

November 10, 2022

Melanie Loyzim
Commissioner
Maine Department of Environmental Protection
17 State House Station
32 Blossom Lane
Augusta, Maine 04333-0017

PFASProducts@maine.gov

Re: **Second Concept Draft Implementing Maine's Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution, 38 M.R.S. § 1614 ("the Act")**

Dear Ms. Loyzim:

The undersigned food industry trade associations appreciate the opportunity to provide comments on the Department's draft proposed regulations (also known as the "second concept draft" and, hereinafter, the Regulations) that would implement the notification requirements under Maine's Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution, 38 M.R.S. § 1614 ("the Act"). We are pleased to share the perspective of our members who will be substantially impacted by the Act as a result of the surprising and unexpected interpretation of the Act's requirements outlined by the Department during its recent October 27, 2022 stakeholder engagement meeting.

As an initial matter, we request that the Department extend the deadline for comments on the Regulations for at least one month to allow industry adequate time to evaluate the proposal and understand its implications more fully. The balance of our comments in this letter focus on three areas: (1) the Department's interpretation of the Act's exemptions and specifically, its application to food packaging; (2) the proposed definition of "intentionally added PFAS", and (3) the information required to be disclosed by manufacturers when making notifications to the Department.

Background

Both the Act and the Department's Regulations include an exemption from the Act's requirements for products "subject to Title 32, Chapter 26-A." ^{1/} Chapter 26-A prohibits the sale of food packaging containing heavy metals, phthalates, and when the Department determines a safer alternative is available, intentionally added per and polyfluoroalkyl substances (PFAS). Since the Act's passage in 2021, the exemption for products "subject to Title 32, Chapter 26-A" has been interpreted as exempting food packaging from the Act's requirements, including the requirement that manufacturers report intentional uses of PFAS in products to the Department (the "notification" requirement). However, during an October 27, 2022 stakeholder engagement meeting, the Department announced that it interprets the exemption for products "subject to Title 32, Chapter 26-A" narrowly, explaining in an FAQ posted on its website that "food packaging containing PFAS is

^{1/} 38 M.R.S. §1614(4)(B); Regulations §4.

subject to Maine Revised Statutes Title 32, chapter 26-A. *when the Department prohibits its sale by rule (32 M.R.S. §1733(3-B))*(emphasis added). As a result, it appears the Department's position is that although Maine's legislature passed a law specifically addressing the intentional use of PFAS in food packaging, the Department does not consider food packaging "subject to" that law and, hence, it is not exempt from the Act and its notification requirements unless and until the Department promulgates a final rule identifying a safer alternative and prohibiting the intentional addition of PFAS to food packaging.

The Department's narrow interpretation of the Act's exemption for product's "subject to Title 32, Chapter 26-A" is neither reasonable nor compelled by the statute.

Regulated industry reasonably interpreted the exemption in the Act for products "subject to Title 32, Chapter 26-A" as exempting food packaging from the scope of the Act's reporting requirement. Several factors weigh in favor of this interpretation. First, the Maine legislature had previously, in separate legislation, specifically addressed the question of PFAS and its intentional use in food packaging, creating a framework for DEP to evaluate the appropriateness of its continued use in food packaging sold in Maine through Title 32, Chapter 26-A. Given that pre-existing framework, it was reasonable to assume the Act's reporting obligations, as well as the general ban it places on all products containing intentionally added PFAS in 2030, passed later, included a carveout for food packaging.^{2/}

Second, although the Department has not yet finalized a rule prohibiting the use of intentionally added PFAS in food packaging and identifying a safer alternative under Title 32, Chapter 26-A, Chapter 26-A is operative, and products are "subject to" it. The chapter prohibits the presence of intentionally added heavy metals and phthalates in food packaging and has since 1994 and 2022 respectively.

Finally, nothing in the language of the Act or its legislative history suggests that the exemption for products "subject to Title 32, Chapter 26-A" was contingent on the DEP undertaking rulemaking to ban PFAS in food packaging. Had the legislature intended that outcome it easily could have chosen language that conveyed that intent. Rather than exempting "a product subject to Title 32, Chapter 26-A" it might, for example, have exempted "a product that is subject to rulemaking by the department pursuant to Chapter 26-A." It did not.

Given these considerations, the exemption for products "subject to Title 32, Chapter 26-A" is properly interpreted as exempting food packaging from the requirements of the Act. The Department's unanticipated and narrow interpretation of the exemption is neither compelled by the Act's plain language nor the overall structure of the Maine legislature's response to the question of PFAS in food packaging in Maine. Consequently, we respectfully ask the Department to reconsider its interpretation of the Act's exemptions and conclude in accordance with the language chosen by the legislature that food packaging is exempt from the Act under 38 M.R.S. § 1614(4)(B).

^{2/} Just as there would be no need to include food packaging in the general ban on PFAS in all products, as food packaging is already subject to a ban through Title 32, Chapter 26-A, so too would food packaging be excluded from the notification requirement. The state already has a means to study and address PFAS in food packaging.

If the DEP nevertheless chooses to maintain a narrow interpretation of the exemption for products “subject to Title 32, Chapter 26-A,” an automatic extension of the notification deadline for all food & beverage manufacturers is warranted.

