-exhaustive list!)

Machinery and equipment manufacturing industry (<u>examples, non-exhaustive list!)</u>	
PFAS missing uses (description of uses/application)	Justification for use
Separation technologies and filter media (PVDF, PTFE, FEP, ECTFE) e.g. used in compressed air or process gas filtration	Coating filter material, cleanability, high filtration performance (fine filtration), food and pharmaceutical application, FDA and Regulation (EC) 1935/2004 conform
Gaskets (PTFE, FEP, PFA, FKM, FFKM, FPM)	High temperature, chemical resistance, mechanical properties of sliding
Shaft sealings for machinery in process technology, construction machinery, crushing machinery (FKM, FFKM)	Performance, chemical persistence
Plain bearing bushes, thrust washers, guide bands, support ring, strips, wiper (PTFE, FKM, FVMQ)	Mechanical properties of sliding, high Temperature and chemical resistance, individual machining possible
Bushings, ball, sleeves, reducers, pipe, hose, elbow (PVDF)	Chemical resistance, Price- performance ratio

Seals (PTFE, FKM, FFKM, FEPM, FVMQ, PTFE, PCTFE, TFM, PVDF, PFA, FEP) for e. g.: heat generators, welding and compressed gas technology, valves, painting / surface technology, air&process gas compressors and their systems; sensors (e.g. dust measuring instruments, gas analyzers etc.), overall mechanical engineering	Thermal resistance >150°C, high chemical resistance, abrasion resistance, water- repellent properties, reduce friction and prevent substances from adhering, extreme durability in heating systems, combination thermal and chemical resistance, sliding and emergency dry-running properties, low friction, low wear, less leakage, long lifetime
Hoses (PTFE, FKM) for e. g.: heat generators, welding and compressed gas technology, valves, painting / surface technology, compressed air systems	High resistance, water-repellent properties, reduce friction and prevent substances from adhering, extreme durability in heating systems
Valves lined with PFA/PTFE used in e. g.: chemical, petrochemical, pharmaceutical, energy sector, food and process industries, air&process gas compressors and their systems	Protection against corrosive, pure and high-purity liquids, gases and vapors
Valves/safety valves (FKM, FPM, FPDM, PTFE, PVDF) for all machines	Combination of high pressures, temperatures and various chemicals
O-rings, mechanical seals, flat and face seals, Piston and rod seals, Wipers, Circlips, Radial shaft seals, Stuffing boxes, e.g. in industrial valves for all machines (like pumps, compressors, etc.)	Long life time, tightness, reduce friction and energy consumption, sustainability, safety, high pressure resistance, chemical resistance
Sliding coatings (PTFE) e.g., machines for food&beaverages industry, oilfree rotating compressors/oilfree piston compressors (piston and compression ring)	Substitution for environmentally incompatible lubricants in sliding surfaces.
Guides (PTFE)	Long life time, tightness, low friction and energy consumption, sustainability, safety, high pressure resistance
Surface treatment (PTFE, PFA, FEP, PVDF) e.g. pistons, wipers, inner tube surfaces, guide rods	Non-stick coating, low friction, smooth running properties, chemical resistance, wear protection
Hydraulic accumulator (PTFE, FPM, FKM)	Combination of high pressures, temperatures and various chemicals and harsh environmental conditions

Hydraulic components e.g. cylinders, pumps, motors, control blocks, valves (PTFE, EPDM, FKM, PVDF)	Combination of high pressures, temperatures and harsh environmental conditions
Parts and coatings for components in refrigeration and heat pump systems (e.g. bearings, thrust washers and dynamically stressed shaft bushings, PTFE), like compressed air refrigeration dryers	Chemical resistance, temperature resistance, dimensional stability even at low temperatures, pressure and temperature fluctuations, low gas permeability and low electrical conductivity. Prevent leakage of the refrigerant e.g. ammonia. At the same time, the good sliding properties of e.g. coated surfaces enable low energy consumption. High wear resistance ensures longevity and significantly reduces the effort required for maintenance and repair
Ring and flat seals as well as packings and other sealing systems (e.g. PTFE, FKM) in refrigeration and heat pump systems (also compressed air refrigeration dryers)	Thermal resistance >150°C, high chemical resistance, abrasion resistance, ensure at various points in the plants that valves can reliably shut off, regulate and perform the safety functions. In order to meet safety requirements and reduce environmental pollution, we depend on that valves close tightly, i.e. that no refrigerant can escape into the environment, and that certain sections of the plant can be safely shut off if necessary
Electrotechnical and electronic components(sensors, electronic controls and components) - used in all machines (FKM, PVDF, FEP or ETFE)	High performance and resistance are only made possible by the use of materials containing PFAS to ensure energy-efficient operation.
Coatings of the windings in motors for many refrigeration components (e. g. refrigerant compressors, refrigerant pumps and control valves)	

