PERFORMANCE FLUOROPOLYMER PARTNERSHIP

August 30, 2024

From: Jay West
Executive Director
Performance Fluoropolymer Partnership

To: Maine Department of Environmental Protection

Re: Concept Draft Language to Implement Title 38 § 1614 for the Maine PFAS in Products Program (August 5, 2024)

Submitted via email to PFASproducts@Maine.gov

Thank you for the opportunity to submit comments to the Maine Department of Environmental Protection (hereafter "the Department") on the "MDEP Concept Draft Language for PFAS in Products Rule" (hereafter "concept draft"[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 draft.

Summary (page 2). The note says that the Department understands that changes to federal laws and regulations referenced in the concept draft are to be incorporated into the program immediately without the need for additional public process. We disagree with the Department's understanding. Stated simply, the regulated community cannot base a compliance plan on "immediately," particularly when a change to a federal law or regulation removes an exemption. Changes to federal laws and regulation referenced in the concept draft could have a significant effect on products covered or not by Maine's program, which in turn has potentially significant compliance and enforcement implications for manufacturers who would lose their Maine exemption because of a change in federal laws and regulations.

We strongly recommend that the Department provide notification and analysis when changes in federal laws or regulations remove an exemption. Furthermore, the Department should invite questions or comments from stakeholders to help ensure alignment of expectations. The Department should also provide a date by which the effect of the federal law or regulation is effective for Maine's program. We are not suggesting a full rule-making process, but there does need to be a clear communication from the Department on the implications of a

[1] https://www.maine.gov/dep/spills/topics/pfas/PFAS-products/Ch%2090%20Products%20Containing%20PFAS%20CONCEPT%20DRAFT.pdf
[2] https://fluoropolymerpartnership.com/

change to relevant federal legislation and regulation that would remove an exemption and the time by which the change will be effective for Maine's program.

2. Definitions

Alternative. It is our understanding that the phrase "functionally equivalent product" in the statutory definition of "alternative" encompasses a temporal dimension such that products with shorter service lives are not "functionally equivalent." Products using or formulated with "alternatives" that have shorter service lives may also have 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.

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 of potential alternatives in the development of rules concerning unavoidable use determinations and in the PFAS source reduction program outlined in the statute. 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, proof or substantiation of not posing "the same or greater potential harm to human health or the environment as the PFAS" is required or expected.

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 38 M.R.S. §1614 (hereafter "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, we are concerned that the Department contemplates accepting data generated by "any test methodology," regardless of whether the method is fit for purpose or

has undergone multi-laboratory validation. We find this approach to be well outside the realm of good regulatory science and have serious concerns about the Department accepting and using for compliance or enforcement purposes results from tests that have not undergone rigorous and publicly documented validation procedures. The Department should modify the definition by substituting "Validated" for "Commercially available."

Analytical methods must be appropriate for the PFAS that are the target of the analysis and for the physical form of the product, e.g., gas, liquid, or solid. Analytical methods differ in which PFAS they are capable of detecting. For example, the analytical method EPA uses to identify PFAS in food contact materials targets 17 PFAS. In contrast, EPA's Draft Method 1633 is designed to identify 40 different PFAS in aqueous media (i.e., water, wastewater, landfill leachate), soil, biosolids, sediment, and biological tissues.

To create an even playing field, the Department must elaborate its intention regarding baseline criteria or performance standards for "any test methodology." The Department must also provide guidance on methods for use with solid matrices. Regardless of the lack of a validated EPA method, the Maine legislature has put the burden of identifying such methods on the Department, given the fact that many notifiable products will likely be solid matrices.

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). 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.

Also, we highlight the very practical matter that, depending on the number of currently unavoidable use (CUU) determinations, there is likely insufficient laboratory capacity to handle all the testing that compliance with the program described in the concept draft 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 laboratory capacity constraints. The Department must make accommodations for such circumstances in the forthcoming draft regulation.

Consumer products. We support the proposed definition of "consumer products" in the concept draft.

Cookware product. It is our understanding that the definition of "cookware product" includes small articles and utensils but does not include appliances such as refrigerators and ranges.

Cosolvent. The term "cosolvent" does not appear elsewhere in the concept draft, 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.

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." In addition, the Department should modify the definition of "distribute for sale" to clarify "sold or offered for sale in Maine by a receiving party subsequent to its delivery."

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.

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." 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."

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.

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.

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 concept draft.

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 concept note 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.

