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Submitted via email to rulecomments.dep@maine.gov

Melanie Loyzim
Commissioner, Maine Department of Environmental Protection (DEP)
17 State House Station
Augusta, ME 04333

Re: Comments on Proposed Chapter 90 Rule for Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS)

Dear Commissioner Loyzim:

The PFAS Pharmaceutical Working Group[1] (PPWG) is a group of manufacturers and distributors of drugs, biologics, animal drugs, and medical devices. PPWG appreciates the opportunity to provide comments on DEP's proposed Chapter 90 rule concerning PFAS in products (the Rule), implementing 38 M.R.S. § 1614. In April 2024, the Maine legislature – with the input of DEP and other stakeholders – passed L.D. 1537 which amended 38 M.R.S. § 1614 to make the law more workable for DEP to implement and for the regulated community to comply with. PPWG urges DEP to take a similar pragmatic approach with the Rule to avoid a situation where DEP struggles to execute a regulatory program in excess of what the legislature intended. A pragmatic approach to this rulemaking will also help ensure that the regulated community is able to comply, thereby facilitating a transition away from PFAS in products to a feasible extent and on a timeline that is appropriate.

L.D. 1537 added several exemptions to all of 38 M.R.S. § 1614's provisions, including for drugs and devices, veterinary products, nonconsumer laboratory equipment, and for equipment directly used in the manufacture or development of exempted products. Notwithstanding these exemptions, PPWG still has serious concerns with how the law's material restrictions, as implemented in the Rule, may impact products in medical, pharmaceutical, and animal health product supply chains to the extent these products are not covered by an exemption.

For example, if the statute's restrictions apply to certain products used by upstream suppliers (e.g., if these upstream products are not directly used in the manufacture or development of a drug or device) or to non-exempted products used in the industry (such as in research and development (R&D) or distribution of a drug or device), that may negatively affect the production and availability of the industry's exempted products or the ability to continue manufacturing these products within the specifications or marketing authorizations granted by the U.S. Food and Drug Administration (FDA). This situation would contribute to uncertainty over whether certain critical medical,

[1] PPWG's member companies, which include their subsidiaries and affiliates, are Amgen Inc.; Bristol Myers Squibb Company; GSK; Merck & Co., Inc.; Pfizer, Inc.; and Roche.

pharmaceutical, and animal health products can remain on the market in Maine, contravening the legislature's intent to ensure Mainers' continued access to these lifesaving and life-enhancing products.

38 M.R.S. § 1614 restricts intentionally added PFAS in products starting in 2032 (and on other dates for some specific products) except for currently unavoidable uses (CUU) of PFAS. "Currently unavoidable use" is defined in the statute as "a use of PFAS that the department has determined by rule under this section to be essential for health, safety or the functioning of society and for which alternatives are not reasonably available." Manufacturers of products covered by CUU determinations must also submit a notification to DEP, or else those products are subject to the 2032 restriction. In line with PPWG's concerns described above, narrow application of the statute's CUU standard paired with other provisions in the Rule that are unworkable could risk impacts on the availability of products that the Maine legislature has specified are exempt from the law's provisions.

PPWG requests that DEP avoid this result in the Rule. Specifically, DEP should:

- Implement criteria that account for how a restriction on a particular PFAS in a product may impact other products and processes up and down supply chains. Specifically, the criteria for assessing what is "essential for health, safety, or the functioning of society" should consider societal impacts that may be broader than direct use of the end product itself. In addition, direct and indirect supply chain costs and risks should be considered in determining whether alternatives are "reasonably available."

- Provide a longer runway to submit CUU determination proposals, timely respond to such proposals, and include a presumption in favor of CUU determination renewals. These provisions will help ensure that the CUU determination process is fair and efficient. For instance, DEP should be required to review and act on proposals submitted as soon as the Rule is finalized, rather than having companies wait until 36 months before the applicable sales prohibition to submit proposals. This longer runway is crucial given the years-long processes involved with adjusting product lines in the industry and to prevent a bottleneck scenario where DEP must review all submitted proposals shortly before the relevant sales prohibition takes effect.

- Where appropriate, make CUU determinations for broad categories of products rather than on a product-by-product basis. For many types of products, making CUU determinations for individual products would almost certainly omit some products that are critical to health, safety, or the functioning of society. Applying CUU determinations to groups of products or categories of products intended for specified uses would be more efficient, would promote consistent treatment across related products, and would accomplish statutory objectives.