Use of FKM, FFKM, PTFE, PVDF in equipment for chemical industry e.g. for polymer washing processes, production of polycarbonate, crude oils, mono ethylene glycol (MEG) within the natural gas production, aromatic heavy fuel oils & residual oils, gas oils & kerosine, diesel oils, biodiesel B100, fatty acid methyl ester (FAME), naphtha, light condensates, NGL-natural gas liquids (Alkane's), methanol, coal water from the coke production, fish processing, special degumming in vegetable oil processes, vaccines etc.(also process gas compressors)	High temperatures, strong abrasion and aggressive chemical conditions
Use of Fluoropolymers und PFPE in textile machinery; machinery equipment for the textile industry: e.g. textile machines for the production of textile materials (clothing, home textiles and technical textiles), e.g. machines for chemical fibre production, machines for nonwovens production, dyeing machines, impregnating machines, drying machines. Pressure vessels for thermochemical treatment of textile recycling material in order to enable circular economy. Fully automatic chemical dispensing systems (used in various industries apart from textile industry: chemical, pharma, food), Heat recovery systems for reduction of need for fossil fuel based thermal process energy. Wastewater treatment technology	As sealing materials to maintain function, reduction of maintenance and prevent leakage. As construction and coating materials for components to ensure energy efficiency, material efficiency of components (reduction of wear) and highest fabric quality of processed textiles. As part of lubricants with PTFE or PFPE used at high temperatures and in harsh conditions. In electrical components as part of drive and controlling to protect them against chemicals and high temperatures
bearings/sliding bushes (PTFE) in air&process gas compressors	
coatings (PTFE, PVDF) e.g. anti corrosion coating of piping and connections for process technology or in process gas compressors, for top coating of v-belts, coatings for bolts in aggressive media like in oil&gas industry	Chemical resistance
Sealing systems in leak detectors	Thermal and chemical resistance, resistance against aggressive gases, dielectric properties
sealing membranes in the valves of gas containers for technical gases, refrigerants, LPG and other	
Corrosion protection for process instrumentation (PTFE, PFA)	Chemical resistance

Tube and hose connectors, flanges, quick release couplings, tube line valves, measuring connectors (PTFE, FKM) e.g. for hydraulic fluids, vlucanisation processes, hot forging processes	
Cables, wires, plugs (PTFE, PFA) e.g. for signal transmitter, pressure and flow switches, valves	Chemical and thermal resistance
Pneumatic components e. g. valves, regulators, actuators, tubes, fittings (FKM, EPDM, PTFE, PVDF)	
Brake Pads - PTFE	
O-ring preloaded PTFE seals for pneumatic applications	Durability, tightness, low friction and energy consumption, sustainability, safety
Support rings based on PTFE for high-pressure hydraulic applications	Durability, tightness, low friction and energy consumption, sustainability, safety, high pressure resistance
PTFE-based guide elements for pistons	Durability, tightness, low friction and energy consumption, sustainability, safety, high pressure resistance
O rings on EKM and EEKM basis	
	Long life time, tightness, reduce friction and energy consumption, sustainability, safety, high pressure resistance
X-rings on FKM and FFKM basis	Long life time, tightness, reduce friction and energy consumption, sustainability, safety, high pressure resistance Durability, tightness, low friction and energy consumption, sustainability, safety, high pressure resistance
X-rings on FKM and FFKM basis O-ring preloaded translational hydraulic seals (PTFE / FKM)	Long life time, tightness, reduce friction and energy consumption, sustainability, safety, high pressure resistance Durability, tightness, low friction and energy consumption, sustainability, safety, high pressure resistance Durability, tightness, low friction and energy consumption, sustainability, safety, high pressure resistance, thermal resistance
X-rings on FKM and FFKM basis O-ring preloaded translational hydraulic seals (PTFE / FKM) O-ring preloaded rotary seals (PTFE / FKM)	Long life time, tightness, reduce friction and energy consumption, sustainability, safety, high pressure resistance Durability, tightness, low friction and energy consumption, sustainability, safety, high pressure resistance Durability, tightness, low friction and energy consumption, sustainability, safety, high pressure resistance, thermal resistance Durability, tightness, low friction and energy consumption, sustainability, safety, high pressure resistance Durability, tightness, low friction and energy consumption, sustainability, safety, high pressure resistance

