Personal Care Products Council
Committed to Safety, Quality & Innovation

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Sent Via Electronic Mail: rulecomments.dep@maine.gov

Re: Comments to DEP's "Posting Draft" of the Proposed Rule to Implement Maine's PFAS in Products Program

The Personal Care Products Council (PCPC)[1] respectfully submits the following comments on the Maine Department of Environmental Protection (DEP) "Posting Draft" of the proposed rule, **Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances.**

PCPC and its member companies have long been supportive of commonsense laws and policies that protect both the consumer and the environment. For this reason, we have supported laws in other states that prohibit certain intentionally added PFAS from use in cosmetics. We have appreciated the opportunity to weigh in on earlier versions of this proposed rule, and we are generally supportive of DEP's efforts in updating the second concept draft to this current version. In an effort to continue improving this proposed rule, we offer the following feedback.

§2. DEFINITIONS

Packaging: PCPC appreciates the intention to exclude packaging from this legislation, as made clear on the DEP website FAQ section. However, this exclusion would be made

[1] Based in Washington, D.C., the Personal Care Products Council (PCPC) is the leading national trade association representing global cosmetics and personal care products companies. Founded in 1894, PCPC's approximately 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the U.S. As the makers of a diverse range of products millions of consumers rely on and trust every day – from sunscreens, toothpaste, and shampoo to moisturizer, lipstick, and fragrance – personal care products companies are global leaders committed to product safety, quality, and innovation.

clearer through the removal of "packaging" from the definition of "product" in this regulation. Based on a plain reading of the legislative text, the Maine legislature intended this law to apply to consumer products themselves, not their packaging, and we understand that the DEP intends to respect that intention. For these reasons, in the interest of clarity, PCPC urges DEP to remove the reference to "packaging" within the draft definition of "product".

- ***Intentionally Added PFAS***: PCPC supports the clarifying language in the definition of Intentionally Added PFAS relating to degradation byproducts. Specifically, we support the language stating that only those 'degradation byproducts' *serving a functional purpose or technical effect within the product or its components* shall be included in the definition. We further support the clarification that Intentionally added PFAS does not include PFAS *present in the final product as a contaminant* or impurity.

  We would again, however, ask for clarity around whether a PFAS used as a processing aid in product manufacturing, but not as an intentionally added ingredient, would have to be reported.

- ***Product – Consumer – Offer for Sale:*** PCPC appreciates the DEP's efforts to clarify the concept of *the sale* of a product to a consumer, as distinguished from products not sold directly to consumers, in this version of the proposed rule. Presumably, based on the text as written, products not sold directly to consumers will not be covered by this law. In the beauty and personal care industry, there are products intended for sale directly to consumers, but there are also 'professional use' products, such as those used by salons, for example, that are *not sold* to consumers. Though the text currently reads as such, PCPC would appreciate explicit clarification that professional use products are not within the scope of this definition and are therefore not subject to the reporting requirements established herein.

- ***Commercially available analytical method***: The proposed definition for this term is challenging for industry because today's commercially available methods are inadequate to detect specific PFAS in the complex matrices that exist for the wide range of products in the market today. There are several reasons for this:
  - PFAS are a highly complex chemical classes of compounds with diverse functional groups attached to the fluoroalkyl moiety (e.g., Perfluoroalkyl acids, Polyfluoroalkyl acids, PFAA precursors, etc.). This could represent hundreds of targets that "commercial methods" will need to be able to target. The referenced EPA methods[2] generally test for PFAS *in soil and water* and are not specific to

[2] EPA PFAS Methods: (1) ASTM D7968: Standard Test Method for Determination of Perfluorinated Compounds in Soil by Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS) (PDF)(17

finished products or packaging. While there are available test methods that measure PFAS in consumer products/cosmetics, they are not necessarily considered "commercial methods" as defined.

- Even established testing methods used for cosmetics products will need to be validated/verified for the corresponding product matrixes – meaning they will require modifications – which is not something that is permitted under the proposed definition.

- The lack of adequate commercially available test methods makes DEP approved "ranges" even more important. PCPC again asks that DEP provide additional clarity on how it will establish such approved ranges. It would be difficult for industry to comply with the reporting requirement as written within the draft – requiring precise analytical results from a commercially available method confirming the level of specific PFAS materials (named by CAS#) – without the publication of DEP approved reporting ranges.

