PERFORMANCE FLUOROPOLYMER PARTNERSHIP

November 10, 2022

Kerri Malinowski Ferris
Maine Department of Environmental Protection

Re: Second Concept Draft for the Maine PFAS in Products Program (October 2022)

Submitted via email to PFASproducts@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.

As stated in our comments of July 18, 2022, 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. 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.

General Comments

1. **Confidential Business Information (CBI).** As described in the second concept draft, Maine's program would require manufacturers to disclose extremely sensitive proprietary

[1] The Partnership's members are 3M, AGC, Inc., The Chemours Company LLC, Daikin America, Inc., ExxonMobil, Gujarat Fluorochemicals Limited, Honeywell, MilliporeSigma, Porex, 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.

information about the types, functions, and amounts of PFAS in their products, as well as commercially sensitive sales projection data. Companies have taken the necessary steps, federally and state, to protect trade secrets. Nevertheless, the concept draft would require reporting of confidential business information that is protected against public disclosure under federal law. In addition, trade secrets that are inadvertently disclosed may compromise national security and infrastructure. While we appreciate the reference to the Uniform Trade Secrets Act (10 M.R.S. §1542(4)(A)(&(B)), the Department has not addressed a host of questions concerning the handling of commercially sensitive and federally protected confidential business information. For example:

a. What types of information can qualify as CBI?
b. How can manufacturers assert CBI claims?
c. Will CBI that has been submitted to the federal government and is federally protected against disclosure to the public also be shielded against public disclosure by DEP and its agents?
d. How will CBI be protected by entities responsible for managing the database and the PFAS in Products Program generally, particularly those who are not Department employees?
e. What systems does the Department have in place to monitor the release of CBI and notify manufacturers of breaches of CBI protection?
f. Will clear CBI guidance be in place for manufacturers with a January 1, 2023, reporting deadline?
g. If not, how will their claims of CBI be handled in the absence of clear guidance?
h. What means of redress are available to a manufacturer whose CBI is revealed, either willfully or unintentionally?

The Department **must** articulate far more clearly than it has done to date how CBI will be managed in the notification process and protected thereafter by both the Department **and** the Interstate Chemicals Clearinghouse (IC2). That the Department has failed to act on any articulation of CBI procedures and protections is surprising, given the articulation of protection at 38 M.R.S. §1310-B, which is referenced in multiple Maine rules.[4] Why is the Department referring to the Uniform Trade Secrets Act and not the policy already established in existing chemical regulations? In the absence of a rationale, the Department's choice seems arbitrary and raises concerns since the Department has not pointed to any rulemakings or other guidance to help manufacturers understand the Uniform Trade Secrets Act, despite the fact that manufacturers may suffer irreparable harm if DEP or its agents release or inadvertently disclose to the public information that is protected as CBI under federal law. In addition, we find it troubling that the Department references only §1542(4)(A)(&(B) but not sections of the Act that describe misappropriation, injunctive relief, and other important dimensions of protection (i.e., §1542(1-3) and §§1543-1548).

[4] See, for example, 38 M.R.S. §1310-B, which is also referenced in 38 M.R.S. §2324(3), 06 ME Code Rules §096-82-2, and 06 ME Code Rules §096-880-5.

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 and sufficiently flexible to allow for reporting of information that may not conform to a particular format contemplated by the Department (e.g., products for which there is not a corresponding "brick" code).

   The Department's failure to act in a timely manner has raised widespread concerns about system overload and potential reporting opportunity delays for which the Department has not articulated contingency plans. More importantly, how will manufacturers with January 1, 2023, reporting obligations know how to report in a manner consistent with the structure (e.g., data fields, choices in drop down menus) of the reporting database? Will they have to conform with reporting requirements that are more onerous than those ultimately included in the Department's final regulations, and will they bear the extra burden of having to report twice?

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 Department's regulatory process, the Department must expect incomplete information and work with notifiers to make appropriate accommodations.

   For products sold directly to distributors outside of Maine and not directly to retailers or individuals in Maine, it will be virtually impossible for the original product manufacturer to report on sales into Maine. For example, if a manufacturer in State #1 sells a product containing intentionally added PFAS to a distributor in State #2, who then sells to retail outlets in Maine, the original manufacturer of the product will not have access to the distributor's data for products sold into Maine. The manufacturer will only know what it sells to the distributor. This is not an uncommon scenario, particularly for common consumer and household products.