Lip ring seals (FKM / FFKM)	Long lifetime, tightness, low friction and energy consumption, sustainability, safety, chemical resistance
O-ring preloaded PTFE wipers	Durability, tightness, low friction and energy consumption, sustainability, safety
O-ring preloaded hydraulic rod seals (PTFE / FKM)	Durability, tightness, low friction and energy consumption, sustainability, safety, high pressure resistance
Special FKM and FFKM rotary seals	Durability, tightness, low friction and energy consumption, sustainability, safety, chemical resistance

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January 28, 2025

Maine Department of Environmental Protection 17 State House Station Augusta, Maine 04333 Submitted via email: rulecomments.dep@maine.gov

Re: Proposed Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

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Please accept the following written comments from W. L. Gore & Associates, Inc. (Gore) regarding the Ch. 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances rulemaking. Gore is a U.S.-based materials science company with approximately 13,000 Associates globally, including 8,000 in the United States, and it solves complex technical challenges in the most demanding environments – from outer space to the world's highest peaks to the inner workings of the human body. Gore appreciates the Maine DEP's work on Ch. 90 rulemaking, including its outreach to the regulated community during the stakeholder process.

Section 2 - Definitions

Commercially Available Analytical Test Method

To help ensure that analytical results being used as a basis for regulatory decisions are reliable and reproduceable, Gore respectfully requests that the Department clarify that a "commercially available analytical test method" must be a method that has been validated using a standard procedure (e.g. ASTM, ISO, NIST) and that the laboratory performing the analysis (whether it is a third-party laboratory or an in-house laboratory) must be able to demonstrate that it meets good laboratory practices regulations or holds a quality certification such as ISO-IEC 17025 (general requirements for the competence of testing and calibration laboratories) or other certification acceptable to the Department.

Personal Protective Equipment

Respectfully, Gore requests clarification that the definition of "textile articles" excludes personal protective equipment, including equipment worn to minimize exposure to occupational hazards that can cause serious injury or illness from contact with or exposure to workplace or professional hazards (for example, hazardous material suits, firefighting turnout gear, electric arc protection gear, outdoor gear designed for enhanced visibility, weather protective gear for outdoor activities, etc.). Under the proposed rule, "textile

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articles" are defined to describe goods that are "customarily and ordinarily used in households and business," and are subject to a January 1, 2026 ban unless they receive a "Currently Unavoidable Use" designation. However, personal protective equipment is distinguishable from the illustrative list included in the definition, not marketed for general consumer use, and necessary for compliance with occupational safety and health regulations and other industry standards (such as NFPA). Confirming that the definition of a "textile article" does not include personal protective equipment would provide clarity that a ban on the use of PFAS in personal protective equipment would go into effect on January 1, 2032, unless such use otherwise receives a "Currently Unavoidable Use" designation, and would also provide the requisite time for identification and commercialization of feasible alternatives, versus the January 1, 2026 ban in place for non-technical textile articles.

If it is the Department's determination that personal protective equipment is included within the scope of "textile articles," then Gore requests that it be managed in line with the requirements for "outdoor apparel for severe wet conditions," which are subject to a disclosure requirement on January 1, 2029, and a ban on January 1, 2032, unless there is an approved "Currently Unavoidable Use." Although personal protective equipment is not necessarily designed for outdoor sports experts, there are categories of personal protective equipment that are designed to "provide protection against extended exposure to extreme rain conditions or against extended immersion in water or wet conditions to protect the health and safety of the user and are not marketed for general consumer use." Other categories of personal protective equipment, such as firefighting turnout gear, are designed to provide protection against extreme conditions to protect the health and safety of the user and have comparable technically demanding performance requirements for severe conditions for which non-PFAS alternatives are still being evaluated for function and performance, and the same disclosure requirement and timeframe as provided for outdoor apparel for severe wet conditions is appropriate.

Furthermore, there is a June 1, 2025 deadline for "Currently Unavoidable Use" proposals for textile articles, which will not provide sufficient time to collect the necessary information to draft and file a CUU request pending finalization of the Department's rulemaking process to ensure continued access to these technically demanding products. If personal protective equipment is determined by the Department to be a textile article subject to the January 1, 2026 ban, Gore respectfully requests that the deadline for submission of CUU requests be extended to six months after the Chapter 90 regulations are finalized and enter into force.