In sum, PCPC continues to strongly urge DEP to build in greater flexibility on the test methodology/ies used to measure PFAS in finished products and to establish DEP-approved ranges as soon as possible.

§3: NOTIFICATION

- As stated in our feedback on the previous draft of this regulation, PCPC supports the ability to claim certain business information as confidential. However, PCPC does not support the change to manage this confidentiality under the Maine Freedom of Information Act, as opposed to the Uniform Trade Secrets Act. This change neglects the relevant interests of the business community impacted by the regulation. The Uniform Trade Secrets Act was designed as a legal framework to provide uniform definitions and protections for trade secrets throughout the country, whereas the Maine Freedom of Information Act exists to govern public records disclosure within the state. The Uniform Trade Secrets Act is thus a much more appropriate means of governing the protection of confidential business information in a manner that enables companies to comply with this new requirement without fear of compromising proprietary material.

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pp, 175 K) [ASTM may charge a fee for this document.] (2) ASTM D7979: Standard Test Method for Determination of Perfluorinated Compounds in Water, Sludge, Influent, Effluent and Wastewater by Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS) (PDF)(18 pp, 181 K) [ASTM may charge a fee for this document.]

- PCPC supports allowing manufacturers to amend a notification to "inactive" status at their convenience whenever a product no longer contains intentionally added PFAS.
    - We again ask DEP to clarify, however, that a manufacturer can make the update to "inactive" status following a formula change that removed intentionally added PFAS *even though* older product may still be on shelf in the state.
- PCPC also supports the language included in the posting draft that permits a manufacturer to refer back to a previously reported notifications in the case of a complex product. We ask DEP to expand this language to also allow a manufacturer to refer back to an article or individual component already notified in other cases as well, not limited specifically to complex products.

§4: EXEMPTIONS

- PCPC appreciates the additional language added regarding federal preemption, but we continue to seek explicit clarification that Over-the-Counter (OTC) drug products are exempt from the law.
    - DEP has previously stated that OTC/Cosmetic combination products are within the scope of the law; however, it has not clarified whether OTC Drug products alone would be regulated.
    - OTC drugs are subject to a federal monograph, or "rule book", which sets forth precise conditions for each therapeutic category – active ingredients, uses, doses, route of administration, labeling, and testing requirements – in order for an OTC drug to be considered generally recognized as safe and effective.
    - PCPC believes that OTC drugs should be exempt under the provisions[3] of DEP's posting draft because such products must, by law, follow the federal monograph, which preempts state authority.
- PCPC also requests clarification that medical devices are exempt from the law, as medical devices are subject to various FDA approval processes to analyze safety and efficacy.

§6: FEES

- While we appreciate the declining fee structure for notifications, we again urge DEP to consider a cap for registration fees. Costs could become prohibitive for large companies

[3] "*A product for which federal law or regulation controls the presence of PFAS in the product in a manner that preempts state authority."* Maine DEP, Chapter 90: Products Containing PFAS Posting Draft, §4 (A)(1).

with multiple products to report. Likewise, many small or midsized companies may not be able to absorb the costs.

- In the alternative, DEP could offer a second option to companies to pay a single, annual fee rather than a per product fee. This would allow companies with multiple SKUs to avoid incurring outsized fees.

- Also, as many companies project budgets out for the next fiscal year, we recommend initiating any fee payments beginning in January 2024, which will allow companies to appropriately account for such costs.

§8: CERTIFICATE OF COMPLIANCE.

- PCPC again asks that DEP provide additional information on the certificate. For example, will DEP require proof of testing that a product doesn't contain PFAS? Greater clarity would be appreciated here.
- PCPC also requests that DEP build in a provision to allow for correction, such that a manufacturer notified about a violation of this policy has a reasonable period of time, such as 30 or 60 days, to bring all relevant products into compliance prior to suffering any consequences.

Thank you for the continued opportunity to engage in this process and provide comments on the proposed draft. Should you have any questions or wish to discuss any of the above points with us, please do not hesitate to contact me.

Sincerely,

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