SUSTAINABLE PFAS ACTION NETWORK

May 19, 2023

Mark Margerum
Maine Department of Environmental Protection
17 State House Station
Augusta, Maine 04333

Re: Proposed Chapter 90 PFAS-Containing Products Regulations

Dear Mr. Margerum:

The Sustainable PFAS Action Network (SPAN) is writing to provide these comments concerning the Department's February 2023 posted edition of its proposed Chapter 90 regulations implementing 38 MRS §1614.[1]

SPAN is a coalition of PFAS users and producers committed to sustainable, risk-based PFAS management. Our members advocate for responsible policies that provide assurance of long-term environmental protection while recognizing the important contribution that certain PFAS have made to economic growth and competitiveness in global markets. PFAS 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 to encourage responsible, risk-based PFAS regulations that are implemented to protect the environment and human health while maintaining America's economic edge. Our comments follow:

Timing of Final Regulations

SPAN encourages DEP to prepare final rules for publication only after the US Environmental Protection Agency has issued its final rules requiring PFAS-reporting pursuant to Section 8(a)(7) of TSCA. Doing so will provide insight to DEP as to what information will be required to be submitted by US manufacturers and importers of PFAS and PFAS-containing products. This will provide an opportunity for the Department to identify ways to take advantage of the federal reporting of PFAS containing products and potentially reduce redundant reporting burdens. This would reduce resource demands on the regulated community and administrative burdens on DEP, and will allow the PFAS in Products program to be harmonized with EPA and reflect efforts to integrate federal PFAS requirements and approaches.

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[1] Because the differences are few between the 2022 "Second Concept Draft" and the February 2023 Posted Proposal, SPAN's comments should be considered in conjunction with comments we submitted on the 2022 Concept Draft in November 2022.

SPAN reiterates our prior recommendation that DEP consider phased in reporting requirements and deadlines, with reporting to be required at later intervals for more complex (e.g., multi- component) products in specific categories.

SPAN also recommends the Department establish the deadline for submitting the initial notifications to DEP not less than one-year following the effective date of the reporting rules.

Information to be Reported and Reporting Methods

SPAN Members recommend DEP's final regulations be limited in nature to capture only those items of information specifically required under the statute that also will contribute to the Department's understanding of the nature and quantities of PFAS in products distributed in the state. The objective of such an elaborate information-gathering exercise should be purposeful and focused on information concerning potential risk to human health and the environment. Requests for product codes and SKU numbers and other commercial information should be made only when having such information will either simplify reporting and data analysis efforts while improving the department's understanding of the presence of PFAS in state commerce and potentially the environment within the state.

DEP should make available well in advance of the final reporting requirements information concerning the mechanism by which reports should be prepared and submitted to DEP. If an on-line, electronic reporting system is envisioned, the program needs to be operational and available for use by regulated entities prior to the final rule takes effect.

Sufficient lead time will 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. An untested platform will inevitably experience technical challenges and failures and will require advance time to train staff on proper reporting procedures, as well educating those who must file reports.

Wherever possible, 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. For example, where other regulatory authorities in the US are implementing similar reporting requirements (e.g., for mercury-containing products), there may be efficiencies that can be gained by relying on such reporting technologies whenever possible.

SPAN recommends that trial versions of the reporting programs should be made available for "beta-testing" exercises involving a sampling of the regulated community. Feedback should be gathered during the testing phase and be used to make changes and improve the users' interface experience prior well in advance of the final reporting regulation taking effect. In addition, SPAN recommends DEP consider hosting live platform demonstrations of the reporting site for industry stakeholders much like the US EPA has done for certain reporting technologies.