If the Department maintains its narrow interpretation of the exemption, food and beverage manufacturers will be required to notify the Department about any PFAS intentionally added to their packaging no later than January 1, 2023. There simply is not adequate time between now and January 1 for manufacturers to gather the extensive, highly detailed information required to do so. Among other things, affected manufacturers will have to rely on their suppliers for information about the function of any intentionally added PFAS present in their packaging and the amount of each PFAS identified by its CAS number and expressed as an exact quantity determined using a “commercially available analytical method.”

Many food and beverage manufacturers have multiple packaging suppliers operating across the world in varying jurisdictions. Most will not have this type of information readily available, let alone in the very specific form called for by the Act and the Regulations. We would expect many suppliers to have to conduct additional testing to provide the information with the level of accuracy the Department expects. Given the lack of available PFAS testing capacity, the lack of validated methods to detect individual types of PFAS with specificity, and the substantial delays suppliers will face in obtaining analytical results from the limited number of available labs (up to 8 weeks in most cases), gathering the information necessary to make the required notification to the Department will at best require months of effort from food and beverage manufacturers, even if they start immediately.

We note as well that state bans on PFAS in food packaging with upcoming effective dates are limited to food packaging comprised in substantial part of paper or plant fibers and which are direct food contact packaging. In contrast, Maine’s notification law applies to all packaging, including non-food contact packaging and is not limited to paper-based materials. Food manufacturers simply do not have information of this breadth available from all suppliers.

Despite this burden, the penalties for failing to adhere to the Act’s reporting requirements are severe, if not draconian. Failure to provide notice by January 1 would leave a food & beverage manufacturer open to potential civil or criminal prosecution, fines up to \$10,000 per day per violation for civil violations, and fines up to \$25,000 per day per violation for criminal violations. In addition, a product containing intentionally added PFAS that has not been notified may not legally be sold in the state. With potential penalties of this magnitude, manufacturers might reasonably conclude they cannot continue to do business and ship products to Maine while they work to gather the information necessary to comply with the Act.

Given the substantial and unexpected burden the notification requirement imposes on food and beverage manufacturers, the lack of notice associated with the Department’s interpretation of the Act’s exemptions, and the severe penalties the Act imposes for failure to provide the required notice, we urge the Department to extend the deadline for reporting by all food & beverage manufacturers to January 1, 2024.^{3/} This extension should be granted automatically to all affected food and beverage

^{3/} This is the date upon which many other state bans affecting PFAS in food packaging will come into effect and, thus, is a date by which manufacturers will have gathered information on PFAS usage

manufacturers without the need to apply individually or have their names published on a public list. The Act gives the Department the authority to provide this type of automatic extension under M.R.S. § Section 1614(3).

The definition of “intentionally added” should be clarified to explicitly exclude processing aids and PFAS present from environmental cross-contamination.

We appreciate that the Regulations include a definition of “intentionally added PFAS,” which triggers the notification requirement under the Act. We interpret the language chosen by the Department – that intentionally added PFAS “means PFAS added to a product or one of its product components in order to provide a specific characteristic, appearance, or quality or to perform a specific function” – as excluding processing aids, which by their definition in the food industry are substances added during processing but have no technical or functional effect in the finished product.^{4/} We ask that the Department clarify this point in the final Regulations.

Further, for purposes of applying the definition of “intentionally added” to all products, including food and food packaging, we urge the Department to expand the definition’s treatment of PFAS present “as a contaminant” by stating clearly and affirmatively that intentionally added PFAS does not include any PFAS present in a product as a result of supply chain cross-contamination or background environmental contamination.

Finally, we ask the Department to clarify that any PFAS present in food packaging pursuant to its authorization by FDA as a food contact substance is exempt by virtue of 38 M.R.S. § 1614(4)(A) and not subject to the notification requirement. Addressing these complicated but important topics directly in the text of the definition itself will provide needed clarity, limit confusion and wasted effort within regulated industry, and help promote prompt compliance.

Requiring manufacturers to provide estimated sales volume for each product as part of the notification adds to the burden on manufacturers without providing value to the Department.

Finally, we question the usefulness of going beyond the requirements of the Act and requiring manufacturers to submit full year estimated sales volume in Maine or nationally for each product for which they provide notification. Insisting on the submission of this information imposes an additional data collection burden on manufacturers with no discernible benefit for the Department. We struggle to understand how *estimated* annual sales for a product for the succeeding full year after notification are in any way indicative of the presence of intentionally added PFAS in commerce in Maine, particularly if the estimate is provided on a national basis. Given the unclear utility of this information to the Department, and the burden it imposes on regulated industry, the Department should eliminate this requirement from the final Regulations.

in food packaging. It also will be a sufficient time after the Department completes its rulemaking on this matter.

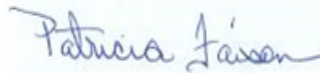
^{4/} 21 C.F.R. §101.100(a)(3).

For the reasons discussed above, we urge the Department to reconsider its interpretation of the Act's exemptions, modify the definition of "intentionally added PFAS", and streamline the required elements of the notification, as outlined above. Please do not hesitate to contact us if we can provide any further information that would be helpful to the Department in considering these points.

Sincerely,



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