Ryan J Carra
1900 N Street, NW, Suite 100
Washington, DC 20036
+1.202.789.6059
RCarra@bdlaw.com

September 2, 2025

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 Amendments to 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 amendments to the Chapter 90 rule to establish initial designations for currently unavoidable uses (CUUs) of intentionally added PFAS in products. These proposed CUU determinations are not only the first in Maine, but also in the country as other U.S. states begin to implement PFAS in products laws similar to Maine's that contain CUU provisions. Accordingly, DEP must ensure that the precedent it will set with these initial CUU determinations is workable and of practical use to DEP and to the thousands of product manufacturers that are expected to apply for and rely on CUU determinations in the coming years.

With this background in mind and as explained in further detail below in these comments, PPWG makes the following recommendations regarding DEP's CUU determination process:

- Apply the law's exemptions for medical, pharmaceutical, and animal health products fully and consistently. Notably, the exemption at 38 M.R.S. § 1614(4)(E) covers not only drugs and medical devices, but also all other products used in medical settings and medical applications regulated by the U.S. Food and Drug Administration (FDA). DEP must apply this exemption to cover all such products, which ultimately means that these products do not require CUU determinations.

- Provide detailed reasons for rejecting CUU proposals. DEP has provided only minimal information for the nine CUU proposals that the Department rejected in connection with the current rulemaking. More detailed justifications for proposal rejections are necessary to help companies decide whether it is appropriate to submit certain CUU proposals, and provide meaningful information to DEP in those proposals, in the future.

[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.

- Do not limit rationales for approving CUU determinations to safety considerations. Instead, as provided in the statute, DEP must approve CUU determinations that are essential for the *health*, *safety*, or the *functioning of society* and for which alternatives are not reasonably available.

- Draft CUU determinations using expansive language, where appropriate. DEP should avoid restrictive language with economic codes that could arbitrarily limit the scope of these determinations.

I. Apply the Law's Exemptions for Medical, Pharmaceutical, and Animal Health Products Fully, Consistent with the Plain Language of the Statute.

Maine's PFAS in products law at 38 M.R.S. § 1614(4)(E) exempts from all of the law's provisions "A prosthetic or orthotic device or any product that is a medical device, drug or biologic or that is otherwise used in a medical setting or in medical applications that are regulated by or under the jurisdiction of the United States Food and Drug Administration" (emphasis added). This exemption was worded by the Maine Legislature to cover not just drugs and medical devices, but also any other products used in medical settings or medical applications regulated by or under the jurisdiction of the FDA. The scope of the exemption in 38 M.R.S. § 1614(4)(E) presumably reflects a recognition that medical care relies on a wide array of products beyond those formally classified as drugs or medical devices. Like drugs and medical devices, this larger array of medical products is often subject to rigorous FDA oversight, and these products warranted the exemption to avoid depriving patients of life-enhancing and life-saving medical treatments.

A DEP Chapter 90 Staff Memo[2] to the Board of Environmental Protection discusses the eleven CUU proposals DEP received for the current cycle and provides DEP's recommendations for rejection or approval of each proposal. One of these proposals was for a component of a hand lotion container, and the proposal notes that this product has uses in healthcare settings. In rejecting this proposal, DEP mentioned that the product is outside the exemption at 38 M.R.S. § 1614(4)(E) without any explanation as to why this exemption is inapplicable. DEP's note could indicate that the Department is interpreting this statutory exemption unduly narrowly. At the very least, when a product has both medical and non-medical applications, the product as used in medical settings should be considered covered by the statutory exemption and not require a CUU determination. A similar conclusion should be made for the exemption at 38 M.R.S. § 1614(4)(F) which encompasses "any product . . . used in a veterinary setting or in veterinary medical applications" that are regulated by or under the jurisdiction of the specified federal agencies.

II. Provide Detailed Reasons for Rejecting CUU Proposals.

The only explanations DEP has provided for rejecting nine of the eleven CUU proposals for the current cycle is found in DEP's Chapter 90 Staff Memo. Those explanations are brief and limited to stating that DEP has determined there is a lack of evidence that the relevant products meet the statutory definition of a CUU. These explanations are conclusory and unhelpful not just for the

[2] DEP, Chapter 90 Staff Memo (July 17, 2025), https://www.maine.gov/dep/bep/2025/07-17-25/Chapter%2090%20Staff%20Memo.pdf.

applicants of these particular proposals but also for the thousands of manufacturers that will likely apply for CUU determinations in the future.

The statutory definition of a CUU – "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" – inherently requires a fact-specific evaluation. Therefore, when DEP rejects a CUU proposal, the Department should explain using fact-specific details how the proposal failed to meet each element of this definition. It is critical that DEP provide clear, detailed reasons for each rejection. Doing so helps ensure that applicants understand how their proposals were evaluated and where DEP has decided these proposals fell short.