Scope of Rules, Definitions, and the Need for Reasonable Exemptions

PFAS Definition. SPAN Members are aware that the Department interprets the legislation to require DEP to codify final rules that do not depart from the definition of PFAS in the underlying law. However, requiring reporting on every substance "containing at least one fully fluorinated carbon atom" will impose unnecessary reporting burdens and capture data on substances of both greater and lesser concern, and overwhelm the regulated community and state officials simultaneously. In addition, the approach being undertaken in Maine is presently in conflict with the National PFAS testing strategy, which uses a different structural definition of PFAS. This will burden reporting entities, provide information that will be administratively burdensome to the state, and will not be focused on substances of the greatest concern. For example, the scope of a reporting requirement based on such a far-reaching definition of PFAS will capture active ingredients in pharmaceuticals and hydrofluoroolefin (HFO) technologies necessary for complying with the state's greenhouse gas reduction program. Under Section 612 of the Clean Air Act (CAA) (which establishes EPA's Significant New Alternatives Policy (SNAP) program, which reviews substitutes for the best available chemistries/gases within a comparative risk framework), these gases have been deemed to be safe for their intended use, energy efficient, and non-persistent, and have low-global warming potential (GWP). EPA recently finalized Rule 25[2] – for the Refrigeration & Air Conditioning and Fire Suppression Sectors. In the published rule EPA clearly states, "Regardless of what definition of PFAS is used, not all PFAS are the same in terms of toxicity or any other risk. Some PFAS have been shown to have extremely low toxicity, for example. If a chemical has been found to present lower overall risk to human health or the environment, it might be found acceptable under SNAP regardless of whether or not it falls under a particular definition of PFAS." These chemistries have clear and tangible societal benefits and could readily be exempted through regulatory efforts on which DEP should be focusing, but which are not reflected in the terms of the current proposal.

Exemptions Under Section 4. DEP should identify in the final rule, and explicitly list such products, those that would "preempt" the state's reporting requirements. Many compounds considered to be PFAS under the Maine statute may have uses in products that are authorized pursuant to federal laws, regulations or government specifications (such as MILSPEC). When such an approval contemplates the end-use applications of the PFAS, it should be exempt from the notification and restrictions requirements in Maine. Examples include substances approved for uses in the Significant New Alternatives Policy (SNAP) program under provisions of the Clean Air Act (CAA). These also include PFAS authorized for uses that are regulated pursuant to Section 5 Orders under the Toxic Substances Control Act (TSCA) and in drugs or devices that are authorized pursuant to the Federal Food Drug and Cosmetics Act (FFDCA) and via pesticide registrations issued by EPA pursuant to FIFRA.

Currently Unavoidable Uses. SPAN recommends that DEP commence using its rulemaking authority under sections 5 and 10 of the underlying law now to affirmatively identify uses of PFAS which are "currently unavoidable" and explicitly exempt them from both the Section 2 notification requirements and the Section 5 product prohibition measures before finalizing the Chapter 90 notification rules. Furthermore, the final rule should articulate a procedure whereby a manufacturer may request an affirmative determination that a specific PFAS/Use combination is a currently unavoidable use. As with other requests submitted to DEP in accordance with the Chapter 90 rules, the products for which a

[2] https://www.epa.gov/system/files/documents/2023-04/SAN%206399_Final%20SNAP%20Rule%2025_signed%20pre-publication.pdf2025_signed%20pre-publication.pdf

manufacturer seeks a currently unavoidable use determination should be considered to be exempt from the notification and prohibitions requirements pending DEP's consideration of the request.

Environmental policy considerations should be a factor when determining unavoidable uses. For example, as part of Maine's program for phasing down the use of HFCs, HFOs emerged as the preeminent alternatives that would help achieve Maine'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, HCFC, and HFC compounds. Chemicals that have been approved under EPA's SNAP program, which include environmental and human health impact reviews, should be identified by DEP as currently unavoidable uses. DEP should take the lead in providing clarifications and provide initial listings of "currently unavoidable" uses that are essential for "Health, Safety or the Functioning of Society."

As another mechanism for streamlining the information gathering burdens, and clarifying the rules, DEP could create a concrete list of specific PFAS that need to be reported. Given that 38 MRS §1614 requires notification by CAS number, DEP should list the CAS numbers of all PFAS that are subject to this law. This will provide greater clarity and transparency and ease with compliance. Conversely, DEP could issue notice that a category of substances (such as fluoropolymers) for which reporting is not required.

