

**06-096 C.M.R. Chapter 890: Designation of PFOS as a Priority Chemical
Basis Statement and Response to Comments**

Basis Statement: The final rule designates perfluorooctane sulfonic acid (“PFOS”) and specific salts of PFOS as priority chemicals and requires reporting for certain categories of product that contain these regulated chemicals and that when used or disposed of will likely result in a child under 12 years of age or a fetus being exposed to these chemicals. The final rule applies to manufacturers of specified product categories that contain intentionally added amounts of these chemicals and seeks to gather information which would clarify the prevalence of use of the listed chemicals.

The designation of PFOS and its salts as Priority Chemicals meets the statutory criteria for designation as specified in 38 M.R.S. § 1694(1). Maine CDC concurrence for the proposed rule is based on the chemicals’ category 1A reproductive toxicity classification on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). The Department hereby accepts and adopts by reference the Maine CDC PFOS Priority Designation Concurrence Letter, dated February 23, 2018, which is attached and incorporated into this Basis Statement. The Department also accepts and adopts by reference the underlying science, data, and documents that Maine CDC developed and utilized with respect to its February 23, 2018 letter.

As this Chapter applies to manufacturers or distributors of certain products, the fiscal impacts will fall mainly on manufacturers of consumer products which contain intentionally added amounts of the proposed priority chemicals. Filing the required report information with the Department is expected to impose only nominal costs. Regulated entities are also expected to pay a one-time reporting fee to the Department to cover the costs associated with information management. This fee is dependent upon the number of regulated products and the concentration of the priority chemical in each.

The proposed rule was originally posted for Departmental rulemaking with a public comment period beginning April 3, 2019. A Department public hearing was held on April 23, 2019, and the comment period closed May 6, 2019. After the close of this initial public comment period, new information about the prevalence of PFOS in Maine’s biosolids highlighted the continuing possibilities of exposure and caused the Department to undertake revisions to the draft rule. This initial rulemaking period terminated with no formal action by the Commissioner. Effective September 19, 2019, responsibility for all rulemaking shifted to the Board of Environmental Protection. A new rulemaking proceeding was initiated by the Board’s posting of the Department’s revised draft rule for a thirty-day written public comment period beginning on October 2, 2019 and closing on November 4, 2019. Before the close of the comment period six requests for a public hearing were received. The comment period was reopened on January 1 and the Board held a public hearing on January 23, 2020. The Department made changes to the draft rule to include specific salts of PFOS and other minor changes, and the Board reopened the comment period on February 3, 2020. This final comment period closed on March 9, 2020. Comments submitted during each of these comment periods are detailed below.

RESPONSE TO COMMENTS

This document summarizes and responds to all substantive comments offered on the proposed rulemaking by members of the public at the public hearings and in writing during the public comment periods as described above.

Comments were received from the following:

Commenter 1: Michael Kuhns, Twin Rivers Paper Company

Commenter 2: Patrick MacRoy, Environmental Health Strategy Center; Phelps Turner, Conservation Law Foundation; Alice D. Elliot, Sierra Club Maine; and Dana Colihan, Toxics Action Center

Commenter 3: Oyebode Taiwo, 3M Company

Commenter 4: Grace Cain, Kennebunk

Summary of Comments and Department Response

1. Comment: Commenter supports the rule as drafted. (Commenter 1)

Response: No changes were made in response to this comment.

2. Comment: Commenter believes that the rule should include those substances that form PFOS through decomposition, degradation, or metabolism (referring to those substances as “precursors”) based on the commenter’s interpretation of the statutory definition of “chemical”. Commenter states that the inclusion of PFOS precursors is vital to addressing the threats posed by PFOS itself. According to the commenter, the inclusion of PFOS precursors would recognize that the exposure potential for PFOS may be largely driven by the presence of its precursors, particularly now that the majority of PFOS production in the U.S. has been phased-out. (Commenter 2)

Response: As required by 38 M.R.S. Chapter 16-D §1694, both the Department and the Maine Center for Disease Control and Prevention reviewed the statutory requirements for Priority Chemical designation relative to PFOS and its salts. One of these requirements is that a chemical must appear on Maine’s Chemicals of High Concern list (38 M.R.S. Chapter 16-D §1693-A) to be considered for priority designation. “PFOS and its salts” appear on this list. Whereas precursors themselves have unique chemical identities, they would need to go through the same scrutiny of having been listed as Chemicals of High Concern before being eligible for Priority status. Because those chemicals commonly identified as precursors of PFOS have not gone through such a review and do not appear on Maine’s Chemicals of High Concern list, it is the Department’s interpretation that the current law does not provide the authority to circumvent this requirement in the manner suggested by the comment. No changes were made in response to these comments.

