SUSTAINABLE PFAS ACTION NETWORK

November 10, 2022

Kerri Malinowski Farris
Safer Chemicals Program Manager
Maine Department of Environmental Protection
17 State House Station
Augusta, Maine 04333

Re: Maine PFAS in Products Second Concept Draft Feedback

Dear Ms. Malinowski Farris:

The Sustainable PFAS Action Network (SPAN) is writing to express its concerns with the second Concept Draft of the Maine PFAS in Products program reporting rules, released on October 13. The second Concept Draft reflects that the rules soon to be proposed by the Department of Environmental Protection (DEP) would require, effective January 1, 2023, reporting of all products with intentionally added perfluoroalkyl and polyfluoroalkyl substances (PFAS) prior to sale or distribution in the state of Maine.

SPAN is a coalition of PFAS users and producers that are committed to sustainable, risk-based PFAS management. Our members work to advocate for responsible policies that provide assurance of long-term environmental protection and also recognize the important contribution that certain PFAS have made to economic growth and competitiveness in global markets. PFAS substances are integral to a vast number of sectors in the American economy. Renewable energy, auto manufacturing, defense contracting, semiconductor production, medical devices and pharmaceuticals are just some of the industries that are inadvertently impacted by arbitrary state-level PFAS regulations. SPAN was formed with these various and critical uses in mind, to ensure the health of the environment and consumers while maintaining America's global economic edge.

SPAN is committed to responsibly regulating PFAS through risk-based analysis anchored in a uniform federal approach. Following the release of its PFAS Strategic Roadmap in 2021, the U.S. Environmental Protection Agency (EPA) has been planning to issue reporting rules under the Toxic Substances Control Act (TSCA) Section 8, likely to take place early next year. These rules will require those that manufacture and import any identified PFAS to report information regarding uses, disposal, exposures, hazards, and production volumes. SPAN believes that EPA's work is an opportunity for Maine to reduce their reporting requirements and utilize the information gathered by the nation's federal environmental regulator. We strongly encourage DEP to formulate final rules for the program following the release of the impending TSCA rules, which will allow the PFAS in Products program to be harmonized with EPA and set an example for productive cooperation between federal and state environmental regulators. EPA conducts a thorough analysis that covers toxicity and other important factors with a wide ranging group of experts who are dedicated to the field and best suited to collect data and create reporting systems. This harmonization will lessen the burden on Maine businesses as well as state government

officials, and is the most effective way to ensure both effective and economically responsible environmental laws.

SPAN appreciates DEP's consideration of our comments on the first Concept Draft released in July. This second Concept Draft includes important additions that will greatly aid in the statute's implementation, such as language addressing CBI and complex products, as well as the inclusion of a waiver of notification. However, the rules set forth in this second draft, if enacted, would present an unprecedented bureaucratic burden to be imposed by the state that will surpass any federal reporting requirements concerning product content. While SPAN is appreciative of the six-month extension granted to all its members, our members and most entities required to comply do not have the information and resources needed to meet the requirements by the date they would conceivably be required to report. It will take months, if not years, for the businesses subject to the rules to begin to identify all of the products they might manufacture or distribute that could contain PFAS and for which reporting could be required. It is not reasonable for DEP to expect businesses that produce products distributed in Maine to contact the suppliers of all of the components that comprise their products to identify and track even negligible sources of PFAS throughout the international supply chains upon which SPAN members rely, even with a brief six-month extension.

SPAN is committed to environmental regulations that protect the health of Maine residents, and intends to work with DEP to develop practical reporting regulations to implement the underlying law. However, the reporting requirement set forth in the second Concept Draft will place a burden on Maine businesses and employers that will ultimately hinder DEP's stated purpose. The time and resources that will be required for reporting businesses to fully comply with the requirements envisioned in the Concept Draft, and the resources required for DEP to implement such rules, will far outweigh any benefit to be derived from the information submitted. Moreover, DEP must clarify several points made in the second Concept Draft that will be required to properly comply with the law, either by January 1, 2023 or six months after promulgation of the final rules.

In accordance with these overarching concerns, we are providing the following suggestions and comments with regard to several specific provisions in the second Concept Draft:

1) **<u>Compliance Date and Reporting Methods</u>**
   While SPAN is appreciative of the six-month extension granted to all its members, the amount of time that responsible parties will be given to comply with the reporting requirement will be unrealistic and vastly underestimate the amount of time, research, and information needed to collect, catalogue, and compile the data required. Many PFAS substances that would presumably require reporting have not been regulated by DEP or by other state or federal regulatory bodies. To identify and collect information on the presence of PFAS in products on this scale has never been undertaken in any major economic market. Doing so will require significant time simply to research the potential sources of PFAS in products and to contact the appropriate parties in the product and component supply chains, a process that needs to be examined within a time frame of several years, not months.