Essential for Health, Safety, or the Functioning of Society. In accordance with beginning the process to determine currently unavoidable uses, DEP should adopt an expanded definition of Essential for Health, Safety, or the Functioning of Society that acknowledges the true scope of critical PFAS usage. The definition included in the draft rules is far too narrow, and doesn't adequately take into account prioritization by risk to human health and the environment. SPAN recommends this definition be expanded, and essential use exemptions be considered for industries such as semiconductors and critical technology, air conditioning and heating, and aerospace. These considerations are critical to the modern 21st century economy and continual functioning of society.

Fluoropolymers should be exempted. SPAN wishes to reiterate our prior comments: Fluoropolymers are substances that have unique properties which are distinct from other PFAS, and meet an internationally recognized criteria for polymers of low concern which are not expected to have significant environmental and health impacts. DEP has the authority to eliminate requirements to capture information on their presence by exercising its rulemaking and exemption authorities under the law. Doing so will reduce burdens and demonstrate DEP's awareness of its own resource limitations and its willingness to focus on the substances most likely to be of greater concern.

Product Definition. DEP should also exercise its administrative discretion to narrow the products for which reporting is required to only those to which consumers are exposed. SPAN believes this would be consistent with the intent of the legislature. This can be easily accomplished by excluding the terms "commercial, or industrial use, including for use in making other products" from the current expansive definition of "Product" in proposed Chapter 90. The legislature gave the Department the authority to issue rules pursuant to Section 10 of the underlying law; it did not instruct DEP that it could not exercise administrative discretion to focus its efforts and limited resources on the underlying purpose of the law – reducing human exposures and environmental release in the context of consumer product use and disposal in the state.

Additional Areas for Improvements and Clarification

Additional clarifications and simplifications can be added to the current Chapter 90 as proposed. For example, DEP would reduce ambiguity by revising its notes in the proposed Chapter 90 concerning CAS numbers. At present, DEP notes that substances for which an entity does not know a CAS number due to CBI issues (i.e., the supplier will not reveal the chemical identity) must still be reported. DEP should instead state that when the CAS number is not known due to such reasons, the notification submitter can note this, and provide a "generic" description and stating the supplier has withheld the substance's specific identity.[3]

De minimis levels. 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.

Reporting and Grouping Categories of Similar Product and the Use of Ranges. SPAN recognizes and appreciates DEP's efforts to improve the proposal to explicitly accommodate reporting by product categories and to report within such categories based on ranges of PFAS present within such products. SPAN also appreciates DEP's expansion of the proposal's terms to provide that the Department will review proposals to report by category and to consider an entity seeking DEP's consent in compliance until a response to such a request is given. However, SPAN recommends such grouping efforts not be limited, as it appears the proposal would do, to products or product components under a single GPC code or HTS Number. Instead, applicants requesting permission to group its products should be permitted to use product categories or current use designations which are commonly employed within its sector, rather than being limited to the use of GPC and HTS codes it might not currently employ. SPAN recommends that DEP recognize that categories outside of the GPC and HTS categories may exist and provide manufacturers whose products are not covered by this system to identify the alternative means they use for product classification.

Currently, the proposal would appear to limit notification of products as a group to circumstances where the products contain the same amount of PFAS or are "substantially similar." This approach should be clarified in the final rule to expressly state that the Department will consider a request for grouping that manufacturers may have considerable variations in PFAS concentrations present among batches of commercially identical products, particularly when PFAS is present in negligible amounts.

Although the rule allows for reporting quantity of PFAS present in a product using a Department-approved range, no such ranges have been provided, nor has any indication been given as to the process the Department will use for establishing ranges or whether they will be substance-specific or general. This information is needed well in advance of reporting so that reporting entities can get information from suppliers.

