PERFORMANCE FLUOROPOLYMER PARTNERSHIP

July 18, 2022

Kerri Malinowski Ferris
Maine Department of Environmental Protection

Re: Concept Draft for the Maine PFAS in Products Program

Submitted via email to kerri.malinowski@maine.gov

Dear Ms. Ferris:

Thank you for the opportunity to submit comments to the Department of Environmental Protection (hereafter "Department) on the "Concept Draft for the Maine PFAS in Products Program"(hereafter "Draft") on behalf of the American Chemistry Council's Performance Fluoropolymer Partnership.[1] 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.

Fluoropolymers are large, stable molecules that have been demonstrated to meet criteria developed by governmental and intergovernmental regulators to identify "polymers of low concern" for potential impacts on humans and the environment.[2,3] Fluoropolymers are insoluble substances and therefore concerns about the mobility of highly water soluble PFAS substances do not apply to fluoropolymers. Fluoropolymers are neither bioavailable nor bioaccumulative, are not long-chain non-polymer PFAS, such as PFOA and PFOS, and do not transform into long-chain non-polymer PFAS in the environment. For these reasons, we request that the Department exempt fluoropolymers and fluoropolymer-based products shown to meet the polymers of low concern criteria from the requirements of 38 M.R.S. §1614.

General Comments

1. **Confidential Business Information (CBI).** Maine's program would require manufacturers to disclose extremely sensitive proprietary information about the types, functions, and amounts of PFAS in specific products. To date, the Department has not addressed critical

[1] The Partnership's members are AGC, Inc., The Chemours Company LLC, Daikin America, Inc., ExxonMobil, Gujarat Fluorochemicals Limited, Honeywell, MilliporeSigma, Shamrock Technologies, Sherwin Williams, and W.L. Gore.
[2] 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.
[3] Korzeniowski, S.H., Buck, R.C., Newkold, R.M., El kassmi, A., Leganis, 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.

questions about the types of information that will qualify as CBI, how notifiers can assert CBI claims, and how CBI will be protected by entities responsible for managing the database and the PFAS in Products Program generally. The Department must better articulate how CBI will be managed in the notification process and protected thereafter by both the Department **and** the Interstate Chemicals Clearinghouse (IC2).

2. **Reporting Database.** As the Department is certainly aware, it will receive notifications for hundreds of thousands of products (if not more) from all sectors of the economy. We are concerned about the ability of the reporting tool being developed and administered by the IC2 to manage this task since, as far as we are aware, IC2 has not previously developed a reporting system of this scope and magnitude. Consequently, it will be essential that the Department take whatever measures are necessary to build in a beta testing phase to ensure that the IC2 system is sufficiently robust to manage the number of users and volume of information anticipated, particularly since the Department has waited until less than 6 months before the statutory reporting deadline to begin implementation conversations with stakeholders. The Department's timing has raised widespread concerns about system overload and potential reporting opportunity delays for which the Department has not articulated contingency plans.

3. **Supply Chain Complexity.** The Draft does not demonstrate an understanding of complex, multi-tiered global supply chains. They include an array of manufacturers, from small private firms to multinational corporations, providing chemicals, component parts, and assemblies that come together in a final manufactured article. Plumbing such supply chains to identify whether a product or product component contains PFAS, the identities of those PFAS, the degradation products of those PFAS, and the quantity of those PFAS is a complicated and time-consuming process. Given the late initiation of the implementation process, the Department must expect incomplete information and work with notifiers to make appropriate accommodations.

4. **Sell Through Period.** The Department stated in the June 30, 2022, stakeholder webinar that products banned as of January 1, 2023, would have to be removed from shelves. This is not a reasonable position, especially when announced so close to the implementation date and particularly in light of ongoing supply chain disruptions. Product recalls based on no risk-based determination will result in unacceptable cost to Maine businesses and consumers, and the Department must provide for a sell-through date for existing inventory in Maine.