- Prioritize review of CUU determination proposals for products used in medical, pharmaceutical, and animal health product supply chains. Given that DEP should expect a very large number of proposals for CUU determinations to be submitted, this prioritization will aid in making sure proposals relevant to the industry (and therefore to products exempted from the statute) do not get lost in the queue.

- Limit the Rule's scope to a finite list of PFAS with CAS Numbers. Without a specified list of chemical names with CAS Numbers, tracking a class of tens of thousands of chemicals through complex supply chains, such as those that exist in this industry, is virtually impossible.

- Include a de minimis threshold in the Rule for PFAS below 0.1% by weight in the product. A 0.1% by weight threshold provides a rational, reasonable level consistent with de minimis chemical levels applied by other regulators, and would help mitigate the due diligence burden on supply chains.

- Incorporate robust protections in the Rule for confidential business information (CBI). DEP's note in the proposed Rule that CUU determinations should not contain CBI claims could have a chilling effect of deterring companies from submitting CUU determination proposals. DEP should therefore implement a process to permit such CBI claims in CUU determination proposals. Relatedly, DEP should be required to include in the reporting portal a mechanism for claiming CBI in notifications.

I. The CUU Determination Process Should Reflect the Impacts a PFAS Restriction May Have Up and Down Supply Chains.

PPWG recommends that DEP include the following provision in section 9 of the Rule:

> *In any subsequent Department CUU rulemaking, the Department shall grant a CUU determination for PFAS applications or end products, and for the supply chain, research, development, and production activities required to produce such PFAS applications or end products, when the Department has evidence, or when a manufacturer, organization, or other entity has submitted evidence, that an application, product, or category of products provides benefits related to health, safety, or the functioning of society and that there are no reasonably available alternatives for that use.*
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> *A product shall be deemed to provide benefits to health, safety, or the functioning of society where the Department has evidence, or the manufacturer, organization, or other entity has submitted evidence, that the product supports:*
>
> *(a) For health – physical or emotional health or wellness;*
> *(b) For safety – the safety or security of the public from danger, injury, or property damage;*
> *(c) For the functioning of society – identified consumer, commercial, or industrial demands for the product; or*
> *(d) The manufacture, distribution, or research and development of any product subject to an exemption in 38 M.R.S. § 1614(12)(D-M).*

This provision would accomplish a number of important objectives. First, section 9 of the Rule as proposed currently does not impose any requirements on DEP for reviewing CUU determination proposals (aside from stating that such an evaluation will occur in a subsequent rulemaking), and this provision would add critical language to provide companies with an understanding of how proposals will be evaluated. Second, this provision helps avoid arbitrary and subjective determinations by stating that DEP "shall" grant the requested determination if the manufacturer

has submitted qualifying evidence meeting the statutory criteria. Relatedly, this provision clarifies that DEP should grant a CUU determination *sua sponte* when the agency has sufficient evidence to do so, since 38 M.R.S. § 1614 does not require that CUU determinations be made only upon manufacturer request. Third, this provision specifies that the determination should apply not only to the end product itself, but to products and processes in the supply chain that are necessary to produce that product; without this, a CUU determination could be substantially undermined, or even rendered meaningless, given that it is not possible to produce end products without upstream activities.

Fourth, this provision appropriately explains what information demonstrates that a PFAS use is essential for health, safety, or the functioning of society. Health, safety, and societal benefits should be described expansively to capture the naturally broad scope of these terms. Moreover, the fact that a PFAS use supports the manufacture, distribution, or R&D of a product subject to an exemption in 38 M.R.S. § 1614(12)(D-M) is sufficient to demonstrate that the PFAS use is essential for health, safety, or the functioning of society, since the Maine legislature exempted these products presumably due to their critical roles in society that could be unduly impacted by the law's PFAS restriction.

PPWG also recommends the following definition of "reasonably available alternative":

> *"Reasonably available alternative" means a substance, material, technology, process, or otherwise that is currently available at commercial scale and that, when used in place of intentionally added PFAS, does not result in:*
>
> *(a) A decrease in availability, performance, life expectancy, quality, or durability of the product or of any upstream or downstream manufacturing, distribution, or research and development activities associated with that product;*
>
> *(b) A significant increase in manufacturing, design, testing, capital investment, or other costs for the product or for any upstream or downstream manufacturing, distribution, or research and development activities associated with that product; or*
>
> *(c) Risks to human health or the environment that would not be present, or present in lesser degrees, with use of the intentionally added PFAS, including but not limited to risks from toxicity, energy consumption, product safety, product unavailability, and disposal.*

The Rule as currently proposed would define this term as "a PFAS alternative which is readily available in sufficient quantity and at a comparable cost to the PFAS, to include changes to the manufacturing process, it is intended to replace and performs as well or better than PFAS in a specific application of PFAS in a product or product component." This proposed definition lacks the needed clarity that PPWG's recommended definition provides. Like with PPWG's requested provision on essentiality, this recommended definition recognizes that the evaluation of any potential alternative must involve an assessment of how the alternative may affect other parts of the supply chain, particularly to avoid unintended impacts on other products such as those covered by an exemption in 38 M.R.S. § 1614(12).