Clarity is still Needed on Reporting Responsibilities. Confusion still exists regarding which companies are required to report on complex and multicomponent products. SPAN interprets the proposed rule to

[3] DEP should address this by permitting a PFAS-supplier or PFAS-containing component supplier and their downstream customers to provide separate but linked "joint submissions" to enable the respective parties to supply the information directly to DEP which they wish to keep confidential among themselves.

mean the responsible party for reporting is the company which markets the finished 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. However, the current wording of the Notifications section of the proposal continues to raise questions for entities throughout the supply chain for multi-component products. The proposed regulations do not make clear whether the responsibility falls upon the maker of the PFAS-containing components, the brand owner, a brand licensee, an importer, or the company that is distributing the finished product.

SPAN requests the final rule (or an accompanying guidance document) clarify (through the use of examples) how the Department interprets the reporting requirements to apply to multiple businesses in the supply chain for finished products with multiple PFAS- containing components.

DEP should consider adding a definition for the term "responsible party," which describes the reporting hierarchy so that companies can make appropriate determinations themselves. Furthermore, the final rule should enable entities within such supply chains to reach agreements among themselves concerning who will report to DEP.

Waiver of Notification Process Needs Further Clarity. SPAN appreciates the efforts made in the proposal to clarify the Waiver of Notification provision which provides a vehicle for an entity to seek a waiver from the notification requirements when substantially equivalent information is publicly available. We recommend that the provision be further amended to include a passage, such as in the "grouping" provision, whereby an entity that requests a waiver of the notification provision would be considered in compliance while the Department reviews and responds to the request.

Clarity is needed prior to reporting concerning what qualifies as substantially equivalent information when waivers are being considered and the parameters DEP will apply when applying these standards. For example, DEP needs to establish the timeline for the waiver process, the substance of the waiver application, the waiting period for response, and how the waiver process will be administered. SPAN recommends that a waiver application be considered by category, rather than by individual components. It is not a reasonable expectation that manufacturers apply for waivers on a product and component-specific basis, nor for DEP to be able to review each such application in a timely manner.

Confidential Business Information

Greater clarity is still needed on the proposal's "note" within Section 3 (Notifications), which states that claims of confidential business information may be asserted at the time of reporting and that such information will be handled in a confidential manner if it were information the courts would find to be "privileged." This is substantially inadequate for purposes of trade secrets and other commercially sensitive information that might require reporting. The Department must have a procedure in place for maintaining the security and confidentiality of the information it collects before the reporting period commences.

SPAN continues to be concerned about DEP's potential use of the Interstate Chemicals Clearinghouse (ICC) Platform, which is a third-party, non-governmental organization, and for which there is no public accountability. It is entirely unclear 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 concerns for manufacturers that must survive in highly competitive fields with technologically sophisticated products

and competitors. Prior to issuing a final rule, it is critical that DEP establish internal procedures and data security capabilities to reliably ensure that any such CBI will not be disclosed. As discussed above, a system should be put in place for reporting of confidential information that might not be transparent between a supplier and the final product manufacturer. This will require establishing a process for making joint submissions (where component suppliers and product manufacturers can report separately and confidentially).

Fees

We appreciate the changes clarifying the Fees provision. However, additional clarification is needed on the timing and mechanism of payment and when the systems for paying fees will become available. DEP should provide for the electronic payment of fees and provide electronic receipts to acknowledge payments and synchronize these with the notifications received.

Clarification Requested for Used Products as Well as Replacement Products Used for Repairs

The rule states that notifications are not required for "used" products. This concept should be expanded to also include existing stocks of discontinued products as well as existing stocks of older products that have not or are no longer being sold in Maine, but which are retained solely for use as replacement parts for products or equipment located in Maine. These items are not newly manufactured for sale in Maine, but might be in the state to fulfil customer requirements that a manufacturer fix or replay a product.

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SPAN is hopeful that additional improvements will be made to the Proposed Chapter 90 regulations on the basis of SPAN's comments above and in advance of the rules being issued in final form. Our members remain available to engage in further dialogue with Maine DEP to offer suggestions to improve and clarify the proposed rules. SPAN would support a study commission chaired by the DEP Commissioner with representatives from the legislature, as well as the business and environmental communities, as has been previously proposed. If the proposal is implemented without the changes discussed in this letter, the final regulations will impose unnecessary and burdensome requirements on businesses and the Department personnel that will do little to expand on current protections of 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)