   The same is true for sales made through on-line platforms where the original manufacturer is not the entity fulfilling the sale of the product into Maine. Products sold to members of the public through on-line platforms can come from anywhere, and the original manufacturer has little to no control over that sale or the ability to get sales information through such channels. The Department needs to address these realities in the definition of

"manufacturer" and in the description of data and information that a "manufacturer" as currently defined can be reasonable expected to provide.

4. **Substance Identity.** As noted in our July 18, 2022, comments to the Department, it should allow for alternatives to CAS numbers, such as EPA-assigned Accession numbers, for proprietary chemicals with CAS numbers that are federally protected CBI. We acknowledge that in the Department's October 28, 2022, Frequently Asked Questions,[5] the Department says, "The statute requires manufacturers to report the amount of intentionally added PFAS in their products by CAS number. Therefore, the Department interprets that PFAS subject to the reporting requirement of the law are limited to those that have a CAS number." This interpretation should be codified in the text of the regulation.

5. **Sell Through Period.** The Department stated in both the June 30, 2022, and October 27, 2022, stakeholder webinars 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 without any determination of product-specific risk on the part of the Department will result in unacceptable cost to Maine businesses and consumers, and likely have significant solid waste implications. The Department must use its extension authority in a way that provides for a sell-through date for existing inventory in Maine.

6. **Definition of PFAS.** The overly broad definition of PFAS in the authorizing legislation creates an overwhelming task for the Department, bringing into play substances that heretofore have not been considered PFAS and those (like fluoropolymers) that have been shown to be substances of low concern for potential risks to human health and the environment. It also puts the Department in a position of spending valuable time and resources on the review of information on substances extensively tested and reviewed for safety and approved for their intended use by federal agencies like the U.S. EPA, FDA, and U.S. Department of Agriculture.

   We suggest that the Department reconsider the working definition of the program to focus on non-polymeric perfluoroalkyl and polyfluoroalkyl substances that contain at least two fully fluorinated sequential carbon atoms, excluding gasses and volatile liquids. This definition of PFAS would focus on smaller, lower molecular weight, soluble PFAS that may move between environmental media, may be more bioavailable and bioaccumulative, and should be of higher priority. It would allow the Department to focus on whether substances phased out by leading PFAS manufacturers and processors in many, but not all, countries are still entering Maine. Doing so will help to direct the Department's limited resources and more quickly identify sources of PFAS that may be of potentially of concern to human or environmental health.

[5] Accessed November 2, 2022, at https://www1.maine.gov/dep/spills/topics/pfas/PFAS-products/index.html#.

7. **Intentionally Added PFAS.** As a general matter, the Department needs to be clear at every mention of "PFAS" that the regulation is referring to "intentionally added PFAS." This is not the case in the Draft and could cause confusion with both compliance and enforcement.

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

Section 2. Definitions.

Alternative. We previously articulated in our comments to the Department dated July 18, 2022, several concerns with the definition of "Alternative", but the Department has made no change to the definition or otherwise addressed our concerns. We repeat those comments here:

> *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?*
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> *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."*
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> *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.*
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> *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.*

Commercially available analytical method. We note in the Department's October 28, 2022, Frequently Asked Questions that the Department says, "The Department may accept commercially available analytical methods that were performed by an in-house laboratory so long as no alterations were made to the methodology. However, a method that was developed at an in-house laboratory and is not offered by a laboratory providing services to third parties will not be accepted."

We appreciate that a commercially available method can be used in-house, but we would argue that where no commercially available methods exist (due to the matrix to be sampled or other consideration related to a formulated product's chemistry; see below), some modifications or proprietary in-house methods may be needed. If a manufacturer can provide information to the Department 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 there is insufficient laboratory capacity to handle all the testing that compliance with the regulation, as currently drafted, 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 regulation.