3. Comment: Commenter seeks an expansion of the definition of “Children’s Products” from the original draft rule as posted on April 3, 2019 (which included certain product definitions that were specific to children under 12 years of age) in order to include a broader range of consumer products that manufacturers will be required to report. Commenter seeks this change in order to include consumer

products that will likely result in a fetus being exposed to the Priority Chemical. Commenter also sought further clarifications of these definitions as contained in the draft posted on October 2, 2019.

(Commenter 2)

Response: The Department amended the April 3, 2019 draft rule to expand the range of consumer products captured by the rule as the commenter suggests. To accomplish this, the specificity of age associated with certain children's product definitions in the draft rule has been removed. The revised draft sought to clarify applicability of the rule such as eliminating age associated with product use and product category specificity, while maintaining consistency with the level of detail in current program rules. These changes were included in the revised draft posted on October 2, 2019. From its experience administering current program rules the Department finds that the proposed language provides a sufficient level of detail for compliance interpretation by the Department and regulated community.

4. Comment: Commenter believes that, because of the significance of the PFOS production phase-out within the U.S., the use of PFOS has decreased to a level that renders the designation of PFOS and its salts as unnecessary, particularly in light of consistently decreasing PFOS serum levels measured in the U.S. population. Commenter suggests that this Priority designation is also duplicative of federal action as the EPA's 2019 PFAS Action Plan intends to evaluate PFAS uses and consider establishing federal maximum contaminant levels in drinking water, having already issued guidance on soil and groundwater remediation for PFOS. Commenter also cites the recently passed National Defense Authorization Act, which includes increased levels of research, reporting, and monitoring related to PFAS as evidence that Maine's Priority designation of PFOS and its salts would be duplicative of federal efforts. Commenter expresses concern that literature analysis associated with this proposed Priority designation was not thorough and did not include the most current peer-reviewed studies which, in some cases, provide conflicting evidence to Maine CDC's rationale for the draft rule. Citing more recent analysis refuting a causal link between PFAS and certain adverse health effects, and the small sample size of studies utilized in the Maine CDC review for Priority designation of PFOS and its salts, commenter suggests that the legal standard for strong credible scientific evidence has not been met in this case. Commenter suggests that the designation of PFOS and its salts is further flawed by several questionable links between PFOS and human health effects, which, therefore, does not meet the Chemical of High Concern hazard criteria as detailed in Maine law. (Commenter 3)

Response: Commenter's assessment of currently available literature on PFAS is a useful summary of information, however, the proposed rulemaking is relative to PFOS and its salts specifically which means that the information provided about the broader PFAS class of chemicals is less relevant to this rule. The Department is confident in the analysis provided by Maine CDC, which provides evidence that PFOS and its salts do meet the statutory criteria for priority designation. Commenter's concern about duplicative policy is focused on federal planning for the capture of largescale information related to the broader PFAS class of chemicals. This proposed rule seeks to determine where PFOS and its salts may be used in common products available in Maine, specifically focused on potential exposure sources in our local communities, information made more reliable and distinct because it is reported directly from the manufacturing source rather than a distilled extrapolation from generalized federal data. The Department, in concurrence with Maine CDC, believes that information gathered through the consumer product

reporting requirement established by this draft rule will provide valuable information about where PFOS and its salts are still used in commerce, which will offer important insight into remaining exposure sources in the general population. No changes were made in response to these comments.

5. Comment: Commenter supports the reporting rule and believes product labelling is more ideal for consumer awareness. (Commenter 4)

Response: No changes were made in response to this comment.