



Kerri Malinowski Farris
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FILED VIA rulecomments.dep@maine.gov

RE: Proposed Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substance under Maine's Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution, 38 M.R.S. § 1614

Dear Ms. Farris:

SPAN is writing to provide these comments in response to the Department of Environmental Protection's ("DEP" or "Department") proposed rule for notification requirements, sales prohibitions, and currently unavoidable use determinations for products containing intentionally added PFAS under Maine's Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances [PFAS] Pollution (the "Proposed Rule").

SPAN appreciates DEP's willingness to confer with SPAN previously and to consider these new comments on the Proposed Rule. As you know, SPAN is a coalition of PFAS users and producers committed to sustainable, risk-based PFAS management. Our members advocate for responsible policies grounded in science that provide assurance of long-term human health and environmental protection while recognizing the critical need for certain PFAS materials for U.S. economic growth and global competitiveness. SPAN was formed with the objectives of ensuring legislators and regulatory agencies are aware of the essentiality of products generated by our members while simultaneously supporting practical regulatory programs focused on protecting human health and the environment and maintaining America's global economic edge.

SPAN has commented on previous versions of the Proposed Rule, so rather than repeating our previous comments, we now offer the following limited, supplemental comments that highlight specific critical issues.

Definitions

- "Commercially available analytical method" is defined as:

"any test methodology used by a laboratory that performs analyses or tests for third parties to determine the concentration of PFAS in a product. Commercially available analytical methods do not need to be performed at a third-party laboratory."

SPAN recommends that the acceptable analytical methods should either be based on established EPA methods or reliable methods recognized by another

equally rigorous regulatory standard-setting body. Similarly, if a product is being tested in a third-party lab, that third-party lab should be a third-party certified lab or one which documents the use of testing methods and internal procedures meeting Good Manufacturing Practice or Good Laboratory Practice standards. Grounding the scientific testing methodologies use with widely accepted methods and well understood testing standards will ensure scientific and regulatory credibility of the results. SPAN notes that methods focused solely on identifying the presence of fluorine in the material tested are not suitable for these purposes as the results are often misinterpreted as representing the presence of PFAS.

- “Reasonably available” is defined as:

“a PFAS alternative which is readily available in sufficient quantity and at a comparable cost to the PFAS, to include changes to the manufacturing process, it is intended to replace and performs as well as or better than PFAS in a specific application of PFAS in a product or product component.”

In addition to the criteria mentioned in the definition, SPAN suggests that the definition also include as a factor whether use of the alternative imposes increased costs to small business and end users, such as potential consequences of less energy efficient equipment, including the energy cost differential.

Furthermore, DEP should establish a transparent and well-defined framework in making its determination of the reasonable availability of alternatives. Subsection (i) of the federal American Innovation and Manufacturing (AIM) Act of 2020 (42USC 7675) could serve as a model for criteria for alternatives.

- “Manufacturer” is defined (via reference to the statutory definition) as:

“the person that manufactures a product or whose brand name is affixed to the product. In the case of a product imported into the United States, “manufacturer” includes the importer or first domestic distributor of the product if the person that manufactured or assembled the product or whose brand name is affixed to the product does not have a presence in the United States.”

As defined, “manufacturer” includes both the entities that manufacture a product or whose brand name is legally affixed to the product. However, there are numerous circumstances when two different entities meet that definition: one may manufacture the product and the other may legally affix their name to the product. SPAN requests that DEP explicitly identify the exact entity in such circumstances that is subject to the reporting requirements. DEP should provide real-life examples in the form of guidance based on input it should solicit from the manufacturing community.

- “Semiconductor” is defined as:

“material having conductivity characteristics intermediate between conductors and insulators, as well as a discrete functional object having two or more layers of metallic, insulating, or semiconductor material, deposited or otherwise placed on, or etched away or otherwise removed from, a piece of semiconductor material in accordance with a predetermined micron or sub-micron pattern and intended to perform electronic and other related functions. Semiconductors do not include commonly associated materials such as printed circuit boards (PCB), PCB mounting solder, PCB mounting flux, external wires, PCB screen printing ink, connectors and sockets, or PCB conformal coatings.”

SPAN appreciates that DEP has revised this definition to reflect the Department’s awareness of the semiconductor chip product definition used at the federal level in 17 U.S.C. § 901(a)(1).

SPAN requests that the text appearing in the final sentence of the proposed semiconductor definition which describes materials that semiconductors “do not include” be omitted and modified to better reflect the intent of the statutory exemption at 38 M.R.S. § 1614(4)(K) and industry practice. Specifically, SPAN suggests the final sentence in the proposed definition be updated to read, “Semiconductor means both a semiconductor material and a type of product that is a discrete assembled functional object which is capable of being incorporated into electronic equipment.” Such changes will ensure the final rule makes clear that a semiconductor is not just an etched and layered material, but also a type of assembled functional product described in the semiconductor exemption in section 4.A.(11) of the Proposed Rule, and capable of being “incorporated into electronic equipment”.

SPAN also requests that the “NOTE” appearing immediately below the semiconductor definition on page 7 of the Proposed Rule be omitted entirely as it is poorly phrased and serves no clear purpose and could create significant confusion in the regulated community and DEP’s enforcement personnel.

Notification and Reporting Provisions

- The Proposed Rule is unclear as to whether product components are subject to the law. While “components” was removed from the “Applicability” section in the Proposed Rule, there are multiple references to obligations concerning components in numerous defined terms, various “notes,” as well as other sections. DEP needs to ensure that the removal of the term “components,” a change that SPAN fully supports, is addressed consistently throughout the rule.