We also bring to the Department's attention that while there will certainly be challenges and delays due to analytical capacity, there will also be issues of analytical understanding. Recently, the standards setting body ASTM International convened a new subcommittee focused on the selection of appropriate analytical standards to measure PFAS in consumer products. Established techniques exist for detection of PFAS in environmental samples, but there is a lack of consistent and validated extraction, leaching, and preparatory methods for application to plastics, rubber, textiles, leather, metals, ceramics, and other material media. The new ASTM International subcommittee will develop a guide to the selection, application, interpretation, and limitations of available preparatory and analytical methods and techniques to identify and determine PFAS in different types of products and material media. A preliminary working draft of the outline of the new guide is expected in December. The lack of both analytical capacity and understanding further supports and underscores our call for the Department to provide a 1-year extension to the reporting deadline.

In addition to the issues detailed above, the Department has made no change to the definition of "Commercially available analytical method" or otherwise addressed the concerns we articulated in our comments to the Department dated July 18, 2022, particularly with respect to the inherent unreliability of data that may be generated using test methods that have not been validated for the purpose for which they are being used. We repeat those comments here:

> *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."*
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> *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. The Department has made no change to the definition of "Consumer" or otherwise addressed the concerns we articulated in our comments to the Department dated July 18, 2022. We repeat those comments here:

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."

Currently unavoidable use. The Department has added this definition from the authorizing statute, making small changes that better conform to regulatory (rather than legislative) language. How the Department will determine when "alternatives are not reasonably available" is unclear and subject to potentially arbitrary interpretation and/or implementation. The Department should propose a definition or articulate objective criteria for determining when alternatives are or are not "reasonably available," taking into consideration factors such as performance, safety, and total cost of ownership, among others, of products or product components made with alternatives to PFAS.

More generally, we urge the Department to bifurcate its rulemaking, to address the immediate requirements of 38 MRS §1614(2) and §1614(5)(A)(B) and (C) in this current rulemaking and, in a separate rulemaking, address the requirements of §1614(5)(D), including the definitions of "currently unavoidable use" and "essential for health, safety or the functioning of society." The requirements of 38 MRS §1614(2) and §1614(5)(A)(B) and (C) will take effect imminently. Consequently, there is an urgent need to finalize regulations implementing those provisions of the statute. By contrast, the provisions of §1614(5)(D) will not take effect until 2030, so the need to finalize regulations implementing those provisions is less urgent. Moreover, the issues raised by those provisions (e.g., what does it mean for a product to be "essential to the functioning of society") are weighty and far-reaching. Regulations to implement these concepts should be developed in a deliberate and thoughtful manner, with ample opportunity for stakeholder input and consideration. For this reason, the Department should decouple regulations implementing §1614(5)(D) from the fast-track regulations needed to implement §1614(2) and §1614(5)(A)(B) and (C).

Distribute for sale. The Department has made no change to the definition of "Distribute for sale or otherwise addressed the concerns we articulated in our comments to the Department dated July 18, 2022. We repeat those comments here:

> *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.*
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> *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.*

Essential for health, safety, or the functioning of society. We appreciate the Department's attempt to articulate this phrase from the authorizing legislation, but we have several concerns. Our first and most significant concern is that an essential use assessment should only be initiated when there is deemed to be a risk to human health or the environment. As noted previously, 95% of the types of fluoropolymers in global commerce have been analyzed against criteria to identify polymers of low concern. If there is no concern about risk, time should not be wasted on an essentiality analysis. Similarly, other PFAS for which exposure will be minimal to non-existent due to the nature of their use should not be subject to an essentially analysis in the absence of a concern about human or environmental impact.

We note that the preamble to the authorizing legislation speaks to "threat to the environment of the State and the health of its citizens" via the "contamination of soil and water". The Department appears to have interpreted the legislature's intent as reviewing all uses of all PFAS in all aspects of commerce, but that was clearly not the intent. If the use of a PFAS in a product or product component creates no potential "contamination of soil and water" that would be a "threat to the environment of the State of the health of its citizens", an essentiality assessment and determination is not needed and would be at odds with the legislature's intent for focusing on "threats" via "contamination of soil and water."

Our second concern is the repetition of the word "significant" (or "significantly") in the first sentence of the definition. As we noted in our comments on "Currently unavoidable use," how the Department will determine "significant" is unclear and subject to potentially arbitrary interpretation and/or implementation. The Department should propose a definition or articulate objective criteria for determining what is "significant" in the context of the first sentence of this definition.