5. **Reporting Waiver.** The authorizing statute clearly gives the Department authority to "waive all or part of the notification requirement . . . if the department determines that substantially equivalent information is already publicly available." Yet, the Draft is silent on waivers or what the Department would consider "substantially equivalent information." The Department should be transparent about its intention to exercise or not exercise its statutory authority with respect to waivers and the criteria for "substantially equivalent information."

Below we provide detailed comments on specific language in the Draft.

Section 2. Definitions.

Alternative. The Department should clarify the difference between "substance" and "chemical" in the first sentence of the definition. Is there a meaningful distinction for the purposes of notification?

We disagree with the use of "similar" to describe alternatives. Given the importance of PFAS, fluoropolymers in particular, for meeting industrial safety and performance standards across the economy, **"equivalent and safer"** should be used instead of "similar."

The Department must 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. Note also that few PFAS have actually been found to present any harm to human health or the environment. In those cases, because there will be no basis for concluding that the alternative presents less harm, the Department should not prohibit the continued use of the PFAS.

We are concerned the language in the Draft appears to contemplate untested alternatives displacing the use of PFAS, opening the door to regrettable substitution. The phrase "has not been shown" can be interpreted as an absence of evaluation and should be changed to "has been shown not," which would unambiguously require data and analysis regarding the alternative relative to the PFAS for which it was substituted.

Carpet or rug. The Department should interpret "carpet or rug" to mean "intended for use in a building." Carpeting used in automobiles, airplanes, and non-building applications should not be included.

Commercially available analytical method. The definition in the Draft envisions the use of "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, let alone requiring, 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 is 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, if not most, notifiable products will be solid matrices.

Consumer. We propose that the Department change this term to "Purchaser." The definition of "Person" in the Draft shows that the Department does not intend to limit the scope to "consumers" as the term is broadly and commonly understood, but to any type of entity that "purchases."

Distribution for sale. One could interpret the proposed definition to include third-party transportation companies, since they "transport a product with the … understanding that it will be sold … by a receiving party." If so interpreted, the transportation company would be subject to the 2023 and 2030 notification requirements (and prohibitions). The Department should clarify that third-party transporters are *not* subject to the forthcoming regulation.

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" and provide illustrative examples that identify which entity in a supply chain would have the notification requirement. There is significant uncertainty on this point.

Fabric treatment. The Department should modify the definition of "Fabric treatment" to reflect clarifying remarks from Department officials on the June 30, 2022, stakeholder call that the term refers to after-market consumer products applied to finished fabric or leather products.

Intentionally added PFAS. The Department should clarify that the term "degradation byproducts" is limited to "degradation byproducts of **intentionally added** PFAS." The language in the Draft can be interpreted as meaning any degradation product of any PFAS, including those of incidental background impurities or contaminants, would be "intentionally added," even if they were not present "in order to provide a specific characteristic, appearance, or quality or to perform a specific function." Regarding the exception for PFAS that "is used in or comes in contact with a product during manufacturing but is not present in the final product," the Department should clarify in the last sentence that the term "intentionally added PFAS" excludes PFAS "not **intentionally** present in the final product **to provide a specific characteristic, appearance, or quality or to perform a specific function**."

Offer for sale. Consistent with comments above regarding "Consumer" and "Distribution for sale," the Department should modify this definition by striking "consumer" and instead insert "purchasers in Maine."

Perfluoroalkyl and polyfluoroalkyl substances (PFAS). The note below the definition is inaccurate. The referenced EPA list provides examples of substances considered to be PFAS, but falls short of providing "clarity," since the EPA's working definition and the statutory definition in Maine are different. The Department should explain this difference and its implication for notification obligations to the potentially regulated community with significantly more clarity than exists in the Draft. The Department should also provide an identified list of

PFAS CASRN prior to the finalization of the IC2 database as a starting point for companies to collect the appropriate data needed for notification.