Likewise, PPWG's recommended definition accounts for how the evaluation of an alternative must consider the real, commercial availability of the alternative. The evaluation must consider not just the direct cost of switching to an alternative in a product, but also the costs of the whole process for designing and implementing the alternative – including the costs that may be borne by other companies in the product's supply chain. Lastly, the risks associated with an alternative can have substantial impacts on the alternative's availability. PPWG's recommended definition reflects how these risks could stem not only from the toxicological profile of the alternative itself, but also from risks across the product's lifecycle. These risks could include, but are not limited to, sustainability considerations (energy consumption, climate impacts, etc.), manufacturing product safety, end product safety and efficacy (e.g., flammability, shelf life, stability), end product unavailability (e.g., health risks of skipping doses or delaying treatment because of unavailability), and disposal.

II. Ensure the CUU Determination Process is Efficient and Fair Through Submission and Review Timelines, and Through Renewals.

DEP should remove the language in section 9(A) of the proposed Rule providing that DEP will not consider any CUU determination proposals submitted prior to 36 months in advance of the applicable sales prohibition. Instead, DEP should review and act on proposals that are submitted starting on the date the Rule is finalized.

It can take several years for companies in the medical, pharmaceutical, and animal health product industry to effectuate product reformulations and redesigns in part because these modifications often require thorough regulatory approvals by the FDA and other bodies and because any such changes need to be extensively vetted for their impact on the health of patients and others that use this industry's products. Moreover, the capital expenditure and other financial planning needed to upgrade equipment, modify production lines, and make other investments in preparation for a change in the composition of a product can take many years to implement. These modification processes cannot go from start to finish within the 36-month period that DEP has proposed, especially given that DEP's decision on a CUU determination proposal would be made even closer than 36 months from the date of the relevant sales prohibition. In other words, it is foreseeable that PFAS applications in the medical, pharmaceutical, and animal health product industry in use as of the date the Rule is finalized may still be unavoidable in 2032, and therefore these PFAS uses constitute *current* unavoidable uses both when the Rule is finalized and in 2032.

While many of this industry's products are covered by exemptions in 38 M.R.S. § 1614(4), as mentioned above, there could be scenarios where the production or availability of these exempted products may be negatively impacted by the law's restrictions. The timeline for when DEP begins accepting and evaluating CUU determination proposals should therefore account for the fact that a decision on a proposal has the potential to impact a large swath of products up and down supply chains that can require several years – and not just 36 months – to effectuate changes to and which are imposed by a new material restriction. Further, DEP should expect a very large number of CUU determination proposals to be submitted. If all companies must submit proposals within the same 36-month period before the applicable sales prohibition, there is a very real possibility of a bottleneck scenario where DEP would be overloaded with proposal reviews and would not be able to come to decisions on all submitted proposals by the applicable compliance date. DEP should prevent this from happening in the Rule.

In addition, PPWG recommends that the following provisions regarding CUU determination proposal review timelines be included in section 9 of the Rule:

> *In the event that the Department fails to, by the applicable sales prohibition, either (1) finalize a rule implementing a timely submitted CUU proposal or (2) decline to issue such a rule, the requested CUU determination shall be automatically approved and remain valid until six months after the Department issues a decision on the proposal.*
>
> *If a proposal for a renewed CUU determination is timely submitted, the Department shall grant that renewal unless the Department determines that there is significant evidence that alternatives to the relevant PFAS use have become reasonably available or that the PFAS use is no longer essential to health, safety or the functioning of society.*
>
> *If a proposal for a renewed CUU determination is denied by the Department, the relevant sales prohibition as applied to the products covered by the previously issued CUU determination shall not go into effect until one year after the expiration of that previously issued CUU determination.*

While the Rule as proposed includes timelines for when companies must submit CUU determination proposals, no such timelines are included for when DEP must act on such proposals. The Rule should require DEP to timely act on CUU determination proposals in advance of the applicable compliance deadline, and if DEP fails to timely respond that should function as an automatically approved CUU determination for at least six months from when DEP issues a decision. This process would be in line with exemption procedures under other chemical regulatory programs, such as under Article 5 of the European Union's Restriction on Hazardous Substances Directive (RoHS) through which an existing exemption to RoHS's restrictions remains valid until the European Commission has decided on a renewal application. PPWG's requested six-month delay for when the sales prohibition would take effect in this situation is necessary to provide a sell-through buffer in the event that DEP denies the proposal after the relevant compliance deadline provided in the statute.