   Even if final rules are promulgated sometime in the next several months, this timeline will unnecessarily burden DEP's resources, and generate enormous new reporting obligations on US companies and their international suppliers of products and product components. Whether required to report on January 1, 2023 or six-months after final rules, these parameters will lead

to widespread non-compliance and poor quality reports. DEP should have an understanding that further extensions may be required to allow businesses to fully ascertain the potential presence of PFAS in products comprised of multiple, complicated component parts. While the inclusion of language addressing complex products in the second Concept Draft is a critical step forward, giving the manufacturer the opportunity to report total PFAS in the product including its components or to refer to the notifications for product components and any PFAS in the remainder of the product does not adequately address the issues with reporting for such products. **SPAN reiterates its recommendation that DEP consider phased in reporting requirements, with reporting to be required at later intervals for more complex (multi-component) products in specific categories.**

DEP must clarify the methods by which it intends for responsible parties to report PFAS quantities, both before the January 1, 2023 deadline and for entities that received the extension. Additional time will likely be required for DEP to establish reporting technologies and to communicate with the regulated community how to access and use what may be an untested reporting platform, once the reporting platform is established and running.. An untested platform will inevitably experience glitches and will require time to train staff on proper reporting procedures, as well educating those who must file reports. DEP should seek administrative efficiencies and to rely on databases and reporting systems that are already familiar to reporting entities and which can be expanded for purposes of this new program. Where other states in the US are implementing similar reporting requirements, there are likely efficiencies that can be gained by relying on existing reporting technologies when possible.

2) <u>Scope of PFAS and Definitions</u>

The definition of PFAS as any substance "containing at least one fully fluorinated carbon atom" is overly broad and has no bearing on the likelihood that contamination in Maine could be caused by a product containing a minimum of one substance with a single fully fluorinated carbon. This definition is far too broad and encompasses many substances that have been deemed of low risk which should be excluded from such a notification requirement. SPAN is also concerned that the definition of "Fully Fluorinated Carbon Atom" is overly broad, vague and confusing. For example, there are active pharmaceutical ingredients in crucial medications that fit within Maine's statutory PFAS definition. This definition also encompasses compounds that have been used to be able to comply with other Maine laws. For example, the hydrofluoroolefin (HFO) technology that was used in 2021 to comply with LD266 (Maine Public Law Chapter 192), which required the state to impose regulations sunsetting the use of the potent greenhouse gases, also fits within the scope of the DEP's expansive PFAS definition. These products have clear and tangible societal benefits that are being disregarded and which could instead be further encouraged if DEP were to consider specific, limited exemptions to the current PFAS definition. To limit unnecessary reporting on substances that do not merit DEP's scrutiny, SPAN recommends:

- **DEP create a concrete list of specific PFAS that need to be reported**, providing Chemical Abstracts Service (CAS) Registry Numbers and chemical names. We acknowledge that in the Department's October 28, 2022, Frequently Asked Questions,[1] 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

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

subject to the reporting requirement of the law are limited to those that have a CAS number." This interpretation should be codified in the regulation.

- **Perfluoroalkyl and polyfluoroalkyl substances (PFAS):** The Department has made no changes to the note below the definition of "Perfluoroalkyl and polyfluoroalkyl substances (PFAS)". The note below the definition in the concept draft 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.

- **Fluoropolymers should be exempted**, as they have unique properties distinct from other PFAS, and meet internationally recognized criteria for polymers of lower concern which are not expected to have significant environmental and health impacts.

The second Concept Draft includes new definitions meant to clarify the scope of products subject to reporting, what products may be eligible for a waiver of notification, and what may qualify as a currently unavoidable use. While the inclusion of these definitions is an important step in making the reporting requirement more efficient, a great deal of clarity is needed on what the process will be for determining what products are eligible. DEP has stated that the process for determining what products qualify under the definition of Essential for Health, Safety, or the Functioning of Society, and would thus be categorized as a Currently Unavoidable Use, will be a separate rulemaking process, subject to legislative review, that will commence in 2023 at the earliest. This is an untenable timeline given the expectation that all responsible entities will be expected to begin reporting sometime in 2023. DEP should provide greater clarity on what falls under the second Concept Draft's current definition of Essential for Health, Safety or the Functioning of Society, or establish a waiver process for products that DEP currently expects to fall under such parameters.