Section 3 – Notification

Grouping Brick and HTS Codes (3A(1)(a))

Gore respectfully requests that the Department provide additional clarification on the use of Global Product Classification (GPC) brick code or Harmonized Tariff Schedule (HTS) code and North American Industry Classification System (NAICS) codes for both Section 3 reporting and Section 9 CUU purposes, to ensure that manufacturers can report using reasonable grouping of similar products. There are 99 identified chapters in the HTS



schedule,¹ each chapter has multiples of Headings and Subheadings, to comprise the sixdigit HTS code – there are hundreds, if not thousands, of different HTS six-digit codes. For products used as components in more complex products (e.g., cable assemblies, laminates, vents), there may be multiple Global Product Classification (GPC) brick codes or Harmonized Tariff Schedule (HTS) codes that are applicable to the product or product category, because the classification of the component product could depend on the final product that incorporates the component product as a part (e.g., HTS code 6201 covers certain apparel for men and boys while HTS code 6202 covers similar apparel for women and girls).

Furthermore, there are more than 700 NAICS 5-digit codes (20 primary sectors, 102 subsectors, 324 industry groups and 710 industries).² If a manufacturer is required to submit separate notifications and CUU requests for each unique combination of NAICS code and GPC brick or HTS code, this could require an extraordinary number of entries, depending on the product component. Gore does not believe that it is the Department's intent to require reporting in this manner.

Although 3.A.(1)(a) and 9.A.(1)(b) refers to a singular GPC brick code or HTS code, it is Gore's understanding that manufacturers may group multiple relevant GPC brick codes or HTS codes in a single CUU proposal or a single notification, in combination with identification of NAICS by primary sector (two-digit code). Gore respectfully requests that the Department confirm this understanding.

Add Engineering Calculations for determination of product content (3A(1)(e))

Engineering calculations based on product knowledge and supplier information is a recognized reliable cost-effective means to determine product composition of articles containing multiple substances. For example, a manufacturer might produce a filtration laminate that is composed of three components: 1) a PTFE membrane weighing 50 grams per square meter; 2) a non-PFAS containing adhesive with a lay down rate of 100 grams per square meter; and 3) a polyester scrim weighing 400 grams per square meter. Using this product knowledge, the manufacturer can calculate that the concentration of PTFE in the laminate would be 9.1% (w/w). Furthermore, the amount of PTFE in any filter cut from that laminate could be calculated based on the weight of filter (e.g., a filter weighing 10 grams would contain 0.91 grams of PTFE).

Gore respectfully requests that 3.A.(1)(e) be amended to expressly include engineering calculations based on product knowledge and/or supplier information for reporting the amount of intentionally added PFAS in a product notification. This could be accomplished with the following amendment (see italicized text):

(e) The amount of each of the intentionally added PFAS in the product or any product component:

¹ https://www.usitc.gov/tariff_affairs/documents/2024_hts_item_count.pdf

² NAICS / Industry codes - Company & Industry Research - Research Guides at Brock University



(i) Reported as an exact *measured* quantity as a concentration, determined using commercially available analytical methods;

(ii) Reported as a calculated quantity of specific PFAS or total PFAS, determined using engineering calculations, based on product knowledge and/or information provided by suppliers;

(iii) The total organic fluorine if the amount of each PFAS is not known or reasonably ascertainable, determined using commercially available analytical methods; or

(iv) Based on information provided by a supplier or as falling within a range approved by the Department.

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Section 10 - Proprietary Information

Gore is concerned about the Department's interpretive note in Section 9A regarding the protection of proprietary information. The Department states that because of its rulemaking process, it may not be able to justify a rulemaking approving a currently unavoidable use determination request that contains claims of confidentiality. However, the Department's criteria required to be included in a CUU request, including but not limited to Sections 9A(3) (detailing the function of the PFAS in the product) and (4) (detailing the analysis of potential alternatives to the PFAS), could require the disclosure of trade secrets and other competitively sensitive information. If a company is not able to protect such disclosures as proprietary information, it is placed in the untenable position of having to relinquish trade secret information that could erode its competitive position globally in order to continue to offer products for sale in Maine. Gore respectfully requests that the Department either clarify the level of technical detail that will be needed to submit a complete CUU package pursuant to Section 9, or establish a means for redacting confidential details from the publicly available aspects of the rulemaking process, similar to its procedures for issuing, for example, Title V air permits, which are also subject to public review and comment.