Product. The Department must clarify its intent regarding the word "item." Is a chemical an "item"? Does "item" refer to what is commonly understood as an "article"? Also, the Department should substitute "purchasers" for "consumers" and clarify that the definition applies to "items . . . sold or distributed **in Maine.**"

Significant change. The Department should align the definition of a "significant change" with existing hazard communication regulations and their requirements for updating safety data sheets.

Section 3. Notification.

Section A. As noted by many stakeholders, the U.S. EPA is finalizing a reporting and record keeping rule for PFAS under Section 8(a)(7) of the Toxic Substances Control Act. Like other Section 8(a) reporting rules, the reporting standard for the forthcoming rule is "known or reasonably ascertainable by", and we strongly urge the Department to adopt such a standard.[4] Notably, the standard does not require extensive new customer or supplier surveys. Also, EPA has clarified in its reporting rule for nanoscale materials that the "known or reasonably ascertainable by" standard does not trigger new testing requirements.[5]

Regarding extensions, the Department has heard from many entities with potential reporting obligations that they will require additional time to collect data to meet the statutory reporting deadline. This will also be true for gathering information needed to request a deadline extension, and we strongly urge the department to grant a 1-year extension to the reporting deadline. It is unworkable to think that manufacturers of complex devices and products that contain PFAS, often in very small amounts (computers, mobile phones, automobiles, medical devices, home appliances, aircraft, cellular communications technologies, watercraft, pharmaceuticals, construction products), will be able to manage the expected level of product evaluation and notification in such a short timeframe. The Department cannot expect companies to meet the notification requirements until they are published in final form and have a reasonable period to undertake the substantial analyses this program requires. One year after the rulemaking is completed and published is a necessary and reasonable extension.

Section 3(A)(2)(a)(iv) of the Draft says that notifying companies must report the "intended use" of PFAS in the notification. How will "intended use" be handled in the IC2 database? Will there be a pre-populated dropdown list of uses, along with clear interpretive

[4] 40 CFR 710.23 "Known to or reasonably ascertainable by" means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know." *See* 76 FR 50829 (August 16, 2011) for EPA's detailed explanation of the standard in the context of the TSCA Chemical Data Reporting Rule.
[5] 82 FR 3647 (January 12, 2017) "Manufacturers and processors are not required to conduct testing or develop new information under this rule. However, they are required to report information that is known or reasonably ascertainable."

guidance on what the terms in the list mean? Without standardized structure for reporting "intended use," the Department should expect to receive responses that vary from notifier to notifier, which will likely lead to confusion and misunderstandings when the Department and others attempt to understand the reported information in aggregate. The Department should provide significant additional detail on how "intended use" will be implemented in the IC2 database so companies can understand and appropriately plan their notification responses in advance of the reporting deadline.

In 3(A)(2)(c), the Department should clarify the section refers to "each ~~of the~~ PFAS **in the product"** and allow for reporting by **"chemical"** name, a descriptive name and EPA Accession Number, or another unique identifier. With regard to reporting ranges approved by the Department, we suggest the following ranges (unless the reporting entity knows the exact quantity):

< 0.01 ppm;
0.01 ppm to <1 ppm;
1 ppm to < 100 ppm (0.01%);
100 ppm (0.01%) to < 0.1%;
0.1% to 10 %; and
> 10%

We strongly suggest the Department not to develop ranges for different types of products. Doing so would create unnecessary uncertainty and further delay the ability of affected entities to report.

Finally, consistent with earlier comments, we ask that the Department strike the use of "consumer" at 3(A)(2)(a)(i) and (iv) use "purchaser" instead.

Section C. In the initial sentence, the Department appears to indicate that a category reporting approach will be identified "through the reporting system" to be implemented, which seems contradictory to a one-time reporting rule. The category approach needs to be built into the reporting system from the beginning, not at some point midstream, as the Draft implies. Deleting the phrase "through the notification process" should eliminate this point of confusion.