Our third concern is the use of "Products" in the first sentence. The definition of "Currently avoidable use" is clear that the concept speaks to "a use of PFAS." That concept should be reflected in the definition of "Essential for health, safety, or the functioning of society"

by replacing "Products" in the first two sentences of the definition with "Uses of PFAS." Doing so would better align the legislative and regulatory texts.

Finally, for the reasons articulated above on "Currently avoidable use," we urge the Department to remove this provision and others intended to implement 38 MRS §1614(5)(D) from the current expedited rulemaking and address them in a separate rulemaking focused specifically on §1614(5)(D).

Intentionally added PFAS. The Department should clarify that the term "degradation byproducts" is limited to "degradation byproducts of **intentionally added** PFAS." Regardless of the newly added phrase about contaminants at the end of the definition, the current language in the Draft can be interpreted as meaning any degradation product of any PFAS, including those of incidental background impurities or contaminants.

Manufacturer. The definition of manufacturer does not account for the way goods are bought, sold, and distributed, either through traditional or on-line markets. Please refer to #3 in the General Comments section above. We also predict significant confusion and a high likelihood of duplicative reporting emerging from the definition of manufacturer, which includes companies whose brand is attached to a product in addition to an actual producer of a good. The definition does not allow the regulated community to identify the precise manufacturer with the reporting obligation. We are concerned that the high likelihood of duplicative reporting will result in meaningful overestimation of the amount of PFAS in products in Maine and any conclusions about human or environmental exposure based on such estimates.

Also, the note that appears below the definition of "Manufacturer" raises many questions about online platforms and whether the U.S. Postal Service, Federal Express, or other traditional carriers of goods purchased through online platforms would be the importer and therefore the manufacturer. The Department must offer more clarity on the entities who will and will not be considered the responsible manufacturer and attempt to make determinations that are more precise and not overlapping or conflicting.

Offer for sale. The Department has made no substantial changes to the definition of "Offer for sale" or otherwise addressed the concerns we articulated in our comments to the Department dated July 18, 2022. We repeat those comments here:

> *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). In addition to the comments offered at #4 in the General Comments above, we observe that the Department has made no changes to the note below the definition of "Perfluoroalkyl and polyfluoroalkyl substances (PFAS)" or otherwise addressed the concerns we articulated in our comments to the Department dated July 18, 2022. We repeat those comments here:

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 has made no changes to the definition of "Product" or otherwise addressed the concerns we articulated in our comments to the Department dated July 18, 2022. We repeat those comments here:

*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 has made changes to the definition of "Significant change" but does not provide a rationale. We stated in our July 18, 2022, comments that the Department should align the definition of a "significant change" with existing hazard communication regulations and their requirements for updating safety data sheets.

Regarding the Department's addition of "10% increase" as the definition of "significant change", we have two concerns. First, a 10% deviation is likely to be very common due to variability in testing methods and understanding of the presence of PFAS in raw materials. At the low levels of PFAS likely to be reported, a 10% deviation in reporting is likely to be very common. A "significant change" should be at least 50% to eliminate this type of analytical and reporting variability and understanding for the potential of non-intentionally added PFAS in raw materials. Second, we suggest addition "or decrease", since the objective of reporting is to understand quantities of PFAS chemicals in products in the state. The results of reporting and the Department's estimates of exposure cannot be accurate if decreases are not captured.

Section 3. Notification.

We appreciate that the Department has elaborated the requirements for a waiver of notification and has taken an initial step to more clearly described the concept of "substantially equivalent information" in the second concept draft, though we still have several concerns as elaborated below.

Section A. The Department has added Global Product Classification brick category and code ("GPC") to the set of minimum notification requirements. Some of our members are unable to locate entries appropriate to their potentially regulated products. The GPC system's focus on traditional consumer products like one might find at a large retailer may not contain appropriate identifiers. Therefore, the Department should establish categories outside of the GPC, include

the phrase “if applicable”, or provide manufacturers whose products are not covered by the GPC system an alternative means of satisfying the “brief description” requirement at A(1)(a).