If you have any questions, please contact Raphy Goodstein at rgoodste@wlgore.com.

Thank you for your time and consideration.

Sincerely,

Raphy Goodstein Government Relations Associate

Page 4 / 4



January 28, 2025

Commissioner Melanie Loyzim Maine Department of Environmental Protection 17 State House Station Augusta, ME 04333

Re: Comments on Proposed Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS)

Dear Commissioner, Loyzim

The Window and Door Manufacturers Association (WDMA) appreciates the opportunity to provide comments on the proposed Chapter 90 rule governing products containing perfluoroalkyl and polyfluoroalkyl substances (PFAS). Our members manufacture high-performance windows, doors, and skylights for residential and commercial applications across the United States and internationally. We are committed to sustainability and environmental stewardship while delivering durable, efficient building products contributing to community well-being.

WDMA recognizes the urgency of addressing PFAS use and is committed to partnering with the Department of Environmental Protection (DEP) to achieve these critical environmental goals. However, several aspects of the proposed rule present challenges that could hinder compliance or create unintended burdens. We respectfully submit the following recommendations for your consideration:

Request for a Categorical Exemption for Building Products

Included in the authorizing legislation for the proposed rule is a reference to "architectural fabric structures" as a "textile article." The proposed rule, however, includes a clarifying definition for building products "intrinsic to the design and construction of buildings."

While we understand the intent of the clarification, it warrants asking whether products that serve a very important purpose -- the health, safety, and welfare of building occupants – should be exempt from the rule provided there is no alternative available to replace PFAS ingredients. Windows, doors, and skylights fall within this scope as they are essential to a building's structural integrity, energy performance, and human health.

WDMA respectfully requests that DEP extend the exemption of products outlined in Section 4 to include windows, doors, and skylights. These building products are required to meet building codes and are considered critical components for any building enclosure, provided there is no

feasible alternative that meets performance requirements.

Clarification of Currently Unavoidable Use (CUU) Determinations

The CUU framework outlined in Section 9 is essential to addressing PFAS use in critical applications. To ensure consistency and usability, we recommend more precise criteria defining "essential for health, safety, or the functioning of society" and more detailed guidance for determining when alternatives are "reasonably available." Strengthening the precision of these provisions will help manufacturers navigate compliance effectively.

Protections for Proprietary Information

The requirement to submit detailed notifications, including the exact chemical identity (CAS numbers) and concentration of PFAS in products, places a substantial burden on manufacturers, particularly when PFAS is present in components supplied by third-party vendors. Further, the requirements to supply confidential business information of manufacturers and their suppliers require greater structure and clarity.

Collecting and storing data and information that could put manufacturers at a competitive disadvantage or compromise intellectual property protections should compel the DEP to confirm what security protections will be in place to protect against theft, loss, or unauthorized access.

Reporting Requirements

The proposed product attribute, ingredient, and lifecycle reporting requirements will pose significant challenges for manufacturers of windows, doors, and skylights. They rely on complex supply chains to supply many of the components for the finished product. Further, the longevity of the typical product, and the lack of end user data available to the manufacturer, will certainly prove to make some requirements practically impossible to collect over time. To mitigate these issues, we suggest:

- Provide the option utilizing aggregated industry data, rather than individual manufacturer data, to provide the needed insight.
- Focusing data collection on products posing the highest environmental risks
- Simplifying the requirements for data from suppliers of components used in the manufacture of finished products.

Fee Structure Recommendations

To ensure fairness and encourage innovation, we recommend the following fee adjustments:

- We believe that companies should be charged on a per-volume basis to ensure fairness in cost distribution.
- Minimize fees for updates reflecting reductions or eliminations of PFAS use to incentivize innovation and compliance.
- Allocate fees to support research into safer alternatives and promote long-term environmental and economic benefits.

WDMA commends the Department's efforts to address the environmental impacts of PFAS while recognizing the importance of practical implementation. The above recommendations provide a balanced approach to achieving these goals.

We look forward to continued collaboration and stand ready to support the Department in advancing this critical initiative. Should you have any questions or require additional information, please do not hesitate to contact Michael Pierce at mpierce@wdma.com.

Sincerely,

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John Crosby President and CEO Window and Door Manufacturers Association

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