While the category approach may potentially ease reporting burdens for some entities, the concept of "same" appears repeatedly in 3(C)(2) and (3), which is unduly restrictive and logically at odds with a category approach. In reality, a product manufactured by one company may contain more or less PFAS than the commercially same product manufactured by a competitor. It is necessary to recognize this variability in PFAS content of PFAS-containing products that for all commercial purposes are considered alike. Separate notifications should not be required simply because one formulation of the product contains somewhat more or less PFAS than another formulation. If the PFAS in each product are sufficiently similar with regard to identity, function, and exposure potential, the Department should build reasonable flexibility in the notification requirement through a category approach that is not unduly constrained by the idea of "same" as currently articulated in the Draft.

Section D. The proposed requirement to update a notification whenever there is a significant change in the reported information needs to be well defined to prevent companies from unknowingly violating the rules when, in their legitimate view, only minor changes have been made to a product.

We do not understand why 3(D)(2)(c) does not start with "Within 30 days" like the other parts of the section. Information does not flow through complex supply chains instantaneously, and we suggest the Department give notifiers 30 days from the time they become aware of a change of the nature described in D(2)(c) to modify their notification.

Also, Section 3(D)(2)(d) requires an updated notification "whenever a product is modified such that it no longer contains any intentionally added PFAS." The Department must develop criteria or processes that elaborate the burden of proof to demonstrate or certify "no longer contains any intentionally added PFAS" and penalties if such claims are found to be false.

Section E. In our reading, this section is duplicative of the definition of "Manufacturer" and can be deleted.

Section 4. Exemptions.

The Department should provide a list of federal regulations that preempt state authority such that a producer would not have a notification requirement. Also, if a product is subject to one or both state packaging laws listed in Section 4(A)(2) and (3), but its PFAS content is not specifically regulated under those laws, is it exempt from additional regulation under 38 M.R.S. §1614? It is our interpretation that the laws listed in Section 4(A)(2) and (3) take precedence where the regulation of PFAS in food packaging are concerned. If that interpretation is incorrect, we would appreciate detailed interpretive guidance on the matter from the Department.

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

We note that, in 5(C), the Department appears to have selectively included only a portion of the relevant language from Section 1612(5)(D) of the authorizing statute. Specifically, the Department has omitted from the Draft ". . .unless the department has determined that the use of PFAS in the product is a currently unavoidable use. The department may specify specific products or product categories in which it has determined the use of PFAS is a currently unavoidable use." We would appreciate an explanation for this omission. **Is the Department's plan to *not* pursue rulemakings to identify products or product categories in which PFAS are currently unavoidable?**

Failure to exercise authority that would allow a product that contains PFAS to continue to be used if its use is "unavoidable" denies a central component of the balance that was struck in the legislation. It will undoubtedly result in critical PFAS-containing products unable to be used in Maine, even though there is no comparable non-PFAS alternatives to replace them. Language must be added to the Department's rule that recognizes this exception when there is a "currently unavoidable use" and that establishes a pre-defined, fair, and transparent process

that: (1) allows companies to petition for an unavoidable use determination and an opportunity to fully support their petition; (2) ensures that the Department's decision on the petition is transparent, based on objective criteria, and issued timely in writing; and (3) allows for judicial review of that decision.

Section 6. Fees.

Fees should be applied to product classes, not to individual products. It is onerous and provides no health or environmental benefit to require individual product registrations. In addition, individual registrations and fees will be unwieldy in volume and much more difficult and resource intensive for the Department to administer.

In addition, companies need a quick, clear method to confirm receipt of payment by the Department. The Department should revise the Draft to allow for electronic payment and payment occurs upon issuance of an electronic receipt from the electronic payment system.

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Thank you for the opportunity to provide these comments on the Draft. Please contact me if you or your colleagues have any questions.

Jay West
Executive Director
Performance Fluoropolymer Partnership