May 19, 2023

VIA EMAIL at rulecomments.dep@maine.gov

Mark Margerum
Maine Department of Environmental Protection
17 State House Station
Augusta, Maine 04333-0017

Re: Department Proposed Rule - Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances.

Dear Mr. Margerum:

As the association for the consumer-packaged goods (CPG) industry, including makers of food, beverage, personal care, and household products, the Consumer Brands Association[1] advocates for uniform, workable, and durable regulatory frameworks that are informed by risk-based science, promote consumer choice, and build consumer trust across the sectors we represent. Consumer Brands is committed to partnering with state and federal policymakers on practical and effective solutions for addressing the use and presence of PFAS in CPG products.

We appreciate the opportunity to again comment on the Maine Department of Environmental Protection's ("DEP's") draft regulation under the Maine PFAS in Products Program. Consumer Brands has been closely engaged throughout the DEP's concept draft development process, and we value the frequent occasions for stakeholder engagement the Department has provided. Our recommendations on the draft regulation, provided below, would bring further clarity to the scope of the requirements for reporters and mitigate negative impacts the rule could have on interstate commerce in Maine.

I. DEP Should Revise the Definition of "Product" to Exclude Bulk or Individually Sold Packaging:

Consumer Brands is appreciative of the fact that the DEP has now acknowledged that the packaging of a product, including all packing, packing components and food packaging as defined in as defined in 32 M.R.S. § 1732, does not need to be reported, regardless of whether the Department has specifically regulated such items. Consumer Brands strongly endorses this statutory interpretation, as the Maine Legislature clearly intended to address the presence of PFAS in packaging through separate and distinct regulatory pathways established under Title 32,

[1] The Consumer Brands Association (Consumer Brands) champions the industry whose products Americans depend on every day, representing more than 2,000 iconic brands. From household and personal care products to food and beverage products, the consumer-packaged goods (CPG) industry plays a vital role in powering the U.S. economy, contributing $2 trillion to the U.S. GDP and supporting more than 20 million American jobs.

chapter 26-A, Reduction of Toxics in Packaging, and Title 32, chapter 26-B, Toxic Chemicals in Food Packaging, which are currently in effect.

However, Consumer Brands is concerned by the DEP's proposal to revise the definition of "product" in manner that is at odds with the underlying statute. The definition of "product" in the statute is as follows:

> "Product" means an item manufactured, assembled, packaged or otherwise prepared for sale to consumers, including its product components, sold or distributed for personal, residential, commercial or industrial use, including for use in making other products.

However, the proposed rule would define "product" as follows:

> "Product" means an item manufactured, assembled, packaged, or otherwise prepared for sale to consumers, including its product components, that is sold or distributed for personal, residential, commercial, or industrial use, including for use in making other products. **Product includes packages, packaging components, and food packaging as defined in 32 M.R.S. § 1732, when sold individually or in bulk and not used in marketing, handling, or protecting a product.** [emphasis added]

Consumer Brands objects to the proposed addition of the second sentence to the statutory definition. This proposed addition, diverges from the underlying statute, and conflicts with the applicability of the requirements as they were intended by the Legislature. It is furthermore inconsistent with the statutory definition's clear focus on "items prepared for sale to consumers" (as opposed to items "not used in marketing, handling, or protecting a product").

Consumer Brands agrees that packaging can be a product when sold as itself. Again, though, both packaging containing products and packaging sold as a product are already regulated under two existing statutory schemes: Reduction of Toxics in Packaging (Title 32, chapter 26-A), and Toxic Chemicals in Food Packaging (Title 32, chapter 26-B). For example, 32 M.R.S. § 1733 specifies that neither products packaged in the disallowed packaging, nor the disallowed packaging itself, can be sold in Maine. *See id.* at (1), (2), (3-A), (3-B). Additionally, a "food package" as defined in both Chapters 26-A and 26-B is "a package that is *designed for* direct food contact", not one that already is in food contact. A food package, whether already touching food (packaging of a product) or intended to touch food in the future (packaging as product), is subject to Chapters 26-A and 26-B, and therefore exempt from Ch. 90.

The implementing law at issue in Title 38 specifically exempts the aforementioned products, i.e. the packaged products as well as packaging sold as a product, as those products are already subject to Chapters 26-A and 26-B. *See* 38 M.R.S.A. § 1614(4)(B). It is evident that the Legislature used the language of exempting all products subject to those chapters, because they intended to exempt packaging in general, which was already regulated, from the new statutory scheme. If they had intended to be very specific about needlessly exempting from the new notification law those products that were already banned, they would have drafted a specific exemption for those products affected by the sales prohibition provisions of Section 1733. The more general language was intended to create a broad exemption for the large category of packaging material already regulated by DEP. Ultimately, the Legislature clearly intended to address products and packaging through two separate and distinct regulatory systems. The DEP's final rule should reflect that reality.

II. DEP Should Revise the Definition of "Offer for Sale" to Specify the Date of Manufacture:

In the proposed rule, the Maine DEP proposes to define "offer for sale" as follows:

> "Offer for sale" means to make a product available for purchase, including through online sales platforms that deliver into the State of Maine.