3) **<u>Reporting Levels & Group Reporting</u>**

SPAN reiterates its previous recommendation of establishing a *de minimis* level for PFAS content in a product, beneath which no reporting would be required. This level should be no less than 0.1% by product weight. This would align with actions taken in the European Union for substances of very high concern when present in articles. After this reporting threshold is established, SPAN recommends DEP permit entities to be able to report on product categories and to report within such categories based on ranges of PFAS present within such products. Currently, the Concept Draft would appear to limit notification of products as a group to circumstances where the products contain the same amount of PFAS or are within the same concentration range. This is an oversimplified approach that does not recognize the complexity of various product markets. Different manufacturing batches of the commercially identical product by a single manufacturer might have considerable variation in the amount of PFAS used, particularly when PFAS is only present in negligible amounts. Wherever possible, it would be preferable to report the quantity of PFAS in ranges, rather than exact amounts that could change, particularly if measured using arbitrary or differing testing method. Ranges used in the High Priority Chemicals Data System (HPCDS) developed by Interstate Chemicals Clearinghouse

for Oregon and Washington provide useful points in determining appropriate ranges for given products.

SPAN is concerned about the confusion that exists over exactly which companies are required to report applications of PFAS as defined by the law to DEP. SPAN's interpretation of the law is that the responsible party is the company which markets the product and whose name appears on the product label. In circumstances where a marketing company is not located within the United States, the importer is the responsible party. 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. However, based on the current wording of the Notifications section of the Concept Draft, there are questions as to whether there are reporting obligations for the rest of the supply chain. The Draft does not appear to account for the complexity of 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. Deconvoluting 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.

For example, it is conceivable that a company might sell a component into Maine to a company that assembles the end-use product in Maine, who then sells the fully assembled product to consumers and other users in the state. In this instance, there is confusion as to whether the supplier of the component would be subject to reporting requirements. In other scenarios in which a component is sold to a company that assembles the final product outside the state of Maine, but then the end-use product is sold within the state, there are questions as to exactly who is responsible. As such, SPAN recommends DEP draft a definition for the term "responsible party", which describes the reporting hierarchy so that companies can make appropriate determinations and utilize clear terminology within the Notification section of the Concept Draft so there is clarity amongst stakeholders compelled to report. In addition, suppliers should also not be required to reveal commercial trade secret information to their downstream customers and the final rule should simplify electronic reporting in a manner that enables "joint submissions".

SPAN also recommends against requiring that estimated sales volume in the state or nationally for the full calendar year following the year in which the product is being reported be included in the notification requirement. This requirement was not included in the legislation establishing the requirement and was not included in the first Concept Draft. This requirement adds an extra burden for little value in return, as it is difficult to forecast the estimated sales volume in a country or state given the lack of control manufacturers may have over this process. For products sold directly to distributors and not directly to retailers or individuals, it will be virtually impossible for the original product manufacturer to report on sales into Maine. 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.

4) **<u>Waiver of Notification Process and Clarify Specific Provisions</u>**

SPAN applauds the inclusion of a Waiver of Notification provision in the second Concept Draft. However, a great deal of clarity is needed prior to the January 1, 2023 deadline for reporting as to what qualifies as substantially equivalent information and the parameters for establishing that a product meets these standards. For example, DEP needs to established what the timeline

will be for the waiver process, what will comprise the substance of the waiver application, waiting period for response, and who will administer the waiver. Given these complexities, SPAN recommends that DEP provide an extension to those seeking a waiver of notification while these details are clarified and applications are reviewed. SPAN also recommends that a waiver applications be considered by category, rather than by individual component. It is not a reasonable expectation for both manufacturers to apply by individual component, or for DEP to be able to review such applications in a timely manner.

Given the scope of products and entities responsible for reporting, there is bound to be overlap between what different businesses report and confusion over who is responsible. Further clarification is required from DEP as to who is responsible for which products along the supply chain, such as clarifying which entity is required to report when the entity that distributes a component or a finished product in Maine acts solely as a "distributor" (and is not the entity that manufactured the component or product, nor the company with its "brand name" on the component or product). Subsection 3 of the law provides DEP the authority to waive all or part of the notification requirement under Subsection 2 if DEP determines that substantially equivalent information is already publicly available. DEP also must identify which federal laws it interprets to preempt the state reporting requirements such that manufacturers of such products would be exempt from reporting. Many compounds classified as PFAS by the Concept Draft's definition have already been approved for their end-use applications by provisions of the Clean Air Act (CAA) and Toxic Substances Control Act (TSCA), and requiring their reporting would be burdensome and unnecessary.