Manufacturer. While we appreciate that the Department has tried to do more to clarify the entity with the principal reporting obligation, the Department must provide additional clarity on the entities that will and will not be considered the responsible manufacturer and attempt to make "manufacturer" determinations that avoid the reporting of duplicative or conflicting information. The definition of "manufacturer" in the concept draft raises the following questions and needs for further clarification.

1. In the first explanatory note in the concept draft, the Department says, "Certain online retail platforms may allow for purchase of products directly from a producer. When no other person meets the definition of manufacturer under this Chapter, and the product is sold, offered for sale, or distributed for sale in the State of Maine, the Department will consider the importer to be the manufacturer." The statute is clear that "manufacturer" can include "the person who manufactures a product or whose brand name is affixed to the product." Furthermore, the statute says the Department can consider "the importer or first domestic distributor of the product" to be the manufacturer "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."

2. Because the statute contemplates when the importer can be considered a manufacturer, we request that the Department clarify more specifically, in the context of online retail platforms, the nature of the importer considered in the note, including whether and how that importer is different from the importer in the statute. Also, DEP should state definitively that shipping entities such as the U.S. Postal Service, Federal Express, or

other traditional carriers of goods purchased through online platforms would *not* be considered the importer.

3. We also request clarification from the Department concerning when the "producer" mentioned in the note would or would not be considered the manufacturer with the principal reporting obligation.

4. In the second explanatory note in the concept draft, the Department says, "When it is possible to consider multiple entities the manufacturer, the Department will consider the party who controls the formulation of the product and its PFAS content to be the manufacturer." Is it correct that the Department would make an exception to this rule "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"? In that case, the statute gives DEP the authority to identify "the importer or first domestic distributor of the product" as the manufacturer.

Reasonably available. We support the proposed definition of "reasonably available" in the concept draft.

Semiconductor. It is our understanding that the Department is defining this term because it appears without definition in the statute. If the Department is defining "semiconductor" for any other purpose, we request clarification.

The definition in the concept draft includes the sentence "Semiconductors do not include commonly associated materials such as printed circuit boards, solder, flux, wires, screen printing ink, connectors and sockets, or conformal coatings." We do not understand how this sentence is workable because semiconductors can be mounted to printed circuit boards. Therefore, the exclusion of printed circuit boards could be interpreted as also including any semiconductors mounted on the board. We suspect the Department's intent may be to exclude the substrate of a printed circuit board from the definition of "semiconductor."

Significant change. As noted in previous public comments submitted to the Department (November 10, 2022), 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, we suggest the addition of reporting when PFAS content decreases since the objective of reporting is to understand the nature and magnitude of human and environmental exposure to quantities of PFAS chemicals in products in the state. The results of reporting and the Department's subsequent exposure estimates cannot be accurate if decreases are not captured.

3. Notification

Section A. The concept draft 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.

Section A interpretive note. The interpretive note can be significantly simplified and made clearer by deleting the first sentence and adding the phrase "listed in Section 5" to the end of the current second sentence.

Section A(1). In the concept draft, the Department appears to have applied selectively the "known or reasonably ascertainable" standard (see 3(e)(ii) and (iv)) in the statute. We do not agree with this approach and believe it is inconsistent with the statute. The plain reading of the statute shows that the "known or reasonable ascertainable" standard applies to *all elements* listed in section 2(A) of the statute and that the Department does not have authority to apply the concept selectively. We suggest that to capture the intent of the legislature, concept draft language at 3(A)(1) should be modified to include the underlined text as follows:

> A notification under this section must include<u>, to the extent known to or reasonably ascertainable by the manufacturer</u>:

Section A(1)(d)(ii). We request that the Department clarify whether it plans to approve alternatives to chemical abstract service (CAS) registry numbers in regulation or implementing guidance, or if whether it will make such determinations on an as needed basis at the request of individual manufacturers. We strongly recommend that the Department allow for alternatives to CAS numbers, such as EPA-assigned Accession numbers, for proprietary chemicals with CAS numbers that are federally protected confidential business information.

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.[3]

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.

Also, the word "easy" should be replaced with "reasonably". There is no definition of the reporting standard "known or easily ascertainable."

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.

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 G. We request that the Department expand upon the phrase "evidence sufficient to demonstrate." 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.

4. Exemptions

Section A. The concept note does not consider the ongoing need for replacement parts for complex products and other equipment under section 4(A). For example, while the concept draft reflects the exemption for watercraft and seaplanes in the statute, 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.

