PERFORMANCE FLUOROPOLYMER PARTNERSHIP

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 science- and 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] https://www.maine.gov/tools/whatsnew/attach.php?id=13139124&an=2
[2] https://fluoropolymerpartnership.com/

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. Commercially available analytical methods must have been independently validated and must include quality control parameters and performance criteria that satisfy method objectives and assure data quality. 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 must remain unmodified when not performed by a third-party laboratory~~, unless modifications are approved by the Department. Any laboratory used by a manufacturer to determine the concentration of PFAS in a product must be certified to the most current version of ISO/IEC 17025 or the Organization for Economic Cooperation and Development's Principles of Good Laboratory Practice.

ISO/IEC 17025[3] 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, https://doi.org/10.1787/9789264012837-en.

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.[5]Therefore, 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 or monitoring instrument or other support equipment that is used~~required~~ to conduct research or generate the results of an analysis. Laboratory equipment includes, but is not limited to, any tool, apparatus, gear, or appliance that is intended to be used in the creation, separation, sampling, or monitoring of a substance, a mixture of substances, a process, or electromagnetic phenomena, such as incubators, fume hoods, laboratory water equipment, reaction vessels, gas generators, sensors, ~~or~~ preparatory or purifying equipment, or single-use laboratory equipment.

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, intentionally added PFAS; a change in the amount of intentionally added PFAS of more than 50% 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. https://www.epa.gov/system/files/documents/2024-04/2024-interim-guidance-on-pfas-destruction-and-disposal.pdf.

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 formulation~~or when there~~ that is a significant change in the amount or type of PFAS present in the product.
>
> <u>(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.</u>

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~~ <u>maintain records documenting the basis for the information contained in the notification and,</u> upon request by the Department,

~~evidence sufficient to demonstrate the accuracy of the information reported in subsection A~~provide 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, ~~expect~~except 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.

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 uses[11];
- 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. https://www.acq.osd.mil/eie/eer/ecc/pfas/docs/reports/Report-on-Critical-PFAS-Substance-Uses.pdf.
[12] https://sdgs.un.org/goals.

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 Department[13] 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%2Frules%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</u> a minimum contain <u>the following information to the degree it is known or reasonably ascertainable</u>:

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