Likewise, DEP should include a presumption in the Rule in favor of CUU determination renewals. Specifically, as mentioned in PPWG's recommended provisions above, DEP should grant renewals unless there is significant evidence that alternatives have become reasonably available or that the use of PFAS is no longer essential for health, safety, or the functioning of society. Moreover, if a proposal for a renewed CUU determination is denied by DEP, there should be a grace period of at least one year for manufacturers to transition to alternatives. These procedures will act as safeguards to ensure that impacted stakeholders from across supply chains are able to properly plan for and then rely on CUU determinations.

III. Where Appropriate, CUU Determinations Should Be Made For Broad Product Categories Rather Than Product-By-Product.

Section 9(A) of the Rule as proposed states that "a separate [CUU] proposal must be submitted for each individual combination of product category and the associated industrial sector." PPWG supports a process where DEP will make CUU determinations for broad categories of products where appropriate, rather than on a product-by-product basis. 38 M.R.S. § 1614 does not require that CUU determinations be made only for individual products, and this process would waste both

public and private resources as manufacturers will likely end up preparing and submitting several proposals for like products, and DEP will need to carefully compare proposals to assess potential duplication. Moreover, product-by-product determinations would almost certainly omit some products that should be covered by a CUU determination but are not because of arbitrary line drawing in the scope of the determination.

DEP should consider making CUU determinations in line with the broad product categories employed by the U.S. Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA) PFAS reporting rule, 40 C.F.R. Part 705. Under that rule, manufacturers are to report PFAS in their products through use of broad consumer and commercial product category codes found in table 5 to 40 C.F.R. § 705.15(c)(4). These codes were taken from EPA's TSCA Chemical Data Reporting program, which were in turn based on Organisation for Economic Co-operation and development harmonized codes.[2]

Relatedly, DEP should remove the requirement in section 9(A)(1)(b) for CUU determination proposals to include the GPC brick category and code (or, if GPC is not applicable then the HTS code). The imposition of a requirement to provide GPC- and HTS-level information does not fit with the type of broad categorical CUU determinations that will need to be granted by DEP. These codes are typically used for specific product classifications that are more suited for detailed trade and inventory purposes rather than broad regulatory determinations such as for CUUs of PFAS. Additionally, it is not practical to expect manufacturers to gather this information to include in proposals, as it requires significant effort and resources to accurately classify products at this granular level. Assessing GPC- and HTS-level information in proposals would also place an undue burden on DEP and potentially lead to some relevant codes being left out of the CUU determination process inadvertently.

IV. Prioritize Review of CUU Determinations for Products Used in Medical, Pharmaceutical, and Animal Health Product Supply Chains.

The Maine legislature recognized the importance of protecting Mainers' access to lifesaving and life-enhancing medical, pharmaceutical, and animal health products through the exemptions for these products in 38 M.R.S. § 11614(12). In addition, states are largely preempted from regulating these products because these items are already heavily regulated by the FDA. Therefore, the exemptions for medical, pharmaceutical, and animal health products in the statute also avoid disputes about the scope of federal preemption as applied to 38 M.R.S. § 1614.

To avoid undermining these exemptions and their critical functions, DEP should prioritize requests for CUU determinations concerning products used in medical, pharmaceutical, and animal health product R&D, manufacturing, distribution, and supply chains. Such prioritization could include, for example, flagging such requests for expedited review outside of a normal, first-come, first-served queue. This prioritization would help protect the integrity of medical, pharmaceutical, and animal health manufacturing, distribution, R&D, and supply chains in the event of a backlog of CUU determination requests.

[2] EPA, Instructions for Reporting PFAS under TSCA Section 8(a)(7), Appendix D (Nov. 2024), https://www.epa.gov/system/files/documents/2024-12/tsca-8a7-reporting-instructions_11-25-24.pdf.

V. Limit the Rule's Scope to a Finite List of PFAS with CAS Numbers.

DEP should limit the scope of the Rule to a finite list of PFAS with CAS Numbers. Without such a list, tracking the vast family of PFAS, which includes tens of thousands of chemicals, through intricate supply chains that exist in the industry becomes nearly impossible.