The Department has also added estimated sales volume to the information required in a notification. We have several comments on this addition:

a. Sales volume is extremely sensitive data, and manufacturers must be allowed to designate it as CBI without question. Moreover, the Department has articulated no reason why this information should be included in a public database.
b. The Department does not tie the concept of reporting estimated sales volume to the Global Product Classification brick category and code at A(1)(a)(i) and the category approach mentioned at 3(C). For the purposes of reporting estimated sales volume, manufacturers should be able to group products under the brick category or the Department-allowed category. Doing so would simplify reporting, as many individual but largely similar products could be grouped together.
c. Estimating sales specific to Maine may not be possible, and the option to provide national estimates that can be scaled to Maine must be preserved.

With the addition of the Global Product Classification (GPC) brick category and code language, we think the “general type of the product” at (1)(a)(iii) is redundant and can be removed or satisfied if the brick and category code are provided. If the Department is looking for a type of information not provided by the brick and category code, or if the Department suspects that there are types of products being sold into Maine that are not covered by the GPC system, the Department should elaborate more clearly in guidance how manufacturers can most accurately provide the information the Department seeks.

Regarding the purpose information noted at (1)(b), will the reporting manufacturer define the purpose of the product, or will the Department establish a list of potential purposes? If the latter, the list should be made public as soon as possible, particularly to assist entities with January 1, 2023, reporting deadlines to aid in their compliance planning. We suggest utilizing three categories of “purpose”: industrial use, commercial use and consumer use. 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.

We appreciate the Department’s effort, in Section 3(A)(1)(c), to streamline reporting for products containing components that have “previously” been reported by the manufacturers of those components. To improve the subsection(s) of this provision we encourage the Department to consider two changes. First, since product manufacturers will, in most instances, have the same reporting deadline as component suppliers, the Department should allow for concurrent reporting by both. Use of the term “previously received notifications” in this provision suggests that concurrent reporting is not possible or permitted. The Department should eliminate the word “previously” from this sentence. Second, to help minimize CBI concerns, the Department should allow product manufacturers and component manufacturers to identify any

intentionally added PFAS compounds by the trade names of those PFAS products provided that the manufacturer of the trade name PFAS product has complied with the reporting requirements of the regulations. This option would ensure that the Department has all the information required to be collected under the statute, while reducing the reporting burden on manufacturers and protecting the confidential business information of companies that supply PFAS-containing products to downstream manufacturers.

In addition to the points above, the Department has not addressed many issues identified in our July 18, 2022, comments to the Department. We repeat the unaddressed portions of those comments here:

> ***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.[6] 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.[7]*
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> *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.*
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> *Section 3(A)(2)(a)(iv) of the Draft[8] 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 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*

[6] 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.
[7] 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."
[8] Now Section 3(A)(1)(a)(iv).

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),[9] 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

[9] Now Section 3(A)(1)(c).

approach that is not unduly constrained by the idea of "same" as currently articulated in the Draft.

***Section D.** 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 F. See comments below in Section 6. Fees.

Section 4. Exemptions.

The Department has not addressed any of the issues articulated in our July 18, 2022, comments to the Department, and we repeat those comments here:

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. Prohibitions on Sales of Products.

For the reasons articulated above, we urge the Department to remove Section 5(C) and other provisions intended to implement 38 MRS §1614(5)(D) from the current expedited rulemaking and address them in a separate rulemaking focused specifically on the implementation of 38 MRS §1614(5)(D).

Section 6. Fees.

We appreciate the changes to this section that would allow a single fee for a Department-determined product category or type according to Section 3(C). However, we have important questions about whether the payment system will be integrated with the reporting database and, presuming that the reporting database will not be available by January 1, 2023, or within 90 days of the effective date of the final rule, how manufacturers with January 1, 2023, reporting obligations can pay in a timely manner such that they are not out of compliance. Good faith efforts to pay fees in a timely manner should not be frustrated by unclear direction or guidance or the Department having adequate infrastructure in place to do so.

Section 3(F) states that a notification is not effective until the Department has received payment of the fee, and Section 7 notes that a product cannot be sold, offered for sale, or distributed for sale in the absence of a notification (e.g., the information required under Section 3). How should manufacturers consider products already in commerce in the State of Maine? What if there is a delay between the submission of Section 3 information and the Department's processing of a payment, which is particularly of concern to entities with a January 1, 2023, notification deadline? The regulated community needs much clearer interpretation from the Department in this regard.

We also take this opportunity to reiterate the following from our July 18, 2022, comments to the Department:

> *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
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Performance Fluoropolymer Partnership