- Even assuming components are not covered, suppliers often are reluctant or unable to provide information on composition of the materials in components they supply due to confidentiality concerns. Even if there are no confidentiality concerns from the suppliers, it is often impossible or technically unfeasible to provide detailed information on PFAS composition in the products due to limited analytical methods (standardized or not), instrumentation, and an inability to accurately characterize unknown PFAS. Current standardized PFAS testing methods cover fewer than 50 PFAS molecules. The Department should provide further guidance and flexibility on reporting PFAS in manufactured products – especially at the CAS number and chemical identity and specific content levels.
- The contents of the notification to be required for materials subject to Currently Unavoidable Use (CUU) determinations can and should be minimized given the extent of information that will already be in DEP’s possession as a result of the CUU application process and the materials concerning the product’s contents provided in the application.
- The proposed rule requires entities that manufacture or distribute exempt items, such as military equipment (e.g., aircraft, weapon systems, vessels) and motor vehicles or watercraft that are required to meet FAA, NASA, DOD or DHS requirements, to submit notifications for “textiles” and “refrigerants” that are included or present as components of such products. DEP should provide a rationale as to why notifications are needed for these particular components and what purpose such reporting would serve.
- Furthermore, DEP needs to provide clarification as to how and when notifications are to be submitted for these textile and refrigerant parts of otherwise exempt items. SPAN recommends such textiles and refrigerants should be exempted when present in such items to avoid confusion and reduce the complexity of the regulations and to simplify the administrative burden on Maine DEP.

Sales Prohibitions

- SPAN requests that DEP include an “existing stocks” exclusion for PFAS-containing products that were manufactured and released into commerce (e.g., from manufacturers to distributors and retailers) prior to the final rule’s effective date for the various prohibitions on non-exempt items. Such previously manufactured items should be excluded from the prohibitions and permitted to continue to move freely in commerce. This will ensure simplicity and reduce the risk of unintentional non-compliance on the part of all parties subject to the regulation.
- SPAN supports the Proposed Rule’s terms that the sales prohibitions do not apply to used products. SPAN recommends that an exemption also should be

provided for replacement parts that are needed for routine repair and maintenance of existing (and used) products throughout their projected lifecycle. This is especially critical for complex and durable goods (such as consumer use appliances) which (if properly maintained) can have a lengthier period of use and reduce waste that would be generated through the unnecessary and premature disposal of such goods.

- Article manufacturers work within complex, often global, supply chains composed potentially of thousands of suppliers. We anticipate that upstream suppliers will need sufficient time and resources to become aware of and inform their downstream customers/manufacturers of the presence of PFAS. Consequently, even with due diligence, end-product manufacturers may only be notified concerning the presence of PFAS in their products after the restriction deadline has passed. SPAN therefore requests that DEP add a provision that explicitly states that manufacturers will not be penalized in such cases provided the manufacturers have made a good-faith effort to reasonably ascertain from their suppliers the presence of PFAS prior to selling the finished product in the state after the effective date of a specific prohibition.

Currently Unavoidable Use Process

- The Proposed Rule states that a CUU Proposed Rule must contain a significant amount of information on alternatives to the PFAS currently in use and information on the human and environmental effects of the PFAS used in a product. For complex product manufacturers, there is a strong likelihood that they will not possess such information. While the Proposed Rule states that the applicant is to provide “known or reasonably ascertainable” information, clarification is needed as to the actual level of due diligence required (and the consequences of not being able to supply such information) to determine how practical and/or burdensome this requirement will be.
- SPAN believes that the timeframes for submitting CUU applications are too rigid. DEP should allow for additional time for manufacturers to submit CUU applications in advance of the dates of a specific prohibition. Moreover, more time should be provided for DEP to review applications. Additional time for DEP’s consideration of applications would prove critical in the event there is a need for dialogue with an applicant or supplemental information needed.
- SPAN requests that deadlines for DEP action on CUU Proposed Rules should be included and articulated in the regulation; provisions should be added for an applicant to supply additional information if needed through interactions with the DEP reviewers.

Proprietary Information

- The Proposed Rule states DEP's position that, because CUUs must be determined through a rulemaking, CUU determinations will not be issued for submissions that contain confidential information. This is simply untenable and impracticable for numerous reasons. For example, the composition of a product is very likely to be considered by the applicant to be confidential for the protection of highly-important trade secrets. If DEP will not allow such confidential information to be submitted (or will deny a CUU application on the basis of it containing confidential content), the CUU exemption process will be unusable for many product manufacturers, who will then be prohibited from selling their products in Maine. DEP's position also is completely unworkable for products that may have uses that are critical to national security and are subject to a variety of secrecy requirements (which often may extend to numerous products that go beyond those specific items that are exempt due to DOD, NASA, or FAA specifications requirements).
- The provision which DEP cites in the Proposed Rule concerning the Department's ability to protect confidential information is not specifically applicable to the underlying PFAS-in-products law (38 M.R.S. § 1614). DEP must explain how confidentiality will be guaranteed under the Proposed Regulations and cite the statutory authority for this interpretation.

Conclusion

SPAN requests that DEP carefully consider these comments and those submitted by other stakeholders. SPAN stresses that failure to implement some of the requested changes will adversely affect the availability of certain products and materials in Maine that are of critical importance. As always, SPAN welcomes the opportunity to meet with DEP staff to discuss and clarify our comments as DEP continues with the rule promulgation process.