Relatedly, release of these fact-specific reasons can help reduce concerns about compliance with the legal requirements for Maine agency action, including those provided in the Maine Administrative Procedure Act and Freedom of Access Act. 5 M.R.S. § 8058; 1 M.R.S. § 407. As discussed by the Maine Supreme Judicial Court in *Christian Fellowship & Renewal Ctr. v. Town of Limington*, 2001 ME 16, 769 A.2d 839, these types of statutory requirements "signif[y] the recognition of the Maine Legislature of the importance of agency findings." In that case, the Court also noted that state courts often recognize the obligation for an agency to provide sufficient findings "whether the requirement for findings comes from a statute or the common law." This is because adequate findings are a key component of due process and "assure more careful administrative considerations, help parties plan cases for rehearing or judicial review and [ ] keep agencies within their jurisdiction" (internal citation omitted). PPWG is concerned that generic or boilerplate denials of CUU proposals do not meet applicable legal requirements.

Moreover, without transparent explanations for rejections, DEP risks discouraging future participation in the CUU process as manufacturers may be less willing to invest time and resources into CUU proposals if the outcome appears unpredictable or opaque. There is also an inefficiency risk as future CUU proposals are unable to be drafted with lessons learned from previous proposals. Without knowing why a proposal was rejected, applicants are left to guess at DEP's expectations, which increases the possibility of repeated errors or omissions in future proposals. This not only wastes applicants' time and resources but also burdens DEP with reviewing proposals that may fail for the same avoidable reasons. Overall, not providing detailed reasons for rejecting CUU proposals hinders the law's goal of phasing out non-essential PFAS uses while preserving access to critical products. DEP should avoid this result.

III. **Do Not Limit Rationales for Approving CUU Determinations to Safety Considerations**.

As indicated in the Chapter 90 Staff Memo, a key reason why DEP seems to have approved the two CUU proposals for cleaning products is due to product safety considerations. It is true that safety is one of the factors in the law's CUU definition justifying a CUU, but safety is just one factor – the other two being health and the functioning of society. In future CUU proposal cycles, PPWG recommends that DEP avoid limiting itself to approving or favoring CUU proposals for products with safety implications. Instead, DEP must approve CUU proposals if any one of the three statutory factors applies.

DEP should likewise consider health, safety, and societal benefits expansively to capture the naturally broad scope of these terms. More specifically, "health" should encompass physical or

emotional health or wellness; "safety" should refer to the safety or security or the public from danger, injury, or property damage; and "functioning of society" should cover identified consumer, commercial, or industrial demands for the product. Any more limited descriptions of these statutory terms risks arbitrary line-drawing and CUU determinations that may be inconsistent with one another.

Relatedly, during the August 21, 2025 hearing before the Board of Environmental Protection to discuss the Department's proposed CUU determinations, a Board member indicated that the "essential" criterion in the statutory CUU definition is a fairly high bar to meet. PPWG cautions DEP against such a stringent interpretation. For one, the statute requires the PFAS use to be essential "for the health, safety or the functioning of society." These three latter terms as chosen by the Legislature are wide-sweeping and flexible, meaning that an unduly constrained interpretation of the predicate term "essential" could in effect undermine application of the three latter terms. An unduly narrow "essential" criterion could also render the CUU process functionally meaningless if the bar is set so high as to only exempt a very small number of PFAS uses. This situation would contradict the statutory purpose of the CUU process which is to provide a transitional buffer from the PFAS restriction for a wide variety of products with demonstrated societal benefits.

IV. **Where Appropriate, Craft CUU Determinations To Be Expansive in Scope.**

DEP's Chapter 90 rule contains a template example for CUU determinations under subsection 9(B). The template states that the relevant use of PFAS within specified HTC/GPC classifications and NAICS codes is a CUU, and the two CUUs DEP has proposed to add to the regulation during the current cycle follow this template. PPWG recommends that DEP modify this template to be more general and not limited to certain codes, or at least avoid limiting itself to drafting future CUU determinations with this restrictive language.

PPWG agrees with the decision to scope out CUU determinations to cover all PFAS as opposed to specific types of PFAS. This approach aligns with the statute which does not require CUU determinations to be compound-specific. On the other hand, limiting CUU determinations to certain HTC/GPC and NAICS codes is not envisioned by the statute, and for good reason. Use of these codes introduces rigid categorical boundaries that may exclude substantively identical PFAS uses simply because these uses fall under different economic and trade categorization codes.

These codes are not designed for chemical regulatory purposes, and especially not for CUU determinations which are to be based on qualitative societal benefits of the product. Moreover, many products containing PFAS are not end-use products but are instead components used in complex, multi-tiered supply chains such as those that exist in the medical, pharmaceutical, and animal health product industry. A single component may be manufactured under one economic code, incorporated into a product classified under another, and ultimately used in a completely different sector of the economy. Limiting CUU determinations to specific economic codes fails to account for this complexity. The Maine Legislature acknowledged supply chain considerations by providing an exemption in 38 M.R.S. § 1614(4)(M) for equipment used in the manufacture or development of the exempt categories of products. DEP should follow the Maine Legislature's lead and similarly address supply chain considerations when drafting CUU determinations.

V. **Conclusion.**

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

Sincerely,

Ryan J. Carra

Counsel for PFAS Pharmaceutical Working Group
Beveridge & Diamond, PC
1900 N Street NW, Suite 100
Washington, DC 20036
(202) 789-6059
rcarra@bdlaw.com