Limiting the Rule to a finite list of PFAS with CAS Numbers is also consistent with PFAS in products regulatory schemes in other jurisdictions. For example, Environment and Climate Change Canada (ECCC) released PFAS reporting requirements in July 2024 that are limited to 312 specific PFAS, each of which carry a CAS Number or Confidential Accession Number (for when the specific chemical identity is confidential).[3] This list of 312 PFAS was chosen because these specific PFAS are known or anticipated to be in Canadian commerce and have not recently been surveyed, as opposed to a larger universe of PFAS without a nexus to commerce.[4] DEP should follow ECCC's direction in the Rule.

VI. Include a De Minimis Threshold in the Rule.

DEP should specify that the Rule's requirements do not apply to products containing less than 0.1% by weight of PFAS. 38 M.R.S. § 1614 only applies to intentionally added PFAS, and PFAS below PPWG's requested de minimis level is very likely to be unintentionally present. Further, this de minimis level aligns with similar thresholds employed in several other chemical reporting and restriction programs, such as EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), which includes a 0.1% by weight reporting threshold for substances of very high concern.[5] Similarly, EU RoHS limits the presence of certain substances to a 0.1% concentration threshold.[6] EPA has also recently incorporated 0.1% concentration thresholds into chemical restrictions under several TSCA rules, including in the agency's restrictions for phenol, isopropylated phosphate (3:1) (PIP (3:1)) and decabromodiphenyl ether (decaBDE),[7] as well as in risk management rules for methylene chloride, trichloroethylene, and perchloroethylene.[8]

A 0.1% de minimis threshold in the Rule is rational and reasonable, and it would help avoid imposing excessive due diligence burdens on companies to detect trace chemical amounts throughout global supply chains. This de minimis threshold would also alleviate administrative burdens on DEP by reducing the number of notifications for items containing only trace amounts of PFAS. We therefore recommend that DEP include the following provision in the Rule:

> *This Chapter does not apply to the sale, offer for sale, or distribution for sale in the State of Maine of products containing less than 0.1% by weight of any PFAS.*

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[3] Canada Gazette, Part I, Volume 158, Number 30: Supplement, Notice with respect to certain per- and polyfluoroalkyl substances (July 27, 2024).
[4] ECCC, Guidance manual for responding to the: Notice with respect to certain PFAS, at page 5 (July 2024), https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/pfas-s71-guidance-manual.html.
[5] EU REACH, Art. 7(2) (this threshold is calculated by reference to the weight of an article).
[6] EU RoHS, Annex II (this threshold is calculated by reference to the wright of a homogenous material).
[7] 89 Fed. Reg. 91486 (November 19, 2024).
[8] 89 Fed. Reg. 39254 (May 8, 2024); 89 Fed. Reg. 102568 (Dec. 17, 2024); 89 Fed. Reg. 103560 (Dec. 18, 2024).

VII. **Incorporate Robust Protections for CBI into the Rule.**

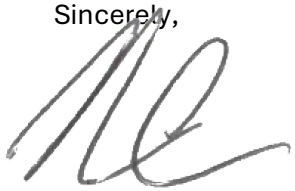
DEP's note on page 20 of the proposed Rule explains that, while 38 M.R.S. § 1614(12) and section 10 of the proposed Rule provide a mechanism for protecting CBI, CUU determinations are subject to the notice-and-comment rulemaking process and therefore DEP "strongly recommends that all proposals for currently unavoidable use determinations do not contain claims of confidentiality." This statement is concerning given that the type of information DEP will require to be included in CUU proposals (such as chemical identities and functions of these chemicals) will undoubtedly contain CBI.

The medical, pharmaceutical, and animal health product industry treats the chemical composition of materials as proprietary information that is carefully protected and of significant commercial value. This proprietary information includes not just PFAS identities, but also the purpose of the PFAS in the product, research being done on potential PFAS alternatives, and related information that may need to be included in CUU proposals. Accordingly, DEP should consider ways in which companies can protect CBI included in CUU proposals, such as by allowing companies to submit unredacted and CBI-redacted versions of requests. DEP could also implement in-camera reviews where DEP assesses unredacted proposals and then summarizes key points and findings for the public while excluding proprietary details. Relatedly, the portal that DEP will use for notifications under the Rule must contain a well-defined CBI framework that permits reporters to claim any and all notification elements as CBI.

VIII. **Conclusion.**

PPWG thanks DEP for considering its comments on the proposed Rule. If you have any questions, please feel free to contact me.

Sincerely,



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