It is also important for DEP to work with stakeholders when the requirements of LD 1503 conflict with other recent legislation in Maine that encourages the use of substances that are captured under the statutory definition to meet various state goals, such as combatting climate change. SPAN recommends that DEP conduct stakeholder outreach to discuss these occurrences; otherwise, the regulated community will be unsure of how to proceed forward within Maine. For example, Maine enacted a law in 2021 (LD 226) phasing down the use of HFCs. HFOs are the preeminent alternatives that would be used to help achieve the state's climate change mitigation goals. EPA has encouraged and effectively driven a transition to these and other low global warming potential (GWP) gases through ozone depletion and climate focused phase-outs of CFC's, HCFC's, and HFC compounds. These chemicals have been approved under EPA's Significant New Alternatives Policy (SNAP) program, which include environmental and human health impact reviews. Without DEP providing appropriate clarifications around the concepts of "currently unavoidable" and essential for "Health, Safety or the Functioning of Society" as exceptions, this overly broad PFAS definition will have innumerable unintended consequences, including the possible prohibition of key low global warming climate friendly technologies like HFOs.

SPAN notes that the DEP has added Global Product Classification brick category and code ("GPC") to the set of minimum notification requirements. SPAN would recommend that DEP establish categories outside of the GPC by including 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). In addition, SPAN would recommend DEP consider hosting live platform demonstrations of the reporting site for industry stakeholders much like EPA did with the TSCA CDX reporting launch before going live to ensure

compliance. Given there is no small business reporting exemption, this will be helpful for small business owners who may not have the necessary funds to hire additional support to ensure compliance.

SPAN is also concerned about what will qualify as a "significant change" that will require notification. We reiterate our previous suggestion that a "significant change" be defined as the change of the PFAS content of a product by more than 50% by weight of overall PFAS content, rather than the 10% increase of the current concentration when compared to the existing notification defined in the draft. SPAN is also concerned the Draft suggests the omission of a PFAS would be a trigger for "significant change" reporting. Such changes are not relevant to the reasons for the reporting requirements and should be dropped from the reporting rules when proposed.

5) **Confidential Business Information**

Greater clarity is needed on what is meant by the draft's claim that Confidential Business Information (CBI) will be managed under the Uniform Trade Secrets Act 10 M.R.S. §1542(4)(A)&(B). This section provides a definition of Trade Secret but does nothing to address how CBI claims will be handled in the online reporting platform yet to be established by DEP. Companies have taken all the necessary steps, federally and state, to protect trade secrets. Trade secrets that are inadvertently disclosed may compromise national security and infrastructure. SPAN has concerns with DEP's potential use of the Interstate Chemicals Clearinghouse (ICC) Platform, which is a third-party, non-governmental organization, for which there is no public accountability. It is entirely unclear to SPAN what steps, technologies, processes, or tools the ICC Platform uses to protect CBI. Moreover, if the CBI is accessed inappropriately, what penalties or remedies are available to the state and impacted companies. Unclear CBI rules will inevitably present hurdles to timely acquisition of information about PFAS composition when a manufacturer is working with suppliers in a highly competitive field with technologically sophisticated products. It is critical that DEP establish internal procedures and data security capabilities to reliably ensure that any such CBI not be disclosed. When necessary for reporting of confidential information that might not be transparent between a supplier and the final product manufacturer, DEP will need to establish a process for making joint submissions when this would satisfactorily accomplish DEP's reporting goal. Similarly, DEP will need to make clear what pieces of information are subject to CBI procedures and how such claims may be asserted. SPAN would recommend that DEP acknowledge that companies will be allowed to assert claims of CBI for any PFAS for which a claim has already been approved by EPA for inclusion on the TSCA Confidential Inventory or for which a claim of protection exists under the Uniform Trade Secrets Act.

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). SPAN would request additional clarification on the timing of when this payment system will become available. Fees should not be applied to individual products, as it will provide no additional health or environmental benefits for Maine residents, but it will create onerous burdens and significant costs for manufacturers. SPAN recommends applying a small fee to product classes. The DEP should revise the Draft to allow for electronic payment and issue an electronic receipt from the electronic payment gateway to acknowledge receipt of payment.

Given the numerous concerns SPAN has with the second Concept Draft of the Maine PFAS in Products reporting requirement, we expect to engage in further dialogue with Maine DEP to further clarify rules and establish procedures that benefits Maine residents and businesses. If implemented as is, the rules in the second Concept Draft would impose unnecessary and burdensome requirements that will do little to further protect human health and environment.

Thank you for your consideration. Please do not hesitate to reach out if you have any questions or need any further information.

Sincerely,

Kevin Fay
Executive Director
Sustainable PFAS Action Network (SPAN)