Personal Care Products Council
Committed to Safety, Quality & Innovation

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Commissioner Melanie Loyzim
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State of Maine
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Emailed to: PFASProducts@Maine.gov

Re: Comments to DEP's Second Concept Draft for PFAS in Products Program

The Personal Care Products Council (PCPC)[1] respectfully submits the following comment on the Maine Department of Environmental Protection (DEP) second concept draft relating to the PFAS in Products registration program.

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. Likewise, PCPC is generally supportive of DEP's proposed changes to the second concept draft to the extent they implement, rather than expand, the underlying law.[2] To that end, and in an effort to improve the text of any proposed rule, we offer the following feedback.

§2: DEFINITIONS

- ***Product Component***: PCPC believes that the second concept draft impermissibly expands the scope of the underlying law to including "packaging" within the definition of

[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.

[2] Public Law c. 477, An Act To Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution (LD 1503, 130th Legislature).

"product component." It very clearly exceeds the plain language and intent of the law, which is intended to regulate PFAS in consumer products, not packaging. DEP also indicated during its October 27 public webinar that packaging would include inks, adhesives, labels, etc., expanding the scope even further.

- Moreover, such an expansion would create an internal inconsistency in the definition of "Product". Consider that the underlying law defines 'Product' as *an item . . . packaged . . . for sale*. In other words, the product is the item that goes into the package, not the package itself.

  Likewise, "Product component" means an identifiable part of the product, which is defined as the item in the package. In short, the Maine legislature intended this law to apply to consumer products, not packaging, based on a plain reading of the text, and for these reasons PCPC opposes this amended definition and urges DEP to remove any reference to 'packaging'.

- ***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, 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:*** The definitions of these three terms are all tied to the concept of *the sale* of a product to a consumer. Presumably, then, products not sold directly to consumers would not be covered by this law. PCPC would ask that DEP confirm and clarify this.

  - In the beauty and personal care industry, there are products intended for sale directly to consumers but also 'professional use' products used by salons, for example, and *not sold* to consumers. It is unclear if such professional use products are within the scope of this definition and must be reported.

- ***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[3] generally test for PFAS *in soil and water* and are not specific to 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 would ask 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 second concept 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 strongly urges 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

- PCPC opposes the new requirement for companies to provide sales data to DEP. Reporting 'sales volume' is problematic as that information is highly proprietary and closely held in a competitive industry.

- PCPC supports the ability to claim certain information as Confidential Business Information to be managed under the Uniform Trade Secrets Act.

[3] 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 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 the waiver process, as described in the second concept draft.

- PCPC supports the change from 30 to 60 days in which companies may notify DEP when there is a significant change to any reported information.

- PCPC supports allowing manufacturers to amend a notification to "inactive" status at their convenience whenever a product no longer contains intentionally added PFAS.

    - DEP should 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 supports reporting a group of products under the same Global Product Brick category with the same PFAS under a single entry. This would apply to cosmetics that are essentially identical and differ only by shade, tint, or fragrance (e.g., lipsticks, nail polish, etc.).

- PCPC would ask that DEP clarify how it will handle "complex product" reporting. For example, in the cosmetic industry, would brushes and applicators sold with a cosmetic be considered a 'product component' for purposes of the regulation? What if these items are sold separately? Would companies refer to any previous notifications for these and report remaining PFAS in the product?

§4: EXEMPTIONS

- PCPC is seeking clarification that 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[4] of DEP's second concept draft because such products must, by law, follow the federal monograph, which preempts state authority.

[4] "*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, Second Concept Draft, §4 (A)(1).

§6: FEES

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

Thank you for the opportunity to provide these comments. 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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