[3] 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.

We offer the following additional provision to address replacement parts:

(14) Replacement parts for products described in Subsections 5 through 12, above.

Section A interpretive note. Regarding the phrase "the acts of applying for a CUU determination and submitting a notification and fee alone do not rise to the level of impossibility", we submit that manufacturers of products or product components subject to export administration regulations of the Department of Commerce's Bureau of Industry and Security or are 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 from revealing information about formulation. In such cases, applying for a CUU determination and submitting a notification and fee may be impossible.

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 $5,000 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 concept document or any other potential approaches to fees. The Department should also cap fees, either as an annual amount or per manufacturer.

We do support a flat fee, as opposed to a fee structure based on the size of a manufacturer's business. A manufacturer with a limited number of reporting obligations should not pay more than a relatively smaller manufacturer with a larger number of reporting obligations. Said differently, a manufacturer should not be disproportionately burdened or subsidized by virtue of the size of the business. We also agree that no fee should be "required for information updates to an existing notification or changes to inactive status."

The Department should not promulgate a fee rule until the cost of administering the program is better understood. 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 proposed 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.

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." We seek clarification on why this apparent exemption is not detailed in Section 2 (Notification) or Section 4 (Exemptions). Also, the Department should provide a definition of "complex product." Neither the concept note nor the statute contain a definition. Lastly, the second sentence could be interpreted to conflict with the sentence at the bottom of page 9 which appears to contemplate the referring of "supplier's submitted notifications for product components." Does "previously received notifications" in that sentence refer only to notifications received by January 1, 2023, under the statute passed on July 15, 2021, or does it have a different meaning? What precisely is the notification requirement (and thus fee obligation) of the manufacturers of components in (undefined) complex products?

Section C. We do not see the need for this section. The Department should clarify why the "receipt confirming digital payment" (Section B) is insufficient for the Department to consider the fee paid. In other words, why are the receipt (Section B) and transfer (Section C) materially different such that Section C is necessary? If the reason is to accommodate non-electronic payment (e.g., payments by check) or another payment scenario, we ask the Department to clarify.

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. We also recommend that the notification contemplated at A(2) should not be required unless the manufacturer fails to meet the deadline in A(1).

9. Currently Unavoidable Use. As an initial matter, we request that the Department clarify what it plans to do, if anything, with information it received in response to the solicitation of proposals for CUU determinations under the previous version of 38 M.R.S. §1614 (late 2023 or early 2024 with a deadline of March 1, 2024). Pursuant to our comments below, we strongly recommend that (a) the Department allow the manufacturers that submitted CUU proposals described above the opportunity to supplement their proposals according to the provisions of the final rule; (b) the Department provide those manufacturers up to 180 days after the effective date of the final rule to submit revised proposals to the Department; and (c) the Department immediately begin to process the updated CUU proposals.

Section A. The Department states in the concept draft that it will not consider CUU proposals prior to 36 months in advance of the applicable sales prohibition. This proposal is unacceptable.

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 (as defined) and their entire supply chains on hold and in limbo for the next 5

years (at least) will have significant disruptive consequences to the availability of fluoropolymers in many use categories the reliability and safety of which Maine's citizens, businesses, and institutions rely on, 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;
- Medical and pharmaceutical packaging;
- Communications (e.g. 5G) and navigation systems;
- Municipal, industrial, and agricultural water and wastewater treatment systems;
- Multiple military and national defense uses[4];
- 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.[5]

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 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.

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[4] *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.

[5] https://sdgs.un.org/goals.

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. It is precisely for this reason that the standard "known or reasonably ascertainable by" exists. In the concept draft, the Department applies the "known or reasonably ascertainable by" standard to item 11. 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.

Section A(5). We request that the Department insert the phrase "intentionally added" so as shown here:

> 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 <u>intentionally added</u> PFAS, including;

Section A(11). Information elements (b), (c), and (d) in this section also should be required, if available, for product or product component formulated with or made of the alternative(s) to the intentionally added PFAS in the product or product component that is the subject of a CUU proposal.

Interpretive note on page 20. 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 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.

10. Proprietary Information. We appreciate that the legislature has directed DEP to protect proprietary information in the administration of the program.

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Thank you again for the opportunity to provide these comments on the concept draft. We would be happy to meet with the Department to discuss any of our questions and concerns in more detail.

Jay West
Executive Director
Performance Fluoropolymer Partnership