Consumer Brands is concerned that the proposed definition does not adequately address the complexities that manufacturers face when their products are released from their chain of custody and enter state and local distribution channels. Given that products can remain in circulation for months (and in some instances over a year depending on localized market conditions and sell-through rates), it would be extremely difficult, if not impossible, for manufacturers to accurately identify product for notification to the DEP once it is out of their control and in retail circulation.

For the proposed regulation to be practicable, Consumer Brands recommends that DEP should revise its definition to specify that "offer for sale" will be applicable to the production date of the finished good that enters Maine commerce, rather than the date at which the product becomes available for purchase on store shelves in the state. Doing so is a reasonable means to ensure that industry can accurately and effectively comply with the notification requirement at the initial point in the supply chain where they have greater control and visibility over its distribution.

III. DEP Should Exempt Federally Approved Drugs, Medical Devices, and Pesticides from Reporting

Section 4(A)(1) includes the statutory exemption from the notification requirements for products "for which federal law or regulation controls the presence of PFAS in the product in a manner that preempts state authority." It is evident that Maine legislators intended the statutory exemption to apply to circumstances where federal regulations directly authorize, manage, or restrict the use of a PFAS containing product. It is not simply a matter of preventing instances where federal laws and regulations might overlap with or duplicate the reporting program at the state level. It is in fact Section 3(2) that addresses circumstances where a waiver of notification can be used when the DEP determines that substantially equivalent information is available. This provision functions as the appropriate mechanism to limit or eliminate overlapping reporting programs. Federal regulations that "control the presence" of the product clearly go far beyond the scope of just notification requirements and should be given appropriate deference by the Department.

Based on the clear meaning of the statutory exemption addressing preemption, Consumer Brands strongly urges DEP to include language in the rule exempting from the notification requirements drug and medical device products approved by the U.S. Food and Drug Administration (FDA) as well as pesticide products approved by the U.S. Environmental Protection Agency (EPA). Under the Federal Food Drug and Cosmetic Act (FFDCA), FDA requires products to undergo multiple phases of review for their efficacy and safety before they may be introduced into the marketplace with the agency's approval and oversight. FDA furthermore ensures the quality of drugs and medical devices through enforceable Good Manufacturing Practice (GMP) regulations, which impose requirements for the facilities, processes, and safety controls used in their production. Similarly, EPA's regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) controls the authorization, distribution, sale, of pesticides in the U.S., which must undergo a rigorous registration and safety review process before being approved for use. These federal frameworks functionally "control the presence" of the product and its

constituent ingredients, and they would be appropriately covered by the exemption under this Section of the proposed rule.

IV. DEP Should Include a Regulatory Mechanism to Allow for Future Extensions of the Reporting Requirement:

The implementing statute notes that for notifications, "The department may extend the deadline for submission by a manufacturer of the information required under subsection 2 if the department determines that more time is needed by the manufacturer to comply with the submission requirement." The law does not specify a limit to the frequency or length in which the Department may extend the deadline for any individual manufacturer.

While the current reporting extension that DEP has provided has been much appreciated by affected companies, Consumer Brands continues to hear concerns that manufacturers still face significant difficulties in complying with the notification requirement. Difficulties include an inability to obtain information from upstream material and ingredient suppliers, the complexity of brand portfolios and production chains, ongoing supply chain disruptions in the global marketplace, as well as limited laboratory capacity and a lack of validated test methods for evaluating the presence or concentration of PFAS in products. We anticipate that these myriad issues will continue to persist for many manufacturers after the DEP finalizes its rule and the extension period for reporting concludes.

Consumer Brands therefore urges the DEP to include a provision in the regulation that allows manufacturers to request additional extensions of the notification period in cases where they can demonstrate in good faith to the DEP that they have taken actions to ascertain the information sought in the regulation, yet still remain unable to meet the applicable requirements. Such a provision is consistent with the statutory obligation to report PFAS-related information to the DEP so long as the additional reporting extensions are time-limited and case specific.

V. DEP Should Provide Clarity on Reporting PFAS Concentration Ranges:

Consumer Brands continues to encourage the DEP to articulate what it considers a "Department-approved range" for the purposes of reporting PFAS concentration ranges in products. The ranges should be practical and structured to help protect confidential business information, improve the feasibility of testing for PFAS, and decrease the amount of time needed to provide notification. DEP should also allow companies to quantify the presence of PFAS on the basis of weight or concentration. The statute does not specify the numerical basis regarding the amount of PFAS in the product, and allowing the use of either concentration or weight as a means of reporting would provide added flexibility for manufacturers.

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Consumer Brands appreciates the opportunity to comment on the draft regulation under the Maine PFAS in Products Program, and we look forward to working with the Department to ensure that Maine consumers can continue to access CPG products essential to their health and wellbeing. Thank you for your attention to our comments.

Sincerely,

Jared Rothstein
Director, Regulatory Affairs
Consumer Brands Association